

THE MEANING OF ADHERENCE AMONG VETERANS
RECEIVING PEGYLATED INTERFERON AND
RIBAVIRIN ANTIVIRAL TREATMENT
FOR CHRONIC HEPATITIS C

By

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DEDICATION

I dedicate this work to my mother and father, who without their love, support and encouragement, this work, as well as my dreams, and my nursing career would not have been possible.

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ABSTRACT

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The purpose of this study was to describe the meaning of adherence and adherence experiences in hepatitis C (HCV) infected Veterans receiving pegylated interferon and ribavirin antiviral treatment. In addition, how these experiences influenced the Veteran's choice to remain adherent or non-adherent was vital to the concept of adherence. The theoretical framework used to guide this project was the Information, Motivation and Behavioral Skills Model of Adherence.

A convenience sample of 21 HCV infected Veterans who were enrolled in a VA HCV treatment clinic were recruited. Those who were receiving antiviral treatment or who had recently completed antiviral treatment were eligible to participate. The researcher conducted a one-time interview with each participant using open-ended questions. The interviews were audio-recorded and transcribed verbatim. Demographic information was collected and a brief telephone conversation followed to ensure the accuracy of each transcript. Data analysis included data

immersion, transformation, and reduction, and the hermeneutic circle.

The following themes emerged from the transcripts, including commitment to the cure, to the treatment, to the healthcare provider and to the discipline necessary to sustain the treatment. The Veterans expressed that they were not ready to leave this world, and were inclined to make healthy lifestyle changes.

The Veterans applied the notion of unfinished business to antiviral treatment in that, they were able to clean up their past mistakes. Also influencing adherence was the family, manner of coping, and disclosure. The Recovery phase was described as a time of hope.

This phenomenological study uncovered several themes that have implications for clinical practice. The themes indicated that HCV infected Veterans may benefit from interventions that streamline patient education, and promote social support. A holistic, case management approach to patient care may be advantageous for the Veteran and may enhance adherence during antiviral treatment.

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CHAPTER 1
INTRODUCTION
1.1 Introduction

Chronic hepatitis C (HCV) is currently the most common cause of liver disease in the United States (U.S.), affecting up to 4 million individuals or approximately 2% of the general population Fraenkel, Chodkowski, Lim, & Garcia-Tsao, 2009; Ghany, Strader, Thomas, & Seeff, 2009; Hoofnagle & Seeff, 2006; Stiffel, 2004). The hepatitis C virus is a small, single-stranded ribonucleic acid (RNA) virus that replicates rapidly in the liver (Hoofnagle & Seeff, 2006). Once exposed, only a few clear the virus. Currently more than 2.7 million or 85% of individuals exposed to the virus remain chronically infected, which is defined as having detectable virus in the blood for six months or longer (Stiffel, 2004).

The disease silently and slowly progresses over two to three decades and is oftentimes referred to as the silent epidemic (Kerbleski, 2005). Even after several years, the majority of individuals with chronic infection, up to 75%, are unaware of having the infection (Mitchell, Calvin, & Beasley, 2010; Stiffel, 2004). The lack of awareness and chronicity of the virus are due to the relatively asymptomatic nature of the disease. When symptoms do occur, they are generally insidious and nonspecific, and may include fatigue, muscle and joint aches, and right upper quadrant discomfort (Stiffel). Therefore, in a majority of cases, the diagnosis of HCV is made fortuitously, during a routine physical examination or blood donation (Stiffel).

Unfortunately, those with chronic infection are also unaware that they are at risk for developing cirrhosis (Fireman, Indest, Blackwell, Whitehead, & Hauser, 2005). Consequently, 10% - 20% of those with chronic infection will develop cirrhosis in 20 – 30 years after initial infection (Firemen et al.). The activity of the HCV virus produces progressive scarring leading to cirrhosis (Stiffel, 2004). Once cirrhosis develops, complications may occur because the liver no

longer functions appropriately and decompensates. The most frequent complications are ascites, encephalopathy, and esophageal variceal bleeding. These complications may lead to end-stage liver disease, failure, and hepatocellular carcinoma (Stiffel). Today, chronic HCV is responsible for 10,000 U.S. deaths per year, and is the major indication for liver transplantation (Conjeevaram, Fried, Jeffers, Terrault, Lucas et al., 2006; Ghany et al., 2009). Thus, with the high incidence of individuals infected before 1989, this silent epidemic is quite extensive (Davis, Alter, El-Serag, Poynard, & Jennings, 2010).

Although the prevalence of chronic HCV peaked in 2001, the incidence of cirrhosis is anticipated to increase and peak around 2020 (Davis et al., 2010). The age of individuals with cirrhosis ranges from 60 to 80 years and the number of HCV related hepatocellular carcinoma cases have doubled (Davis et al.). The mortality rate is anticipated to double or even triple in the next decade due to the complications associated with chronic HCV infection (Hoofnagle & Seeff, 2006).

1.1.1 Background

1.1.1.1 Incidence

The incidence of HCV infection escalated in the U.S. during the 1960s and 1970s, and reached the highest point in the 1980s (Stiffel, 2004). One large cohort of individuals infected with chronic HCV is the cohort of veterans who served during the Vietnam era (Dominitz, Boyko, Koepsell, Heagerty, Maynard, et al., 2005). Within the Department of Veterans Affairs (VA) Healthcare System, the prevalence of individuals infected with HCV is 5.4% which is about three times the prevalence of the general U.S. population (Dominitz et al.; Firemen et al., 2005; Ho, Groessl, Dollarhide, Robinson, Kravetz, et al., 2008). Among veterans who receive healthcare at the VA facilities, the incidence of chronic HCV infection may be as high as 35% to 51% in select veteran subgroups (Fraenkel et al., 2009; Ho et al., 2008). The higher prevalence in the veteran subgroup may be associated with the greater risks of percutaneous exposures through contaminated blood which include male gender, intravenous drug use, snorting cocaine, receiving blood transfusion before 1992, multiple sexual partners and combat wounds sustained during the

Vietnam era (Desai, Rosenbeck, & Agnello, 2003).

Since the discovery of the virus in 1989, the rate of new cases of acute infection has declined by 80% (Hoofnagle & Seeff, 2006). This decline in new cases is due to the screening of HCV antibodies in the blood (Hoofnagle & Seeff; Ong, Collantes, Pitts, Martin, Sheridan et al., 2005). Screening, which became available in 1992, is indicated for individuals at risk for percutaneous exposure of infected blood (Ghany et al., 2009; Hoofnagle & Seeff). The VA healthcare system is actively screening at risk individuals and confirming the presence of viremia through laboratory testing (Payvar & Lam, 2007).

1.1.1.2 Healthcare Burden And Cost

Since a majority of individuals have not been diagnosed, but will likely seek medical care in the next decade, the proportion of individuals with advanced disease, such as cirrhosis, will increase substantially by 2020 (Ho et al., 2008). Thus by 2020, the incidence in liver failure is a projected to increase by 106%, in hepatocellular carcinoma by 81%, and in liver-related mortality by 180% (Ho et al.). Additionally, this increase in liver related-morbidity and mortality is projected to increase direct medical costs to \$1 billion per year (Ho et al).

The healthcare burden due to chronic HCV infection is estimated to be \$10.7 billion for the current decade (Young & Hildebrandt, 2009). The societal burden of indirect health care costs based on morbidity from decompensated liver disease and premature mortality are expected to be over \$65 billion from 2010 to 2019 (Ong et al., 2005).

The higher prevalence among Vietnam era veterans makes chronic HCV a major healthcare initiative in the VA healthcare system (Centers for Quality Management in Public Health, 2010; Payvar & Lam, 2007). Today, the VA healthcare system is the nation's largest healthcare provider that delivers healthcare for individuals infected with chronic HCV (Congressional & Legislative Affairs, 2004; Payvar & Lam, 2007). In 2001, 38,000 veterans were newly diagnosed, and during 2002, 180,000 veterans received HCV related care. In 2007, the VA's expenditures for HCV related care exceeded \$100 million (Payvar & Lam). Included in the expenditures is the cost for one year of the antiviral treatment, pegylated interferon and ribavirin,

which ranges from \$30,000 - \$40,000 per patient (Hoofnagle & Seeff, 2006).

Additionally, the societal burden of employment, social and family support, and overall quality of life are impacted by chronic HCV (Young & Hildebrandt, 2009). Thus, there is an urgent need for those infected to receive antiviral treatment and achieve viral clearance. Viral clearance through treatment will minimize the associated health, social, and financial consequences of this major public health and silent epidemic (Young & Hildebrandt).

1.1.1.3 Natural History And Disease Progression

The natural history of hepatitis C infection is problematic because the exact timing of exposure to the virus is often unknown (Stiffel, 2004). Approximately 85% of those who become infected fail to clear the virus on their own and progress to chronic infection (Liang, Rehermann, Seeff, & Hoofnagle, 2000). Chronic HCV infection progresses over 20 to 30 years and is associated with an unpredictable disease trajectory (Davis et al., 2010). In most cases, individuals who progress to chronic infection have non-specific clinical symptoms and insidious disease progression (Liang et al., 2000). Chronic HCV viremia can exist silently with normal or fluctuating liver enzymes and with or without liver damage (Liang et al.). These individuals remain asymptomatic with long term stability.

Approximately 20% - 30% of chronically infected individuals progress to cirrhosis, which is complete liver scarring (Davis et al., 2010; Hoofnagle & Seeff, 2006). During 2005, approximately 212,500 individuals in the U.S. were diagnosed with HCV cirrhosis (Everson, 2005). Patients with cirrhosis are at risk for further disease progression and clinical deterioration referred to as decompensation (Everson). The term decompensation defines individuals whose liver fails to function appropriately and who are experiencing clinical complications (Everson; Liang et al., 2000). The clinical complications of decompensated liver disease are ascites, esophageal varices, and/or hepatic encephalopathy, and hepatocellular carcinoma (Everson; Ghany et al., 2009). Approximately 1%-4% of individuals with cirrhosis develop hepatocellular carcinoma annually (Hoofnagle & Seeff).

In a HCV cirrhotic individual with decompensated liver disease, the life expectancy is

reduced by 28 years (Wong, 2006). These individuals have a 5-year survival rate of only 50% without a liver transplant (Everson, 2005). With a liver transplant, the life expectancy is reduced by 22 years (Wong).

Stiffel (2004) cites several factors that may influence the natural history of chronic HCV infection. Males, people over 40 years of age, and those who have received blood transfusions suffer more active liver damage. Comorbid conditions such as diabetes, fatty liver (steatosis) and iron overload may accelerate the course of infection (Stiffel). Extrinsic factors that may exacerbate liver fibrosis include heavy alcohol use, viral co-infections, smoking and immunosuppression. Certain HCV genotypes may be more virulent and more likely to lead to progressive liver disease (Stiffel).

1.1.1.4 Evolution Of Treatment

The treatment for chronic HCV has progressed over the last 25 years. Interferon alpha monotherapy was first introduced in 1986 for the treatment of "non-A, non-B hepatitis (Mishra & Jensen, 2008). Then, a decade later in 1996, interferon alpha was developed for use in the treatment of chronic HCV (Mishra & Jensen) Interferon alpha, a cytokine, was thought to induce the virally infected cells to produce proteins which inhibited viral replication (Perry & Jarvis, 2001). Furthermore, interferon alpha had an additional immunomodulatory effect which strengthened the host immune response against the virus. This was accomplished through the activation of macrophages, natural killer cells, cytotoxic T lymphocytes and the production of helper T cells (Hoofnagle & Seeff, 2006; Perry & Jarvis). Ribavirin was later added to interferon alpha which resulted in better response rates (Hoofnagle & Seef). Ribavirin, a nucleoside guanosine analogue, induced mutations in the viral genome which led to replication error and viral extinction (Hoofnagle & Seeff; Mishra & Jensen).

Today, the major advancement in HCV treatment is the attachment of polyethylene glycol to the interferon molecule, known as pegylated interferon. Introduced in 2001, this new pegylated interferon is a long-acting interferon with an increased half-life (Hoofnagle & Seeff, 2006). The rationale of this long- acting interferon is to produce a more constant plasma concentration,

increase the amount of time the interferon is effective and reduce the rate of elimination from the body (Hoofnagle & Seeff). Pegylated interferon and ribavirin combination treatment has increased the percentage of patients who achieve viral eradication and is currently the gold standard of HCV treatment (Ghany et al., 2009).

1.1.1.5 Treatment Response

The aim of antiviral treatment is to eradicate the virus and decrease the progression of fibrosis or liver scarring. Unfortunately, the overall response rate is only 40% - 45% with the current standard of pegylated interferon and ribavirin treatment (Backus, Boothroyd, Phillips, & Mole, 2007). Adherence to pegylated interferon and ribavirin is crucial in order to achieve viral eradication or a sustained viral response (McHutchison, Manns, Patel, Poynard, Lindsay, et al., 2002). Once treatment begins, the patient must follow a complicated schedule of laboratory tests, clinic visits, and medications with many debilitating side effects. During treatment, the majority of patients experience fatigue, flu-like symptoms, gastrointestinal disturbances, neuropsychiatric symptoms, and hematologic abnormalities (Backus et al., 2007; Fried, 2002). These intolerable side effects often result in suboptimal dosing and early discontinuation (Weiss, Brau, Stivala, Swans, & Fishbein, 2009). For a majority, suboptimal dosing leads to treatment failure as evidenced in the poor overall response rate. In the VA HCV population, the overall response rate of viral eradication is only 23% - 24% (Backus et al., 2007; Chainuvati, Khalid, Kancir, Shea, Edwards, et al., 2006; Weiss et al.). This lower response rate is partially due to the high number of veterans who fall in the difficult to treat category which consists of advanced to moderately staged liver disease and HCV genotype 1 (Backus et al.). This "difficult to treat" category in combination with the numerous associated side effects often leads to dose reductions and early treatment discontinuation (Weiss et al.).

1.2.1 Significance Of The Problem

1.2.1.1 Substantial Issues

A multitude of issues play important roles and are quite substantial in the significance of chronic HCV infection. First, in the U.S. the mortality associated with chronic HCV infection is

anticipated to double or even triple during the next 10-20 years, and secondly, the cost spent annually for HCV-related healthcare is currently \$600 million (Howie & Hutchinson, 2004). Third, advances are desperately needed in the knowledge and awareness of chronic HCV, and in the integration of healthcare services that are necessary to combat the disease (Mitchell et al., 2010). For instance, the lack of awareness about the disease prevalence, at-risk populations, and appropriate medical management of HCV, in all likelihood contribute to poor health outcomes in infected individuals (Mitchell et al.). Cost-effective treatment strategies are needed to reduce the burden of the disease (Howie & Hutchison).

1.2.1.2 Pegylated Interferon And Ribavirin Antiviral Treatment

The current and most effective treatment strategy is the combination of pegylated interferon and ribavirin antiviral treatment for hepatitis C (Weiss et al., 2009). Unfortunately, pegylated interferon and ribavirin antiviral treatment is difficult to tolerate due to the large number of side effects. The intolerable side effects directly influence treatment adherence and viral clearance (McHutchison et al., 2002).

1.2.1.3 Antiviral Treatment Adherence

HCV treatment success is proportionate to the degree of adherence (Weiss et al., 2009). The 80% pegylated interferon, 80% ribavirin, and 80% duration of treatment has been implied as the gold standard of HCV treatment adherence (Weiss et al.). This 80-80-80 rule means that if a patient takes at least 80% of both the medications for at least 80% of the time, the patient is more likely to clear the virus. Yet this 80-80-80 rule only includes dose reductions and early discontinuations by the healthcare provider and not the patient (Weiss, Bhatti, Dieterich, Edlins, Fishbein et al., 2008). Equally important, is the description of adherence or non-adherence by the patient which also includes dose reductions, early discontinuation and/or missed doses. The literature has only presented a handful of studies that mention missed doses by the patient.

The definition of HCV adherence has been ambiguous. The term adherence most often refers to patient persistence with the medical regimen. In other words, adherence is defined as the amount or duration of treatment that the patient completed. For instance, the patient

completed 36 weeks out of 48 weeks of treatment. In measuring patient adherence, patient as well as provider initiated dose reductions, early treatment discontinuations, and missed doses need to be included. Strategies to improve adherence are vague. There are no standards or guidelines that address adherence in antiviral treatment (Weiss et al., 2009).

1.2.1.3 Antiviral Treatment Eligibility

Although a large portion of HCV infected veterans are evaluated for treatment, only a small portion actually receive treatment. This is partially due to the multiple comorbid medical psychiatric diseases. Also among veterans who receive treatment, a higher discontinuation rate exists when compared to the general population (Backus et al.).

1.3.1 Theoretical Framework

The theoretical framework used to guide this hermeneutic phenomenological prospective study is the Information, Motivation, and Behavioral Skills Model of Adherence (Fisher, Fisher, Amico, & Harman, 2006). This theoretical framework captures the essential components necessary for adherence. These components include information, motivation and behavioral skills, and an additional feedback loop component that accounts for ongoing, long term persistence and maintenance of adherence to a medical regimen. For example, a well-informed and motivated individual, who has the objective skills necessary to take the medication accurately and has self-efficacy, will more likely establish and maintain adequate adherence. Ultimately, high levels of antiviral adherence will result in positive health outcomes (Fisher et al.).

This theoretical framework best fits the aim of this study, which is to uncover the meaning of adherence among HCV veterans receiving antiviral treatment. Importantly, this theoretical framework provides the construction and arrangement of the interview questions. By asking specific open ended questions related to information, motivation, and behavioral skills of HCV antiviral treatment, the participants may reveal a more meaningful definition of adherence through conversational dialogues.

1.4.1 Gap In Knowledge

The majority of today's research has focused on the epidemiology, natural history, and the progression of HCV-related liver disease, and the advances in medical treatment. Adherence to treatment usually refers to dose reductions and early discontinuation by the provider and rarely mentions missed doses by the patient (Weiss et al., 2009). Unfortunately, among the HCV veterans who are receiving pegylated interferon and ribavirin antiviral treatment, the degree of adherence to the medical regimen is unknown. Furthermore, the definition, measurement and interventional strategies used for antiviral adherence remain unknown (Weiss et al.). Until recently there has been little research dedicated to the systematic exploration of the qualitative psychosocial issues related to living with chronic HCV and the

treatment (Hopwood & Southgate, 2003). The qualitative psychosocial issues of living day to day with a contagious, life threatening disease, and the experiences during antiviral treatment are equally as important as the quantitative research. Thus, a gap in the literature exists that addresses the meaning of adherence to the experiences of HCV infected veterans during pegylated interferon and ribavirin treatment.

1.5.1. Phenomenological Perspectives: Philosophy and Method

Phenomenology's philosophical premises accept individual experience as a valuable source of knowledge, and its methodological approaches allow and encourage the complexity and depth of human experience to be expressed (Mackey, 2005). As with any type of research, there must be a correspondence between the philosophical foundation of the study and the methodological processes of the research protocol (Speziale & Carpenter, 2003).

1.5.1.1 Philosophy

Phenomenology is a philosophical approach to the study of phenomena or human experiences (Lopez & Willis, 2004). Phenomenology seeks to answer the question of what it is like to have a certain experience. In phenomenology, there is not one single reality since each individual has his or her own reality. Reality is subjective and each experience is unique to the individual.

A hermeneutic or interpretive phenomenological philosophy is the understanding of a phenomenon with the scientific interpretation of the phenomena documented in the written narratives (Speziale & Carpenter, 2003). The aim of hermeneutic phenomenology is to uncover what is normally hidden in individual experiences (Lopez & Willis, 2004). The basis of interpretive inquiry is the relationship of the individual to his or hers lifeworld. The individual's "lifeworld" is composed of the realities which are influenced by the world in which he or she lives. An individual cannot be separated or removed from his or her world (Lopez & Willis; Malt, 1999). Implanted in their worlds, individuals are socially, culturally and politically integrated.

Heidegger's philosophical conceptualization can be divided into the following categories: being-in the-world, fore-structures, time, and space (Mackey, 2005). As an individual becomes aware of "being" the individual has access and becomes aware of his or her own existence which represents "being in the world" in the everyday, average life (Mackey). Fore-structure is described as what the individual already knows, or a pre-understanding which simply needs to be expressed (Mackey). Heidegger considers the individual to be temporally grounded or situated in-the-world. Temporality joins together the past, present and the future. In other words, what is experienced in the present is meaningful with what was experienced in the past and what is anticipated to be experienced in the future. The chronological date and time are not as important as the point in time. For instance, the point in time at which a diagnosis is made known to the individual changes the individual's average daily life and trouble-free future. Space is not a geographical place, but rather a sense of being in a particular space, or spatial existence (Mackey; McConnell, Chapman, & Francis, 2009). The notion of what it means to be in that space and how that feeling influences the experiences becomes important. Space also refers to the experiences that an individual may hold either close or at a distance.

Utilizing the hermeneutic philosophical approach, the researcher listens to the descriptions of the phenomena, situations, and experiences of the participants. Through the interpretive process of understanding, the researcher strives to describe, analyze and reflect upon the phenomenon experienced (Mackey, 2005). This philosophical approach allows for an

interpretation of the meaning of those lived experiences and the interpretation is the basis of all understanding (Mackey).

1.5.1.2 Method

In a Heideggerian research method, the experiences of the participants are interpreted and analyzed through the researcher's own knowledge and experiences (Snow, 2009). Interpretation and understanding are gained through the engagement of the researcher's own biases and preconceptions through the conversational dialogues with the participants (Denzin & Lincoln, 2005). These conversational dialogues begin with the researcher's questions in order to eventually unravel the meaning of the phenomenon through the answers of the participants (McConnell et al., 2009). In essence, the understanding becomes a mutually negotiated interpretation between the researcher and the participant (Denzin & Lincoln).

Heidegger conceived interpretation as a circular process, a circle of understanding. Initially, each individual brings his or her own understanding of the phenomenon into the research study. These individual understandings are considered parts of the whole phenomenon. The flow of understanding is a process known as the hermeneutic circle. There is a back and forth movement between partial understanding and the more complete understanding of the whole phenomenon. Each gives meaning to the other, resulting in a circular repetition of interpretation and understanding (Ajjawi & Higgs, 2008).

Mackey (2005) describes the hermeneutic circle as beginning with reading and listening to the data. The researcher interacts with the data through transcribing and underlining meaningful sections of transcripts, then asking questions and proposing ideas about its meaning. Writing involves reflecting on the experiences as described by the participants. The researcher steps back and looks for the characteristics within the experiences which may reveal a better understanding of the aspects of the phenomenon being studied (Mackey). The methodology of the hermeneutic circle becomes linked with the philosophical interpretation of the daily experiences of being in the world.

1.5.1.3 Rationale

The research method was determined by the research question, purpose of the study, and the resources and skills that were available to the researcher (Denzin & Lincoln 2000). In this study, the research question concerned the meaning of the phenomenon of patient adherence, therefore the best method suited to answer the question was phenomenology. This researcher sought to understand and interpret the phenomenon of patient adherence through the lived experiences of veterans who received antiviral treatment.

Phenomenological research emphasized that a rich description may have been found in the experiences of everyday living. Subjective processes, such as narratives, allowed individuals to communicate their unique experiences and allowed the researcher to inquire and interpret the meaning of the lived experiences (Denzin & Lincoln, 2005). Thus, hermeneutic phenomenology fit nicely with the aim of this study which was to uncover the unique meaning of the lived experiences of treatment adherence. The hermeneutic phenomenological method may have provided insight through the descriptions of the participants daily worlds and sort out the meanings of their experiences of treatment adherence. The interpretation of these daily life experiences during treatment may have created a better understanding of what adherence actually meant, thereby filling in the gap with new scientific knowledge.

1.6.1 Statement Of The Purpose

The purpose of this study was to describe the meaning of adherence and adherence experienced in HCV infected veterans who received antiviral treatment. Furthermore, how these experiences influenced the choice to remain adherent or non-adherent to treatment were vital to the concept of adherence. Qualitative phenomenological research may have significantly contributed to the understanding of the daily life experiences among HCV infected veterans during antiviral treatment and has given adherence a meaning which was desperately needed.

1.7.1 Statement Of Essential Assumptions And Limitations

1.7.1.1 Assumptions

The essential assumptions for this study were:

1. All patients who began pegylated interferon and ribavirin treatment did so on their own volition.
2. All patients who began pegylated interferon and ribavirin treatment do so with the intention of completing the course of treatment and clearing the virus.
3. U.S. military veterans with chronic HCV and who were receiving antiviral treatment were capable of explaining their lived experiences with the disease and its treatment.

1.7.1.2 Limitations

The limitations for this study were as follows:

1. A majority of HCV infected veterans have comorbid medical illnesses which may influence adherence during antiviral treatment.
2. A majority of HCV infected veterans have comorbid psychiatric illnesses which may influence adherence during antiviral treatment.
3. A majority of HCV infected veterans have addictive and high risk behavior disorders which may influence adherence during antiviral treatment.
4. Findings attributable to the HCV infected veterans who received care at the Dallas VA, may not be transferrable to other patients receiving antiviral treatment.

1.8.1 Summary Of Chapter

Hepatitis C has been a major public health problem and the leading cause for liver disease in the U.S. (Ghany et al., 2009). Death from HCV related liver failure and/or hepatocellular carcinoma has increased during this decade (Ghany et al.). This increase in morbidity and mortality immensely has affected the VA healthcare system. The prevalence of

chronic HCV has been much higher among veterans who use the VA healthcare facilities in comparison to the general population, making HCV a major healthcare issue for the VA (Payvar & Lam, 2007). For instance, the VA's expenditures for HCV related care during 2007 exceeded \$100 million (Payvar & Lam).

The gold standard of treatment has been the combination of pegylated interferon and ribavirin which has focused on clearing the virus and preventing the progression of liver disease (Ghany et al., 2009). The duration of treatment varied from 24 to 48 weeks depending on genotype and serial viral loads during treatment (Ghany et al.). Sadly, only about half of the patients who started treatment achieved viral clearance (Backus et al., 2007; Mishra & Jensen, 2008). This poor response rate might be related to inadequate dosing and poor adherence (Weiss et al., 2009).

Clearly, the review of the HCV adherence literature uncovered several important issues. Adherence has been and continues to be an important factor in treatment success. Individuals receiving antiviral treatment have often experienced difficulty in adhering to treatment because of the numerous associated bio-psycho-social issues. For instance, suboptimal adherence was common in the HCV veteran population as evidenced by 68% discontinuation rate (Backus et al., 2007).

As the number of symptomatic veterans were diagnosed with chronic HCV increases, the need for phenomenological research became vital. There was a crucial need to understand the experiences of living with hepatitis C while receiving antiviral treatment and the impact on daily life (Hopwood & Southgate, 2003). The review of the literature demonstrated that qualitative research has uncovered how individuals coped with treatment and the related side effects and how these side effects impacted quality of life and treatment adherence.

Without understanding the dynamics of adherence, it was difficult to address the potential vulnerabilities that non-adherence created. By exploring the patient's definition, categories, vocabulary and behavioral approaches during HCV treatment has provided insight into the meaning of adherence. A hermeneutic phenomenological prospective study among U.S. HCV

infected veterans supplemented the research findings helped to better understand and improved patient adherence.

CHAPTER 2

CRITICAL REVIEW OF RELEVANT LITERATURE

2.1 Introduction

The purpose of this chapter was to provide an overview of adherence in chronic medical and psychiatric diseases which supported the related issues of adherence in hepatitis C (HCV) treatment with pegylated interferon and ribavirin. The population studied and the healthcare problem of adherence during pegylated interferon and ribavirin antiviral treatment for HCV is described. The key concepts of adherence was reviewed, including adherence issues in chronic medical, psychiatric, and viral diseases. A brief discussion of the behavioral theory most appropriate for this study was presented. Importantly, this chapter provides comparisons and contrasts in the qualitative literature that exists between non-veterans and veterans. A synthesis of the findings is presented. The chapter summary includes a discussion of the existing scientific knowledge base of adherence among veterans receiving pegylated interferon and ribavirin antiviral treatment for HCV. Additionally, the gaps in the knowledge base and how these gaps are linked to the current study are discussed.

2.2 Review of Relevant Literature

2.2.1 Population and Health Care Problem

Hepatitis C virus (HCV), a blood-borne infection, continues to be a major public health problem world wide and the leading cause of chronic liver disease (Ghany et al., 2009). It affects approximately 3% of the world's population (180 million people) and nearly 2% of the general United States (U.S.) population (Ghany et al.; Fraenkel, Chadkowski, Lim, & Garcia-Tsao, 2009; Stiffel, 2004). Among veterans receiving care at Department of Veterans Affairs (VA) facilities, the prevalence of chronic HCV infection is as high as 35% (Fraenkel et al).

2.2.1.1 Transmission

HCV is transmitted through percutaneous exposure of contaminated blood (Ghany et al., 2009). Risk factors included using intravenous needles that are contaminated with HCV infected blood, blood transfusion before 1992, and high risk sexual activity with multiple partners (Ghany et al.). Vietnam era veterans have a higher prevalence of chronic HCV infection, perhaps because of combat exposure to contaminated blood, having received multiple blood transfusions for war injuries, unclean tattooing practices, increased rates of substance abuse, including intravenous and snorting drugs, and multiple sexual partners (Desai et al., 2003).

2.2.1.2 Course Of The Disease

Once exposed to the virus, the disease trajectory is highly unpredictable (Desai et al., 2003; Stiffel, 2004). Approximately 15% of individuals exposed to the virus during the acute phase have immune systems that eradicated the virus without treatment but the remaining 85% develop a chronic HCV infection (Yee, Currie, Darling, & Wright, 2006). For some with chronic HCV infection, the virus quietly existed and produced only mild liver damage (Liang, Rehermann, Seeff, & Hoofnagle, 2000). Others have had chronic infection with elevated liver enzymes but without signs of disease progression (Liang et al.). In the most unfortunate, the virus slowly progressed over decades, causing moderate fibrosis or liver scarring. Approximately 20% of those with chronic HCV infection ultimately resulted in cirrhosis or complete liver scarring (Everson, 2005). The development of cirrhosis slowly progressed over 20 years of active infection and the development of hepatocellular carcinoma usually required 30 years of active infection (Everson). Approximately 5% of patients with HCV cirrhosis are at risk of developing hepatocellular carcinoma (Stiffel). Sadly, without intervention, the median survival after diagnosis has been seven to eight months (Everson; Stiffel).

The progression to cirrhosis is responsible for an increase in liver related morbidity and mortality (Stiffel, 2004). In the early stages of cirrhosis, the liver was able to compensate and the individual had no clinical symptoms (Everson, 2005). As the disease progressed, the damage

became too great for the liver to compensate and the individual developed obvious symptoms and complications such as: ascites, esophageal varices, and hepatic encephalopathy, referred to as decompensation (Ghany et al., 2009). Only 50% of individuals with decompensated HCV cirrhosis survived five years unless they had liver transplantation (Everson). Currently, HCV cirrhosis accounted for 50% of the newly diagnosed cases of hepatocellular carcinoma and for approximately 10,000 deaths annually (Conjeevaram et al., 2006).

2.2.1.3 Treatment

Eradicating the virus and slowing disease progression are the primary aims of HCV treatment (Stiffel, 2004). The combination of pegylated interferon and ribavirin was the gold standard of HCV treatment and is indicated for individuals who meet criteria for treatment and are at the greatest risk for disease progression (Yee et al., 2006).

Several factors influenced treatment effectiveness. Patients who were women, individuals less than 40 years old, those who were not African American, and individuals who weighed less than 75 kilograms (Kg) are more likely to respond successfully to treatment (Ghany et al., 2009). It is also important that the patient not be resistant to insulin or have had bridging fibrosis of the liver or cirrhosis. Treatment is also more effective if patients were able to tolerate adequate doses of the two available pegylated interferons (1 .5mcg/kg/week of α 2b pegylated interferon or 1 80mcg/week of α 2a pegylated interferon) and an adequate dose (more than 10.6mcg/kg/day) of ribavirin (Ghany et al.).

However, the two most important predictors of success were HCV genotype and pretreatment viral load (Ghany et al. 2009). HCV is an enveloped, single-stranded RNA or ribonucleic acid virus with considerable heterogeneity (Stiffel, 2004). This heterogeneity was most commonly classified into groups, known as strains, or genotypes (Ghany et al.; Stiffel). The most prevalent genotype in the U.S. was genotype 1, which was responsible for 75% of cases of HCV; only 15% of Americans have genotypes 2 and 7% have genotype 3 (Ghany et al.; Hoofnagle & Seeff, 2006). Unfortunately the most common genotype in the US (genotype 1) was least

responsive to treatment (Ghany et al.; Stiffel).

The amount of virus in the liver was of equal importance in determining viral response to treatment. The virus replicated quickly in the liver resulting in an average of 1 to 2 million genomes equivalents per milliliter (Hoofnagle & Seeff, 2006). Viral eradication or sustained viral response rates were higher among individuals with a pretreatment viral load of less than 600,000 IU/ml (Ghany et al.). In other words, treatment was most effective for individuals who do not have genotype 1, had lower viral loads, and had less severe liver disease.

The drugs were given for 24 weeks to 48 weeks depending on the individual's HCV genotype (Yee et al., 2006). Patients gave themselves a subcutaneous injection of pegylated interferon once a week and took ribavirin capsules twice a day with food. The medical regimen also involved frequent monitoring through laboratory testing and clinic visits.

In clinical trials, viral eradication was achieved in 54% - 56% of patients but in the VA HCV population, the overall response of viral eradication was only 23% - 24% (Backus et al., 2007; Chainuvati, et al., 2006; McHutchison et al., 2002; Weiss et al., 2009). This lower response rate was due to the high number of veterans who fell in the "difficult to treat" category which consisted of male gender, advanced to moderately staged fibrosis and HCV genotype 1 (Backus et al.).

Pegylated interferon and ribavirin antiviral treatment for HCV was difficult to tolerate due to the severe side effects. Fatigue, flu-like symptoms, gastrointestinal disturbances, neuropsychiatric symptoms, and hematologic abnormalities were commonly experienced side effects (Backus, et al.; Fried, 2002). This difficult to treat category in combination with the numerous associated severe side effects often lead to suboptimal dosing, through dose reductions and early treatment discontinuation (Weiss et al., 2009). As a result, not all patients completed the course of treatment.

Treatment was clearly indicated for individuals who meet the criteria. These criteria included being at least 18 years of age, positive HCV viremia, significant liver scarring per

liver biopsy, compensated liver disease, acceptable hematological and biochemical laboratory levels, and willingness and readiness for treatment (Ghany et al., 2009). Certain individuals had diseases that made it very difficult to tolerate the doses needed for effective treatment. For example, pegylated interferon could cause such depression that individuals attempted suicide or such aggression that they attempted homicide. This was particularly a concern in veterans who have been exposed to the traumas of battle and who have been trained to kill through marksmanship and weaponry. Treatment was contraindicated for individuals with uncontrolled depression or psychiatric disorders. Ribavirin caused severe birth defects and cannot be given during pregnancy. Treatment was also contraindicated for patients with autoimmune hepatitis, untreated thyroid disease, severe coronary heart disease, uncontrolled diabetes, chronic obstructive pulmonary disease, and known hypersensitivity to the medications (Ghany et al.). Patients with HCV should not drink alcohol because it speeds disease progression and abstinence was necessary during treatment (Ghany et al.).

In summary, HCV is a chronic infection with increased morbidity and mortality and is difficult to treat (Backus et al., 2007). The combination of pegylated interferon and ribavirin antiviral treatment for HCV was associated with severe side effects that often times resulted in dose reductions and early discontinuation (Weiss et al., 2009). This led to suboptimal dosing. Ultimately, only half of the individuals were successfully treated (McHutchison et al., 2002).

The success of HCV treatment was proportionate to the degree of adherence (Weiss et al., 2009). In the literature, HCV adherence referred to dose reductions and early discontinuation initiated by the healthcare provider and not the patient. The extent of dose reductions, early discontinuations, and missed doses among individual patients was unclear, resulting in a gap in knowledge of treatment adherence (Weiss et al.). Among veterans who were receiving pegylated interferon and ribavirin antiviral treatment for HCV, the degree of adherence to the medical regimen was unknown (Weiss et al.).

2.2.2 Key Concepts

2.2.2.1 Adherence And Non-adherence

Adherence to a prescribed medical regimen was crucial for preventing disease, avoiding complications, improving quality of life, and reducing healthcare costs (Bosworth, Oddone, & Weinberger, 2006). Unfortunately, there is no consensus about the definition of adherence in the research literature. Progress has been slow-moving in the direction of adherence, yet researchers continue to pursue the concept and definition of adherence, as well as the most effective methods and strategies for measurements and interventions (Bosworth et al; DiMatteo, 2004). The key concepts related to adherence and non-adherence, the definitions, measurements and interventions, are presented in this section.

2.2.2.2 Definition

Adherence and compliance were often used interchangeably in the literature, but have different meanings. Compliance suggested passive obedience to medical advice, whereas, adherence implied collaboration or active participation and was persistent with the treatment regimen (Cohen, 2009). Adherence was characterized by a sense of mutual goal setting and shared decision-making between the healthcare provider and the patient. Thus, adherence was collaboration between the healthcare provider and the patient in the persistence and maintenance of desired health behaviors (Cohen).

Medication adherence refers to the extent to which the patient conformed to a recommendation of continued treatment for a prescribe length of time (Cramer et al., 2008). Medication persistence was the duration of treatment from the initiation of the prescribed drug to its discontinuation. Medication persistence was relatively high in acute disease processes; however persistence drops after the first six months of treatment in chronic disease (Osterberg & Blaschke, 2005).

Rates of adherence are reported as the percentage of the prescribed doses actually taken by the patient over a specified period which also included information on the correct dose

taking and timing (Osterberg & Blaschke, 2005). In clinical trials, adherence rates for treating chronic conditions were usually reported between 43% and 78% (Osterberg & Blaschke). There were no standards for what validated adequate adherence, although 80% may have been arbitrarily acceptable in chronic HCV treatment, whereas, 95% seemed to be necessary in HIV treatment (Cooper, Hall, Penland, Krueger, & May, 2009; McHutchison, et al., 2002; Osterberg & Blaschke; Wagner & Rabkin, 2000).

Vital to the concept of adherence was the term “missed dose”. In a majority of studies, the term was not defined, resulting in unsuspected discrepancy in expected health outcomes (Sankar, Nevedal, Neufeld, & Luborsky, 2007). Missing a dose implied a dose was delayed for a particular length of time. Some patients felt adherent when they took their medication at some point within a 24 hour period. Nonetheless, a missed-dose was actually any dose that was totally missed, whether the time lapse was 2 or 24 hours (Sankar et al.).

In the management of chronic disease, non-adherence may be blamed for an increase in disease morbidity, mortality, and health care costs (Cooper et al., 2009). In most chronic diseases, adherence included not only prescribed medications but also prescribed health-promoting behavioral lifestyle changes. Unfortunately in this combination, nonadherence rates were estimated between 50% and 80% (Cohen, 2009; Weiss et al., 2009). For instance, within the U.S., statistics showed that less than 50% of patients achieved their cholesterol goals, or exercised regularly despite medical advice to do so (Cohen).

2.2.2.3 Measurement

Measuring adherence was challenging. Adherence may be measured directly or indirectly. Direct methods included bioassays and biomarkers as well as directly observing the patient taking the medication. Indirect methods consisted of self-report, electronic monitoring, pill counts and pharmacy refill rates (Hawkshead & Wood, 2007). Each method has limitations and no one method was considered the gold standard.

Direct methods of measure included directly observed therapy and the measurement of a

drug, metabolite or biologic marker in blood or urine. Direct observation provided direct proof of taking the medication as seen in the treatment of tuberculosis; however, this method was impractical in the outpatient setting (Hsieh, Lin, Kuo, Chiang, Su, et al., 2008). Biomarkers and bioassays provided objective data with direct proof that the medication had been taken, verify recent use and can result in dose-response data, however, these laboratory tests were invasive, expensive and fluctuations in adherence between visits cannot be detected.

Indirect methods of measurement involved patient self-report, pharmacy refills, pill counts and electronic monitoring. Each method had advantages, limitations, and introduces its own type of measurement error. For instance, recall bias may have overestimated adherence. The electronic monitoring device did not document whether the patient actually took the correct drug or correct dose at the correct time. Patients may stockpile their medications, or switch medicines between bottles or discard pills before visits to appear adherent. Some patients may take drug holidays or use more than one pharmacy (Hawkshead & Wood, 2007; Llabre, Weaver, Duran, Antoni, McPherson-Baker, et al., 2006; Osterberg & Blaschke, 2005). Measuring medication adherence was challenging, yet using more than one method may reduce error and improve accuracy.

Researchers have tried to measure adherence to HCV therapy in a number of ways including self-report, interviews, patient diaries, and electronic monitoring (McHutchison et al., 2002; Thompson et al., 2009). The overall mean adherence, defined as percent of doses taken, was found to be 85 to 94 % with self-reporting, 90 to 93% with interviews and patient diaries, and 57 to 81% with electronic monitoring (Llabre, et al., 2006; Mannheimer et al., 2008; Wagner & Rabkin, 2000). Forgetfulness was the most frequently cited reasons for missed doses (Wagner, 2002).

The goal of HCV treatment was to get the patients to take 80% of their medications over at least 80% of the recommended duration of treatment. Sometimes, patients were not able to achieve this goal because they were not able to tolerate the medications at the recommended

dosages and therefore, must have the doses reduced. Researchers have studied treatment success when the doses are reduced. In a retrospective study of clinical trials (n=1,521), McHutchison et al. (2002) assessed the effect of dose reduction on sustained viral response in chronic HCV with interferon α 2a plus ribavirin and pegylated interferon α 2b plus ribavirin. The subjects were divided into two groups: those who achieved 80% of each medication for 80% of the duration of treatment, known as the “80-80-80- rule” and those who received less than 80% of medications and duration of treatment. Adherence rates were verified by pharmacy refill histories and patient diaries. McHutchison et al. concluded that patients who received more than 80% of both medications for at least 80% of the duration of treatment, in a clinical trial setting, demonstrated higher sustained viral response rates, from 54% to 63%. These researchers commented that patient self-reporting was less reliable but convenient.

In a nonrandomized, multicenter clinical trial, adherence and response rates were compared in 401 patients who were receiving pegylated interferon and ribavirin antiviral treatment for the first time (Smith et al., 2007). Adherence was measured using electronic monitoring devices and by asking subjects to report their own adherence on a touch screen computer during each clinic visit. Adherence rates by self-report ranged from 97% to 100% (pegylated interferon) and 85% to 97% (ribavirin).and by electronic monitoring, from 84% to 100% (pegylated interferon) and 69% to 90% (ribavirin). Overall, adherence was higher for pegylated interferon α 2b than ribavirin, but both decreased over time.

In a retrospective VA cohort study, Lo Re et al (2009) evaluated early virologic response and adherence rates in 188 patients undergoing treatment for chronic HCV. Adherence was measured by pharmacy refill data and was confirmed by HCV RNA viral load by polymerase chain reaction. The pharmacy refill data consisted of the following: prescription fill dates, the number of pegylated interferon syringes and ribavirin capsules dispensed with each prescription, the prescribed frequency of administration and the medication dosages during the first 12 weeks. Results indicated that adherence of more than 85% of both medications during the first 12 weeks,

as measured by pharmacy refill rates, was associated with increased HCV RNA suppression and early viral response.

Measuring medication adherence was challenging. Using more than one method may have reduced error and improved accuracy. The choice of a measurement tool depended on the intended use of the information, the available resources, and convenience and acceptability by the patient (Hawkshead & Wood, 2007).

2.2.2.4 Intervention

Strategies to improve adherence consisted of education, simplification of dosing schedules, management of drug side effects, and improvement with access to healthcare and communication (Osterberg & Blaschke, 2005). Education was generally accepted as a key to adherence but the complexity of regimen, as number of pills, may override the benefits of education (Peterson, Takiya, & Finley, 2003). Strategies to simplify dosing schedules included once daily dosing when possible, organizing daily medications in a pill box and developing cues to remind patients to take their medications. Unfortunately, these adherence interventions have not demonstrated significant improvements in adherence or treatment outcomes (Van Dulmen, Sluijs, van Dijk, de Ridder, Heerdink, et al., 2007).

Adherence is an ever-changing process (Cohen, 2009). Efforts to enhance shared decision making between the healthcare provider and the patient need to be defined and established. Measurement and behavioral intervention strategies need to be specific to the healthcare issues and their effectiveness evaluated (Cohen). Adherence is necessary for preventing disease progression, avoiding complications, and improving quality of life, especially for individuals with chronic disease (Bosworth et al., 2006).

2.2.2.5 Adherence And Influence Of Co-existing Chronic Diseases On HCV

Chronic disorders may impact both eligibility and adherence during pegylated interferon and ribavirin antiviral treatment for HCV. Kwan, Cronkite, Yiu, Goldstein, Kazis, et al. (2008) analyzed data from the 1999 Large Health Survey of Veterans and found that 3023 veterans were

diagnosed with HCV. These HCV infected veterans also had significant concomitant medical conditions and psychiatric disorders. Hypertension, diabetes mellitus, and cancer were included in the ten most common medical conditions, while alcohol dependence, bipolar disease, depression, and posttraumatic stress disorder were included in the six most common psychiatric disorders. Psychiatric, drug and alcohol use disorders were present in up to 85% of HCV infected veterans (Chainuvati, et al., 2006; El-Serag, Kunik, Richardson, & Rabeneck, 2002). Consequently, almost 50% of veterans with chronic HCV have been excluded from pegylated interferon and ribavirin antiviral treatment due to concomitant medical, psychiatric, and substance use comorbidities (Knott et. al., 2006). As a result, only 12% who were evaluated for treatment receive pegylated interferon and ribavirin antiviral treatment for HCV (Kwan et al.).

Chronic HCV infection has characteristics that are similar to other types of disease. For example, in a majority of patients, the presenting clinical symptoms of chronic HCV are non-specific and insidious which are consistent with the symptoms of hypertension. In cancer, chemotherapy is aimed at eliminating the invading malignancy which is similar to eradicating the virus with pegylated interferon and ribavirin antiviral treatment for HCV. In both therapies, the side effects are severe. The chronicity of diabetes mellitus requires life long behavior changes and long term persistence with medications. In some patients with diabetes, adherence with self-administration of insulin injections is a requirement for glycemic control. Similarly in chronic HCV, life-long behavior changes with abstinence from drugs and alcohol is required to prevent further liver scarring and to be considered for HCV antiviral treatment. Likewise, adherence with pegylated interferon injections requires self-administration on a weekly basis for better treatment response.

In most instances, HCV veterans with concomitant comorbidities, such as hypertension, diabetes or bipolar disease, were already taking a number of prescription medications for control of their chronic diseases. These veterans may have also been adjusting to behavioral life style changes necessary for adherence to the medical regimen. HCV treatment made the daily medical

regimen even more complicated. Importantly, adherence issues associated with these chronic comorbidities may be applied to that of HCV.

2.2.2.6 Lessons Learned From Other Chronic Medical Diseases

Lessons learned from helping individuals manage other chronic diseases may have helped increase adherence during HCV treatment. Since a large portion of HCV infected veterans had significant concomitant comorbidities, issues of adherence associated with these chronic comorbidities is presented in this section.

Issues included self-administration of medications in settings without supervision, concomitant psychosocial concerns, difficult side effect management, and the tendency to decrease adherence over time (Barbour, 2008; Bedell, 2003; Choudhry et al., 2009; Hartman, 2008; Perreault, Dragomir, White, Lalonde, Blais, et al., 2009; Rivellese et al., 2008; Uzun, Kara, Yokusoglu, Arslan, Yilmaz, et al., 2009; Viele, 2007). For instance, the main goal in the treatment of hypertension was the control of blood pressure. Uzun et al. discovered that the control of high blood pressure was low even with the numerous advances in antihypertensive medications. Uzun et al. found subjects adhered to the prescribed regimen 72% of the time with medications, 65% of the time with diet, 31% of the time with exercise, 63% of the time with home blood pressure monitoring and 83% of the time for stopping smoking. Only 13% of the patients were adherent to all five categories, whereas, 11% of the patients were adherent to one category.

Diabetes is characterized as being a life-long chronic illness. Living with the illness requires frequent attention to capillary blood glucose levels, nutrition, physical activity, medications, and treatment for other comorbid conditions. Generally, adherence rates range from 36% - 93% in patients who are taking oral glucose lowering agents (Hartman, 2008). An Italian study which evaluated the adherence of diabetic patients to daily dietary recommendations, found that 43% of the 540 patients had a 10% higher daily intake of saturated fats than recommended and only 6% of the sample obtained the ideal intake of daily fiber (Rivellese et al., 2008). In a U.S. study, Delamater (2006) found similar results with self-monitoring glucose levels of patients

with type 2 diabetes. Twenty-four percent of insulin-treated patients, 65% of patients on oral medications, and 80% of those treated by diet and exercise alone either never performed self-monitoring blood glucose or did so less than once per month.

Cancer is recognized as a chronic treatable disease (Bedell, 2003). The self-administration of the newer oral chemotherapeutic agents in settings without supervision may alter the degree of adherence (Viele, 2007). In this study, Viele analyzed the adherence rates to the widely prescribed oral agent, tamoxifen, and found adherence rates to range from 20% - 100%. The increased responsibility and accountability of the patient to self-administration the oral chemotherapeutic agents at home without supervision may help explain this wide range of adherence (O'Donohue & Levensky, 2006).

Psychosocial issues related to chronic disease may influence adherence. Barbour (2008) reviewed the literature on breast cancer and determined that the success of oral therapy depended upon the ability of the patient to take the medication correctly. Several factors influenced the patients ability for adherence, such as, misunderstanding the directions, hearing conflicting information, being older, having comorbid medical conditions, cognitive impairment, anxiety or depression, experiencing side effects and social and financial constraints. Thirty percent of senior citizens have no prescription drug coverage, and thus cannot afford and receive effective chemotherapy which can cost between \$1900 and \$2500 per month (Bedell, 2003). In addition, the harsh side effects of chemotherapy may also influence adherence. Among the newer agents, common side effects consist of gastrointestinal symptoms, hypertension, myelosuppression, peripheral edema, rash, pruritis, and fatigue, all of which may impact adherence, from 20% - 100% (Viele, 2007). Of interest is the chemotherapeutic agent, sorafenib, used in the treatment of hepatocellular carcinoma. The side effects of sorafenib include hypertension which requires careful monitoring of blood pressure and hand-foot skin reactions resulting in pain, numbness and tingling in the hands or feet (Viele). The nature of side effects and lack of supervision may be problematic in patient adherence.

In chronic medical illnesses, there is a tendency among patients to decrease adherence over time. For example, untreated hypertension can progress to heart failure. Perreault et al. (2009) analyzed the level of adherence to antihypertensive medications and the relationship to the onset of heart failure. Adherence was achieved if the patient took 80% or more of the prescribed medication. The rate of adherence decreased over time, and the rate of developing heart failure was 11% lower in the group with the highest adherence rate.

2.2.2.7 Lessons Learned From Other Chronic Psychiatric Diseases

Alcohol dependence, bipolar disease, depression, and posttraumatic stress disorder are the four most common psychiatric disorders in veterans with chronic HCV (Kwan et al., 2008). Improving adherence among patients with these psychiatric diseases is a major struggle in today's healthcare. Nonadherence in psychiatric disease increases social, economic and clinical costs as well as is directly associated with relapse, hospitalizations, and poor health outcomes (Bosworth et al., 2006).

Medication adherence among patients receiving treatment for psychiatric disorders may be worse than patients with non-psychiatric medical problems (Osterberg & Blaschke, 2005; Spont, Sayer, & Nelson, 2005). Poor adherence may be due to a multitude of reasons including adverse effects of the medication, complexity of regimen, lack of information and concomitant alcohol and drug use. These issues of poor adherence in veterans with chronic HCV with concomitant psychiatric disorders are presented in this section.

Adverse effects are the primary cause of nonadherence in numerous psychiatric disease states (Peterson, 2007). For instance, the anticipation of adverse effects of disulfiram can decrease medication adherence. Disulfiram is an aversive medication that dissuades alcohol intake by inducing unpleasant consequences even with a small amount of alcohol intake. In a large VA study, Fuller et al. (1986) compared the adherence rates between patients receiving the standard dose of disulfiram, a minimal dose of disulfiram and the third group receiving vitamins. All three groups received counseling. The overall adherence rate was 23% (Fuller et al.).

Although the unpleasant adverse events of disulfiram include peripheral neuritis, peripheral neuropathy, drowsiness, rash, psychosis and hepatitis, most of the patients in this study only experienced drowsiness. Chick et al., (2000) used the drug acamprosate to prevent alcohol consumption, and found only 35% of the patients were taking the prescribed doses at six months follow-up. The most frequently experienced adverse events were headaches, diarrhea, nausea and vomiting which led to the high drop out rates. In addition, the complexity of scheduling two pills three times a day was thought to be related to poor adherence (Chick et al.).

Complexity of the medical regimen influences adherence. Claxton, Cramer and Pierce (2001) performed a systematic review of 76 studies to examine the associations between dose regimens and medication adherence among a variety of chronic medical and psychiatric illnesses. The chronic illnesses varied from cardiovascular, infectious diseases, cancer, and psychiatric diseases. Clayton et al. found adherence decreased as the number of doses per day increased. In this analysis, adherence to one dose of medication was 79%, to two, 69%; to three, 65%; and to four, 51%. In contrast, when dosing frequency was reduced from daily to weekly dosing, adherence improved.

In many cases, poor adherence among patients with psychiatric disorders, such as depression and posttraumatic stress disorder, is associated with lack of disease insight and lack of information (Dieperink, Leskela, Dieperink, Evans, Thuras et al., 2008). For instance, the presence of depression may affect adherence in patients receiving concomitant medical treatment. DiMatteo, Lepper and Croghan (2000) found that patients with depression have a three-fold greater increase of poor-adherence. Poor adherence was associated with lack of disease insight (DiMatteo et al.). Posttraumatic stress disorder is frequently associated with medication underuse, missed appointments and abuse of prescribed psychoactive medications (Spoont et al., 2005). In this study of 55 subjects, Spoont et al. found 27 subjects who were considered medication underusers and 18 were considered overusers. Interestingly, 13 admitted using alcohol and illicit drugs to medicate their symptoms at least weekly. This uncertainty of the

effectiveness of medications, the lack of disease insight and misunderstanding of the whole medical regimen may have negatively influenced the patterns of adherence (Weiss, 2004).

Concomitant alcohol and/or drug use is prevalent among bipolar patients. In one VA study among bipolar patients, alcohol was the highest substance abuse disorder (Kilbourne et al., 2005). Substance abuse may precipitate non-adherence in a variety of ways. For instance, alcohol or drug abuse often leads to a disorganized lifestyle making adherence difficult. Additionally, substance abuse can bring on impaired judgment about health behaviors as well as the attempt for self-medication, resulting in over or under using psychiatric medications (Weiss, 2004).

2.2.2.8 Lessons Learned From Other Chronic Viral Diseases

Although Kwan et al. (2008) did not include HBV and human immunodeficiency virus (HIV) infections in the 1999 survey results, these viral diseases persist as chronic diseases. The aims of treatment for HBV and HIV are viral suppression, in contrast to chronic HCV, where the aim is viral eradication (Rustgi, Carriero, Bachtold, & Zeldin, 2010; Weiss et al., 2009). Viral resistance mutations occur in both HBV and HIV infections and develop with suboptimal dosing (Rustgi et al.; Weiss et al.). This is important to HCV infections because as HCV treatment becomes more comprehensive with new classes and combinations of drugs, viral mutations may develop as a result of suboptimal dosing (Wagner, Ryan, Osilla, Bhatti, Goetz et al., 2009; Weiss et al.). As a result, adherence to treatment becomes even more crucial. The lessons learned from these chronic viral diseases are presented in this section.

One of the main goals of antiviral treatment for HBV is viral suppression without drug-resistant mutations (Rustgi et al., 2010). Yet the emergence of resistance is a major concern for the treatment of HBV. Viral resistance occurs when the virus is exposed to drug levels below the viral inhibitory level allowing the virus to partially replicate. Mutant viral strains emerge leading to drug resistance (Weiss, et al., 2009). When drug resistance occurs, a cross-resistance develops within the same class of drugs, limiting therapeutic options (Lok & McMahon, 2007; Martin, 2010).

For instance, once resistance occurs with a nucleoside analogue, the subsequent use of a similar acting nucleoside analogue will speed the rate of drug resistance. Thus, a combination of different classes of antiviral drugs are given to prevent further drug resistance (Martin)

The first evidence of antiviral drug resistance is virologic breakthrough. This may occur in patients who achieve undetectable virus during treatment, but at some point, develop higher than pretreatment levels of the virus in the serum (Lok & McMahon, 2007). Thirty percent of virologic breakthrough occurs in patients who have had long lapses in antiviral medications (Lok & McMahon). Therefore, adherence to antiviral treatment is vital in the maintenance of virologic suppression.

In HIV, viral suppression is contingent on adherence levels of 80% to 95%, yet less than 50% of patients achieve this level (Gray, 2006; Watermeyer & Penn, 2009; Weiss, French, Finkelstein, Waters, Mukherjee et al., 2003). Initially, most patients achieve viral suppression; yet over time, adherence with therapy diminishes and viral rebound occurs (Bangsberg, 2008). Similar to HBV, suboptimal levels of antiretroviral adherence in HIV treatment have been associated with the highest occurrence of drug resistance mutations (Weiss et al.)

As HCV antiviral treatment continues to evolve, poor adherence may result in virological drug resistance (Weiss et al., 2009). Adherence of 80% has been shown to improve sustained viral response rates (McHutchison, et al., 2002; Tanioka et al., 2009; Weiss, et al., 2009). Thus, the assessment of adherence becomes increasingly important to treatment success as resistance mutations may develop with suboptimal dosing of HCV antiviral medications (Weiss et al.).

2.2.2.9 Adherence And Psychosocial Issues In Chronic Viral Diseases

Medication adherence is patient driven, that is, the patient is responsible for following the prescribed medication regimen at the recommended dosages, according to the individualized schedule and instructions (van Servellen & Lombardi, 2005). Yet, common to both HIV and HCV, psychosocial factors present barriers influencing adherence. Factors associated with lower adherence consist of misinformation, missed clinic visits, language barriers, negative perceptions

between healthcare provider and patient, and poor support systems (Bangsberg, 2008). In HIV, some patients may tolerate the side effects without missing one dose, while others may simply discontinue treatment altogether. Gastrointestinal and central nervous system symptoms are often experienced (Bangsberg).

The patient's understanding of their disease, treatment, and the potential side effects affected adherence (Bangsberg, 2008). In a VA Connecticut study, Fraenkel et al. (2009) recruited patients eligible for HCV treatment to determine their preferences for pegylated interferon and ribavirin antiviral treatment for HCV at the time of decision making. One hundred and forty consecutive patients from private and VA liver clinics were enrolled. When treatment side effects were perceived to be mild, 67% endorsed pegylated interferon and ribavirin antiviral treatment for HCV but when treatment side effects were perceived to be severe, only 51 % endorsed treatment. Interestingly, all VA patients with more severe liver scarring and perceived risk of cirrhosis favored treatment, whereas this association was much lower among private patients. The most common reason for postponing treatment was the asymptomatic nature of HCV and the potentially severe side effects of treatment. In conclusion, the degree and relative prognosis of liver disease were stronger predictors than HCV-related quality of life for initiating treatment.

2.2.2.10 Summary

In conclusion adherence to treatment in chronic disease, includes taking medications as prescribed and maintaining lifestyle changes of a prescribed medical regimen is the principal factor in treatment success (Bosworth et al., 2006). Adherence to the prescribed treatment improved clinical outcomes and health-related quality of life of patients with chronic disease. Yet, adherence remains suboptimal. Oftentimes patients overestimate their adherence behavior. Likewise difficult social circumstances, financial barriers, access to care, and psychiatric and chronic disease disorders are associated with suboptimal adherence (Bosworth et al.). In the HCV veteran population, properly diagnosing and managing chronic diseases, such as hypertension and alcohol abuse, may increase the 12% of HCV veterans who receive pegylated

interferon and ribavirin antiviral treatment (Kwan et al., 2008). By optimizing patient outcomes through therapeutic alliance and adherence, more HCV veterans may present eligible for pegylated interferon and ribavirin antiviral treatment and achieve a sustained virological response.

2.2.3 Theoretical Framework

In general, adherence to treatment regimens required at least some degree of behavior change by the patient and many treatment regimens required major life time behavior changes (O'Donohue & Levensky, 2006). Adherence is complex and alludes to a wide variety of actual behaviors, ranging from simple to complex, adding or subtracting behaviors, and experiencing untoward or unpleasant side effects. It is influenced by psychological and cognitive demands (O'Donohue & Levensky). These complex and dynamic set of adherence health behaviors are not easily changed (Glanz, Rimer & Lewis, 2002).

Overall, health behavior theories proposed that an individual must believe that he or she will be able to perform the behavior correctly, a favorable health outcome will result, and the benefits of the behavior change outweigh the risks of poorer health outcomes (Cohen, 2009). There are two assumptions that form the basis of the selected health behavior theory (DiClemente, Crosby & Kegler, 2002). First, an individual appreciates good health and will make the necessary changes to achieve good health. Second, an individual changes his or her behavior under his or her own volition, and these changes are driven by the individual's values, attitudes, beliefs and perceptions (DiClemente, et al.).

The theoretical framework that best fits treatment adherence is the Information-Motivation Behavioral Skills Model of Adherence (IMB, see Fig 2.1). Originally designed to promote behaviors to decrease the risk for acquiring HIV, and sexually transmitted diseases, the IMB focuses on the components of information, motivation and behavioral skills in relation to health outcomes (Amico, Alfonso & Fisher, 2005; DiClemente, et al., 2002; Munro, Lewin, Swart, & Volmink, 2007). Within this theoretical framework, Amico et al. maintains that an individual who

is well informed, motivated to act, and possesses the behavioral skills required to act effectively, will more likely initiate and maintain patterns of HIV preventive behavior.

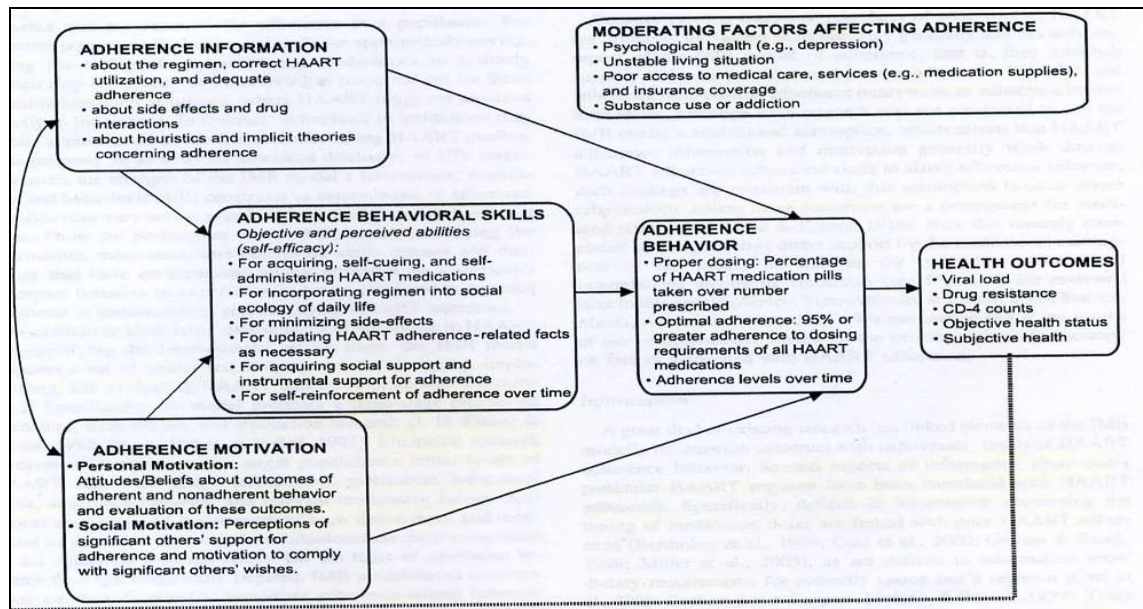


Figure 2.1 IMB Model of Adherence. An information-motivation-behavioral skills model analysis of adherence to antiretroviral medication. Adapted from Fisher, Fisher, Amico, & Harman (2006).

2.2.3.1 Information-Motivation-Behavioral Skills Model Of Adherence (IMB)

The right theoretical fit for adherence during pegylated interferon and ribavirin treatment among HCV infected veterans is the IMB model. This theoretical framework captured the essential components necessary for adherence, including information, motivation and behavioral skills, with an additional feedback loop component that accounts for ongoing, long term persistence and maintenance of adherence to a medical regimen.

Using the original components of information, motivation and behavioral skills, the model was updated to incorporate interventions that promote adherence to antiretroviral therapy (Amico, et al., 2005; Munro et al., 2007). Amico et al. describe that adherence-related information consists of accurate information about the medical regimen, specific medication doses, potential side

effects, and potential drug interactions. Adherence-related motivation consisted of personal and social factors which motivate the individual to follow the prescribed medical regimen. Personal motivation referred to the individual's attitudes, values and beliefs about the sequelae of both adherence and non-adherence. Social motivation included the support and encouragement of others for adherence behaviors.

Amico et al. (2005) suggested that separately, the components of adherence-related information or adherence-related motivation were not necessarily related to or promote behavioral skills. For example, an individual may be highly motivated but lack the information to carry out the medical regimen. Yet in combination, there was a direct relationship between adherence-related information and motivation to adherence behavioral skills.

Adherence behavioral skills referred to both the objective ability and the perceived efficacy for performing critical behaviors (Amico et al., 2005). This included acquiring and administering the antiretroviral medications accurately and consistently over time and achieving a good fit with daily life. Additionally, the individual learned to take steps to minimize side effects, and to seek information and support when necessary. Eventually, the individual developed strategies to reward and reinforce adherence behaviors (Amico et al.). Once developed, these adherence behavioral skills had a direct relationship with adherence behavior. For example, a well-informed and motivated individual, who had the objective skills necessary to take the medication accurately and has self-efficacy, will more likely establish and maintain adequate adherence. Ultimately, high levels of antiretroviral adherence resulted in positive health outcomes (Amico et al.). The favorable or unfavorable health outcomes resulting from antiretroviral adherence, as objective lab values or subjective quality of life outcomes are linked back, via a feedback loop, to strengthen or weaken subsequent antiretroviral adherence (Fisher, Fisher, Amico, & Harmon, 2006).

Finally, the IMB model recognized potential personal and environmental factors that may have affected the relationships between adherence-related information, motivation, behavioral

skills, and adherence (Amico et al., 2005). Factors, such as, substance abuse, stable or unstable living conditions, difficulty or ease of access to medications and medical services, and uncontrolled mental health issues, can strengthen or weaken the relationships between the components (Amico et al.).

Although the goals of treatment and chronicity of disease differ, HIV and HCV have several commonalities. Both are viral diseases, with similar risk factors, modes of transmission, and medications and severe side effects. Both have complex medical regimens of medications, clinic visits and laboratory testing. Therefore, the application of the IMB Model of Adherence for both HIV and HCV are presented in this section.

2.2.3.2 Application To HIV

The application of the IMB Model of Adherence provided a better understanding of antiretroviral adherence. Starace, Massa, Amico, and Fisher (2006) recruited 100 patients from a regional AIDS clinic and assigned the participants to two groups, those who routinely took at least 95% of their HIV medication and those who took less than 95%. Consistent with the model, adherence-related information and motivation significantly related to adherence-related behavioral skills, and behavioral skills significantly related to self-reported adherence. Another study, which examined a sample of 200 HIV patients on antiretroviral therapy, Amico et al. (2005) found support for the interrelations between adherence-related information, motivation, behavioral skills and adherence behavior. Amico et al. found strong support for the IMB model of antiretroviral adherence with the analyses providing support for both the overall and specific structural propositions of the IMB model.

2.2.3.3 Application To Chronic HCV

Since the application of the model has been primarily used with prevention of transmission of sexually transmitted diseases, HIV, and the promotion of antiretroviral adherence, one disadvantage is that there has been little research supporting the use in the management of other chronic diseases. However, HIV and HCV are both chronic viral infections with many

common features, such as risk factors, transmission, medications and severe side effects. Advantages are the simplicity of the structural components of the IMB model of adherence, along with the pragmatic and common sense approaches, which may be easily applied to adherence in antiviral HCV treatment.

In application to pegylated interferon and ribavirin antiviral treatment for HCV, first the patient received accurate information, such as the potential side effects. Throughout treatment, monitoring the decreasing viral load, and liver function tests, and discussing and monitoring potential side effects may have provided the necessary motivation for adherence. If a side effect such as depression was intolerable, the patient may have started an antidepressant, and used stress reducing techniques. The behavioral skills related to adherence, such as taking the pegylated interferon and the ribavirin as prescribed are developed and continually reinforced. In combination, information, motivation and behavioral skills enhance adherence. The feedback loop allowed for long term monitoring of adherence.

The IMB Model of Adherence provided a common sense, pragmatic approach to adherence. It provided the best theoretical fit and most appropriate application for treatment adherence among veterans receiving pegylated interferon and ribavirin treatment for HCV.

2.3 Comparison, Contrast, And Synthesis Of The Qualitative Literature

A diagnosis of HCV can be traumatic and caused significant anxiety for newly diagnosed patients. The diagnosis itself has been reported to be more stressful than divorce, loss of employment or relocation (Saunders, 2008). There is little research that has focused on the psychosocial and cultural aspects of living with HCV (Hopwood & Southgate, 2003). Yet, qualitative research extends across the globe, uses a variety of methodologies, and has one common thread, the stigmatization among patients who live with HCV (Groessler, Weingart, Kaplan, Clark, Gifford, et al., 2008; Hopwood & Southgate; Janke, McGraw, Tsao & Fraenkel, 2008; Khaw, Stobbart & Murtagh, 2007; Lang et al., 2006; Moore, Hawley & Bradley, 2009; Stoller et al., 2009). The following section focuses on the phenomenological qualitative studies that

describe the “non-veterans” and the “veterans” experiences of living with HCV as well as living during pegylated interferon and ribavirin antiviral treatment for HCV. Importantly, this section will provide comparisons and contrasts in the qualitative literature that exists between non-veterans and veterans. A synthesis of the findings will be presented.

2.3.1 Living With Chronic HCV - Non-Veteran

While the qualitative literature on living with chronic HCV is a mixture of nascent scholarly research, several psychosocial key issues are emerging across populations and cultures (Hopwood & Southgate, 2003). The key issues commonly found in the phenomenological research literature may be categorized in the following manner: experience of diagnosis, stigmatization, and disclosure of HCV status and relationships, and symptom burden and self-management.

2.3.1.1 Experience Of Diagnosis

Individuals newly diagnosed with chronic HCV often described a sense of feeling different and flawed, while expressing fear and uncertainty about the future (Copeland, 2004; Crockett & Gifford, 2004; Fraser & Treloar, 2006; Hopwood & Southgate, 2003; Khaw et al., 2007). Some individuals made positive changes in their health behavior by practicing safe sex and reducing or stopping alcohol. For others, the diagnosis brought past behaviors into the present, for example, past intravenous drug use. Nonetheless, for the majority, the diagnosis resulted in negative feelings and experiences, not only for the individual, but also for the individual’s support system.

Copeland (2004) conducted an interpretative phenomenological study among Scotland’s marginalized injecting drug users to explore the perception and meaning of self-esteem while living with chronic HCV. The participants were older drug users, 30 years to 49 years of age who had lived with the “drug user” label for many years. The participants were female, lived with their families, viewed themselves as unemployable, were in poor health, and felt stigmatized due to HCV. When describing their feelings at diagnosis, many felt that the diagnosis gave a medical label to how they had been feeling. Some felt relief that their health problems were formally

identified. Others were unsure if their feelings of poor health were related to having a diagnosis of HCV. Surprisingly, some generally felt unwell anyway and did not relate poor health to having chronic HCV. In general, those who felt relief at diagnosis attempted to make positive health care changes by decreasing alcohol consumption. Those who were apathetic at diagnosis made no effort to change, because they thought little could be done for chronic HCV. With their troubled backgrounds, the Scotland participants felt a sense of hopelessness and ongoing problems in all areas of their lives. With so many ongoing problems, some were indifferent towards HCV.

Similarly, in an Australian study, Fraser and Treloar (2006) found that those being diagnosed with chronic HCV experienced a shift from healthy to sick, clean to contaminated, and good to bad. These researchers conducted an interpretative phenomenological study to explore the responses of despair and absolute contamination associated with the diagnosis of chronic HCV. The feelings of despair and contamination tended to fluctuate, but were always present. Some of the participants felt that since they already had chronic HCV, then acquiring another blood-borne virus, such as HIV or HBV, did not matter.

These same experiences were described in a second Australian study where the participants reported having negative experiences at the time of diagnosis, which reinforced the feelings of being dirty and infectious (Crockett & Gifford, 2004). The participants were all women with a history of intravenous drug use, were unemployable and homeless and experienced depression. The women said that healthcare providers failed to provide even minimum routine healthcare, time, or information about HCV at the time of diagnosis, resulting in negative feelings. Subsequently the majority of these women felt unworthy to receive medical care. Yet in a United Kingdom (U.K.) prison population, women were motivated to seek healthcare and be tested for HCV (Khaw et al., 2007). These women wanted to know whether they needed to take action to avoid infecting others.

2.3.1.2 Stigmatization

HCV stigmatization has been described as a complex, subjectively experienced phenomenon that significantly influenced individuals living with chronic HCV (Moore et al., 2009). Stigmatized individuals have been considered inferior or a deviant from the normal society. Stigmas were either enacted or felt, in other words, were actual discriminations or the fear of actual discrimination. Stigmas were seen as an emotional response, as anxiety or depression (Moore et al.). Stigmas influenced the Individual's attempt to disclose their HCV status, as well as influenced the individual's willingness to use the healthcare system. Stigmas existed in the healthcare setting, employment, and within the family and home (Copeland, 2004; Crockett & Gifford, 2004; Fraser & Treloar, 2006; Hopwood & Southgate, 2003; Khaw et al., 2007; Moore et al.).

Moore et al. (2009) identified five themes associated with the stigmas of living with chronic HCV. These themes included transmission, disclosure, health practice, relationships and workplace which have also been identified in other qualitative studies (Copeland, 2004; Crockett & Gifford, 2004; Fraser & Treloar, 2006; Hopwood & Southgate, 2003; Khaw et al., 2007).

2.3.1.3 Transmission

Transmission related concepts consisted of giving HCV to others, feeling contagious and recognizing the various modes of acquisition. Moore et al.(2009) explained that some participants implied stigmatization because they were concerned about transmitting the HCV infection to others. Explicit stigmatization occurred when other individuals avoided close contact with the participants, due to the fear of becoming infected. The majority of transmitted related stigmas were associated with sharing contaminated intravenous needles (Copeland, 2004; Moore et al).

2.3.1.4 Disclosure Of HCV Status, Healthcare And Relationships

Disclosure was decided by fear of the others reactions, before and after disclosure. This was evident in the study by Crockett and Gifford (2004), where the HCV women found it difficult

to disclose their HCV status to their partners in fear of negative reactions following disclosure. In some, disclosure was seen as a self-induced stigma due to the individual's own decision to withhold their HCV status (Moore et al., 2009). One participant admitted "I was my own worst enemy... I feared other people's fear of me." Crockett and Gifford commented that the fear of being stigmatized motivated many of the women to hide their HCV status, not only from family and friends, but also from employers and health services.

Most preferred to keep their positive HCV status quiet. This prevented the stereotypical label of an injecting drug user and the associated stigmas of living with chronic HCV. In the workplace, the majority of individuals felt stigmatized by their own decision to withhold disclosure. These individuals commented that they could get fired if they told their employers or did not tell their employers about having HCV, depending on their workplace policies (Moore et al., 2009).

Participants who decided to discuss their HCV status with others experienced a variety of stigmas. Invariably, the diagnosis was associated with injecting drug use. Relationships suffered because others feared the contagious nature of the disease. Interestingly, there were stigmas among healthcare providers (Moore et al., 2009). For instance, 84% of the participants experienced stigmatization by healthcare providers (Crockett & Gifford, 2004; Moore et al.). Healthcare providers spent only minimal amount of time, and effort, and in some instances, referred the individual to a hepatologist. Most healthcare providers did not offer any HCV education (Hopwood & Southgate, 2003). As a result, some participants decreased their health seeking behavior and felt unworthy of medical care. Some participants experienced the notion that they deserved having the disease, since they "did it to themselves through injecting drugs" (Copeland, 2004; Fraser & Treloar, 2006).

Others experienced a mixture of reactions from healthcare providers, such as double gloving, and denial of dental care (Moore et al., 2009). One Australian participant commented that a person with HCV would receive less medical care when compared to someone with any other type of chronic illness (Sgorbini, O'Brien & Jackson, 2009).

After disclosure of the diagnosis of HCV, most participants noticed deterioration in their casual and marital relationships. In casual relationships, some individuals physically moved away from them, avoided coming near them, and decreased or completely stopped communication because of the HCV infection. In marital relationships, some experienced changes in their emotional and sexual involvements with their spouse. Several described a sense of distancing or withdrawal behavior from their spouse. One participant expressed that his sexual relationship with his wife completely stopped, “she could not handle or deal with HCV” (Moore et al., 2009).

For a few, disclosure of the diagnosis brought about positive changes in family relationships. Sgorbini et al. (2009) discovered that some of the participants developed stronger relationships within their families. Sharing the experience with their partners was vital but at times, fatigue, irritability and mood swings compromised their relationships. Surprisingly a few felt that living with chronic HCV provided an avenue for bonding and testing the strength of their familial relationships.

2.3.1.5 Symptom Burden And Self-Management

Lang et al. (2006) identified 21 symptoms that were associated with living with chronic HCV. The symptoms were clustered into neuropsychiatric, gastrointestinal, endogenous pain, and unpleasant abnormal sensations. One participant referred to these symptoms as “hepC attacks”. The most prevalent symptoms were fatigue, depression, irritability, and abdominal pain. Surprisingly, this study identified several previously unreported symptoms including day and night sweats, and light and noise sensitivity.

In a U.S. study, Stoller et al. (2009) examined the experiences, goals and management of symptom burden of persons living with chronic HCV. Management strategies for fighting the virus consisted of complementary medications, diet, exercise, hygiene practices, and the avoidance of hepatotoxic contaminants in the environment. The participants also coped through prayer and downward comparison which was defined as “there was always someone else with more severe problems.” Crockett and Gifford (2004) commented that all the women struggled to cope with the

physical and emotional symptoms of HCV on a daily basis, especially fatigue. Interestingly, even though the majority of participants living with HCV experienced considerable symptom burden, there were some with no symptoms (Crockett & Gifford).

2.3.2 Living With Chronic HCV - Veteran

There is only one phenomenological study which examined the daily experiences of U.S. veterans living with chronic HCV (Groessler et al., 2008). In the phenomenological research literature, key issues comparable and common to both non-veterans and veterans living with chronic HCV are experiences at diagnosis and transmission, stigmatization and strained relationships, symptom burden, and self-management.

2.3.2.1 Diagnosis And Transmission

Groessler et al. (2008) conducted a descriptive phenomenological study to gather information on the experiences and challenges of U.S. veterans living with HCV. In this study, initial reaction to diagnosis varied from fear, denial and shame to relief, hopelessness and worry about death. Similar to the non- veterans, some felt relief, while others were not surprised by the diagnosis because of their drug use.

One veteran, who was attempting to quit injecting drugs, thought “what’s the point, I’m going to die from drugs or from liver disease” and immediately began using drugs again. In contrast, some veterans experienced motivation to stay clean and sober when they were diagnosed with HCV (Groessler et al).

For the majority the method of transmission was intravenous drug use which was similar to non- veterans. Interestingly, a number of veterans felt that the immunization guns used during the Vietnam era were the culprits responsible for disease transmission (Groessler et al., 2008). In spite of that, a good number of veterans recognized that their risky behavior likely contributed to contracting HCV, while others remained ambivalent towards the etiology of their acquisition.

2.3.2.2 Stigma And Relationships

Nearly all commented that the stigma of having HCV impacted their interpersonal

relationships (Grossel et al., 2008). One veteran expressed difficulty in his marriage, “a bunch of arguments over the hepatitis C thing. My wife swears I got it from screwing around with some girl. I haven’t had sex with my wife since she found out I had HepC.” In contrast, some of the participants expressed family support even the kids showed increased concern, asking me what’s going on.”

2.3.2.3 Symptom Burden

The quality of life among veterans was proportionate to the degree of the physical and psychological symptoms associated with chronic HCV (Groessler et al., 2008). Living with HCV was frequently associated with impaired concentration, fatigue, and the stress of living with a chronic disease. One participant noted that having HCV resulted in long-term “irritability, not being able to control stuff, emotional issues.” When considering the option of pegylated interferon and ribavirin antiviral treatment for HCV, participants viewed psychiatric issues as being very important. “I was in Vietnam; my PTSD (posttraumatic stress disorder) has gotten me way out in left field. I’ve talked to others who have taken the treatment and it really messed them up.” Other medical comorbidities weighed heavily on the decision whether or not to start treatment. These included emphysema, arthritis, congestive heart failure, and degenerative disc disease.

2.3.2.4 Self-Management

Common among the veterans was the need to learn more about how to prevent further liver damage and prevent transmission to others (Groessler et al., 2008). In this study, Groessler et al. designed a self-management educational program to help veterans cope while living with HCV. Topics included coping with difficult emotions, depression, pain and fatigue management and relaxation techniques. One veteran remarked, “I’ve quit drinking. I’ve quit smoking. I’ve quit drugging.” Another, “I was 297 pounds, now I am 262. I was told that it’ll help my liver” (Groessler et al.).

2.3.2.5 Summation: Living With Chronic HCV

Living with chronic HCV was seen as a disease which was brought on by one’s own

behavior for which society, in general, has little tolerance or sympathy. As seen throughout these phenomenological studies, the associated issues of living with HCV enormously impacts the daily lives of non-veterans and veterans.

With only one veteran phenomenological study available to compare to the six non-veteran phenomenological studies it was difficult to find distinction between the two. Even though the non-veteran groups tended to be females and the veteran group were males, both expressed similar experiences with diagnosis, disclosure, stigmas, relationships, and self-management. The majority of the women were marginalized, unemployed, and living with their families. They were either current or recent intravenous drug users. In these studies, I could not help but wonder if their negative and low self esteem was due to the drugs and living conditions rather than living with HCV. Relationships were problematic for both groups. One woman participant was told by her own mother that she could not use the same soap for bathing as everyone else in the family. Likewise, one veteran was told that he could only use paper cups, paper plates and plastic ware for meals while living with his family. These two descriptions also demonstrated the misconceptions related to the transmission of the disease.

For the non-veterans, access to healthcare was difficult and minimal, whereas, veterans had access to healthcare through the VA facilities. Veterans were able to attend a HCV clinic which specialized in the treatment and management of chronic HCV as non-veterans received minimal health care. Yet both non-veterans and veterans expressed difficulty with their healthcare providers. Both groups described how their healthcare providers automatically judged them to be injecting drug abusers. HCV veterans maintained their mode of acquisition was the immunization air guns used during the Vietnam era, which differed from the non-veterans. For the majority of veterans there has been more than one risky behavior attributable to the acquisition of chronic HCV (Dominitz et al., 2005). Perhaps these veterans were likely unable to accept their own responsibility for their past or current risky behaviors. This was not seen in the non-veteran groups, as the majority admitted their own risky behavior as the mode of HCV transmission. Both

groups expressed emotional distress, depression, fear and anger directed towards living with a chronic virus infection. The veterans seemed to acknowledge a higher degree of irritability which may be related to the comorbid diagnosis of post traumatic stress disorder.

Similarly, in these individuals living with chronic HCV, there will continually be a before and after the diagnosis. Non-veterans and veterans alike will persistently have a sense of good and bad while coping with daily life. The notion of being well and sick will always be relevant to the varying degrees of symptom burden. Last, the feelings of isolation and acceptance from others will be ever present in relation to disclosure, stigmas and relationships (Fraser & Treloar, 2006).

2.3.3 Antiviral Hepatitis C Treatment Non-Veteran

In the following phenomenological qualitative studies, the primary purpose was to explore the patient's experiences during pegylated interferon and ribavirin antiviral treatment for HCV. Among the patient's experiences, the side effects of treatment, the lack of HCV education and the decreased quality of life were dominant themes throughout the narratives. Side effects included not only the expected and actual side effects, but also the notion of unrealistic optimism during treatment. Most participants expressed that HCV educational and support programs did not meet their needs. Equally important were the quality of life issues. These consisted of coping strategies, emotional disruptions, and the need to maintain relationships and social support during pegylated interferon and ribavirin antiviral treatment for HCV (Hopwood & Treloar, 2005; Hopwood & Treloar, 2008; Sgorbini, et al., 2009; Sheppard & Hubbert, 2006).

2.3.3.1 Treatment Side Effects

Hopwood and Treloar (2005) conducted a descriptive study to explore the key issues related to the side effects of treatment. A majority of the participants experienced a variety of side effects, which included atrial fibrillation requiring hospitalization, insomnia, anxiety associated with self-injections, obsessive thoughts, depression and suicide ideation, and mood disorders. These participants expressed that the side effects associated with HCV antiviral treatment were

debilitating and weakened their capacity to function on a daily basis (Hopwood & Treloar). For the most, participants expected side effects but the actual side effects experienced were quite different. Some expressed a sense of unrealistic optimism before antiviral treatment started. In other words, they would easily be able to manage the side effects (Hopwood & Treloar, 2008; Sheppard & Hubbert, 2006; Treloar & Hopwood, 2008).

Expected and actual. In the study by Sheppard and Hubbert (2006), the participants experienced unremitting fatigue which was an expected side effect. Yet the actual experiences of fatigue were severe and debilitating. One participant described fatigue as “feeling like a drugged-out rag doll.” Fatigue also altered their self-perceptions, “I’m usually high energy, but I feel like I have been in a boxing match and got cold-cocked.” Although the participants were aware of the side effect of depression, many were confused about the use of antidepressants. One admitted “When normal, I would never need an antidepressant.” Some were reluctant to start an antidepressant.

Importantly, Hopwood and Treloar (2005) found that the definition of side effects differed from individual to individual. For instance, one participant commented that he “Did not have any side effects, and his health improved while on treatment.” This participant did not consider the treatment related depression and arthralgia as side effects, but as an exacerbation of pre-existing disorders.

Unrealistic optimism. Treloar and Hopwood (2008) conducted a study to explore the patient’s sense of unrealistic optimism. The participant’s felt protected from treatment side effects. One commented that since she had already experienced depression, she perceived herself “to be protected from developing psychiatric side effects.” A number of the participants felt they would be immune to the side effects, because they suspected their healthcare provider was being “overly dramatic” when discussing the side effects. Once the side effects occurred, these participants had difficulty in coping. When the severity of the side effects were underestimated or overestimated, the participants were unprepared and unable to cope, and subsequently stopped

treatment (Hopwood & Treloar, 2008).

2.3.3.2 Education And Information

Despite the quantity of information provided on HCV treatment, Sheppard and Hubbert (2006) found the quality to be ineffective. For example, one participant reported, "I just got too much, I was saturated and scared." Once antiviral treatment started, many commented that healthcare providers failed to take the time to address their questions and concerns. Most participants were involved in HCV support groups during treatment. Two participants found more emotional support from 12-step programs. "Don't bother with HCV support groups. You'll do better with A.A. (Alcoholics Anonymous)." Another commented, "Don't go to HCV support groups, if you have anything bad at all, when you walk in the door, it will get worse." Sadly, most participants expressed disappointment in the preparation and education they received before and during treatment (Sheppard & Hubbert).

2.3.3.3 Quality Of Life

Negative stigmatization and discrimination associated with living with chronic HCV may result in a reduced quality of life. The associated treatment side effects are debilitating and further reduce the quality of life. Functioning on a daily basis during antiviral treatment for HCV becomes difficult. Poor self-esteem, coping, emotional disruptions and poor interpersonal relationships may further decrease the quality of life during antiviral treatment (Hopwood & Treloar, 2005; Hopwood & Treloar, 2008; Sheppard & Hubbert, 2006; Sgorbini et al., 2009).

Self-esteem, coping and emotional disruptions. Hopwood and Treloar (2008) explored the notion that the experiences of social and economical deprivation could prepare HCV infected individuals with adaptive or resilient coping strategies. Nearly all of the participants, who lived in socially and economically deprived conditions, relied on the experiences of previous hardships to assist with coping during treatment. For instance, these participants easily accessed available community resources, such as counseling, twelve-step programs, and food and financial assistance. In contrast, participants, who were not socially or economically deprived, relied on

stress reducing techniques such as reducing work hours and increasing relaxation as suggested by their healthcare providers.

Sheppard and Hubbert (2006) found the most dominant experience and coping strategy among the participants was having faith. Coping by turning their faith toward a higher power was expressed by each of the participants. "I trust my health to the Lord." Emotional disruptions were felt by a majority during treatment. In an Australian study, one participant developed suicidal ideation during treatment, saying that "interferon made the depression worse, so you have to look at ending it" (Hopwood & Treloar, 2005). Another commented that she "would burst into tears one minute and in the next minute, burst into anger" (Sgorbini et al., 2009).

Relationships and support. In a study conducted by Sheppard and Hubbert (2006) participants expressed their experiences during pegylated interferon and ribavirin antiviral treatment for HCV as, "That's not who I am," and "Looking beyond the experience." Common emotions repeatedly expressed were frustration, anger, fear and sadness. Anger and fear were directed toward their healthcare provider, whereas once on treatment, there was a sense of abandonment. Nearly all the participants felt this was due to the change in how they were perceived by others, "that's not who I am." Another commented "it's like he (the physician) doesn't know me now." All participants relied heavily on their social networks and support system. Social support allowed the participants to look beyond the experience of pegylated interferon and ribavirin antiviral treatment for HCV. After all, "there was more to life than HCV" (Sheppard & Hubbert).

2.3.4 Antiviral Hepatitis C Treatment - Veteran

In the literature, there are only two phenomenological qualitative studies which examined the veterans' experiences during pegylated interferon and ribavirin antiviral treatment for HCV. However, both non-veterans and veterans expressed similar experiences. Common to both are the variations between the expected and actual experiences of treatment side effects and the quality of care.

2.3.4.1 Expectations And Actual Treatment Side Effects

Fraenkel et al. (2006) conducted a study to obtain the patients' descriptions of their own experiences during pegylated interferon and ribavirin antiviral treatment for HCV. Although most of the participants expected side effects, such as fatigue, flu-like symptoms and general aches and pains, many were surprised by the severity and timing, and the unanticipated symptoms of the side effects. One admitted that he thought he would "be a little hot or cold, .I was wrapped up in an electric blanket and then I was soaked in sweat. I didn't expect that." Participants were ill-prepared to cope with the emotional roller coaster associated with pegylated interferon and ribavirin antiviral treatment. "I would be laughing and joking one minute and the next minute I would be crying like a baby." Another commented, "it was like uncontrollable anger. I am surprised I have any friends left. I did not want to deal with people in any way, shape or form". Janke et al. (2008) found similar emotional instability. Participants described experiencing intense feelings of situational irritability, anger and rage. Some expressed a loss of impulse control where others expressed abrupt and unexpected fluctuations with irritability. One expressed, "my fuse is definitely shortened. I get really anxious at traffic lights, enough to get me punching the dashboard sometimes." Another, "I had a problem with my neighbor, I wanted to go out there and beat him up. If somebody was not there holding me back, I would have hit the guy."

Bothersome unanticipated side effects included altered taste, insomnia, and impaired cognitive functioning (Fraenkel et al., 2006; Janke et al., 2008). One participant remarked, "I could not make decisions, I could not meet deadlines. I'd forget where my car was. I could not remember anything". All of the participants were frustrated about the persistence of the side effects, which were summarized as "relentless, 24/7." Changes in emotions were unanticipated and unpredicted which resulted in a feeling of

loss of self. "I cannot help it. I just do not know who I am now." Another commented, "I get so aggravated I just shut down completely. I go home and go into the basement. Don't bother me."

2.3.4.2 Quality Of Care

Poor communication between the primary care providers and the HCV specialists was perceived as deficient in the quality of care received by the participants (Fraenkel et al., 2006). For instance, one participant explained that his “liver provider would refer him to his primary care provider for medical management of his chronic back pain. Before prescribing a medication, the primary care provider would refer him back to the liver provider for approval of the medication.” Many felt that healthcare providers assumed that their HCV infection resulted from risky behaviors such as intravenous substance abuse. One participant commented “the first thing they think about is that you have done something wrong to acquire this.” This strain on communication and perceived stigmatization negatively influenced the health-seeking behaviors among HCV infected veterans (Janke et al., 2008).

Lack of social support was perceived as inadequate by the veterans in the quality of their care (Fraenkel et al., 2006). When HCV support groups were offered, the participants who attended described the benefit of talking with others. Participating in HCV support groups helped prepare them for treatment and the side effects. One commented that unless you “actively seek out a liver support group, you are really kind of lost out there.” Especially helpful was the addition of patient testimonials during HCV support groups. Patients who previously completed treatment provided a “realistic picture of treatment.” Also, pairing up patients during treatment, in a “buddy system,” provided realistic treatment expectations and enhanced communication among the participants (Fraenkel et al.)

2.3.4.3 Summation: Receiving HCV Treatment

In general, these phenomenological qualitative studies, which examined non-veterans and veterans experiences during pegylated interferon and ribavirin antiviral treatment for HCV, were quite similar. Both groups held negative feelings toward their healthcare providers. Both expressed comparable descriptions of the treatment side effects. The non-veterans and the veterans both agreed that the expected side effects differed from the actual experienced side

effects. For instance, most of the participants in both groups expected fatigue, flu-like symptoms, depression and general aches and pains. In actuality the extent of these side effects varied from unnoticeable to relentless, 24/7. Although some of the non-veterans experienced various degrees of anxiety, irritability and depression, a few seemed to be confused about the explanation of these side effects. For instance, depression was seen as a pretreatment diagnosis, therefore, a number of the non-veterans felt protected from developing or worsening symptoms of depression as treatment progressed. The most significant side effect experienced was depression for one female non-veteran, (Hopwood & Treloar, 2008). Her prior drug use counseling, combined with her ability to access and utilize mental healthcare services assisted her in managing depression during treatment.

In contrast, some of the veterans equated irritability with depression and frequently developed spontaneous emotional, volatile outbursts. These outbursts were described as uncontrollable rage and anger (Janke et al., 2008). In my opinion, the greatest contrast between the non-veterans and veterans during pegylated interferon and ribavirin antiviral treatment was the degree of emotional volatility. In every focus group, the participants described experiencing intense feelings of irritability, anger, rage and intense hostility which intensified their psychosocial problems. These hostile feelings were bothersome, unanticipated and unfamiliar and usually directed toward the people around them. The participants described these feelings as loss of impulse control which led to impaired relationships, social isolation, and poor quality of life.

Coping strategies during treatment differed. The non-veterans, who were living in deprived conditions, developed a resiliency in coping which enabled them to access and take advantage of the available public resources (Hopwood & Treloar, 2008). The non-veterans also coped through prayer and social networks. Even though some veterans attended HCV support groups, a number of veterans coped through social isolation.

The increase in psychosocial problems and reduction in quality of life among veterans during antiviral treatment for HCV has been supported in the literature (Fraenkel et al., 2006).

Data have shown that psychiatric, drug and alcohol use disorders are present in up to 85% of HCV infected veterans which may have played a part in the enormity and severity of their psychosocial problems (Chainuvati et al., 2006; El-Serag et al., 2002). These problems were different from the psychosocial problems facing non- veterans with HCV. These psychosocial problems included a higher number of veterans on disability or unemployed, less were married, more were considered to be in poor health and a greater number were diagnosed with mental illness (Fraenkel et al).

Among HCV veterans, the abundance and perilous nature of their psychosocial problems and symptom burden, not only differed from non-veterans, but impacted every aspect of their daily lives (Janke et al., 2008). Their emotional volatility, depression and anxiety created difficulty interacting with others, impacted interpersonal and intrapersonal relationships, and led to social isolation (Fraenkel et al., 2006; Janke et al.).

2.4 Summary

2.4.1 Existing Scientific Knowledge Base

Existing scientific research has provided a broad foundation in the knowledge of adherence. First, adherence was collaboration between the healthcare provider and the patient in the persistence and maintenance of desired health behaviors and outcomes (Cohen, 2009). Second, adherence involved the accuracy of the prescribed doses of medications actually taken, at the correct times and for the correct duration (Osterberg & Blaschke, 2005). Third, adherence was crucial for preventing disease and the associated complications which resulted in a better quality of life and an overall reduction in healthcare costs (Bosworth et al., 2006). Lastly, adherence was usually high in acute diseases, but diminished after the first six months of treatment in chronic diseases (Osterberg & Blaschke, 2005).

2.4.1.1 Relevant Issues Of Adherence In Chronic Disease

In the management of chronic disease, adherence typically included prescribed medications, and prescribed health-promoting behavioral lifestyle changes. In chronic disease,

increased accountability for self-administration, ability to take the medications as prescribed and the need to understand disease, treatment, and potential side effects all influence adherence. For example, patients with hypertension must not only have taken medications at various times during the day, but also adopted health-promoting behaviors such as smoking cessation, blood pressure monitoring and improved diet and exercise. Unfortunately, these changes were difficult.

The increased responsibility and accountability of self-administration impacted the patient's adherence (O'Donohue & Levensky, 2006). In cancer patients, this increased responsibility of self-administration may have been the reason for the wide range of adherence with the oral agent, tamoxifen, from 20% - 100% (Viele, 2007). In many cases, poor adherence among patients with psychiatric disorders, especially depression, was associated with lack of disease insight and lack of information. DiMatteo et al. (2000) reported a three-fold increase in non-adherence among patients with depression who were also receiving concomitant medical treatment.

Literature supports a wide array of additional issues that alter the patient's ability to take medications correctly. These issues may be biological, psychological, and/or social. Older age, comorbid medical conditions, cognitive impairment, and medication side effects are biological issues that may influence adherence (Bangsberg, 2008). Complexity of regimen, misunderstanding, hearing conflicting information, and anxiety or depression may present as psychological issues influencing adherence. Negative perceptions between the healthcare provider and the patient may hinder adherence. Social issues involved social support, language barrier, and restricted access to healthcare and financial constraints all of which may impact adherence (Barbour, 2008).

As of today there is no ideal measurement tool available to measure adherence or the perfect behavioral intervention to increase adherence. The methods of measurement were categorized as either direct or indirect. Direct methods include bioassays and biomarkers and direct observation of the patient taking the medication. Indirect methods consisted of self-report,

electronic monitoring, pill counts and pharmacy refill rates (Hawkshead & Wood, 2007). Each method had limitations and no one method was considered the gold standard for adherence measurement.

Behavioral interventions were the strategies aimed at increasing adherence. The strategies were education, simplification of the medical regimen, improved access to healthcare and encouraging better communication between the healthcare provider and the patient (Osterberg & Blaschke, 2005). Education has been considered the gold standard of adherence, but the complexity of the regimen may override the benefits, especially when education is only offered once (Peterson et al., 2003).

These bio-psycho-social issues, along with the measurement and intervention strategies relative to adherence may best be examined through the application of the Information-Motivation-Behavioral Skills Model of Adherence (IMB). Within this theoretical model, Amico et al. (2005) maintained that an individual who was well informed, motivated to act, and possessed the behavioral skills required to act effectively, was more likely to initiate and maintain patterns of HIV retroviral adherence. Since both HIV and HCV had common issues, this model may easily be applied to the research problem of adherence during pegylated interferon and ribavirin antiviral treatment among HCV infected veterans. In combination, information, motivation, and behavioral skills promoted adherence. The feedback loop allowed for long term monitoring of adherence (Amico et al., 2005).

2.4.1.2 Relevant Issues Of Adherence In Chronic HCV

Adherence to the prescribed complex medical regimen of HCV treatment has been shown to improve the virologic response (McHutchison et al., 2002). Currently HCV patients taking pegylated interferon and ribavirin antiviral treatment for HCV are categorized as: adherent or nonadherent by their healthcare provider. This dichotomy was based on the percentage of medication that was actually taken during a prescribed period of time (Weiss et al., 2008). This dichotomous categorization of adherence and non-adherence did not capture the dynamic and

complex nature of adherence behavior. Adherence could not be categorized as a yes or no as perceived by healthcare providers because each patient had various degrees of sociodemographic characteristics that influenced adherence. These characteristics included social support, overall health status, HCV-related quality of life, as well as mental illness, alcohol and drug use, and trust in health care providers. Thus, patients often described several health behaviors as patterns of adherence behaviors, in contrast to the dichotomous categorizations described by the health care provider.

The definition of HCV adherence in the literature was difficult to interpret. Although the term adherence has been used, Weiss et al. (2009) found that adherence actually referred to the patient's persistence in treatment. In other words, HCV adherence was defined as the duration of treatment or the amount of treatment the patient completes. For instance, the patient completed 16 or 36 weeks out of a total of 48 weeks.

The measurement of antiviral adherence was driven by the 80-80-80 rule. Yet this measurement was interpreted only through the dose reductions and early discontinuation at the discretion of the healthcare provider. This rarely accounted for the patient's missed doses, dose reductions and early discontinuation. Thus measurement of adherence was calculated by the healthcare provider and may not represent the actual amount of the medications and time actually taken by the patient (Weiss et al., 2009).

Although sparsely addressed in the literature, behavioral interventions included both the patients and their support system. Patients and their support systems were encouraged to participate in family education programs and support groups. Interventions directed toward patients involved frequent telephone calls, the use of pill boxes and simplification of medical regimen which may have enhanced adherence (McHutchison et al., 2002)

2.5. Relevant Issues Of Adherence In The Phenomenological HCV Literature

2.5.1 Living With Chronic HCV

The majority of today's research has focused on the epidemiology, natural history, and the progression of HCV-related liver disease, and the medical treatment. Yet of equal importance, is the systematic exploration of the psychosocial issues experienced by individuals living with chronic HCV.

Currently available in the literature, 253 participants enrolled in the phenomenological studies. Approximately 95 participants were enrolled in U.S. studies while the remaining 158 participants were enrolled in Australian or the United Kingdom studies. Of these 253 participants, 22 were U.S. veterans. Data were collected through interviewing, focus groups and written narratives. Injecting drug use was recognized by the majority of the participants as the mode of HCV transmission. In the data, the emerging themes ranged from screening, diagnosis, and transmission of the virus to the need for accurate education and social support. Realistic expectations of an altered quality of life and the impact of symptom burden were included in the participants narratives (Copeland, 2004; Crockett & Gifford, 2004; Fraser & Treloar, 2006; Hopwood & Southgate, 2003; Khaw et al., 2007)(Copeland, 2004; Crockett & Gifford, 2004; Fraser & Treloar, 2006; Groessl et al., 2008; Hopwood & Southgate, 2003; Khaw et al., 2007; Moore et al., 2009).

Sadly, society has marginalized and unsupported individuals living with chronic HCV, in part, because of the unpopular association of injecting drug users (Copeland, 2004). Many participants described feelings of vulnerability and low self-esteem in which their needs were fulfilled in the drug culture (Copeland). Some were indifferent and lackadaisical about having another viral infection, and some felt relief, while others were frightened of the unknown.

Data has demonstrated that living day to day with a contagious disease, and the fear of disclosure, discrimination, and stigmatization among casual and intimate relationships has impacted the daily lives of those infected. The non-veteran participants were females and viewed

themselves as unemployable, unhealthy and lived with low expectations and a sense of hopelessness (Copeland, 2004; Fraser & Treloar, 2006). The veteran participants similarly expressed negative feelings at diagnosis and experienced difficulty living day to day. Some lived with their sense of hopelessness and continued to use alcohol and illicit drugs. Some alleviated their worry by obtaining reliable information, support, and healthcare resources at the VA (Groessler et al., 2008). Interestingly, in both groups, some became motivated to seek treatment for their substance use disorders once they were diagnosed with HCV. Others were unwilling to do anything about their HCV infection until they became abstinent from substance use (Copeland; Fraser & Treloar; Groessler et al.).

For the majority in both non-veterans and veterans, their psychosocial problems might have possibly prevented them from seeking pegylated interferon and ribavirin antiviral treatment for HCV. Life was difficult living day to day. Pegylated interferon and ribavirin antiviral treatment for HCV has not been recommended for individuals who have uncontrolled mental health disorders and/or those who are actively drinking alcohol or using illicit drugs (Fraenkel et al., 2009). If treatment was offered, the side effects might become intolerable resulting in early treatment discontinuation.

Individuals living with chronic HCV have adopted various strategies to cope with daily living. One strategy was the reliance of over the counter herbal medications (Stoller et al., 2009). Milk thistle was most frequently used and a multitude of others. Often patients consulted with other providers such as homeopaths, naturalists, chiropractors, practitioners of traditional Chinese medicine, and energy healers (Stoller et al.). In order to initiate HCV treatment, these remedies must be discontinued and are contraindicated. Several patients have been reluctant to stop these practices which make them non-adherent even before treatment starts. Even though alternative medicines have been perceived as beneficial with minimal side effects by the users, these therapies have not been proven effective in liver disease (White, Hirsch, Patel, Adams, & Peltekian, 2007). Through personal observations, acute liver failure and death have resulted from

the use of herbal remedies in patients with chronic HCV.

2.5.2 Receiving HCV Pegylated Interferon And Ribavirin Antiviral Treatment For HCV

In the literature there are few phenomenological studies published describing the patients' experiences during HCV pegylated interferon and ribavirin antiviral treatment for HCV. From 2005 to 2008, four descriptive phenomenological studies were published in Australia and between 2006 and 2008, two U.S. studies were published using samples that included both HCV infected non-veterans and veterans. There were a total of 139 participants, 62 were U.S. veterans, 18 were U.S. males, and the remaining 59 were Australian participants (Fraenkel et al., 2006; Hopwood and Treloar, 2007; Hopwood and Treloar, 2008; Janke et al. 2008).

Among non-veterans. Antiviral HCV treatment is associated with several physical and psychosocial side effects. Healthcare providers focus on preparing patients to cope with these side effects. In the Australian study, Hopwood and Treloar (2007) found that both healthcare providers and HCV participants described unrealistic optimism in preparation for treatment. In some instances, patients began treatment with optimism in their ability to cope with side effects, such as depression, but as treatment progressed, they became unprepared and stop treatment early. In another Australian study, the marginalized HCV participants adapted their coping strategies which they learned from past experiences of adversity and applied them to their HCV treatment (Hopwood & Treloar, 2008). These strategies included the use of several public resources which served as pathways for enhancing adherence.

Among veterans. Participants described a difference between anticipated and actual experiences during treatment (Fraenkel et al., 2006). To improve the accuracy of treatment expectations, Fraenkel et al. suggested using testimonials from patients who previously completed HCV treatment. Another strategy was the buddy system. This strategy was helpful in alleviating some of the differences and confusion between expected and actual experiences during treatment. Janke et al. (2008) commented that the psychosocial issues most frequently found among HCV infected veterans were emotional volatility and the perception of

stigmatization. Both emotional volatility and stigmatization increased social isolation. Among veterans, psychosocial distress and a reduced quality of life was experienced during treatment (Janke et al.).

2.5.3 Gaps In The Scientific Knowledge Base Of Adherence

2.5.3.1 Adherence In General

1. Adherence is complex, and difficult to measure. Strategies used to enhance adherence are limited. The literature lacks consensus regarding the definition of adherence, reliable measurement tools, and good behavioral interventions for adherence.
2. There is a critical need for the development, implementation and evaluation of effective behavioral interventions to improve adherence.

2.5.3.2 Living Day To Day

1. The patients enrolled in these phenomenological studies represent both HCV positive antibody patients and those with positive viremia. Positive antibody indicates exposure to the virus, whereas, viremia indicates chronic HCV infection. Study findings remain inconclusive. For instance, the clusters of symptom burden directly due to chronic HCV remain unknown (Lang et al., 2006)
2. The knowledge, perceptions, and feelings of intravenous drug users in relation to chronic HCV remains unknown. Both intravenous drug users and HCV infected individuals experience feelings of low self-esteem, depression and hopelessness.. Further exploration is needed to determine if these feelings are a result of the trajectory of IVDA, chronic HCV, or both.
3. There is a paucity of literature addressing the psychosocial issues that exists for non-veterans and veterans living with chronic HCV.
4. The experiences of day to day living with chronic HCV and how these experiences influence treatment adherence remain unknown. Rigorous and systematic

exploration is needed to better understand daily experiences and how these experiences influence treatment adherence.

2.5.4 Adherence In HCV Treatment

1. Although the 80-80-80 rule is considered the gold standard for treatment adherence, this rule only refers to dose reductions and early discontinuation by the healthcare provider and not the patient (Weiss et al., 2008). In the literature the amount of pegylated interferon and ribavirin actually taken by the patient is unknown (Weiss et al., 2009).
2. No formal guidelines exist for evaluating HCV treatment adherence. The degree to which healthcare providers have integrated their evaluation of adherence is unknown (Weiss et al., 2009). The degree to which patients have taken their pegylated interferon and the ribavirin at the correct time and the correct dose is unknown.
3. Interestingly, patients use multiple and inconsistent approaches to take their antiviral HCV medications. These include missed doses, dose reduction and/or treatment discontinuation. There is little in the literature that mentions missed doses by the patient.
4. The degree of adherence to pegylated interferon and ribavirin antiviral treatment for HCV required for maximal virologic suppression during the first 12 weeks of treatment is unclear (LoRe et al., 2009). The amount of viral suppression during the first 12 weeks determines the course of treatment. Lacking in the literature is the critical need to ascertain adherence risk factors early in treatment in order to achieve the best viral response.
5. There is little in the literature addressing the number of HCV infected veterans who are referred for psychiatric comorbidities and eventually become eligible and receive pegylated interferon and ribavirin antiviral treatment for HCV (Rowan, Dunn, El-Serag & Kunik, 2007).

6. Little is known about how non-veterans and veterans perceive and evaluate their own treatment experiences.
7. There have been limited phenomenological data on the relationship between the side effects of HCV pegylated interferon and ribavirin antiviral treatment for HCV, and how these side effects impact daily living. For the most, the phenomenological studies conducted outside of the U.S. were completed while patients were receiving unmodified interferon (Hopwood & Treloar, 2005). This medical regimen is different from today's pegylated interferon and ribavirin.
8. Some of the participants enrolled in these phenomenological studies received treatment before 2000 and relied on memory recall, others refused treatment but were eligible to participate, and some were completing treatment (Hopwood & Treloar, 2005). Since some were not receiving pegylated interferon and ribavirin at the time of the interviews, the experiences of pegylated interferon and ribavirin antiviral treatment for HCV remains questionable.
9. In the literature, there are only two phenomenological studies examining the treatment experiences of HCV infected veterans (Fraenkel et al., 2006; Janke et al., 2008). Participants included a heterogeneous sample which consisted of those who refused treatment, non-veterans and veterans. There is limited phenomenological data on the experiences of veterans receiving pegylated interferon and ribavirin antiviral treatment for HCV.

2.5.5 What Is The Gap For Current Study?

A gap in the literature exists that addresses the meaning of adherence with the experiences of HCV infected veterans during pegylated interferon and ribavirin treatment.

2.5.6 Link To Current Study

Clearly, the review of the HCV adherence literature uncovered several important issues. Adherence has been and continues to be an important factor of treatment success. Individuals

receiving pegylated interferon and ribavirin antiviral treatment for HCV have often experienced difficulty in adhering to treatment because of the numerous associated bio-psycho-social spiritual issues. For instance, suboptimal adherence is common in the HCV veteran population as evidenced by 68% discontinuation rate (Backus et al., 2007).

As the number of veterans who become symptomatic and are diagnosed with chronic HCV increases, the need for phenomenological research becomes vital. There is a crucial need to understand the experiences of living with hepatitis C during pegylated interferon and ribavirin antiviral treatment for HCV and the impact on daily life (Hopwood & Southgate, 2003). The review of the literature has shown that qualitative research may uncover how individuals cope with treatment and the related side effects and how these side effects impact quality of life and treatment adherence. The HCV phenomenological studies provide insight into the understanding of the chronicity of HCV infection, the treatment and the associated changes in quality of life.

The purpose of this study was to explore the meaning of adherence and connect adherence to the experiences of HCV infected veterans while they were receiving pegylated interferon and ribavirin antiviral treatment for HCV. Experiences during treatment probably influenced the choice to remain adherent or non-adherent to treatment are therefore vital when studying adherence. Qualitative phenomenological research significantly contributed to the understanding of the daily life experiences among HCV infected veterans during pegylated interferon and ribavirin antiviral treatment and gave adherence a meaning which was desperately needed.

Without understanding the dynamics of adherence, it was difficult to address the potential vulnerabilities that non-adherence creates. By exploring the patient's definition, categories, vocabulary and behavioral approaches during HCV treatment provided insight into the meaning of adherence. A hermeneutic phenomenological prospective study among U.S. HCV infected veterans may supplement the current research findings in order to better understand and improve patient adherence. The most appropriate and pragmatic approach to find the meaning of

adherence during treatment was to simply ask the patients. The knowledge gained was the foundation on which to build further adherence research.

CHAPTER 3

METHODS AND PROCEDURES

3.1 Introduction

The purpose of this chapter was to explain the use of hermeneutic phenomenology to examine what taking pegylated interferon and ribavirin medications means to HCV infected veterans. It provided an overview of hermeneutic phenomenology as a philosophy and methodology and explains the method's appropriateness for the current research study and research question. This chapter defines any relevant terms and diagnoses used in the research design. It identifies the study population and sample, study setting, and data collection methods. This chapter provides additional information on the recruitment of participants and the process of obtaining informed consent. In this chapter, data collection focuses on the assumptions, the software and the journaling necessary for data analysis. It also addresses additional methodological issues such as rigor and credibility necessary for data analysis, as well as the delimitations of the study.

3.2 Method

3.2.1 Type of Study

Hermeneutic phenomenological research has been used to answer questions of meaning. This research method has been useful when the researcher wants to understand an experience as it was understood by those who were having the experience (Cohen, Kahn, & Steeves, 2000). This method has been appropriate for studying an issue that needed an innovative perspective, such as adherence with pegylated interferon and ribavirin in the veteran population. Currently, the definition, measurement, and effective behavioral interventions of adherence during HCV antiviral treatment remain unknown. The hermeneutic phenomenological method has allowed the researcher to ask the participants to describe their experiences they

have lived. For instance, asking the participants to describe their experiences of adherence during antiviral treatment may provide a better understanding and the meaning of the phenomena of adherence. Since hermeneutic phenomenology has strived to understand another's experience, this method was an ideal starting point to study the experiences of adherence and what it meant to be adherent while receiving HCV antiviral treatment in the veteran population.

3.2.2 Philosophical Foundations

The term phenomenology was derived from the Greek words *phainoemn*, meaning appearance, and *logos*, meaning reason (Gearing, 2004; Vivilaki & Johnson, 2008). Phenomena were everything that was revealed to our realm of understanding and logos were the ability of humans to think and articulate thoughts in language (Vivilaki & Johnson).

A phenomenological study described the meaning of the lived experiences for individuals about a concept or phenomenon of interest (Creswell, 1998). The intent was to search for the central underlying meaning of the phenomenon (Cottrell & McKenzie, 2005). Understanding the meaning of the lived experiences marked phenomenology as a philosophy and a method (Creswell, 2003).

3.2.2.1 Philosophy

Phenomenology was a philosophical approach to the study of phenomena or appearances and human experiences (Lopez & Willis, 2004). Phenomenology strived to answer the question of what it was like to have a certain experience. In phenomenology, there was not one single reality; each individual has their own reality. Reality was subjective and each experience was unique to the individual.

Two phenomenological philosophers commonly associated with qualitative research were Husserl and Heidegger, who differed in their views of the individual and his or her world. Husserl's philosophical ideas about scientific inquiry gave rise to descriptive phenomenology (Lopez & Willis, 2004). Husserl's philosophy was that experience, as perceived by human consciousness, had significance and should be examined through scientific study. This subjective information of

human consciousness was important to science because human actions were influenced by what individuals perceived to be real. A scientific approach other than empiricism was necessary to determine the essential components of the lived experiences as described by an individual (Lopez & Willis).

One important component of Husserlian phenomenology was the belief that the researcher removed all prior personal knowledge in order to understand the essential components of the lived experiences of the participants (Lopez & Willis, 2004). This included all expert knowledge, preconceptions, personal biases and past experiences (Gearing, 2004; Hopp, 2007). The goal of the researcher was to achieve transcendental subjectivity, which meant that the researcher's biases and preconceptions remained neutral and did not have an effect on the study (Lopez & Willis). This was referred to as bracketing. This was a technique used while listening and reflecting on the lived experiences of the participants (Snow, 2009). Another important component of Husserlian phenomenology was the notion of universal essences or eidetic structures (Lopez & Willis). This meant that certain features associated with any lived experience were common to all individuals who had the experience. These commonalities provided a general description which represented the true nature of the phenomenon being studied (Lopez & Willis).

Husserl, through descriptive phenomenology, brought philosophical questioning back to seeing the world as it really was, and shifted the focus of scientific inquiry away from empiricism (Gearing, 2004; Giorgi, 2005). Heidegger, a student and later colleague of Husserl, disagreed with the philosophy of descriptive phenomenology as a guide for meaningful scientific inquiry (Laverty, 2003; Lopez & Willis, 2004). Heidegger's ideas supported the notion of interpretative phenomenology, known as hermeneutics. The word 'hermeneutics' came from the Greek god, Hermes, who was assigned as the messenger of the gods by Zeus (Lopez & Willis). It was his task to keep all of the gods well informed.

A hermeneutic phenomenological philosophy was essentially the understanding of a

particular phenomenon with the scientific interpretation of phenomena documented in the written narratives (Speziale & Carpenter, 2003). The aim of hermeneutic or interpretative phenomenology was to uncover what was normally hidden in individual experiences (Lopez & Willis, 2004).

The relationship of the individual to his or her lifeworld was the basis of interpretative inquiry. 'Lifeworld' proposed that individuals' realities were influenced by the world in which they lived, and 'being-in-the-world' implied that individuals could not remove themselves from their world (Lopez & Willis, 2004; Malt, 1999). Implanted in their world, individuals were socially, culturally and politically integrated. Individuals acquired situated freedom, which meant they were free to make choices, but their freedom was connected to the specific conditions of their daily lives (Lopez & Willis).

Heidegger's philosophical conceptualization has been divided into the following categories: being-in-the-world, fore-structures, time, and space (Mackey, 2005). The principal theme of Heidegger's philosophy was that the individual existed as being-in-the-world and could not be separate from the world. The most significant way an individual was 'being-in-the-world' was by being aware of 'being'. As an individual became aware of 'being' and began to wonder about his or her own existence, Heidegger referred to this as 'dasein'. In this dasein, the individual had access and became aware of his or her own existence which represented 'being' in the everyday, average life (Mackey).

Fore-structure, one of the fundamental components of Heideggerian interpretation, was described as what the individual already knew, or a pre-understanding which simply needed to be expressed (Mackey, 2005). For example, the fore-structure was described as the opinions and experiences the researcher and the participant brought to the research study. Interpretation allowed for this pre-understanding to be revealed and meaningful. Therefore, when meaning became evident, the phenomenon was revealed.

Interestingly, understanding through interpretation could not be achieved without the consideration of time. The concept of time was essential for human existence and was not

necessarily chronological, linear or a measurable entity (Mackey, 2005; McConnell, Chapman & Francis, 2009). Heidegger considered the individual to be temporally grounded or situated in-the-world. Temporality joined together the past, present and the future. In other words, what was experienced in the present was meaningful with what was experienced in the past and what is anticipated to be experienced in the future. This awareness became one in the present.

Temporality referred to a point in time where something stood out from the smooth flow of everyday life. Temporality could be limiting and dismantling of an individual's 'being-in-the-world' (Mackey, 2005). For instance, once an illness occurred or a diagnosis of chronic disease was made known to an individual, the previously average daily life and the carefree future became both distant and unclear. Heidegger referred to these experiences that stood out in time as 'ecstatical character.' The chronological date and time were not really important. It was the point in time that was important. Recognition of those things that stood out in the participants' descriptions enhanced the understanding of the experience (Mackey).

In addition to temporality, 'being-in-the-world' also referred to spatial existence, because everyone and everything belonged somewhere (Mackey, 2005). Space was not a geographical place, but rather a sense of being in a particular space (McConnell et al. 2009). In addition, the notion of what it meant to be in that space and how that feeling influenced the individual's experiences became important. For instance, adherence was not a geographical place but rather a sense of being in a particular space. What did it mean to be in the space of adherence and how did this feeling influence the individual's experience?

Heidegger referred to spatial situatedness as 'there.' As being 'there', an individual either brought something close (here) or experienced something at a distance (yonder). Yet closeness was not merely a measurable distance, but something that an individual cared about, and was something of concern. The term 'sorge' referred to care or concern which brought a notion of wholeness to the individual and the individual's sense of being-in-the-world'. Therefore it was essential for the researcher to be aware of what was in the background and the foreground and

what was concerning for the participant and how this situatedness and 'sorge' were unique to the participant (Mackey, 2005)

The hermeneutic phenomenological researcher needed to listen to the descriptions of the phenomena, situations, and experiences of the participants. It was important to listen for those experiences that were close and/or remote to the participants' attention. Through the interpretive process of understanding, the researcher strived to describe, analyze and reflect upon the state of concern that existed between the person and the phenomenon experienced (Mackey, 2005).

3.2.2.2 Method

In a Heideggerian research method, the experiences of the participants were interpreted and analyzed through the researcher's own knowledge and experiences (Snow, 2009). Interpretation and understanding could not be gained through bracketing, but by the engagement of the researcher's own biases and preconceptions (Denzin & Lincoln, 2005). The researcher opened his or her own biases and preconceptions to testing through the conversational dialogues with the participants. In this manner, conversational dialogues not only test biases and preconceptions, but also brought an in-depth understanding of the phenomenon through the process of questions and answers. These conversational dialogues began with the researcher's questions in order to eventually unravel the meaning of the phenomenon through the answers of the participants (McConnell et al., 2009). In essence, the understanding became a mutually negotiated interpretation between the researcher and the participant (Denzin & Lincoln).

Methodological frameworks for research were found in the conceptualization of philosophical ideas (Mackey, 2005). Heideggerian interpretation was conceived as a circular process, a circle of understanding. Initially, each individual brought his or her fore-structures of understanding into the research study. These individual fore-structures were considered parts of the whole phenomenon. The researcher then combined the fore-structure parts and considered these fore-structures parts in terms of the whole understanding of the phenomenon. The understanding was then reassessed in a new way. This process was expressed as the

hermeneutic circle, which referred to the flow of understanding. There was a back and forth movement between partial understanding and the more complete understanding of the whole phenomenon. Each gave meaning to the other, resulting in a circular repetition of interpretation and understanding (Ajjawi & Higgs, 2008).

Benner (1994) explained the process of the hermeneutic circle method as facilitated through identification of exemplars. For instance, the researcher read and analyzed the narratives as fully as possible for overall understanding, and then read and analyzed the parts of the narrative for examples of themes. Each gave meaning to the other (Ajjawi & Higgs, 2008). Van Manen (1990) described the circular process as hermeneutical phenomenological writing. Through writing and rewriting, the researcher refined and reflected, allowing for deeper meaning to emerge. Mackey (2005) described the hermeneutic circle as beginning with reading and listening to the data. The researcher interacted with the data through transcribing and underlining meaningful sections of transcripts, then asked questions and proposed ideas about its meaning. Writing involved reflecting on the experiences as described and wondering what was missing. To further the circular process, the researcher stepped back and looked for the characteristics within the experiences which revealed a better understanding of the aspects of the phenomenon being studied (Mackey). The philosophy of being-in-the-world was now linked with the methodology of the hermeneutic circle.

Phenomenology's philosophical premises accepted individual experience as a valuable source of knowledge, and its methodological approaches allowed and encouraged the complexity and depth of human experience to be expressed (Mackey, 2005). As with any type of research, there must be a correspondence between the philosophical foundation of the study and the methodological processes of the research protocol (Speziale & Carpenter, 2003).

3.2.3 Rationale

The research method was determined by the research question, purpose of the study, and the resources and skills available to the researcher (Denzin & Lincoln 2000). In this study, the

research question concerned the meaning of a phenomenon, therefore, the best method suited to answer the question was phenomenology. In Heideggerian phenomenology, each individual brought a historicity or background of experiences that could not be separated from the individual. The narratives of the participants merged together with the researcher's background of experiences. The researcher strived to understand and interpret the phenomenon through the lived experiences of the participants. More appropriately the researcher might ask, "What was the nature or what was the meaning of the lived experience of a certain phenomenon?" (Denzin & Lincoln). In this study, the phenomenon was adherence.

The phenomenon of adherence to a prescribed medical regimen in chronic HCV has not been thoroughly understood. Perhaps, the manner in which adherence was defined, measured, and evaluated could be better understood through the experiences of everyday living during HCV antiviral treatment. Phenomenological research emphasized that a rich description was found in the experiences of everyday living. Subjective processes, such as narratives or storytelling, allowed individuals to communicate their unique experiences and allowed the researcher to inquire and interpret the meaning of the lived experiences (Denzin & Lincoln, 2005). This approach allowed for an interpretation of the meaning of those lived experiences and the interpretation was the basis of all understanding (Mackey, 2005). In consequence, interpretations through the rich descriptions enhanced the knowledge of the phenomenon of adherence.

Hermeneutic phenomenology suited the aim of the study which was to uncover the unique meaning of the lived experiences of adherence of HCV infected veterans during pegylated interferon and ribavirin treatment. The hermeneutic phenomenological method provided insight through the descriptions of the participants' daily worlds and unraveled the meanings of their experiences of treatment adherence. The interpretation of these daily life experiences during antiviral treatment adherence created a better understanding, thereby filling in the gap with new scientific knowledge.

3.3 Sample

3.3.1 Target Population and Sampling Criteria

The population targeted for this study consisted of male or female adult veterans of any ethnicity who have a diagnosis of chronic HCV, and are currently receiving, or received in the previous year, pegylated interferon and ribavirin treatment within the VA Health Care System. A convenience sample of eligible veterans were recruited from the Dallas VA hepatitis C treatment clinic where they were treated and managed for chronic HCV infection.

Eligibility consisted of veterans who were 18 years of age or older, enrolled, and were currently receiving or previously received within the last twelve months, pegylated interferon and ribavirin antiviral treatment in the HCV clinic at the Dallas VANTHCS. Although the majority of veterans who received their healthcare at the VANTHCS were male, both males and females were eligible for participation. In addition, eligible veterans needed to be able to read, write, and communicate in English in order to complete the consent and demographic forms, and participate during the interviews. All veterans who met eligibility criteria, regardless of severity of chronic HCV illness and/or demographic characteristics, were invited to participate.

Ineligible veterans would be anyone who was also HIV positive or a liver transplant patient. Those veterans were seen in a different VA clinic, and not enrolled in the Hepatitis C treatment clinic.

3.3.2 Sampling Rationale

Qualitative sampling was based on a purposive strategy, which consisted of choosing participants, not for their representativeness, but for their relevance to the research question, purpose, and analytical framework (Maxwell, 2005; Schwandt, 2007; Speziale & Carpenter, 2003). Relevance in this research proposal was the uniqueness of the participants, that is, the HCV infected veterans who received antiviral treatment within the VA Health Care System. The Dallas VANTHCS was chosen as the site to recruit HCV infected veterans. These veterans were receiving pegylated interferon and ribavirin antiviral treatment in the HCV treatment clinic. The

Dallas VA HCV treatment clinic was appropriate because this site allowed the researcher to use a purposive strategy for convenience sampling.

In support of the research question, aim, and analytical framework, these unique veterans might provide insight to the issues of antiviral treatment adherence. The participants were chosen based on their lived experiences of pegylated interferon and ribavirin treatment. They were selected for the purpose of describing and giving meaning to their experiences of taking their medications. The outcome of the study was to produce a greater understanding of adherence to antiviral treatment.

Creswell (1998) proposed a criterion type of sampling strategy, which similarly meant that the participants met some criterion. Interestingly, purposive sampling included not only explicit information on the attributes of relevant selection criteria, but also the strategy for checking that the participants were not chosen simply because they supported the research. For this study, purposive sampling included both the relevant selection criteria and the criterion sampling strategies which were explicitly detailed in the sampling criteria within the target population.

3.3.3 Definition of Relevant Terms

1. Veteran: U.S. citizen who served time in the military and received an honorable discharge.
2. Chronic HCV: an active infection with the hepatitis C RNA virus for more than 6 months as evidenced by positive HCV antibody and virus detected through a HCV RNA qualitative and/or quantitative assay.
3. Hepatitis C (HCV) Clinic: a clinical area dedicated to the treatment and management of HCV infected veterans during antiviral treatment.
4. Antiviral Treatment:
 - a. Combination of two medications which consisted of pegylated interferon α 2a or α 2b injections, self-administered subcutaneously once a week and ribavirin capsules taken twice daily orally with food.

- b. Coverage from the initial start-date of pegylated interferon and ribavirin treatment, extending through the six month (24 weeks) period post treatment, which at this time, the presence of viremia was determined.
 - c. Treatment recovery consisted of the time after the participant was determined to achieve sustained viral response or non-response. For this study, the treatment recovery phase was any point in time during the twelve months post-treatment.
5. Responses to Treatment:
- a. End of Treatment Response: undetectable HCV RNA levels at the completion of therapy.
 - b. Sustained Viral Response: undetectable HCV RNA levels 24 weeks after the completions of therapy or viral clearance.
 - c. Relapser: undetectable HCV RNA levels at the completion of therapy but detectable HCV RNA levels 24 weeks after the completion of therapy. A Relapser was considered a non-responder.
 - d. Non-responder: insufficient virologic response at 12 weeks (detectable HCV RNA or less than a 2 log drop in the HCV RNA level from baseline) or at 24 weeks (detectable HCV RNA level).

3.3.4 Factors Determining Sample Size

Since the majority of clinical practice entailed the treatment and management of HCV veterans, the method of sampling was through primary selection. In primary selection, the researcher maintained control of the sample due to the relationships of prospective participants (Morse, 1991). In order to identify the commonalities associated with the experiences of treatment adherence, all interested individuals who met eligibility, were enrolled and consented. For this study, the sample size included up to 30 veterans or until saturation or repetition of information was achieved.

3.3.4.1 Rationale

In phenomenology, the sample size has been relatively small. Commonly, the data were gathered through interviews with the number of participants ranging from five to 25 (Creswell, 1998). The preciseness of the sample size depended on previous studies and clinical experience (Cohen et al., 2000). Review of the literature revealed sample sizes that range from six to 40 participants in qualitative studies examining chronic HCV.

Speziale and Carpenter (2003) referred to saturation as the repetition of learned information and affirmation of previously collected data. In other words, rather than sampling a specific number of individuals to gain significance, the researcher collected data on the participants until the information was repetitive and/or no longer obtained new information. At this point, saturation was reached. At best, the researcher was able to saturate the specific phenomenon at a particular time, space, and sample of participants.

3.4 Setting

3.4.1 Description of Setting

The setting for this study was the Dallas VANTHCS. This facility was a large inpatient and outpatient medical center located in southeastern Dallas County. The potential participants received their healthcare at the Dallas VANTHCS and were currently receiving, or received in the previous year, pegylated interferon and ribavirin treatment in the outpatient HCV clinic. In this clinic, the HCV treatment team monitored the management and treatment of HCV infected veterans. This clinical setting was appropriate and offered a convenience sample of veterans who met the eligibility criteria for this study.

3.4.2 Relevant Terms

1. VANTHCS: VA facility who treated eligible veterans for health care and who resided within the catchment area of North Texas.

2. Healthcare provider: a licensed practitioner authorized to deliver health care through the provisions approved in a scope of practice. This included physicians, advanced practice nurses, and physician's assistant.
3. HCV treatment team: team of healthcare providers and ancillary staff. This included a supervising attending physician (hepatologist), rotating GI/liver fellows, mid-level providers (advanced practice nurses, physician's assistant), psychologist, psychology interns, pharmacist D students, and one mastered prepared Registered Nurse. Additionally, one administrative clerk, one Registered Nurse, two Licensed Vocational Nurses and two health technicians were assigned to the GI/Liver service clinical area.
4. HCV Treatment Clinic: was a geographical location on the third floor of the Clinical Addition at the Dallas VANTHCS with private examination rooms. This was the clinic where the HCV treatment team managed and monitored HCV patients receiving pegylated interferon and ribavirin treatment.
5. Clinical research unit (CRU): was a geographical location on the eighth floor of the main building on Dallas VANTHCS campus. The research unit was designed with private rooms dedicated to the intake of clinical research information.

3.5 Data Collection Method

3.5.1 Procedures

This study consisted of a one-time qualitative interview with each participant. A brief follow-up telephone conversation with each participant took place to ensure the accuracy of each transcript.

3.5.1.1 Identification and Recruitment

The HCV clinic was available for all HCV infected veterans who met antiviral treatment criteria. Each patient received the current standard of care, pegylated interferon and ribavirin and was managed in the HCV clinic until he or she became either a non-responder or achieved a sustained viral response. The length of time a patient was enrolled in this clinic varied from 24

weeks to 72 weeks depending on treatment response. All patients enrolled in this clinic were identified as potential participants in this research study.

Following appropriate approval of the study from both the University of Texas at Arlington and the Dallas VA Research Corporation, the researcher met with members of the HCV treatment team to explain the purpose and significance of the study. The researcher provided an example of an oral script for recruitment (Appendix A) and an informative flyer for distribution (Appendix B). Identification and recruitment for the research study would be initiated by the members of the HCV treatment team as patients were seen in the HCV clinic. If the patient showed an interest to the research study, then the team member would introduce the patient to the researcher in the clinic. If a more convenient time for the patient was needed, then he or she would be able to telephone the researcher for further description of the study. Either in person or by telephone, the researcher described the research study in more detail (Appendix A). The researcher screened the patient over the telephone or in person to determine criteria eligibility and if the patient was agreeable to the interview. If the patient was interested in participating, an appointment was scheduled for the informed consent and the interview.

3.5.1.2 Description of Obtaining Informed Consent

The scheduled appointment was held in the clinical research unit or a private room setting at the Dallas VANTHCS. The potential participant was given a copy of the consent form to read while the researcher verbally read the form out loud (Appendix C). The description and the purpose of the research were thoroughly explained. The risks and benefits associated with participation were reviewed. The amount of time necessary for participation, data collection procedures including audio-tape recording and analysis of data was discussed with emphasis on the participants' confidentiality. The ability of the participant to withdraw or ask questions at any time during the research process was explained. All potential participants were given the opportunity to choose to participate or not to participate in the research study and their decision would not influence their ongoing healthcare. Although the interview process consisted of audio-

tape recording, the potential participant had the ability to request that certain information not be recorded. Once the questions of the research study were answered and the potential participant agreed to participate, the consent form was signed by the participant and the researcher. Their signatures were witnessed by a third person. A printed copy was given to the participant.

An electronic copy of the consent form was documented in the computerized patient's record. A research enrollment note was entered which communicated to healthcare providers that the patient was participating in a research study.

3.5.1.3 Interview Process

The interview process between the researcher and the participant was audio-taped and recorded in a private room setting or in the clinical research unit at the Dallas VA NTHCS. The time needed for the interview process was not more than 60 minutes. The interview method and rationale will be presented in more detail in the methods section.

3.5.1.4 Demographic Data

Once the interview was finished, the participant was asked to complete the demographic data form. This form consisted of sociodemographic data which would provide baseline characteristics of the participants. Demographic characteristics included gender, age, and ethnicity. Social characteristics included marriage status, employment, level of education, and language (s) proficient/spoken at home. A reliable telephone number was a requirement in order to contact the participant for follow up confirmation of data.

3.5.2 Methods

The methods of data collection for this study were interviews, listening, and the researcher's observations and journaling. The interviews were semi-structured or open-ended questions, audio-taped and recorded. The recordings were transcribed verbatim for data analysis. This allowed the researcher to study and evaluate the parts as well as the whole of the data, as required in the hermeneutic circle.

3.5.2.1 Rationale

The underlying principle behind data collection in hermeneutic phenomenology was the notion that life experiences take place in the present, yet the meanings given to those experiences were examined and studied at a later time (Cohen et al., 2000). Therefore, as the participants told of their experiences, their narratives were transformed into verbal textual data that were later studied. As the conversational dialogues continued, data became a compilation of recorded verbal textual data, and were converted to written texts about the experiences of adherence during antiviral treatment.

3.5.2.2 Interview

Cohen et al. (2000) explained that by asking questions that resembled conversations produced narratives specific to the phenomenon of interest. The aim of the interview process was to elicit sufficient information about the participant's experiences of adherence in their daily lives. The tasks of the researcher were to explore the commonalities within the narratives as they emerged and later to interpret these mutual commonalities. The intent of the researcher throughout the interview process was to learn from the participants' experiences, focus on these findings, and generate new knowledge (Vandermause, 2007).

3.5.2.3 Listening

The method of listening was an interactive process (Vandermause, 2007). In this interactive process, the researcher listened to the participant's narrative with a degree of hesitancy. This hesitancy was just long enough to allow the story to develop. As the researcher questioned further and continued to listen, she began to actually hear the story. Importantly, this interactive process reinforced the hermeneutic circle. The researcher listened initially to the parts, which consisted of the various points of views, the silences and responses of the participant. The researcher then engaged in the whole of the phenomenon by further questioning through conversational dialogue. This continued back and forth, reinforcing the information gathered during the interview process.

3.5.2.4 Researcher's Observations And Journaling

Observations provided contextual information and insight for the narrative data collected during interviews (Cohen et al., 2000). Observations were written as soon as possible protecting the accuracy and thoroughness and were written after the interview. For example, observations of the physical setting included the surrounding conditions, disturbances or interruptions. Characteristics of the participant, such as body language, tone of voice, or appearance augmented the narrative. The researcher's observations were especially helpful when information became evident after the tape recorder was turned off. A journal provided an opportunity for the researcher's self-reflection and provided a written story of the researcher's own experiences of inquiry and meaning.

Hermeneutic phenomenology was the most appropriate method for the proposed research design. The hermeneutic phenomenological method allowed this researcher to obtain the descriptions and to study the experiences of treatment adherence through the participants' own narratives. This method provided an avenue for this researcher to develop an in-depth understanding of the meaning of treatment adherence within the context of those experiencing it (Snow, 2009).

3.5.2.5 Grand Tour Question

Grand tour questions were descriptive and often introductory. They were very broad, open-ended general questions through which the researcher attempted to draw out a rich descriptive narrative by the participant (Crabtree & Miller, 1992; Speziale & Carpenter, 2003; Spradley, 1979). For this study, the interview was initiated with the grand tour question, "What does it mean to take your HepC medications every day during treatment?" The grand tour question and subsequent typical questions would follow the interview guide for consistency of questions for each participant (Appendix E).

3.5.2.6 Typical Questions

In addition to descriptive questions, the researcher used structural and contrast questions

(Crabtree & Miller, 1992; Spradley, 1979). A descriptive type of question was how the diagnosis of HCV impacted the participant's life. Structural questions were questions of inclusion to gain further detail on the phenomenon of interest. In this study, the researcher asked questions to develop a better understanding of the phenomenon of adherence. For instance, "Describe what taking your HepC medication means to you". Then the researcher asked a verification question to prove or disprove the researchers' understanding of the phenomenon (Spradley). For instance, "Does taking your medication mean taking all the medications as prescribed or are there different kinds or degrees of taking your medications?" Substitution questions were used which removed one term and the participant replaced the term with another. For example, "When I feel depressed, I usually take my medication;" may be replaced with, "When I feel depressed, I usually (the participant answers in his or her own words)."

Contrast questions clarified the phenomenon through the use of exclusion (Crabtree & Miller, 1992; Spradley, 1979). These questions began with what was known of the phenomenon and then asked about contrasts within the phenomenon. For example, "I understand what you mean by taking all of your medications, but if you run out of your medication, and take only half a dose, are you still taking your HepC medications?" Additionally, rating questions were used to better understand the phenomenon. An example included, "What is your best day during treatment?" versus, "What is your worst day during treatment?"

Descriptive, structural, and contrast questions were intermingled throughout the interview process (Crabtree & Miller, 1992). The variety of questions allowed the researcher to gain a better understanding of the phenomenon of interest through the conversational dialogues within the narratives.

3.5.3 Rigor and Credibility During Data Collection

Credibility was analogous to the internal validity of the data (Waltz, Strickland, & Lenz, 2005). In other words, the researcher was measuring or observing what was thought to be consistent with the research question. Generally, numerous sources influenced the quality of data

collected, threatening validity, reliability and generalizability (Waltz et al.). These sources were the participant, the data collector/researcher, and the methods used during data collection.

3.5.3.1 Participants

In this study, participants were chosen because they had recently, or were currently experiencing the issues of adherence with HCV antiviral treatment. The quality of data rested with the participant's ability to sort out and talk about the everyday experiences of adherence during treatment. Although the researcher relied on the honesty of the participants during the conversational dialogues, the possibility existed that a participant merely told the researcher what he or she felt the researcher wanted to know. To diminish the threat to credibility, the researcher varied the different types of interview questions. For example, alternating descriptive, structural, and contrast questions increased the credibility of the narratives.

A good interview was one where most of the dialogue was through the participant and less by the researcher (Waltz et al., 2005). Open-ended questions were asked allowing ample time for the participant to answer the question. Importantly, the researcher summarized the participant's dialogue when needed to ensure the researcher understood what the participant was saying. Once the transcripts were written, studied and coded, the researcher performed member checks or participant validation to assure the accuracy of the transcripts. Member checks or participant validation was the most important method of assuring that the researcher was accurately interpreting the meaning of what the participants said (Maxwell, 2005). In similarity, the researcher's own biases and misunderstandings of what she observed were identified and/or reinforced by performing member checks (Maxwell).

3.5.3.2 Researcher

The researcher influenced the quality and accuracy of the data collected. Inherent in the interview process were threats to validity and reliability (Waltz et al., 2005). As the interviewer, the researcher's personal characteristics influenced how well the interviewer and the interviewee connected. For instance, the age and gender of the researcher might have influenced how the

participant communicated his or her experiences of adherence. To protect the quality and accuracy of the data collection process, this researcher interviewed each participant, used the interview guide, and used a private room setting to conduct the interviews. This repetition during the interview process helped rule out any spurious associations within the data (Maxwell, 2005).

The researcher was also a healthcare provider in the same clinic where the sample was recruited. She clearly explained that the study interview had no bearing on the client's health care through the VA, or health care received from her. The study interview took place at a location and time separate from a normal health care visit. No questions were asked regarding alcohol and/or drug use that the researcher/healthcare provider would be required to disclose to the VA or to the clinic.

3.5.3.3 Methods of data collection.

The interview began with broad questions and proceeded with more focused and prompting questions. Observations by the researcher during the interview provided additional parts of the picture and were written once the tape recorder is off. For example, if a participant was not able to easily verbalize an experience, he or she might provide valuable information through unconscious behavior. Together, these methods of dialogue, listening, observation, and researcher notes provided a detailed array of rich data, revealing a clearer picture of the phenomenon of adherence.

Furthermore, a sample size of 21 veterans with saturation minimized the threats to reliability and validity (Waltz et al., 2005). Collecting data from several HCV patients and using the above methods of data collection minimized the risks of chance associations and systematic biases (Maxwell, 2005). Therefore, using the above methods of data collection with the larger sample size, the data gathered was rigorous and credible (Polit & Hungler, 1995).

3.6 Ethical Considerations

3.6.1 Review Process

Institutional Review Boards (IRBs) were responsible for approving, monitoring, and reviewing research projects and were dedicated to the protection of human subjects. The two IRBs involved with this study were the University of Texas at Arlington and the Dallas VANTHCS Research and Development Service. This research study was first submitted to the Dallas VANTHCS, as the primary IRB, with the anticipation of either exempt or expedited status. Phenomenological studies were often considered exempt because data were obtained in interviews and pose no known medical risks to patients (Cohen et al., 2000). Expedited status was a study in which there was minimal risk, which meant those risks in which the magnitude of discomfort was equivalent to those encountered in daily life or during routine physical or psychological exams (VANTHCS: Research and Development Service, 2007). The level of review was determined by the guidelines of the individual IRB. Once approved by the VANTHCS, the same approved materials were submitted to the UTA IRB for their secondary approval, since the PI was a doctoral student.

3.6.2 Description of Risks and Benefits and Adverse Events

Another responsibility of the IRBs was to evaluate the risks and benefits of a research project. The risks consisted of the overall evaluation of the probability, magnitude, and the consequences of an adverse event occurring (VANTHCS: Research and Development Service, 2007). An adverse event was defined as any untoward event associated with a research study (VANTHCS: Research and Development Service). In this study, the participants were discussing important and emotionally charged events, which might result in their feelings of distress (Cohen et al., 2000). Although feelings of distress were not considered a serious risk or life-threatening, feelings associated with the difficulties of treatment adherence might be unpleasant and stressful. If the researcher observed extreme distress, she would stop the interview. If the distress continued, the participant would be referred to the HCV team psychologist.

Loss of privacy was an associated risk of any research. The principal investigator did not disclose any private information gathered from the participants during the research study. There were no known social, legal or economic risks.

The benefit of a research project was the overall positive experience of the participants (VANTHCS: Research and Development Service, 2007). In this study it might be beneficial and helpful for the participants to discuss important and emotionally charged issues with the interviewer. Some participants might feel that by their participation in the study, they were contributing to research aimed at improving patient care, especially in the HCV infected veteran (Cohen et al, 2000). All participants who completed the research interview received a \$25.00 Wal-Mart gift card at the completion of participation to thank them for their time commitment.

The potential risks associated with this study were minimal. The potential benefits included the generation of new knowledge of improving adherence among veterans receiving antiviral treatment. With the improvement of adherence, more veterans will clear the HCV virus, benefiting not only the individual veteran, but healthcare and society as a whole. The potential benefits outweighed the potential risks.

3.6.3 Anonymity and Confidentiality

Commonly, the ethical agreement between the researcher and the participant was the preservation of anonymity and confidentiality (Cohen et al., 2000). Anonymity and confidentiality included the privacy of any patient identifiable information, for example, name, date of birth, social security number, address, or telephone number. In order to protect the confidentiality of the participants, this researcher created a master list which identified the participants with an assigned alphabetical letter. This master list was kept secured, locked, and available only to the researcher. Additionally, this list was kept separate from the recorded transcripts and audiotapes. The tape recordings and the transcripts did not contain any identifiable information linking data to a specific participant. During data collection and data analysis, protection of the participant's anonymity and confidentiality was preserved. All research information was kept under double

lock. Once the study was terminated, the research information including the master list and the tape recordings was destroyed.

3.6.4 Gender and Minority Inclusion

Although the population of veterans at the Dallas VANTHCS was predominantly male, every effort was given to recruiting any potential participant who meets inclusion criteria. These potential participants, irrespective of gender or race, were included in this research project.

3.7 Data Analysis

In qualitative research, the data were usually narrative descriptions, rather than numerical values (Polit & Hungler, 1995; Waltz et al., 2005). The researcher wrote the narratives of the participants which in this study, was a collaborative effort between the researcher and the participant.

3.7.1 Data Preparation

Hermeneutic phenomenological studies generated a significant amount of data through the use of interviews, verbatim audiotapes, and the researcher's observations and journaling. Cohen et al. (2000) suggested that the preparation and the management of data involve two principles. First, the data management strategy needed to be developed before data was collected. Secondly, the interview and researcher's observations needed to be transcribed as soon as possible. In this study, each audio-taped interview were transcribed word-for-word, and checked meticulously for correctness. Additionally, the printed transcripts had wide margins, sentence and page numbering, and documentation of the associated alphabetical letter designating the interview. Microsoft word computer software was used in data management.

3.7.2 Method and Procedure for Qualitative Data Analysis

The methods and procedures for data analysis for this study were the phases described by Cohen et al. (2000) which included immersion, data transformation, thematic analysis and summary. First, analysis began during the interview. The researcher observed, listened, and thought of the meanings of the words spoken by the participant. Possible labels began to be

assembled. The researcher read and re-read the narratives and became immersed in the data. Distinctive characteristics from each of the narratives were identified in the data. This immersion phase allowed the researcher to establish some initial interpretation or coding of the data.

Following immersion, data transformation or data reduction began. During this phase the researcher determined what information was relevant, similar to editing. For instance, the researcher sorted through the data and placed similar topics together. Thematic analysis ensued. Data were examined line-by-line. Similar phrases within the texts were underlined, labeled, and tentative themes were written in the margins of the text. The process of coding reorganized the themes into categories or clusters. Coding facilitated comparisons between categories and aids in the development of broader themes (Maxwell, 2005). Categories were thought of as organizational, substantive, and theoretical. Organizational were broad areas which were established prior to the data collection, whereas, substantive and theoretical categories were descriptive of the participants' beliefs and provided insight into the data (Maxwell). For instance an organizational category was a special issue, such as, access to medications. Substantive categories were emic, and from the participants own words or the researcher's interpretation. Theoretical categories reflected the etic or the researcher's concepts and were derived from the Information, Motivation and Behavioral Skills Model of Adherence. Accordingly, the research question was concerned with the similarities and differences in the meanings of adherence among the veterans who were receiving antiviral treatment. The research question was answered through categorizing the analytical data (Maxwell).

The last phase, essential to hermeneutic phenomenology, was the process of writing and rewriting. This reflective process allowed for better understanding and interpretation of narratives of the participant's experiences. During this phase of writing and rewriting, the themes were transformed into textural descriptions of the participants' experiences (Creswell, 1998).

In summary, this hermeneutic process transformed the conversational dialogues between the researcher and the participant into a logical narrative text. From this text, themes emerged

and were verified by the participants.

3.7.3 Software

The computer software for this study was Microsoft Word 2010 for data management and analysis.

3.7.4 Audit Trail

An audit trail represented a methodically maintained documentation system. In general, an audit trail consisted of an organized collection of materials that might include documents, photographs, researcher's written observations, maps, drawings, personal notes, transcribed interviews, coding schemes, themes and indicators, and the text of data reduction and analysis (Munhall, 2007; Schwandt, 2007). In this study, the audit trail served as a means of managing record keeping and encouraging reflexivity of the procedures by the researcher. In addition, the audit trail served as a means of substantiating the use of dependable procedures and the generation of confirmable findings by a third party examiner (Schwandt). When analyzing the same material, perfect agreement was not always realistic. However, the reader should be able to audit the methodical decisions, theoretical influences and actions of the researcher thereby establishing the rigor of the study (Koch, 1994; Moody, 1990).

3.7.4.1 Trustworthiness

The criteria for establishing the rigor or trustworthiness of qualitative data were credibility, transferability, dependability, and confirmability (Koch, 1994; Munhall, 2007; Waltz et al., 2005). Credibility was referred to as the authenticity of the findings or internal validity. In other words, the researcher was observing what she intended to observe. Findings needed to make sense and be credible to both the participants and the readers. For this study, the use of different methods of data collection, such as verbatim transcripts and the researcher's observations and notes augmented the credibility of the findings. Additionally, reviewing the transcripts and emergent themes with the participants for accuracy and genuineness of findings enhanced the credibility of the study (Koch).

Transferability referred to the generalizability, fittingness or the applicability of the data (Koch, 1994; Waltz et al., 2005). Thus, the study findings should fit into contexts outside of the study situation. Transferability was enhanced by having an adequate sample size, sample diversity, and appropriate purposive sampling. Phenomenology findings were not considered generalizable beyond the participants in this particular sample (Waltz et al.).

Dependability of the data referred to the stability of data with objectivity and confirmability over time, over conditions, and across researchers (Polit & Hungler, 1995; Waltz et al., 2005). This stability or reliability of data existed when another researcher could clearly follow the decision trail and come to the same or comparable conclusion (Koch, 1994). Internal reliability was concerned with the auditability of the research design (Waltz et al.). Accordingly, the research design was appropriate for the research question, methods of data collection, and the role of the researcher. For this study, hermeneutic phenomenology was the best method of finding the meaning of adherence among patients who were receiving HCV antiviral treatment. External reliability was the extent to which an audit trail existed. External reliability or auditability involved whether another researcher arrived at the same findings, in the same setting, following the same decision trail (Waltz et al.; Whitehead, 2002). The methods and procedures were well described, including the sequence of data collection. The researcher's biases were addressed. The decision trail included the decisions made at each step of the research process and were detailed in data analysis section.

Confirmability was established when credibility, transferability and dependability were achieved (Koch, 1994). Confirmability referred to the objectivity of the data. Two or more independent people agreed about the relevance or meaning of the data (Polit & Hungler, 1995). The focus was the data not the biases, interests, or motives of the researcher. In this study, the analysis strategies were described and detailed in data analysis section. Additionally, the findings of this study will be compared to the existing literature.

3.7.5 Written Journal

In addition to the researcher's observations during the interview process, the researcher kept a journal of notes (Spradley, 1979). This journal, similar to a diary, contained written descriptions of experiences, ideas, fears, mistakes, problems and/or breakthroughs that took place during researcher's data collection. According to Spradley, this journal provided the personal side of data collection, including the researcher's reaction to the participants. The journal became a vital source of data. Each entry was dated and reread at a later time. This allowed the researcher to become more aware of personal biases and feelings, and to better understand how these feelings might have influenced the research (Spradley).

3.7.6 Delimitations

The delimitations for this study are as follows:

1. The experiences of adherence during HCV antiviral treatment was restricted to the patients' experiences and did not include those of the healthcare provider.
2. Only patients who previously, or who were actually receiving HCV antiviral treatment were included. Those patients who were diagnosed with chronic HCV, and who were never treated or refused treatment, were not included.

3.7.7 Chapter Summary

Heideggerian hermeneutic phenomenological method allowed for exploration of the experiences of antiviral treatment adherence and gave meaning and language to the otherwise vague world of the HCV infected veterans during antiviral treatment. Through the interpretation of the lived experiences of everyday life during treatment, a better understanding emerged, bridging the gap between what was known and what was unknown in adherence (Hodges, Keeley, & Grier, 2001).

During this study, the researcher appreciated the philosophical perspective behind the research method, especially the concept of how individuals experience a phenomenon (Creswell, 1998). As a philosophy, hermeneutic phenomenology focused on describing the meanings of

individuals' being-in-the-world and how these meanings influenced the choices they made (Lopez & Willis, 2004). As a philosophy, the researcher focused on the descriptions of what the participants experienced rather than what they consciously knew (McDonald & Brown, 2008). Subsequently, the researcher concentrated on capturing the meanings of their narratives that described treatment adherence within the context of the participants' worlds or environments. In continuation, the researcher focused on how these meanings influenced the choices they made. As a method, the experiences of the participants were interpreted and analyzed through the researcher's own knowledge and experiences (Snow, 2009). This interpretation and analysis was reflected through observations and journaling. The narratives of the participants were gathered through conversational dialogues of semi-structured interview questions and answers. The researcher entered into the process of interpreting, analyzing and understanding through the hermeneutic circle (McDonald & Brown). This methodology guided the interpretation of data analysis beyond mere description, but importantly, did not move beyond the data and/or out of the hermeneutic circle (Whitehead, 2002).

According to Whitehead (2002), hermeneutic phenomenology was highly appropriate for answering the 'what' and 'how' questions about human issues and concerns. This method provided a better understanding of what the issues and concerns of adherence were for the veterans during HCV antiviral treatment. Additionally, this method provided insight and helped to anticipate the future issues and concerns of adherence during HCV triple antiviral therapy.

CHAPTER 4

FINDINGS

4.1 Introduction

In this chapter, the analyses of data are presented. Guided by the research question, the participant's narrative words are collected, the data are transformed, and the themes and categories important to the participants are provided. The research findings are explained. The characteristics of the sample, the findings of the study, and a summary of the results are presented and discussed in this chapter.

4.2 Sample And Description

A total of 21 participants were included in the sample (Table 4.1). All the participants were either receiving pegylated interferon and ribavirin antiviral treatment for HCV or had completed the treatment within the previous 12 months.

Nineteen of the participants were male, two were females, and ages ranged from 36 years to 67 years, with an average age of 57 years. The participants' ethnicity included White (67%), Black (19%), and Hispanic (14%). The majority were married (43%), with the remaining divorced (38%) or single (19%). Most of the participants lived in a household with other family members (38%), which consisted of their spouse, children, step or adopted children, and/or grandchildren. The remaining participants either lived with others who were not family (34%), or lived alone (28%). Education consisted of 67% who either graduated with college degrees or completed college courses and 33% who earned high school diplomas. All participants were proficient in speaking, writing and reading English. Of the total participants, 9% were proficient in both English and Spanish, and spoke both languages at home. The majority were employed (57%), whereas the remaining was retired (34%), or disabled (9%).

Table 4.1 Demographic Characteristics of the Participants (n = 21)

Characteristic	(n)	(%)
Gender		
Male	19	90%
Female	2	10%
Ethnicity		
White	14	67%
African American	4	19%
Hispanic	3	14%
Age		
Range		36-67yrs
Average		57 yrs
Marital Status		
Single	4	19%
Married	9	43%
Divorced	8	38%
Living Arrangements		
With Family	8	38%
With Others	7	34%
Alone	6	28%
Education		
College	14	67%
High School	7	33%
Language		
English	21	100%
Employment		
Employed	12	57%
Retired	7	34%
Disabled	2	9%

4.2.1 Treatment Status

Treatment status, defined as the amount of treatment medication taken at the time of enrollment, was widely spread among the participants. At the time of enrollment, 62% of the participants were taking the antiviral medications and the remaining 38% were either in the 6 months post treatment phase or in the treatment recovery phase (Table 4.2). The mean length or number of weeks on treatment medications at enrollment was 28 weeks.

Of the 21 participants, 33% were in the first twelve weeks of treatment, and 29% were midway or near completion. Nineteen percent had completed the full course of treatment medications. These participants were in the six months post-treatment medication period. Thus, after completing six months duration without treatment medication, a laboratory test was performed to determine the presence or absence of HCV viremia. If the virus was absent or non-detected, the participant was cured and achieved a sustained virologic response. If the virus was present or detected, then the participant was considered a non-responder and failed the antiviral treatment. Irrespective of whether or not the treatment was a success, the participant then began the treatment recovery phase. Nineteen percent were in the treatment recovery phase and were not more than one year post-treatment. In this group, two participants were cured of HCV, and the other two were considered treatment failures.

Table 4.2 Treatment Status at Time of Enrollment

Treatment Status of Pegylated Interferon & Ribavirin	(n)	(%)
Genotype		
1	13	62%
2,3	8	38%
Total Receiving Medications	13	62%
(Receiving first half of treatment)	(7)	(33%)
(Receiving last half of treatment)	(6)	(29%)
6 Months Post Treatment	4	19%
Treatment Recovery	4	19%

4.2.2 Comorbid Conditions

The veterans described various comorbid physical and psychological conditions. The medical comorbid conditions consisted of coronary artery disease, hypertension, diabetes mellitus, chronic obstructive pulmonary disease, chronic low back pain, migraine headaches and morbid obesity. Psychological comorbid conditions included paranoid schizophrenia, manic-

depression, depression, post- traumatic stress disorder, as well as alcohol and drug abuse, in remission. Four participants were caregivers. They were responsible for family members who were diagnosed with a variety of chronic catastrophic illnesses, including 24 hour care-dependent illnesses.

These comorbid conditions may have played a role in the tolerability of treatment side effects. For instance, those with prior diagnoses of depression may have experienced and exacerbation of depression during treatment. This experience may or may not have been related to the treatment medications. Likewise, it may have been difficult to distinguish if shortness of breath was due to chronic obstructive pulmonary disease, tobacco use, or treatment medications. Their comorbid conditions may have influenced the course and tolerability of the treatment medications.

4.3 Knowledge Of Disease Progression, Treatment, Medications, And Side Effects

4.3.1 Disease Progression

The veterans were aware of the progressive nature of chronic HCV and were specifically concerned about cirrhosis and the complications of cirrhosis. All acknowledged that the treatment medications were designed to either eliminate the virus or slow down viral progression. They wanted treatment, irrespective of the outcome. One remarked, "HCV is going to kill me, with cirrhosis and liver cancer, I don't want HCV looming over my head." One participant described, "If I waited and did nothing, by the time my disease progressed, I would be too old for a liver transplant. I just wish the odds of clearing the virus were higher." Another commented that he wanted to treat the disease while it was treatable and to nip it in the bud. In other words, he wanted to get rid of the disease before the disease progressed. This knowledge of disease progression might have been a motivating factor for the participants seeking antiviral treatment.

4.3.2 Treatment

During the interviews, the veterans were able to describe the progressive nature of chronic HCV, yet in contrast, they were unable to describe their own HCV parameters. These

parameters, HCV genotype and viral load, were essential in determining length of treatment and treatment response. Of the participants, 62% did not know or understand their HCV genotype and 76% did not know their initial viral load. However, 76% did understand how long the treatment would last. They verbalized exactly how many weeks or injections they had taken and how many more weeks or injections they needed in order to complete treatment.

4.3.3 Medications

Of the participants, 62% were originally prescribed 48 weeks of pegylated interferon and ribavirin antiviral treatment medications and 38% were prescribed a course of 24 weeks. All the participants were able to name their treatment medications, state their doses, and describe how to correctly take them. All the participants injected the pegylated interferon once a week and took the ribavirin capsules twice a day. Most referred to the pegylated interferon as a “shot or needle” and the ribavirin capsules as “pills”. The majority gave their own injections, commenting, “It’s not really that bad.” A few admitted to feeling skittish or afraid of needles, and relied on others for their injections. For instance, one veteran remarked that he went to the VA emergency room for his first injection, whereas, another participant conceded that his “...sister did all of his needle-work.”

Throughout the narratives, the participants admitted to taking their pegylated interferon and ribavirin as they were instructed. Only 9% of the participants missed one week’s dose of the pegylated interferon injection. An additional 9% described being a couple of days late with their injections. Similarly, only 19% admitted to missing one to two doses of ribavirin. One participant overslept, two merely forgot and one divulged that he took extra doses of the ribavirin to catch up. Although some acknowledged being a couple hours late on their ribavirin capsules, they took them as soon as they remembered.

The participants arranged their medications around their daily schedules. Most were at home to take their medications, if not, they took their medications with them. “I programmed my life around my medications. My HepC meds I can’t miss.” To these participants, each dose of

medication taken represents “One less that I have to take.”

4.3.4 Medication Side Effects

All experienced an assortment of side effects, ranging from “None at all.” to “My body feels dead.” Side effects were described as “Coming in waves.” and “Feeling bad the whole time.” Side effects interfered with their daily activities, work, and family relationships. Generally, fatigue was the most common side effect and was described as loss of stamina, loss of energy, exhaustion and lethargy. Fatigue was described as, “Being too tired to do anything.” and “To be exhausted from doing nothing.” The majority described the need to pace themselves throughout their daily activities. Flu-like symptoms were commonly experienced after the pegylated interferon injections, lasting up to two to four days. Symptoms included fever, chills, whole body aches, bone and joint aches, and muscle aches. One expressed flu-like symptoms as “Being cold one minute and sweating the next.” One described flu-like symptoms as “Feeling immobilized.” A few stayed in bed all day. Although two participants described not having any side effects, one admitted to feeling a little tired and the other expressed feeling impatient during antiviral treatment.

The most often experienced side effects included neurological, gastrointestinal, and psychological symptoms. Headache, insomnia, dizziness, impaired vision, impaired concentration, and feeling off- balanced comprised the neurological symptoms. Feelings of being off-balanced were described as “Walking on a tilt.” or “Being in left field.” Insomnia interfered with work and family life, one participant complained that she could not get enough sleep. Another complained of daily headaches which caused frequent absences from work. A multitude of gastrointestinal symptoms persisted, which included weight loss, anorexia, cotton mouth, altered taste, queasy stomach, dry heaves, nausea and vomiting, and stool incontinence. One participant explained that he was having daily episodes of nausea and vomiting. He exclaimed, “My stomach was irritated because I was giving my shot in the fat of my stomach.” In addition, they experienced psychological side effects. Most commonly felt were depression, irritability, and

anxiety. One remarked that he was overly emotional and teary eyed. This sense of sadness oftentimes made communication difficult with his wife. Another described his depression as, "Better dead than to have to take these medications every day." Less experienced side effects included skin rashes, pruritus, atrial fibrillation, chest pain, shortness of breath, and hyperventilation.

For three of the participants, the side effects experienced during pegylated interferon and ribavirin antiviral treatment were severe enough to require hospitalizations. The first participant was admitted to his local community hospital twice for dehydration due to nausea and vomiting. He was given intravenous fluid replacement and his antiviral medications were continued. Also, his depression became increasingly unpredictable and episodic. As his treatment progressed, he became more irritable and aggressive with his family members. He began having thoughts of suicide and exhibiting homicidal behavior. He required close and careful clinical monitoring by his mental healthcare provider and continued treatment. In addition, he developed a tooth abscess which required the treatment medications to be stopped for one week. The second participant experienced chest pains and pneumonia. While he was hospitalized, the treatment medications were stopped. After two weeks of recuperation, he resumed the treatment medications. He later developed cellulitis and treatment medications were again stopped for a week. The third participant developed new onset of atrial fibrillation, which required hospitalization. His treatment was discontinued. These examples demonstrated how difficult pegylated interferon and ribavirin antiviral treatment could be, as well as, how intense the side effects could become.

4.4 Thematic Analysis

Throughout the narratives, the participants described their experiences of taking pegylated interferon and ribavirin antiviral treatment medications, and how these experiences influenced their daily lives. The recurring themes woven through the narratives included: making a commitment to the treatment, not ready to leave this world, unfinished business, family: support

and burden, coping: daily life during treatment, and disclosure: who needs to know?

4.4.1 Making A Commitment To The Treatment

The essence of taking the pegylated interferon and ribavirin antiviral treatment medications for HCV was simply making a commitment to the treatment. This commitment was initiated and motivated by the desire and the determination to clear the hepatitis C virus. The following expressions were frequently heard throughout the narratives: “To be cured of HCV.” “I’m going to be HCV free.” “I want to get rid of this H CV.”

Second, making a commitment to the treatment involved starting and finishing the treatment. Irrespective of unforeseen challenges, the commitment of these veterans continued with the determination to complete the treatment from start to finish. They acknowledged that the odds of clearing the virus were much higher when the full course of treatment medications is completed. Given this opportunity to become HCV free, participants felt strongly, that once treatment was started, he or she was committed to finish and complete the treatment. The following statements illustrated their individual commitments: “I’m determined and I’m going to finish.” “I want to complete this program. It was a commitment from start to finish. I’m sticking to it.” One veteran commented, “You have to experience discomfort and pain in order to come out on the other end to get better.” Admittedly, some participants were nervous and anxious about starting the treatment. In the beginning of treatment, one commented, “It stresses me out when I’m going to take the injection, because I am afraid I’m going to be sick.” Nonetheless, as treatment continued, the resolve and determination to complete the treatment strengthened. Another commented, “I kind of felt like superhuman... because that’s what the deal was from the start... I’m still taking it and I am going to finish it to the end.” Another one admitted that he was willing to take the treatment forever to be cured.

Third, making a commitment to the treatment involved sustaining the necessary discipline for treatment tolerability. The cornerstone of staying with the commitment was discipline. Intriguingly, the discipline necessary to commit to the treatment may have been a consequence of

past military service. Life within the military is described as regimented and disciplined. The discipline is motivating, but strict. Discipline became a way of life. The military discipline instilled during basic training teaches responsibility for one's own actions, and respect for others, especially those in authority. For these veterans, military discipline continued after their military service and was carried over into their private and personal lives. One participant remarked, "Some people give up on the army discipline, but I have kept it." Another agreed, "Yes, if you're disciplined, there's a way to do everything... military discipline had a lot to do with my discipline and it still does." Military discipline was following orders. One veteran commented, "Just go with the flow, that's from being in the service, you learned to follow orders." Intriguingly, another veteran used his past combat experiences to fight and annihilate the HCV virus. "You go into battle with the mindset of winning, never go into a battle with a mindset of losing, if you do, then you have already lost." Thus, the discipline learned during their military service was vital for sustaining the commitment from start to finish.

Although these veterans agreed that military discipline was strict and motivating, there were some who felt that discipline was a combination of their childhood and the military. One participant believed that his father's strict discipline was more influential on commitment than the military. He considered that his upbringing motivated him more to stay with the treatment. Another participant felt that the military definitely intensified the discipline he learned growing up. Perhaps the discipline learned growing up, and in combination with the intensified military discipline, the participants were more likely to follow orders and take their treatment medications correctly from start to finish.

Last, making a commitment involved developing rapport with the HCV healthcare provider with the outcome resulting in teamwork. The collaborative team was built on trust and open communication. The participants relied on their healthcare provider to manage their antiviral treatment with expertise, and the healthcare provider relied on the participant to follow the instructions. "I felt that she knew what she was doing and knew all the answers to all of my

questions.” Another commented, “I put my life into her hands and I was willing to follow her instructions.” One veteran remarked, “A+ team.” Open communication strengthened the team commitment. “When I started hearing the results... whatever you are doing, keep doing. I was just doing what he told me to do.” Another, “Every time we did blood work ...it was encouraging. It provided me hope.” One participant exclaimed, “Every checkup my count was going down and progressing... it makes it a lot easier.”

In contrast, one veteran described an episode where her previous HCV healthcare provider was not supportive. This occurred during her first course of antiviral treatment in 1993. She remarked that the healthcare provider did not seem to care. “So why should I care; it was here take this and go away... I felt like it wasn’t going to work, so what’s the point of taking it? I thought it was going to kill me.” Consequently this veteran did not complete her initial course of treatment.

4.4.2 Not Ready To Leave This World

The notion of not ready to leave this world was frequently expressed throughout the narratives. These veterans were aware of their HCV diagnosis, and the progressive nature of the disease included cirrhosis, liver cancer, and/or even death. Treatment provided hope. Treatment provided a new sense of value and a will to live. If successful, treatment offered a cure and a longer life span. “I want to be in my daughter’s life and I want to provide for her and care for myself. I want to travel. There are a lot of things I want to do.” If not totally successful, treatment may slow down the disease progression. After all, one participant exclaimed, “If treatment was not an option, then, I might go on and die early.”

Veterans with HCV were committed to the treatment for a cure and a longer life. They want a cure not only for themselves, but also for their families. “Treatment would add about ten years to my life.” “Even if it didn’t clear it, I would have a longer life span.” Some desire a longer life because their families depend on them. For instance, one participant expressed the desire to live long enough to walk his granddaughter down the aisle. Another confided, “I have a 14 year

old son. I'm his only family." Veterans with HCV have responsibilities for themselves and for their families. Each acknowledged that clearing the virus and living longer without the disease will likely lighten the weight of their daily life.

The notion of not ready to leave this world was nicely summarized in the following statement. "Live as long as I can, to be healthy, and to help others. It is better than not taking the treatment and die early." These veterans are looking forward to the future and living healthy lives without a chronic and debilitating disease.

4.4.3 Unfinished Business

The perception of unfinished business brought to mind the notion of a second chance to correct, for many, a negative problem. A negative problem was described by the participants as everything bad, especially the disease itself. Some of these veterans acquired HCV by sharing contaminated needle; others are unsure how they got it. For those who did acknowledge past intravenous drug use, antiviral treatment offered them a chance to go back and try to clean up their past. For instance, one veteran admits, "Treatment allows me to put my past intravenous drug use behind me. It is the last chapter of that period of my life, and by taking the treatment, I have a chance to end that part and get rid of the HCV." Another commented, "Treatment puts closure to drug use, not only am I drug free now, but I can erase the HCV infection and close that part of my life by being HCV cured." By having a second chance, antiviral treatment offered the participants a way to eliminate the virus brought on by past risky behaviors. "It was an opportunity to right some of the bad choices, and give me a second chance." Treatment provided the participants with an opportunity to transform past risky behaviors into a lifestyle that is long and healthy with a positive future. One veteran expressed, "...after repairing the damage I caused the first 60 years, I'm looking forward to my next 60 years."

The veterans felt guilty about their past risky behaviors. Admittedly, some gave themselves the disease through sharing contaminated needles. They felt that their HCV infection was their own fault. "I feel guilty because I did this to myself." Another participant felt guilty about her past drug

use, but now that she is sober and is clearing the HCV virus with treatment, her guilt is disappearing. She comments, "Clearing the virus finishes that business (drug use) and now I can move on with my life with less guilt." Treatment allowed the veterans to purge the guilt of their past mistakes. Guilt diminished. For these veterans, their past mistakes were left behind. Treatment presented the opportunity to remedy unfinished business.

The commitment to the treatment, the notion of not being ready to leave the world and the belief in taking care of unfinished business were motivators for taking the treatment medications correctly. These motivators influenced the participants to start and complete the treatment, and to take their medications as prescribed by the HCV healthcare provider. Most importantly, treatment allowed the participants to maintain sobriety and to remain determined to get better and to clear the virus. As expressed by one participant, "It has given me another sense of value and a will to live, a sense of tranquility and contentment."

4.4.4 Family: Support And Burden

Family support was quite often thought of as a positive relationship with family members, but in some instances, a family could be a burden. Although the majority of participants live with family members, the few who lived alone did have family members living close. Family members consisted of wife, teenage and adult children, step and adopted children, grandchildren, siblings, in-laws, and parents.

4.4.4.1 Support

Treatment was difficult to tolerate for both the veteran and the family, yet some family members remained motivated and supportive while others do not. Support existed when family members took an active role and participated in the treatment process. For instance, some of the wives attended the clinic visits. This allowed for the participant, wife, and healthcare provider to discuss treatment-related issues, and to provide information for better understanding of the treatment. For some, family members lent practical support. For instance, family members actively contributed by filling pillboxes, administering the injection, and/or making sure the participant took

the medications on time. Emotionally, family members were generally happy that the participant is on treatment and provided encouragement. To them, this meant that the participant had a chance to be cured and to live a longer and healthier life.

One veteran commented about his family support, "Everybody felt the same. If you want to be around a little longer you do what it takes to stay here." A few participants relied on their girlfriends for support. "We take care of each other," and "We've been each other's shoulder for the last couple of months." Another participant relied on his mother, "She's a retired RN and she understands". One relied on his wife, "...Stood by me through thick and thin for the last twenty-six years."

For one participant, his family was his support group. He had positive interactions with his family. Before he started treatment, he gathered his family together to discuss the treatment, the side effects and his need for support. Once started, and as treatment progressed, they were all encouraging. He remarked, "If I got to feeling bad, I could call them and they would talk to me. They were basically there for me."

4.4.4.2 Burden

Some families were burdensome during antiviral treatment and interfered with the daily responsibilities of the participants. For some, families may be perceived as an inconvenience. Families became overbearing as the demands of daily responsibilities persist during treatment. Some participants struggled day-to-day to fulfill their family responsibilities and obligations, and at the same time, endured the fatigue and flu-like symptoms that were often experienced during antiviral treatment.

Although the family responsibilities might be the same as before treatment, they became burdensome during treatment. This became obvious as the participants discussed their living arrangements and family dynamics during treatment. Living arrangements varied from participant to participant. Those who lived with their parents were often burdened with the care of their parents, which may have included partial assistance or total dependence. For instance, one

participant lived with his mother who was totally dependent on him for transportation, grocery shopping, cooking and cleaning. Another participant was a full-time caregiver for his father who had dementia. He lived in a travel trailer on his father's property. He commented that his living situation was quite depressing. One participant was raising his two teenage children alone, but also had the burden of his live-in girlfriend who stayed drunk all the time. Others lived alone in their own home or apartment. For one participant, his mother and sister were completely dependent on him, especially for their daily transportation. He remarked, "Always seemed like a lot of people are dependent on me. That's what I do most daily." Another participant who lived alone, commented, "The worst day during treatment is when my girlfriend wants to go somewhere and I want to come home and relax, then we have a problem."

The majority lived in their own homes with their wives, children, or other close family members. Family dynamics changed during treatment possibly due to the physical and psychological side effects. Depression and irritability ran rampant. The veterans admitted to easily becoming irritated and described the irritability as "Being testy," "Getting ticked," "Arguing," and "Staying sideways." For example, one participant's family consisted of his wife, granddaughter, a stepson and brother-in-law. Living arrangements were cramped, and family dynamics were quite stressful. He admitted that he didn't want to get homicidal, so he avoided his stepson and brother-in-law. Another participant remarked that his wife was irritable and his son and daughter made him more irritable. He said, "I never thought about committing suicide in my life until I started taking this medication." Sadly, another participant lost his marriage, home and bank account during treatment. He became homeless and penniless.

Family dynamics crumbled and roles and responsibilities became fragmented. For a few, the effort to maintain family roles and responsibilities became insurmountable. Treatment side effects became overpowering. For example, one participant was responsible for assisting her parents, raising her teenage son, and working full-time. She experienced several side effects of the treatment medications. She said, "My dad would come wake me up about my son and I had

just gotten to sleep and I would have to go get him. One night I just started yelling..." My dad tells me not to play the Hepatitis C card." To her, this meant not to use the medication as an excuse to be angry and to avoid responsibilities.

At first glance, families might give the impression of a caring and sympathetic group, but they might not always be what they seem. Families could be supportive, helpful and encouraging, or unaccommodating, obstructive and burdensome. Family living arrangements, dynamics, responsibilities and roles all influenced the degree of support and burden that existed within each family.

4.4.5 Coping: Daily Life During Treatment

Coping during pegylated interferon and ribavirin antiviral treatment for HCV could be effortless for a few but quite strenuous for others. Coping strategies varied and ranged from conserving energy to staying busy, and from hibernating to socializing. Spirituality was also a strong coping strategy for the overwhelming majority of participants. These coping strategies fluctuated among the participants but aid in the tolerability of the treatment medications.

4.4.5.1 Conserving Energy And Staying Busy

All veterans receiving treatment experienced some degree of fatigue. Some expressed fatigue as extreme exhaustion while others expressed fatigue as being a little tired. Such phrases as slower pace, staying inside, and cutting back on everything described how participants conserve energy. Few stayed in bed all day with the covers over their heads, while others, stayed in their recliners and watched television all day. One participant spent most of his time in his recliner. He kept a remote in each hand, one remote was for the television and the other was for his massage recliner. Others toiled around their shops, and worked on hobbies such as wood work. "You've got to keep your mind occupied and find something that's not physically taxing, but taxes your mind." Others read, napped, kept journals, and as one says, "Watch the clouds go by."

For those who worked, they stayed busy but still conserved their energy. "There's

always something to do. I garden, own my own yard work service, and care for my mom. I just keep a slower pace” Another veteran, also self-employed, was able to make his own work schedule and conserved energy. The participants who were employed, enjoyed their work, but enjoyed coming home and relaxing. Intriguingly, two of the participants coped by choosing to live healthier lifestyles. Their days were occupied by choosing the right foods, exercising, and relaxing.

4.4.5.2 Hibernation And Socialization

Hibernation was described as being a loner, or not being a social butterfly. One participant described hibernation as intellectual coping. A few were more comfortable being alone, and chose to watch television, to relax and listen to music, or to work in their shops. One participant only left his house to go to his clinic appointments. He commented that he had anxiety, panic attacks, and anger issues around people. Another participant avoided people and preferred to sit on his front porch and watch the neighborhood. These participants, who preferred to be alone, enjoyed the company of their dogs.

Socialization involved personal relationships with close acquaintances, members of recovery groups, childhood friends and neighbors. Participants enjoyed casual conversations with others, for instance, customers at work, close friends, and neighbors. Socialization also included going shopping with friends, going to the movies, and out to dinner. Some shared in treatment recovery groups such as Narcotics Anonymous and Alcoholic Anonymous. Surprisingly, one of the participants socialized on Facebook and another through texting.

4.4.5.3 Spirituality

Spirituality offered a sense of direction and came in the form of prayer, meditation, and preaching. Prayer and meditation were important, as one veteran confided that he started his day with prayer and meditation before he did anything. “I made conscience contact with my higher power every morning.” Another participant had deep faith in Jesus Christ, and prayed for healing. Although he did not attend church, he watched Sunday morning evangelism on television. One of the participants was a preacher. He was deeply involved in prayer, prayer

groups, the congregation, and his church. He held community prayer groups in his home for healing on the evenings of his injections.

4.4.6 Disclosure: Who Needs To Know

All the veterans disclosed their HCV treatment status with their families, and close friends and disclose their disease and treatment status to others, such as their congregation and church members, treatment recovery groups, and everyone, including Facebook. These are referred to as the "nothing to hide" group.

4.4.6.1 Need To Know

These participants disclosed their disease and treatment status to their families and close acquaintances. They disclosed only on a need to know basis. These veterans agreed that the stigma is not only the disease itself, but also the manner in which a person may become infected, that is, through sharing contaminated intravenous needles. Stigma was not being on the treatment. They felt embarrassed and guilty and feel that the disease is misunderstood. One participant preferred to keep all his healthcare matters private, but does admit to having been embarrassed by the drug use associated with HCV. Another says that she was embarrassed about having the disease, but not being on treatment. She also preferred to conceal her treatment status from others because she felt guilty as if she was asking for sympathy, as if she has cancer. A few commented that there was no need to tell anyone except family because they avoided people and stayed close to home.

Misunderstanding also existed among family members and friends. For instance, one family was very cautious about one participant playing with her small nieces and nephews. She commented that they did not know what to do around her. "They boiled and bleached the toys..." The participants who attended recovery groups were careful about disclosure because of the general misunderstanding of the disease. "...the walking dead, so I just don't throw the subject out there." If the topic came up, sharing was on a one-to-one basis. "If somebody came to me that had HCV, and I've got it, then we could share something, we got a bond."

Work related disclosure was restrained for those who were not self-employed. One participant learned to conceal her status from her employer due to prior unpleasant experiences. She admitted that once she disclosed her status, she was treated differently and was restricted in her work assignments. Another participant discussed treatment with customers who had been on treatment which helped, but not with her employer.

These participants disclosed their status to family members and close friends and were not treated differently. They received encouragement to continue the treatment. Disclosure of HCV and treatment status was not something that they felt comfortable sharing with just anybody.

4.4.6.2 Nothing To Hide

Other participants seemed to be cautiously open with their HCV infection and treatment status. These veterans disclosed to family members and close friends. For one participant, his family generally felt, "If you want to be around a little longer, you do what it takes to stay here." He admitted to having a close group of friends that he socialized with and said, "They're all on medications of some type, so if you need it, that's what you do." Another participant felt comfortable disclosing his status only in certain situations. He felt, "...ask a lot of questions how I think I got HepC... just trying to dig up dirt... not genuinely concerned nor did they honestly want information about HCV."

Some participants had nothing to hide and were not ashamed of their HCV status. They felt that by disclosing their HCV status to others, they were increasing the awareness of the disease and preventing disease transmission. One participant claimed, "There were people who didn't know they had the disease and others who had the disease, didn't do anything about it." Thus by talking about the disease, more people became aware. Another participant preached about his status from the pulpit. He felt that there was nothing to hide and talking about it helped him cope during treatment. He told the younger members of his congregation about disease prevention ... "Wash your hands, don't have unprotected sex, and take care of your bodies, if you don't, it will catch up with you." The congregation was encouraging and

supportive. He commented that he felt better in his mind talking to others about HCV.

4.4.7 Treatment Recovery: Something To Look Forward To

The participants, who were considered in the treatment recovery phase consisted of two who did not clear the virus (non-responders) and two who cleared the virus and were cured (sustained virologic response). Interestingly, all four described the notion of something to look forward to as the treatment recovery phase. However, the two non-responders were looking forward to some hope, whereas, the other two were looking forward to starting their lives over without the chronic disease.

4.4.7.1 Still Looking For Some Hope

The two non-responders have similar characteristics. Discipline, social support and camaraderie with other HCV veterans were beneficial and important for both the veterans during treatment. Both agreed that stopping or missing a dose of the treatment medication may have jeopardized the potential for a successful outcome. Both are still looking for some hope.

Treatment provided a chance to live and offered a new lease on life. "Whatever it takes, I don't care how much it wipes me out, it is worth it." Neither cleared the virus during treatment. One participant expressed worry over leaving his wife alone, if he died early of HCV, whereas, the other participant described being in limbo, still with the disease and not eligible for a liver transplant. Although the first participant was disappointed that treatment stopped, he remains hopeful for new therapy. The second participant became angry, depressed and stayed home by himself when treatment was stopped. He remarked that if he did not go to work, he would not have talked to another person. After nine months of hibernating, he was just now making an effort to get out of the house.

Both relied on the discipline they acquired during their military tours in Vietnam. Both looked at life in the present and not in the past. The past was simply water under the bridge and could not be corrected. During treatment, both disclosed their status to family, close acquaintances and co-workers. Talking about treatment was helpful, "I just wanted to help him out."

Both expressed the need to be around other HCV veterans during the treatment. The clinic waiting area provided a great opportunity to network. In the waiting area, the veterans exchanged phone numbers, shared emails and discussed treatment challenges.

Both recalled episodes during treatment where the pegylated interferon was either discontinued or administered late. Both felt that stopping the medications, even temporarily, may have resulted in the non-response to treatment. "I wasn't too sure when I missed that shot if I messed it up or not." The other commented, "I didn't want to stop. I really felt that if I would have continued, there would have been a positive outcome." Both of these veterans looked forward to the future when better treatment would be available. "New treatment gives hope."

The two veterans were both trying to get into better physical and emotional shape for future antiviral treatment. Both endorsed instituting healthy lifestyles. One commented that he "Regularly takes all his prescribed medications, and avoids medications that may be harmful to his liver, as Tylenol." He started walking and eating right. He felt that his energy level was almost back to where he was before treatment. He still felt confident that he could "Beat HepC, if it's beatable." The other non-responder, commented that he was more energetic and stronger. He described the need to be more physical and active. "Sitting around the house being depressed weakens you... not only your brain, but also your body." He bought a motorcycle to get out of the house. "I want to live. So maybe with the bike, I'll get in better shape... use that as a tool...if something else comes along (treatment) ... I'll be prepared..."

Both strongly agreed that any break in antiviral treatment is not good. Both were looking to the future for some hope in the newer treatments. Both remained hopeful for a cure.

4.4.7.2 Starting Over

The two participants who cleared the virus had a mixture of characteristics. Discipline, disclosure, and correcting a negative problem were advantageous. Coping strategies differed and one of the two participants admittedly did not take two doses of ribavirin.

For these two participants, discipline was a way of life. Both expressed their own

responsibility to take the treatment medications as prescribed. One followed a regimen of coming home from work, taking a shower and then self-administering the pegylated interferon. Both conveyed the need to talk about HCV with others. The more people that heard about the disease, then the more people knew and would understand the disease. One participant commented that he talked about HCV treatment in his Narcotic Anonymous group meetings. People were interested in learning about the disease. He did not disclose how he might have acquired the disease. "... Trying to bring up dirt..." Both felt that going through treatment and clearing the virus corrected a negative problem. For one, the constant fear of transmitting the disease to others around him disappeared, and the other, the fear of returning back to risky behavior was eliminated.

Today, both have felt excellent and full of energy. Both have been able to complete each task from start to finish. One has found a potential mate and the other has achieved a savings account, a job, and a home of his own. Both express hope for the future.

4.5 Summary

Taking their antiviral HCV medications meant commitment to the treatment which was motivated by curing their HCV infection. The participants made a commitment to start and finish the treatment, and hopefully, a cure. The military discipline and for some, their childhood upbringing, provided a necessary way of life to take their treatment medications as instructed and to follow orders. The outcome of treatment was contingent on taking the medications as prescribed. The HCV healthcare providers were quite knowledgeable of the treatment and these veterans took their treatment medications as instructed. Antiviral treatment became a team effort. Their HCV healthcare providers were encouraging and motivating. One participant commented, "Knowing someone cared, that didn't even know me that was unreal to me."

Antiviral treatment provided the opportunity to live a longer life and to correct past negatives. Negatives included the disease itself as well as past risky behaviors, such as drugs and alcohol. Families were not always supportive. The veterans found support and understanding

from close acquaintances, coworkers and other veterans with HCV. Coping with daily life during treatment was difficult. Coping strategies varied from hibernating and socializing, to conserving energy and staying busy. A majority relied on spirituality and meditation. Participants either remained very private about their HCV status or tell everyone, because the more people heard about the disease, the more they understood.

Treatment recovery revealed that there was something to look forward to, and hope for the future. The non-responders looked forward to future antiviral treatment and hope for a cure. They were trying to improve their emotional and physical health status to be prepared for the new generation of antiviral treatment for HCV. Those who cleared the virus, looked forward to starting their lives over without the chronic infection.

CHAPTER 5

SUMMARY

5.1 Introduction

This is one of the first qualitative studies to examine what it means for HCV infected veterans to adhere to pegylated interferon and ribavirin antiviral treatment while they are receiving treatment. The findings in this prospective phenomenological study support the current scientific knowledge published in the literature, as well as bring to the forefront new insights into the meaning of adherence. The success of adherence for these 21 veterans may be related to the major themes uncovered during the interviews.

5.1.1 Interpretation Of Themes

This study accentuated several important themes which provided a better understanding of the dynamic nature of adherence during pegylated interferon and ribavirin antiviral treatment for HCV infected veterans. Among the HCV infected veterans, the treatment status, comorbid conditions, knowledge of the disease, the treatment, and the medication side effects were similar to the published literature (Backus et al., 2007; Butt, Khan, McGinnis, Skanderson, & Kwoh, 2008; Groessl, Weingart, Kaplan, Clark, Gifford, et al., 2008; Janke, McGraw, Tsao & Fraenkel, 2008; Sutton & Treloar, 2007; Treloar & Holt, 2008; Treloar, Hull, Bryant, Hopwood, Grebely et al., 2011). Additionally, the major findings that involved commitment, family support, strategies for coping, and disclosure of the diagnosis have been reported in the published literature (Blacklaws, Veysey, Skinner, Sheather, Hawken, et al., 2008; Groessl et al., 2008; Hopwood, Nakamura & Treloar, 2010; Kinder, 2009; O' Brien, Cross, Biggs, Munro, & Chou, 2010; Sgorbini, O' Brien, & Jackson, 2009; Silberbogen, Ulloa, Janke, & Mori, 2009; Zuure, Heijman, Urbanus, Prins, Kok et al, 2011). Furthermore, this study produced innovative data about commitment, unfinished business, and the treatment recovery phase of treatment. The themes will be discussed in the

following section.

5.1.2 Knowledge Of The Disease

Knowledge of the disease, treatment, and medication side effects among HCV infected individuals have been reported to vary from fairly good to poor (Groessl et al., 2008; Treloar et al., 2010). Even though veterans received HCV education from the VA staff, Groessl et al. found that misconceptions existed regarding the acquisition and transmission, and the progressive nature of chronic HCV. Fraenkel et al. (2006) found that veterans retained limited knowledge of the treatment regimen, and were unprepared for the volatile nature of antiviral treatment side effects. The participants in the current study were reasonably knowledgeable of disease acquisition, transmission, and natural progression, but were unable to accurately identify their genotype or the amount of virus in their blood. All the participants knew how and when to take their antiviral medications, and how many weeks they had been on treatment, and how many weeks were left to complete the treatment. Conceivably, the knowledge of how, when, and for how long to take the antiviral medications was more valuable and relevant for the veterans. This finding suggested that further efforts were needed to provide veterans with a more relevant and pragmatic HCV educational program for better adherence during antiviral treatment.

5.1.3 Commitment

McHutchison and Dev (2004) pointed out that antiviral treatment required considerable patient commitment in order to maximize patient adherence and viral clearance. Among veterans, the theme of “commitment” consisted of commitment for a cure, commitment to complete the treatment, commitment to the HCV healthcare provider, and commitment to discipline. In this study, these parts of commitment were equally important and together represented the wholeness of “commitment” to the HCV veterans receiving antiviral treatment.

The theme of “commitment” among veterans was similar to the theme of “treatment decision making” in Kinder’s (2009) study that explored the lived experiences of male participants

undergoing HCV treatment. In Kinder's study, once the diagnosis of HCV was established, the participants were determined to start the treatment even though the side effects were debilitating and the response rates were low. During the interviews, the participants made the decision to start and finish treatment irrespective of treatment challenges. They commented that not taking treatment was not an option. These experiences were similarly expressed by the veterans in the current study. The veterans were committed not only for the cure but also for the successful completion of the treatment, from start to finish.

The commitment between the HCV individual undergoing antiviral treatment and the HCV healthcare provider has been reported in the published literature, but reported only once in the qualitative literature involving veterans enrolled in the VA healthcare system. In the VA study, Fraenkel et al. (2006) described a lack of communication between the primary care provider and the HCV specialist provider which resulted in the veterans being shuffled from physician to physician without receiving proper HCV management. Sheppard and Hubbert (2006) reported a similar lack of communication. In their study, the participants expressed disappointment with their HCV healthcare providers because they did not take the time to listen or to value their unique experiences during treatment. These participants were given adequate medical management for their treatment side effects but their psychosocial needs were neglected. In contrast, Hopwood and Treloar (2007) noted that a positive relationship existed between the patient and the HCV healthcare provider, and that their rapport was beneficial, especially during difficult times throughout treatment. The responsibility of the HCV healthcare provider was to manage the medical aspects of care, as well as address the patient's psychosocial needs. These findings were congruent and were descriptive of the findings in the current study. Rapport developed between the veterans and their HCV healthcare providers. This relationship was referred to as a team. The veterans agreed that their provider was supportive of their needs and was concerned about their overall wellbeing.

The rapport and positive relationships reported by the veterans in this study were

possibly due to the dedicated HCV healthcare providers, both the advanced practice nurses and the ancillary staff. The same provider followed the patient through the treatment process, beginning with the pre-assessment phase and ending with the treatment recovery phase. During this time, the HCV healthcare provider began to holistically understand the person. Benner and Wrubel (1989) commented that the best nurse practitioners understood that each illness had a story, and that story was influenced by what was happening in the patient's life. These providers took the time to listen to their HCV veterans tell their stories. Within the team there was trust. This finding suggests that the delivery of holistic care might enrich the commitment necessary between the HCV veteran and their HCV healthcare provider. Every effort should be given to pair the HCV veteran with the same dedicated HCV healthcare provider during treatment.

Unique to this study was the theme of "commitment" in relation to military discipline. In the published literature, Kinder (2009) commented that one veteran used his past military training as a coping strategy during antiviral treatment. Yet, the veterans in the current study applied their past experiences of basic training and combat to the commitment necessary to sustain the duration of the antiviral treatment regimen. Military training meant following orders, respecting those in authority, developing a sense of camaraderie, and completing the mission. This new finding suggests that adherence during treatment might improve if HCV healthcare providers integrate these military principles to their treatment plan.

Integration of these principles could be easily adapted to the treatment plan. Explicit was the mission of combating and eliminating the virus through correctly following the prescribed orders given by the HCV healthcare provider. Implicit was the development of respect for their HCV healthcare provider by the veterans. Camaraderie among the veterans, who were in various stages of antiviral treatment, might be developed informally or formally. The clinic waiting area provided an informal environment for sharing treatment experiences. Formally, Fraenkel et al. (2006) suggested a patient-buddy system in which volunteers, who completed treatment, join up with those who were beginning treatment. A HCV support group for veterans at various stages of

treatment might provide a formal, structured avenue to enhance their camaraderie and to strengthen the commitment to the treatment regimen.

5.1.4 Not Ready To Leave This World

The theme of “not ready to leave this world” was also supported in the published literature. Sutton and Treloar (2007) conducted a qualitative study on the experiences of living with chronic HCV and found that the participants were determined and committed to managing their chronic HCV through healthier lifestyles. The diagnosis itself prompted the participants to change priorities and place more appreciation and value on life and people. These participants attempted to change their lifestyles by eating healthier and by abstaining from alcohol and drug use. Likewise, Silberbogen et al. (2009) found that knowledge and education of HCV status among HCV infected patients were highly predictive of both treatment completion and sustained alcohol abstinence. In their study, patients with a greater understanding of the synergistic relationship between chronic HCV and alcohol use were more likely to make and maintain healthy lifestyle changes. Groessl et al. (2008) similarly found that veterans became motivated to get treatment for their drug and alcohol use disorders once they became aware of their HCV status. In the current study, the veterans also adopted healthy life styles, some through dietary discretion, and exercise, and all through drug and alcohol abstinence. The finding suggests that a multidisciplinary approach, that incorporates both substance abuse and chronic HCV, be offered to veterans receiving pegylated interferon and ribavirin antiviral treatment. This approach might be a more profitable way to endorse healthy lifestyles, to abstain from drugs and alcohol, and to improve antiviral treatment adherence.

5.1.5 Unfinished Business

Sgorbini et al. (2009) described that society considered chronic HCV infection a condition that was brought on by one’s own behavior. This was the focal point of “unfinished business” in the current study. The theme “unfinished business” was defined by the veterans as the opportunity to right the wrongs of their past mistakes. The veterans, who admittedly acquired

the HCV virus from sharing contaminated intravenous needles through illicit drug use, felt that being infected was their fault. Antiviral treatment offered these veterans the chance to get rid of the virus and erase the mistakes of their past behaviors. If treatment resulted in a sustained viral response, then these veterans could begin to make amends to themselves and close this chapter of their lives. This finding suggests that the HCV multidisciplinary team include a mental health provider and incorporate a HCV support group to optimize successful treatment outcomes. The HCV support group provides a comfortable environment among peers, for sharing and talking through their psychosocial experiences, and for realizing that they are not alone.

5.1.6 Family Support And Burden

The theme of “family support and burden” was supported by Silberbogen et al. (2009) who reviewed the psychosocial issues relevant to individuals with chronic HCV. In their study, the roles within family relationships changed. Learning how to be in a relationship with someone who was diagnosed with chronic HCV was difficult. Adjustment to the realities of chronic HCV and antiviral treatment oftentimes produced stress within the family. This might explain why some families became supportive and some became burdensome. In a study by Blacklaws et al. (2009) the participants receiving antiviral treatment perceived themselves as losing their parental and social roles. These feelings of loss included loss of finances, self-image, and well-being. They sensed a loss of equal partnership with their spouse. They lost their normal lifestyle and daily routines. Those receiving treatment described these feelings as loss of control. Their family members seemed to be more receptive, and positive. They realized that these role changes were only temporary and their daily routines would be restored once treatment was completed. The families in the current study were quite polarized, for instance, one family rallied in support and another family ended in divorce. Nevertheless, the role changes should be evaluated frequently by their HCV healthcare provider because families have a key role in supporting antiviral treatment and influencing adherence.

5.1.7 Coping Strategies

The various strategies used to cope during antiviral treatment were consistent with Kinder's (2009) description of the lived experiences of men receiving HCV antiviral treatment. Similar to the current study, the participants used a variety of mechanisms to dull the side effects which included prayer, medication, recommendations from healthcare professionals, and exercise. HCV support groups and twelve-step programs were also useful. Sheppard and Hubbert (2006) found that humor, strength and determination appeared to counterbalance the negative side effects of treatment. In a study by Hopwood and Treloar (2005) many participants coped through lifestyle modifications, such as reducing work hours, and using relaxation techniques, as well as used prescription medications, and counseling.

In the current study, the participants expressed coping through staying busy and hibernating, socializing with friends, or through being alone. Important to all the participants was the use of prayer. Supported in the published literature, Richmond et al. (2010) found that prayer was commonly used as a coping mechanism among HCV patients receiving antiviral treatment. Prayer endorsed relaxation, stimulated a feeling of general well-being, and provided an opportunity for self-reflection. Prayer was essential to the veteran and should be taken into consideration during antiviral treatment to accurately understand the patients needs, beliefs, and behaviors (Richmond et al.).

5.1.8 Disclosure

The theme of "disclosure" was consistent with the descriptions of disclosure in the published literature (Hopwood et al., 2010; O'Brien et al., 2010). Hopwood et al. found that most individuals disclosed their HCV diagnosis to family and close friends. Disclosure was also more prevalent among individuals who were in frequent contact with other HCV infected individuals. They were more likely to share their diagnosis and personal experiences. Nonetheless, Hopwood et al. found that disclosure was an individual decision that presented a substantial risk to the psychosocial and physical well-being of the individual. In the current study,

some shared on a need to know basis which included family and close friends. Others disclosed their HCV status widely and without discretion. The need to know group were reluctant to disclose their diagnosis because of the negative association between illicit intravenous drug use and the disease. For instance, the veterans who attended twelve step programs gained support from the other members, felt comfortable discussing the twelve steps, but kept their HCV diagnosis a secret. These veterans only disclosed on a one-to-one basis if they thought the individual was genuinely interested. The other veterans, who did not feel the discrimination associated with the disease and disclosed widely without psychological risk, did so in hopes of teaching others about the disease, transmission, and prevention. For instance, the preacher who disclosed his HCV diagnosis and journey through antiviral treatment to his congregation hoped to prevent adolescents and other church members from becoming infected. This finding suggests that the option to disclose an individual's HCV status should be left up to the individual.

5.1.9 Treatment Recovery

The theme of "treatment recovery" was lacking in the published literature. The participants in the current study described treatment recovery in terms of hope and of the future. Those who did not clear the virus needed hope for the future, whereas, the ones who cleared the virus were hopeful for the future. Each individual experienced the treatment recovery phase differently. Adjusting to living without a debilitating chronic disease was difficult for those who cleared the virus. Likewise, the reality of living the rest of their life with HCV generated feelings of overwhelming doom and helplessness. Both were in need of further physical and psychosocial support. Perhaps these veterans would benefit from a psychoeducation program. One psychoeducation program, first developed for patients and families dealing with severe mental illness, was recently adapted to HCV patients and their families in preparation for antiviral treatment (Hong, North, Pollio, Abbacchi, Debold et al. 2011). These sessions consisted of didactic education, group support, and problem-solving elements that could supplement and possibly strengthen the medical and psychological care that is needed during the treatment

recovery phase.

5.2 Support Of Theoretical Framework

The themes by themselves were substantial, but together they brought meaning and a better understanding of adherence during antiviral treatment for HCV. These themes were applied to the Information – Motivation – Behavioral Skills Model of Adherence (Amico et al., 2005; Fisher et al., 2006). Adherence related information consisted of the knowledge of what, when, and how to take their medications, as well as the knowledge of the potential medication side effects. Adherence related motivation consisted of personal and social factors. The personal factors were the commitment to the cure and the commitment to the start and finish of the treatment which were considered the values, attitudes and beliefs of the veterans. Other personal factors included the will to live, and the notion of unfinished business. The social factors consisted of commitment to the healthcare provider and to the commitment of discipline which was necessary to sustain treatment. The social factors were designed to support and encourage adherence. The veterans also received support and encouragement through family members, close friends, and their social networks. These personal and social factors provided the veterans with the adherence-related motivation to follow the prescribed treatment regimen.

The adherence behavioral skills referred to the objective ability and the perceived efficacy for performing critical behaviors (Amico et al., 2005; Fisher et al., 2006). These behavioral skills were expressed in the narratives by their ability to take their antiviral medications correctly despite the variability of their daily lives. This also included the ability to minimize side effects, and to seek information and support when necessary. The veterans learned to time their injections according to their work schedules or daily activities and often phoned their HCV healthcare provider when questions arose. Ultimately, high levels of antiviral treatment adherence should result in positive health outcomes (Amico et al.). The health outcomes noted during clinic visits, as lab values or quality of life issues, would be linked back, via a feedback loop, to improve or to worsen subsequent treatment adherence (Fisher et al.). Additional personal and

environmental factors impacted adherence. These consisted of stable or unstable living conditions, access to medical care and to treatment medications, and uncontrolled mental health issues, such as depression. These factors could strengthen or weaken the relationship between adherence related information, motivation and behavioral skills (Amico et al., Fisher et al.).

The themes of the current study were well suited and appropriate for the Information – Motivation – Behavioral Skills Model of Adherence. A well-informed and motivated HCV veteran, who had the ability and self-belief to take the medications correctly, would more likely establish and maintain adequate adherence (Fisher et al., 2006). Consistent with the published literature, improved HCV viral clearance was directly related to higher levels of adherence (Weiss et al., 2008). These themes whether separate or as a whole, provided a pivotal starting point for future research.

5.3 Limitations

There were limitations to the current study. The experiences of the veterans taking their antiviral medications were gathered during the interviews which relied on self-report. Accurate recall of taking their medications may have been overstated or understated. The researcher was also a HCV healthcare provider for some of the veterans enrolled in the study. The dual roles of the researcher might have influenced how the questions were asked as well as how the veterans responded. The veterans may have responded by answering what they thought the researcher wanted to know.

5.4 Implications For Advanced Practice Nursing

Antiviral treatment for chronic HCV can be debilitating and relentless. This study provides many implications for nursing practice. First and foremost is patient education. The findings of this study suggest that patients may not need to know what their HCV genotype and viral loads are or how they impact treatment success. Although these parameters are important for the healthcare providers, the patient may only need to know what, how and when to take their

medications. This also supports the notion of relying on their past military training of following orders. Veterans receiving antiviral treatment for HCV need to know what the mission is and how to achieve it. Additionally, the findings suggest that patient education focus on the practicality of treatment medications, including side effect management. Nurses can improve individual patient education by exploring successful coping strategies, and by discussing the changing dynamics of family roles.

Secondly, the implications for nursing practice include the development of trusting relationships with patients receiving antiviral treatment. The findings suggest that this can be accomplished through a case management style of nursing practice. In this study, the relationship began at the preassessment evaluation appointment visit where each patient was assigned a specific advanced practice nurse. This relationship provided the opportunity to dialogue about coping, disclosure, family issues and general functioning. The relationship continued until treatment response was determined, which was six months post-treatment medication. This nursing approach allowed for a holistic approach to patient care and possibly accounted for the high level of adherence among the veterans enrolled in this study.

Third, this research suggests that veterans living with HCV and receiving treatment may benefit from a HCV support group. The more these veterans were around others with chronic HCV, the more they shared their experiences. In this study, the veterans seemed to have found the clinic waiting area an informal environment for sharing their experiences. They shared their side effect experiences, and enjoyed being around other HCV veterans who were going through the same treatment. Formally, this data suggest that nurses could be instrumental in implementing a HCV support group. Furthermore, nurses should consider implementing a support group to include family members in order to highlight and educate how antiviral treatment might change family roles.

Understanding the patient's perspectives and their physical and psychosocial issues during the initial phase of treatment can assist the advanced practice nurse in offering honest

and trustworthy care to veterans as they go through their journey of HCV treatment. In this study, the veterans expressed that not taking the treatment was never an option. Treatment was because they wanted to live.

5.5 Conclusions

This phenomenological study uncovered several themes pertaining to adherence during HCV treatment. Motivated through commitment, these participants were determined to be cured of their illness. They took their medications correctly from the start to the finish which resulted in a high adherence rate. Commitment was also motivated through the relationship between the participant and the HCV healthcare provider. This relationship was a cohesive team, essential and with clear boundaries, dedicated to eradicating the virus, irrespective of the challenges. Remarkably, commitment depended on their past military training which provided the motivation to stay the course, follow orders and complete the mission.

Following commitment, the participants were motivated to make healthy life style changes because they wanted to live. Once on treatment, the participants were given an opportunity to right the wrongs of their past by attempting to eradicate the virus. As they progressed and began to experience the side effects of treatment, their family roles began to change. They adapted coping skills to endure the challenges. Prayer became essential. For some, disclosure was nebulous and presented a psychosocial risk. Yet others found disclosure invigorating, especially if it helped others to know about the nature of the disease. Last was the treatment recovery phase, which was considered a period of future hopes.

5.6 Recommendations For Additional Research

Future research should be directed at strategies to improve adherence of antiviral medications during treatment. Qualitative as well as quantitative methods need to be explored. Qualitative research that explores the commitment motivated by the veterans past military training might be an interesting approach as a strategy for improving adherence. The psychosocial issues related to adherence need further research. First, is the notion of unfinished business. Does

having the opportunity to right past wrongs stimulate adherence? Second, how do the changing family roles influence adherence? A phenomenological study exploring the journey of the family through antiviral treatment and that of their HCV healthcare provider should be entertained. Third, although there is research examining the use of mind-body medicine, little is known on how prayer/meditation/visualization influences adherence. Fourth, data supports that disclosure is an individual's decision, but how does disclosure influence disease prevention, treatment seeking behavior, and adherence during treatment?

Future research should also be dedicated to the treatment recovery phase. The participants in the current study described treatment recovery in terms of the future. Those who did not clear the virus needed hope for the future, whereas, the ones who cleared the virus were hopeful for the future. Research supports that adherence plays a part in the success or failure of treatment, but there is an absence of published research that examines how individuals adjust physically and psychosocially during the treatment recovery phase. A mixed method approach may be interesting in providing meaning and information to this phase of antiviral treatment. Comparison of standard of care follow up versus psychoeducation sessions, to include grief therapy, may be a starting point for research in this population.

Today, with the advent of triple therapy for chronic HCV, adherence becomes even more imperative due to the risk of viral mutations with missed doses (McHutchison & Dev, 2004). Quantitatively, the themes in this study overwhelmingly support the need for the development of a measurement tool for HCV adherence during antiviral treatment. Future research is needed to measure adherence outcomes by comparing educational, behavioral, and/or psychosocial interventions. Quantitative analysis is needed to determine the reasons why some who are ineligible for treatment due to drugs and alcohol use, become either eligible or remain ineligible.

Adherence studies are needed to explore the lived experiences of veterans diagnosed with chronic HCV, their treatment and psychosocial issues. Adherence studies are needed to

quantify and measure data in order to provide meaningful statistical and clinical significance for veterans with chronic HCV.

5.7 Summary

Chronic HCV is an illness with a enormous trajectory if left untreated. The treatment is long, harsh, and debilitating. Once completed, only a portion of individuals successfully eradicate the virus. Treatment plays havoc with the person's psychosocial and physical health impacting their whole well-being. Adherence to the treatment is difficult, and response dependent. Using the hermeneutic circle, these study results integrated the parts of the narratives into the whole, which provided the meaning of adherence among veterans receiving pegylated interferon and ribavirin antiviral treatment for HCV.

APPENDIX A
ORAL SCRIPT FOR RECRUITMENT

Oral Script for Recruitment: HCV Treatment Team Members

Since you are receiving hepatitis C treatment in clinic 6, you are invited to participate in a research study. The purpose of the study is to find out what taking your hepatitis C medications means to you. The study provides an opportunity for you to talk with the researcher about staying on your HepC medications during treatment. If you are interested, please take a flyer with the contact information. Please feel free to contact the researcher or I can introduce the researcher to you for further information. The researcher will schedule an appointment to meet with you.

Oral Script for Recruitment: Researcher

Since you are receiving hepatitis C antiviral treatment, you are eligible to participate in this research study. The purpose of the study is to find out what staying on your HepC medications means to you.

If you agree to participate, you will receive an appointment date for an interview with the principal investigator. The interview will take place in the Clinical Research Unit, 8th floor, building 2, or a private room setting at the Dallas VANTHCS. The principal investigator will read the research informed consent form with you to describe the study. The informed consent form will be completed, signed and dated by you and the principal investigator. A third person will witness the signatures. You will be asked to complete a demographic data form. This demographic form will ask you general questions about your age, gender, and telephone number.

All information provided by you will be kept private and confidential. Your demographic form will be coded with an alphabetical letter and will not have any identifying information about you. Additionally, your interview will be coded with the same letter. Only the principal investigator will have access to the information.

The interview will last no longer than one hour. The interview will consist of a tape recorded conversational narrative between you and the principal investigator. After a couple of

weeks, the principal investigator will call you by telephone to make sure your tape recorded narrative is correct.

There are no known physical risks associated with participation in the interview. You may experience emotional discomfort when answering questions during the interview process. You may feel uncomfortable talking about feelings, emotions, and reactions in relation to your experiences while receiving HepC medications. If you feel uncomfortable, you may chose not to answer the question.

Participating in the study will give you the opportunity to discuss your experiences, perceptions, feelings and reactions while receiving HCV treatment. You will be offered remuneration in appreciation of your time and effort. Once you have completed the one time interview and the follow up phone call, you will receive a \$25.00 gift card from Wal-Mart. This gift card will either be mailed to you or given to you in person. The information learned from this study may benefit others who are and will be receiving HCV treatment in the future. The results of this study will be used to gain information on the issues associated with staying on your medication during HCV treatment. Your participation in this study is completely voluntary. You may change your mind at any time and withdraw from the study. Your decision to participate or not participate will have no effect on your hepatitis C treatment. Would you like to participate and schedule an appointment?

APPENDIX B
RECRUITMENT FLYER

Are you undergoing treatment for Hepatitis C at the Dallas VA?

**If so, you are invited
to join a research study.**

The purpose of this study is
to determine what taking your
Hepatitis C medication means to you.

Participating in this study can improve the
knowledge of what it means to take your
Hepatitis C medication and help other
Veterans who receive HCV treatment.

☆ *Compensation for time and effort is included.*

If interested, please contact



**Frankie Phillips, MS, RN, ACNS, BC
Doctoral Student**

214-857-1487 or 214-857-1590

APPENDIX C
CONSENT FORMS

Subject Name: _____ Date: _____
 Title of Study: The Meaning of Adherence Among Veterans Receiving Pegylated Interferon and Ribavirin Antiviral Treatment for Hepatitis C. #11-009
 Principal Investigator: Frances Phillips MS. RN. ACNS. BC
 Co-Investigator(s): _____
 Study Coordinators: _____

Before agreeing to take part in this research study, it is important that you **read and understand the proposed research explained below**. It describes the procedures, benefits, risks and discomforts of the study. It also describes other treatments that are open to you and your right to withdraw from the study at any time. It is important for you to understand that no promises can be made about the results of the study.

1. WHAT IS THIS RESEARCH STUDY ABOUT?

The purpose of this research is to find out what taking your HepC medications (pegylated interferon and ribavirin) mean to you and how you live day to day during treatment. This research involves talking about how the changes in your day to day life persuade you to either take or not take your HepC medications correctly. You were selected as a possible participant in this study because you are positive for hepatitis C and are taking HepC medications in the HepC treatment clinic at the Dallas VA.

How patients take their HepC medications are related to the success of treatment. For some of the patients, the healthcare provider decreases the dose of the HepC medications or stops them completely. For others, some patients decide on their own to miss doses of their HepC medications, change the doses, or stop taking the HepC medications altogether. The extent to which patients miss their HepC medications, change the doses or stop altogether is unknown.

The expected duration of your participation is to be no more than one hour for a one time interview with the researcher. There will be one additional follow-up telephone call. This telephone call will be to confirm that the researcher correctly understands what you said during the interview.

The approximate number of research participants involved in this study will be between 15 and 30 veterans who receive their HepC medications at the Dallas VA in the hepatitis C treatment clinic.

This study is sponsored by The Society of Gastroenterology Nurses and Associates, Inc.

SUBJECTS IDENTIFICATION (I.D., plate or give name-last, first, middle)

2. WHAT WILL HAPPEN DURING THE STUDY?

If you choose to participate and are currently taking HepC medications, the principal investigator (researcher) will contact you in person in the Dallas VA HepC clinic to invite you to participate in the research study. A meeting will be scheduled in the clinical research unit or in a private room setting at the Dallas VANTHCS.

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 Research Revision dated 08-30-10

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Version Number: _____

Submission/Revision Date: _____

Patient Initials: _____

Subject Name: _____ Date: _____
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 Principal Investigator: Frances Phillips MS, RN, ACNS, BC
 Co-Investigator(s): _____
 Study Coordinators: _____

During this meeting you and the principal investigator will discuss the purpose of the research, the risks and benefits, and the amount of time necessary for participation. You will be given the opportunity to choose to participate or not to participate in the research study and your decision will not influence your ongoing healthcare. Following, if in agreement to participate, the consent form will be read, signed, witnessed and a printed copy will be given to you. The completed research consent form will be electronically entered into your computerized patient record system. A research enrollment note will be entered identifying you as being enrolled in a research study.

A one-time interview will take place at a convenient time for you and should last approximately 30 minutes, not more than 60 minutes. Although the interview process consists of tape recording, you will have the ability to request that certain information not be recorded. No medical records will be searched and no medical information will be recorded other than what you choose to say during the interview. Throughout the interview, the principal investigator will attempt to find out what taking your HepC medications mean to you and how your daily life activities influence you to take or not take your HepC medications correctly. You will also be asked to complete a short demographic data form. Once all participants have completed the interview process, you will receive a follow up telephone call. This is to confirm that the principal investigator correctly understands what you said during the interview. The follow-up telephone call should not be more than 15 minutes.

You may experience emotional discomfort when answering some questions during the interview process. You may feel uncomfortable talking about your personal thoughts, feelings and emotions in relation to your experiences associated with your HepC treatment. You could possibly become upset when discussing your hepatitis C diagnosis. You may choose not to answer any question with which you feel uncomfortable or request that specific information not be recorded.

Although every effort will be given to provide convenience in scheduling the interview appointment, you may find traveling to the appointments inconvenient. Likewise, every effort will be given to arrange a convenient time for the follow-up telephone call.

3. WHAT ARE MY RISKS?

There are no known physical risks associated with participation in the personal interview or completing the demographic form. While this research does not involve medical procedures, you may experience various medical complications arising from existing medical diagnoses, chronic hepatitis C and HepC treatment. During participation in this study, you will continue to be followed and evaluated in the hepatitis C treatment clinic. If you become ill during the research as a complication of existing medical conditions, chronic hepatitis C, and/or HepC treatment you should notify your healthcare provider or the principal investigator for further medical evaluation.

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Although feelings of distress may accompany the interview conversation, these feelings may not be considered a serious risk or life-threatening. These feelings may be associated with the difficulties of taking your HepC medications correctly which can be unpleasant and stressful. If necessary, consultation for mental health referrals is available. The principal investigator is an advanced practice nurse who can also end the interview if she observes any anxiety.

Loss of privacy is an associated risk of any research. The principal investigator will not make known any private information gathered from you during the research study. There are no known social, legal or economic risks.

Unforeseen risks: A previously unknown problem could result from your taking part in this research. Any new findings will be given to you that may affect your willingness to take part in this study. If new findings are discovered, you will be asked to sign a new (updated) informed consent form to document that new information provided in the updated Consent Form has been explained to you.

4. WILL THE RESEARCH BENEFIT ME OR OTHERS?

By participating in this study, it may be beneficial and helpful for you to discuss important and emotionally charged issues and tell your story with the principal investigator, a neutral person. You may feel that by your participation in this study, you are contributing to research aimed at improving patient care, especially in the HCV infected veteran and HepC treatment. There are potential benefits to society and to future hepatitis C veterans who receive HepC treatment. The knowledge obtained may be used to improve how patients take their HepC medications and increase the success rates in clearing the HepC virus.

The principal investigator cannot guarantee that you will receive any benefit from participating in this study.

5. WHAT ARE MY ALTERNATIVES TO BEING A RESEARCH SUBJECT?

This is not a treatment study. Your healthcare will not change if you choose to participate or not anticipate in this study.

6. WILL I GET PAID?

Once you have completed the research interview and the follow up telephone call, you will receive a Wal-Mart gift certificate of \$25.00 for your time and participation. The gift card will be

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 Study Coordinators: _____

given to you in person as requested. There are no funds available to pay for transportation to and from the research unit, lost time away from work or other expenses as child care.

7. WILL I HAVE TO PAY?

Subjects do not pay for treatment associated with participation in a VA research program. This research does not involve a study drug.

You will not be charged for anything related to this research study. If you receive medical care during the research study which is not related to this study you will be expected to provide co-payment according to your VA eligibility. If you need referral to Mental Health Service, this will be provided to you, but the study is not responsible for the cost of any mental health treatment. Additionally, if you receive medical care during this research study, the study is not responsible for the cost of any medical treatment. Your medical care and services provided by the VA that are not part of this study may require co-payments if your VA eligibility category requires co-payment

8. DOES BEING PREGNANT OR THE POSSIBILITY OF BEING PREGNANT PREVENT ME FROM TAKING PART?

Every effort will be made to have females enter this study on an equal basis with male subjects.

However, this study does exclude any woman who is pregnant. Pregnancy is contraindicated for patients during HepC (pegylated interferon and ribavirin) antiviral treatment.

You will be excluded from this study if you are or become pregnant during pegylated interferon and ribavirin treatment. Pegylated interferon and ribavirin treatment is contraindicated during pregnancy due to miscarriage, birth defects or other problems for the fetus.

9. WHAT IF I GET INJURED?

The VA has the authority to provide medical treatment to participants injured by participation in a VA study. If you are injured as a result of being in this study, the VA will provide the necessary medical treatment in accordance with federal law. If you want to make a legal claim against the VA or anyone who works for the VA, special laws may apply. The Federal Tort Claims Act (28 U.S.C. 1346(b), 2671-2680) is a federal law that controls when and how a person can bring a claim against the U.S. Government. If you sign this document you are not giving up your right to make a legal claim against the United States.

It is important that you report any illness or injury during this research immediately to the principle investigator.

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 Co-Investigator(s): _____
 Study Coordinators: _____

10. ARE MY RESEARCH RECORDS SAFE FROM THE PUBLIC?

The study doctors keep your research records private in the same way as your other medical records. No one has access to your records except as required by law. You are, however, authorizing the Dallas VA Institutional Review Board (IRB), the Dallas VA Research and Development Committee and the members of the Dallas VA Research Office to inspect your medical and research records. These committees, people, and offices at the Dallas VAMC are responsible for overseeing human research studies.

In order to protect your confidentiality the principal investigator will create a master list which identifies you with an assigned alphabetical code. The list of participants will be kept secured, locked, and available only to the principal investigator. Additionally, this list will be separate from the recorded transcripts and audiotapes. During data collection and data analysis, protection of your anonymity and confidentiality will be preserved. All research information will be kept under double lock.

By signing this form, you will allow the Veterans Health Administration (VHA) to provide Frances Phillips MS, RN, ACNS, BC and his/her research team access to the following health data about you which may be used or disclosed in connection with this research study, including, but not limited to: demographic characteristics, and interview conversations between you and the principal investigator..

No medical records will be searched and no medical information will be recorded other than what you choose to say during the interview and make known on the demographic form..

If you do not sign this form, you will not be part of the study.

This approval to use your health data will have no expiration date.

VHA complies with the requirements of the Health Insurance Portability and Accountability Act of 1996 and all other laws that protect your privacy. We will protect your health data according to these laws. Despite these protections, there is a possibility that your health data could be used or disclosed in a way that it will no longer be protected. Our Notice of Privacy Practices (a separate document) provides more information on how we protect your health data. If you do not have a copy of the Notice, the research team will provide one to you.

If you choose to take part in the study, certain government agencies (such as the FDA or VA) may look at your research records. Your name as a subject in this study is private, and will not be included in any report prepared as a result of this study.

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 Co-Investigator(s): _____
 Study Coordinators: _____

11. DO I HAVE TO TAKE PART IN THIS STUDY, OR CAN I WITHDRAW FROM THE STUDY?

Taking part in this study is voluntary and you may refuse to take part without penalty or loss of benefits to which you are otherwise entitled. You are free to withdraw your consent and stop taking part at any time. Not taking part in the study will in no way affect the quality of care you receive now or in the future from the VA. This will also not affect your right to take part in other studies. The study doctors will answer any questions you may have about the study.

This is not a treatment study and there are no withdrawal procedures. If you decide to withdraw from the study, you are free to stop participating at any time. You do not need to be part of this research study to receive healthcare.

You can also take back your authorization for the VHA or the study doctors to access or to share your health data with outside parties at any time. To stop taking part in the study or to take back your authorization, you should contact both:

- 1) Frances Phillips MS, RN, ACNS, BC or his/her representative listed at the bottom of this form, and
- 2) the IRB Administrator of the Dallas VA Medical Center [telephone: 214-857-0291]; mail: Dallas VA Medical Center, IRB Administrator (151) 4500 S. Lancaster Rd. Dallas, TX 75216.

If you decide to take back your authorization, you will be given a form to show your desire in writing. If you take back your authorization, you will not be able to continue to take part in the study. This will not affect your rights as a VHA patient.

If you take back your authorization, Frances Phillips MS, RN, ACNS, BC and his/her research team can keep using health data about you that has been collected. No health data will be collected after you take back the authorization.

Your healthcare provider may also take you out of the study without your consent for medical or administrative reasons. Any significant new findings that develop during the course of the research study that the study investigator thinks may affect your willingness to continue to take part will be given to you as soon as possible.

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 Co-Investigator(s): _____
 Study Coordinators: _____

12. WHOM SHOULD I CONTACT FOR QUESTIONS OR PROBLEMS?

If you have any questions about this study or have any bad effects of your treatment, you should call the study investigator at 214-857-1487 or a member of the research team at 214-857-1590. You should also contact the study investigator or a member of the research team to discuss problems, concerns you may presently have, or offer input about the research.

If you have any questions about whether this is a VA North Texas Healthcare System-approved research study, you may contact the Research Compliance Officer at 214-857-0341.

If you have any questions about your rights as a patient, complaints about your treatment or general concerns about the conduct of the research study, of if you have questions, complains, concerns you may contact the Dallas VAMC Patient Representatives at 214-857-0482. The Patient Representative will guide you in resolving your question or complaint.

If you have a medical emergency you should immediately call 911 for assistance.

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 Co-Investigator(s): _____
 Study Coordinators: _____

RESEARCH SUBJECT'S RIGHTS:

I have read or have had read to me all of the above. The study has been explained to me and all of my questions have been answered. If I have questions later, it has been explained to me that I can contact Frances Phillips MS, RN, ACNS, BC. I have been told of the risks or discomforts and possible benefits of the study. I have been told of other choices of treatment open to me.

It has been explained to me that I do not have to take part in this study and my refusal to take part will involve no penalty or loss of rights to which I am entitled. I may withdraw at any time without penalty or loss of VA or other benefits to which I am entitled. The study investigator can take me out of the study at any time if it appears to be medically harmful to me, if I fail to follow directions for taking part in this study, if it is discovered that I do not meet the study requirements, or if the study is canceled.

In case there are medical problems or questions, I have been told I can call Frances Phillips MS, RN, ACNS, BC at 214-857-1487 during the day or at 800-725-4436 after hours.

I was informed of my rights as a research subject, and I voluntarily consent to take part in this study. I authorize the use of my identifiable patient health information as described in this form. I will receive a signed copy of this consent form.

Subject's Printed Name & Signature Date

Printed Name & Signature of Witness Date

Printed name & Signature of Person Obtaining Informed Consent Date

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Research Subject's Bill of Rights

1. Be informed of the nature and purpose of the research.
2. Be clearly told of the procedures to be followed in the medical research, and any drug or device to be used.
3. Be clearly told of any discomforts and risks that might be expected from the research.
4. Be clearly told of any benefits that the patient might expect from the research.
5. Be clearly told of any other appropriate procedures, drugs, or devices that might be helpful to the patient, and their risks and benefits.
6. Be clearly told how to get medical treatment, if needed, after the research is finished if problems should arise.
7. Be given the chance to ask any questions about the research or the procedures involved.
8. Be clearly told that consent to take part in the medical research and/or release of identifiable patient health information may be taken back at any time. The patient may stop taking part in the medical research without any penalty or loss of VA or other benefits.
9. Be given a copy of the signed and dated written consent form.
10. Be given the chance to decide to consent or not to consent to a medical research study without any force, fraud, deceit, duress, coercion, or undue influence on the patient's decision.



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 Principal Investigator: Frances Phillips MS, RN, ACNS, BC
 Co-Investigator(s): _____
 Study Coordinators: _____

Before agreeing to take part in this research study, it is important that you read and understand the proposed research explained below. It describes the procedures, benefits, risks and discomforts of the study. It also describes other treatments that are open to you and your right to withdraw from the study at any time. It is important for you to understand that no promises can be made about the results of the study.

1. WHAT IS THIS RESEARCH STUDY ABOUT?

The purpose of this research is to find out what taking your HepC medications (pegylated interferon and ribavirin) mean to you and how you live day to day during treatment. **This research involves** talking about how the changes in your day to day life persuade you to either take or not take your HepC medications correctly. You were selected as a possible participant in this study because you are positive for hepatitis C and are taking HepC medications or have received HepC medications in the last 12 months in the HepC treatment clinic at the Dallas VA.

How patients take their HepC medications are related to the success of treatment. For some of the patients, the healthcare provider decreases the dose of the HepC medications or stops them completely. For others, some patients decide on their own to miss doses of their HepC medications, change the doses, or stop taking the HepC medications altogether. The extent to which patients miss their HepC medications, change the doses or stop altogether is unknown.

The expected duration of your participation is to be no more than one hour for a one time interview with the researcher. There will be one additional follow-up telephone call. This telephone call will be to confirm that the researcher correctly understands what you said during the interview.

The approximate number of research participants involved in this study will be between 15 and 30 veterans who receive their HepC medications at the Dallas VA in the hepatitis C treatment clinic.

This study is sponsored by The Society of Gastroenterology Nurses and Associates, Inc.

SUBJECTS IDENTIFICATION (I.D., plate or give name-last, first, middle)

2. WHAT WILL HAPPEN DURING THE STUDY?

If you choose to participate and are currently taking HepC medications, the principal investigator (researcher) will contact you in person in the Dallas VA HepC clinic to invite you to participate in the research study. A meeting will be scheduled in the clinical research unit or in a private room setting at the Dallas VANTHCS.

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Version Number: _____
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Subject Name: _____ Date: _____
 Title of Study: The Meaning of Adherence Among Veterans Receiving Pegylated Interferon and Ribavirin Antiviral Treatment for Hepatitis C, #11-009
 Principal Investigator: Frances Phillips MS, RN, ACNS, BC
 Co-Investigator(s): _____
 Study Coordinators: _____

During this meeting you and the principal investigator will discuss the purpose of the research, the risks and benefits, and the amount of time necessary for participation. You will be given the opportunity to choose to participate or not to participate in the research study and your decision will not influence your ongoing healthcare. Following, if in agreement to participate, the consent form will be read, signed, witnessed and a printed copy will be given to you. The completed research consent form will be electronically entered into your computerized patient record system. A research enrollment note will be entered identifying you as being enrolled in a research study.

A one-time interview will take place at a convenient time for you and should last approximately 30 minutes, not more than 60 minutes. Although the interview process consists of tape recording, you will have the ability to request that certain information not be recorded. No medical records will be searched and no medical information will be recorded other than what you choose to say during the interview. Throughout the interview, the principal investigator will attempt to find out what taking your HepC medications mean to you and how your daily life activities influence you to take or not take your HepC medications correctly. You will also be asked to complete a short demographic data form. Once all participants have completed the interview process, you will receive a follow up telephone call. This is to confirm that the principal investigator correctly understands what you said during the interview. The follow-up telephone call should not be more than 15 minutes.

You may experience emotional discomfort when answering some questions during the interview process. You may feel uncomfortable talking about your personal thoughts, feelings and emotions in relation to your experiences associated with your HepC treatment. You could possibly become upset when discussing your hepatitis C diagnosis. You may choose not to answer any question with which you feel uncomfortable or request that specific information not be recorded.

Although every effort will be given to provide convenience in scheduling the interview appointment, you may find traveling to the appointments inconvenient. Likewise, every effort will be given to arrange a convenient time for the follow-up telephone call.

3. WHAT ARE MY RISKS?

There are no known physical risks associated with participation in the personal interview or completing the demographic form. While this research does not involve medical procedures, you may experience various medical complications arising from existing medical diagnoses, chronic hepatitis C and HepC treatment. During participation in this study, you will continue to be followed and evaluated in the hepatitis C treatment clinic. If you become ill during the research as a complication of existing medical conditions, chronic hepatitis C, and/or HepC treatment you should notify your healthcare provider or the principal investigator for further medical evaluation.

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 Principal Investigator: Frances Phillips MS, RN, ACNS, BC
 Co-Investigator(s): _____
 Study Coordinators: _____

Although feelings of distress may accompany the interview conversation, these feelings may not be considered a serious risk or life-threatening. These feelings may be associated with the difficulties of taking your HepC medications correctly which can be unpleasant and stressful. If necessary, consultation for mental health referrals is available. The principal investigator is an advanced practice nurse who can also end the interview if she observes any anxiety.

Loss of privacy is an associated risk of any research. The principal investigator will not make known any private information gathered from you during the research study. There are no known social, legal or economic risks.

Unforeseen risks: A previously unknown problem could result from your taking part in this research. Any new findings will be given to you that may affect your willingness to take part in this study. If new findings are discovered, you will be asked to sign a new (updated) informed consent form to document that new information provided in the updated Consent Form has been explained to you.

4. WILL THE RESEARCH BENEFIT ME OR OTHERS?

By participating in this study, it may be beneficial and helpful for you to discuss important and emotionally charged issues and tell your story with the principal investigator, a neutral person. You may feel that by your participation in this study, you are contributing to research aimed at improving patient care, especially in the HCV infected veteran and HepC treatment. There are potential benefits to society and to future hepatitis C veterans who receive HepC treatment. The knowledge obtained may be used to improve how patients take their HepC medications and increase the success rates in clearing the HepC virus.

The principal investigator cannot guarantee that you will receive any benefit from participating in this study.

5. WHAT ARE MY ALTERNATIVES TO BEING A RESEARCH SUBJECT?

This is not a treatment study. Your healthcare will not change if you choose to participate or not anticipate in this study.

6. WILL I GET PAID?

Once you have completed the research interview and the follow up telephone call, you will receive a Wal-Mart gift certificate of \$25.00 for your time and participation. The gift card will be

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given to you in person as requested. There are no funds available to pay for transportation to and from the research unit, lost time away from work or other expenses as child care.

7. WILL I HAVE TO PAY?

Subjects do not pay for treatment associated with participation in a VA research program. This research does not involve a study drug.

You will not be charged for anything related to this research study. IF you receive medical care during the research study which is not related to this study you will be expected to provide co-payment according to your VA eligibility. If you need referral to Mental Health Service, this will be provided to you, but the study is not responsible for the cost of any mental health treatment. Additionally, if you receive medical care during this research study, the study is not responsible for the cost of any medical treatment. Your medical care and services provided by the VA that are not part of this study may require co-payments if your VA eligibility category requires co-payment

8. DOES BEING PREGNANT OR THE POSSIBILITY OF BEING PREGNANT PREVENT ME FROM TAKING PART?

Every effort will be made to have females enter this study on an equal basis with male subjects.

However, this study does exclude any woman who is pregnant. Pregnancy is contraindicated for patients during HepC (pegylated interferon and ribavirin) antiviral treatment.

You will be excluded from this study if you are or become pregnant during pegylated interferon and ribavirin treatment. Pegylated interferon and ribavirin treatment is contraindicated during pregnancy due to miscarriage, birth defects or other problems for the fetus.

9. WHAT IF I GET INJURED?

The VA has the authority to provide medical treatment to participants injured by participation in a VA study. If you are injured as a result of being in this study, the VA will provide the necessary medical treatment in accordance with federal law. If you want to make a legal claim against the VA or anyone who works for the VA, special laws may apply. The Federal Tort Claims Act (28 U.S.C. 1346(b), 2671-2680) is a federal law that controls when and how a person can bring a claim against the U.S. Government. If you sign this document you are not giving up your right to make a legal claim against the United States.

It is important that you report any illness or injury during this research immediately to the principle investigator.

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 Co-Investigator(s): _____
 Study Coordinators: _____

10. ARE MY RESEARCH RECORDS SAFE FROM THE PUBLIC?

The study doctors keep your research records private in the same way as your other medical records. No one has access to your records except as required by law. You are, however, authorizing the Dallas VA Institutional Review Board (IRB), the Dallas VA Research and Development Committee and the members of the Dallas VA Research Office to inspect your medical and research records. These committees, people, and offices at the Dallas VAMC are responsible for overseeing human research studies.

In order to protect your confidentiality the principal investigator will create a master list which identifies you with an assigned alphabetical code. The list of participants will be kept secured, locked, and available only to the principal investigator. Additionally, this list will be separate from the recorded transcripts and audiotapes. During data collection and data analysis, protection of your anonymity and confidentiality will be preserved. All research information will be kept under double lock.

By signing this form, you will allow the Veterans Health Administration (VHA) to provide Frances Phillips MS, RN, ACNS, BC and his/her research team access to the following health data about you which may be used or disclosed in connection with this research study, including, but not limited to: demographic characteristics, and interview conversations between you and the principal investigator..

No medical records will be searched and no medical information will be recorded other than what you choose to say during the interview and make known on the demographic form..

If you do not sign this form, you will not be part of the study.

This approval to use your health data will have no expiration date.

VHA complies with the requirements of the Health Insurance Portability and Accountability Act of 1996 and all other laws that protect your privacy. We will protect your health data according to these laws. Despite these protections, there is a possibility that your health data could be used or disclosed in a way that it will no longer be protected. Our Notice of Privacy Practices (a separate document) provides more information on how we protect your health data. If you do not have a copy of the Notice, the research team will provide one to you.

If you choose to take part in the study, certain government agencies (such as the FDA or VA) may look at your research records. Your name as a subject in this study is private, and will not be included in any report prepared as a result of this study.

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 Co-Investigator(s): _____
 Study Coordinators: _____

11. DO I HAVE TO TAKE PART IN THIS STUDY, OR CAN I WITHDRAW FROM THE STUDY?

Taking part in this study is voluntary and you may refuse to take part without penalty or loss of benefits to which you are otherwise entitled. You are free to withdraw your consent and stop taking part at any time. Not taking part in the study will in no way affect the quality of care you receive now or in the future from the VA. This will also not affect your right to take part in other studies. The study doctors will answer any questions you may have about the study.

This is not a treatment study and there are no withdrawal procedures. If you decide to withdraw from the study, you are free to stop participating at any time. You do not need to be part of this research study to receive healthcare.

You can also take back your authorization for the VHA or the study doctors to access or to share your health data with outside parties at any time. To stop taking part in the study or to take back your authorization, you should contact both:

- 1) Frances Phillips MS, RN, ACNS, BC or his/her representative listed at the bottom of this form, and
- 2) the IRB Administrator of the Dallas VA Medical Center [telephone: 214-857-0291]; mail: Dallas VA Medical Center, IRB Administrator (151) 4500 S. Lancaster Rd. Dallas, TX 75216.

If you decide to take back your authorization, you will be given a form to show your desire in writing. If you take back your authorization, you will not be able to continue to take part in the study. This will not affect your rights as a VHA patient.

If you take back your authorization, Frances Phillips MS, RN, ACNS, BC and his/her research team can keep using health data about you that has been collected. No health data will be collected after you take back the authorization.

Your healthcare provider may also take you out of the study without your consent for medical or administrative reasons. Any significant new findings that develop during the course of the research study that the study investigator thinks may affect your willingness to continue to take part will be given to you as soon as possible.

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 Co-Investigator(s): _____
 Study Coordinators: _____

12. WHOM SHOULD I CONTACT FOR QUESTIONS OR PROBLEMS?

If you have any questions about this study or have any bad effects of your treatment, you should call the study investigator at 214-857-1487 or a member of the research team at 214-857-1590. You should also contact the study investigator or a member of the research team to discuss problems, concerns you may presently have, or offer input about the research.

If you have any questions about whether this is a VA North Texas Healthcare System-approved research study, you may contact the Research Compliance Officer at 214-857-0341.

If you have any questions about your rights as a patient, complaints about your treatment or general concerns about the conduct of the research study, or if you have questions, complains, concerns you may contact the Dallas VAMC Patient Representatives at 214-857-0482. The Patient Representative will guide you in resolving your question or complaint.

If you have a medical emergency you should immediately call 911 for assistance.

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RESEARCH SUBJECT'S RIGHTS:

I have read or have had read to me all of the above. The study has been explained to me and all of my questions have been answered. If I have questions later, it has been explained to me that I can contact Frances Phillips MS, RN, ACNS, BC. I have been told of the risks or discomforts and possible benefits of the study. I have been told of other choices of treatment open to me.

It has been explained to me that I do not have to take part in this study and my refusal to take part will involve no penalty or loss of rights to which I am entitled. I may withdraw at any time without penalty or loss of VA or other benefits to which I am entitled. The study investigator can take me out of the study at any time if it appears to be medically harmful to me, if I fail to follow directions for taking part in this study, if it is discovered that I do not meet the study requirements, or if the study is canceled.

In case there are medical problems or questions, I have been told I can call Frances Phillips MS, RN, ACNS, BC at 214-857-1487 during the day or at 800-725-4436 after hours.

I was informed of my rights as a research subject, and I voluntarily consent to take part in this study. I authorize the use of my identifiable patient health information as described in this form. I will receive a signed copy of this consent form.

Subject's Printed Name & Signature	Date
Printed Name & Signature of Witness	Date
Printed name & Signature of Person Obtaining Informed Consent	Date

VA Form 10-1086 Research Revision dated 08-30-10	IRB Approved 05/09/11-01/02/12	<table border="0" style="width: 100%;"> <tr> <td style="width: 50%;">Version Number:</td> <td style="width: 50%; border-bottom: 1px solid black;"></td> </tr> <tr> <td>Submission/Revision Date:</td> <td style="border-bottom: 1px solid black;">5/3/11</td> </tr> <tr> <td>Patient Initials:</td> <td style="border-bottom: 1px solid black;"></td> </tr> </table>	Version Number:		Submission/Revision Date:	5/3/11	Patient Initials:	
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Patient Initials:								



Department of Veterans Affairs

Dallas VA Medical Center Research Consent Form

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Subject Name: _____ Date: _____
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 Principal Investigator: Frances Phillips MS, RN, ACNS, BC
 Co-Investigator(s): _____
 Study Coordinators: _____

VA Form 10-1086
Research Revision dated 08-30-10

IRB Approved
05/09/11-01/02/12



Version Number: _____
 Submission/Revision Date: 5/3/11
 Patient Initials: _____

Research Subject's Bill of Rights

1. Be informed of the nature and purpose of the research.
2. Be clearly told of the procedures to be followed in the medical research, and any drug or device to be used.
3. Be clearly told of any discomforts and risks that might be expected from the research.
4. Be clearly told of any benefits that the patient might expect from the research.
5. Be clearly told of any other appropriate procedures, drugs, or devices that might be helpful to the patient, and their risks and benefits.
6. Be clearly told how to get medical treatment, if needed, after the research is finished if problems should arise.
7. Be given the chance to ask any questions about the research or the procedures involved.
8. Be clearly told that consent to take part in the medical research and/or release of identifiable patient health information may be taken back at any time. The patient may stop taking part in the medical research without any penalty or loss of VA or other benefits.
9. Be given a copy of the signed and dated written consent form.
10. Be given the chance to decide to consent or not to consent to a medical research study without any force, fraud, deceit, duress, coercion, or undue influence on the patient's decision.



THE UNIVERSITY
OF TEXAS
AT ARLINGTON

Office of Research Administration
Box 19188
202 E. Border St., Suite 214
Arlington, Texas
76019-0188

T 817.272.3723
F 817.272.1111

<http://www.uta.edu/research>

[Expertise at UT Arlington](http://www.uta.edu/expertise)

<http://www.uta.edu/expertise>

June 1, 2011

Frances Hinshaw Phillips
Dr. Donelle Barnes
School of Nursing
Box 19407
Arlington, Texas 76019

Re: UT Arlington Institutional Review Board
Acknowledgement of Minor Modification

Project Title: *The Meaning of Adherence Among Veterans Receiving
Pegylated Interferon and Ribavirin Antiviral Treatment for
hepatitis C*

Dallas VA Medical Center Research IRB No. : 11-009

Principal Investigator: Frances Phillips

UTA IRB No.: 2011-0296

Dear Frances Phillips,

The UT Arlington Office of Research Administration and the UT Arlington Institutional Review Board are pleased to acknowledge approval for **Minor Modifications** on your study titled "*The Meaning of Adherence Among Veterans Receiving Pegylated Interferon and Ribavirin Antiviral Treatment for hepatitis C*" by the IRB of record Dallas VA Medical Center Research.

Dallas VA Medical Center Research is noted as the IRB of record for the project, approved the listed modification on May 31st 2011:

- Update Eligibility criteria consisting of veterans with positive HCV antibody with detectable HCV RNA viremia, 18 years of age or older and are receiving pegylated interferon and ribavirin antiviral treatment or have received antiviral treatment within the last 12 months.
- Changes reflected in Updated consent documents.

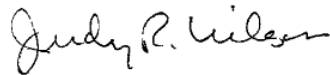
BeAMaverick™

Pursuant to Title 45 CFR 46.103(b)(4)(iii), investigators are required to, “promptly report to the IRB any proposed changes in the research activity, and ensure that such changes in approved research, during the period for which IRB approval has already been given, **are not initiated without IRB review and approval** except when necessary to eliminate apparent immediate hazards to the subject.”

The modification as approved by the IRB of record will additionally be presented to the convened board on June 14th 2011 for full IRB acknowledgment [45 CFR 46.110(c)]. All investigators and key personnel identified in the protocol must have documented *Human Subjects Involved in Research (Tier II) Training* or other UT Arlington approved compliance education in the responsible conduct of human subject research on file with the UT Arlington Office of Research Administration Regulatory Services.

The UT Arlington Office of Research Administration appreciates your continuing commitment to the protection of human research subjects. Should you have questions or require further assistance, please contact Philip Oilepo at oilepo@uta.edu or you may contact the office of Regulatory Services at 817-272-3723.

Sincerely,



Dr. Judy R. Wilson
Associate Professor
UT Arlington IRB Vice-Chair



March 8, 2011

Frances Hinshaw Philips
Dr. Donelle Barnes
College of Nursing
The University of Texas at Arlington
Box 19407

Office of Research
Administration
Box 19188
202 E. Border St., Suite 214
Arlington, Texas
76019-0188

Re: UT Arlington Institutional Review Board

Acknowledgement of Approved Research Activity

Project Title: *The Meaning of Adherence Among Veterans Receiving Pegylated Interferon and Ribavirin Antiviral Treatment for hepatitis C*

T 817.272.3723

UT Arlington IRB No: 2011-0296

F 817.272.1111

Dallas VA Medical Center IRB No: 11-009

<http://www.uta.edu/research>

Expertise at UT Arlington

<http://www.uta.edu/expertise>

Dear Frances Philips,

The UT Arlington Office of Research Administration and the UT Arlington Institutional Review Board are pleased to acknowledge your participation in the "*The Meaning of Adherence Among Veterans Receiving Pegylated Interferon and Ribavirin Antiviral Treatment for hepatitis C*" protocol.

The Dallas VA Medical Center Institutional Review Board is noted as the IRB of record for the project. last approved on January 24, 2011 you will not be required to submit a protocol for UT Arlington IRB approval.

In agreement with the IRB of record, this project is approved as follows:

Review: Full Board
Number of Subjects: 30

Having met the conditions set forth by the Institutional Review Board at The Dallas VA Medical Center IRB and in compliance with applicable regulations this acknowledgment is granted for a period not to exceed one year from the date of last review. Current approval is scheduled to expire in January 2012.

Please be advised that you will be responsible for forwarding to the Office of Research Administration; Regulatory Services, at minimum, a copy of the approval letter forwarded to you upon each continuation review period, modification approval or adverse event acknowledgment as documentation of assertion that the project remains in compliance with all applicable mandates, assurances and institution policies and procedures. In the conduct of cooperative research projects, each institution is responsible for safeguarding the rights and welfare of human subjects and for complying with 45 CFR 46 and 46.114.

BeAMaerik

The UT Arlington Institutional Review Board and the Office of Regulatory Services appreciate your continuing commitment to the protection of human subjects engaged in research and wish you all the best in your research endeavors. Should you require further assistance, please contact Robin Dickey at 817-272-3723.

Sincerely,

Patricia Turpin  Digitally signed by Patricia Turpin
DN: o=The University of Texas System, ou=The University of Texas at
Arlington CA, ou=www.verisign.com/repository/CPS Incomp. by
Ref,UJAB.LTD(c)99, cn=Patricia Turpin, email=pturpin@uta.edu
Date: 2011.03.12 04:48:19 -06'00'

Patricia Turpin, Ph.D., RN, NEA, BC
Clinical Associate Professor
UT Arlington IRB Chair

**Department of
Veterans Affairs**

Memorandum

Date: January 24, 2011

From: Chair, IRB

Subj: Notification of Action of IRB, #11-009, The Meaning of Adherence Among Veterans Receiving Pegylated Interferon and Ribavirin Antiviral Treatment for Hepatitis C

To: Frankie Phillips, MS, RN

1. The Subcommittee on Human Studies met on Monday, January 3, 2011 to review your above referenced protocol. Your research proposal for the study referenced above was not approved, pending minor modifications. The changes have been received and the study has now been Approved by the Subcommittee on Human Studies for 12 months. The study will be subject to Continuing Review on or before January 2, 2012.
2. The study will now be forwarded to the Research & Development Committee for their consideration. Patients may not be enrolled, and the study is not to be considered fully approved, until the R&D committee has met and granted their approval of the study.
3. When you are ready to begin, a stamped copy of an approved consent form must be used for any new patients enrolled into this study. Please forward to the IRB Administrator an electronic copy of the most recent version of the approved consent form for this study so that the IRB approval stamp may be affixed. All signed Consent Forms for any new patients enrolled into this study must have a current stamp.
4. During the approval period, you should inform the IRB of any adverse events associated with this study, deviations from the approved protocol, requested changes to the consent form, or any other events that might affect the patient's perception of the risks and benefits associated with the study.
5. Thank you for your submission.



Jonathan Dowell, M.D.
Chair, IRB

APPENDIX D
DEMOGRAPHIC FORM

Demographic Data

Code (Interview) Number:

Number of total interview minutes: Date/Place of interview:

Please list the following:

1. Phone number:
2. Age:

Please circle:

3. Gender: Male Female
4. Ethnicity: Asian/Pacific Black Hispanic Native American White Other
5. Marital status: Single Married Divorced Widow

6. Household composition: (list members living within the household)

- Alone
- With spouse
- With spouse and children
- Share living conditions with others who are not family
- Other:

7. Highest level of education completed:

- High school or GED
- College Associate Degree Bachelor Degree
- Completed number of years ____ -

8. What language do you speak at home?

- English Spanish Other

9. What language(s) can you speak, read and write?

- English Spanish Other

10. Are you currently employed?

- a. If yes, what is your occupation?
- b. If not, what is your usual occupation?

APPENDIX E
INTERVIEW GUIDE

INTERVIEW GUIDE

The following format indicates the types of questions to be used during each interview. Each interview will begin with the grand tour question and then follow with individualized questions concerning the key elements of information, motivation, behavioral skills and adherence.

Grand tour question

1. "Tell me about what it means to take your pegylated interferon and ribavirin during hepatitis C antiviral treatment."

Typical Questions

Information

1. What does HCV viral load and genotype mean?
2. How is HCV transmitted?
3. How long do you expect to be taking pegylated interferon and ribavirin?
4. Describe how you take your medicines on a routine basis.
5. Tell me about the medication side effects.
6. How do you manage your side effects? [Do you do anything to diminish the side effects?]
7. I know that the medications for HCV have numerous side effects. Describe how the side effects make you feel about taking your medication.
8. I define adherence as taking all of your medications every day. If you run out of your medication, and take only half a dose, are you being adherent in your opinion?

Motivation

9. Tell me the about the most important thing that has happened to you recently regarding HCV treatment.
10. Tell me about a recent experience that had an opposite effect. [Assumes they shared something in the above question. If not, skip this question.]
11. Give me an example when you did not take your medication.
12. What made you decide not to take your medication?

13. Describe your support system. Who supports you and how?
14. Does your support system always have a positive influence and support your treatment or do they have a negative effect sometimes?
15. Describe how you feel while you are taking your medications. Do the medications remind you that you have HCV?

Behavioral Skills

16. Describe what you do if you miss a medication.
17. How do you manage taking your medication when your routine schedule changes, for instance, work or traveling?
18. How do you live your life around your medication schedule?

Adherence

19. Describe a normal day during treatment.
20. Describe how you feel when you take your antiviral medication as prescribed by your healthcare provider.
21. Describe what taking your medication means. For instance, does adherence mean taking all the medications as prescribed or are there different kinds or degrees of adherence?
[For instance, when I feel depressed, I usually take my medication anyway. But you may say, when I feel depressed, I usually (Fill in the blank...).]
22. What has been/is your best day during treatment?
23. What has been/is your worst day during treatment?
24. Is there anything else that you would like to add

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BIOGRAPHICAL STATEMENT

Frances Marie Hinshaw Phillips was born in Bartlesville, Oklahoma, November, 16, 1949. She graduated from Midland High School in May, 1967. She graduated from Odessa College, School of Nursing, in May, 1971, with an Associate Degree in nursing. She began her nursing career in cardiac care and medical intensive care units. She married and began to raise her family while still pursuing her interests in nursing. She worked in a variety of settings, including medical-surgical units, house supervisor, home health care, hospice, and office nurse for an Ear Nose and Throat, & Allergy clinic. Her family moved to the Dallas area and began working with a local internist and then in the local hospital. She attended Texas Woman's University, Parkland campus, and earned her bachelor degree in nursing in 1993, and her master degree in nursing in 1996. She continued her nursing career as a Clinical Nurse Specialist at the Dallas VA. She became certified in Adult nursing by the American Nurses Credentialing Center. She worked as a Staff Development Specialist in the VA medical-surgical nursing units. In 1997, she was awarded as one of the Great 100 Nurses among the metroplex nurses. She attended the University of Incarnate Word in San Antonio in order to complete her courses to obtain prescriptive authority. In 2000, she transferred to the Dallas VA's liver service and began her advanced practice nursing career as a clinician. She continues to practice as an advanced practice nurse with her cadre of chronic liver disease patients. She serves as the manager of the liver service.

Frances Phillips is a member of several organizations. She is an associate member of the American Association of the Study of Liver Disease. She is a member of the Nurses Organization of Veterans Administration, Sigma Theta Tau, beta-beta chapter, American Red Cross, National Organization of Clinical Nurse Specialists and Texas Clinical Nurse Specialists. She is currently serving as president of the Texas Nurses Association, district 4,

and is a member of the American Nurses Association.

She is currently an online peer reviewer for *Gastroenterology Nursing* journal. She plans to continue her research in the study of liver disease. Funding for this research was provided by the Society of Gastroenterology Nurses Association.