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# Risk Factors and Associations for Hepatitis C Infection among Hispanic/Latino Intravenous Drug Users in Miami-Dade County, Florida

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# RISK FACTORS AND ASSOCIATIONS FOR HEPATITIS C INFECTION AMONG HISPANIC/LATINO INTRAVENOUS DRUG USERS IN MIAMI-DADE COUNTY, FLORIDA

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by

Arturo E. Rodríguez

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To: Dean Michele Ciccazzo
Robert Stempel College of Public Health and Social Work

This dissertation, written by Arturo E. Rodríguez, and entitled Risk Factors and Associations for Hepatitis C Infection among Hispanic/Latino Intravenous Drug Users in Miami-Dade County, Florida, having been approved in respect to style and intellectual content, is referred to you for judgment.

We have read this dissertation and recommend that it be approved.

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Date of Defense: November 5, 2012

The dissertation of Arturo E. Rodríguez is approved.

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Dean Lakshmi N. Reddi
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Florida International University, 2012

# DEDICATION

I would like to dedicate this to my family. To my wife, Monica, who did not let me quit and kept me moving forward all the time. To my son Nikolas, I hope that you get to see this dedication later on in your life and it inspires you to be the best that you can. I believe in you. You need to believe in yourself. To my mother, Joselyn, who unconditionally believed in me, no matter what decisions I made. Thank you and I love you all.

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ABSTRACT OF THE DISSERTATION

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by

Arturo E. Rodríguez

Florida International University, 2012

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Professor Jessy G. Dévieux, Major Professor

Hepatitis C infection (HCV) continues to disproportionately affect Hispanics/Latinos in the United States. Hispanic/Latino intravenous drug users (IDUs), because of their risky injection and sexual behaviors, are prone to HCV infection and rapid transmission of the virus to others via several routes. With a prevalence rate of approximately 75% among IDUs, it is imperative that transmission of HCV be prevented in this population. This study aims to examine the associations between demographic, injection and sexual risk factors to HCV infection in a group Hispanic/Latino IDUs in Miami-Dade County, Florida. Preliminary unadjusted results in this sample reveal that age (OR=4.592, p=0.004), weekly injection (OR=5.171, p=0.000), daily injection frequency (OR=3.856, p=0.000) and use of a dirty needle (OR=2.320, p= 0.006) were all significantly associated with HCV infection. Being born outside the U.S. was significantly negatively associated with HCV infection (OR=0.349, p=0.004). Additionally, having two or more sex partners in the past three months (OR=0.472, p=0.014) was negatively associated with HCV infection. After adjusting for all other variables, older age (AOR=7.470, p=0.006),

weekly injection (AOR=3.238, p=0.007) and daily injection frequency (AOR=2.625, p=0.010) were all significantly associated with HCV infection. Being born outside the U.S. (AOR=0.369, p=0.019) was a significant protective factor for HCV infection, along with having two or more sex partners in the past three months (AOR=0.481, p=0.037). When analyzing the significant variables in a backward regression model, having 2 or more sex partners in the past three months was not significant at the $p<0.05$ level, meaning that it could be a confounder in the final model. Utilizing these results, a targeted intervention aimed at reducing HCV infection in the Hispanic/Latino IDU population is proposed, utilizing individual risk factors that were found to be significantly associated with HCV infection. The intervention is tailored around 1) assessing the individual's readiness to change the selected behavior, and 2) systematic activities aimed at moving individuals from one stage to another, with established outcomes needed to successfully move to another stage. If significant risk factors could be readily identified and modified, taking into consideration the unique differences between people in different Hispanic/Latino groups, as well as protective factors, an effective prevention program that targets these behaviors could be developed.

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# CHAPTER I

## INTRODUCTION

Hepatitis C (HCV) infects approximately 4 million Americans today and has become a major public health concern in the past decade (Centers for Disease Control and Prevention [CDC], 2011; CDC, 2008a; Birkhead et al., 2007). Most people who are chronically infected are unaware of their infection because they generally do not show signs of being clinically ill (CDC, 1998). HCV related mortality is likely to surpass deaths related to human immunodeficiency virus (HIV) and to triple by the year 2030 if current screening and treatment efforts for HCV infection are not improved (Deuffic-Burban, Poynard, Sulkowski, & Wong, 2007). The economic impact of chronic HCV infection in the United States (U.S.) is projected to exceed $1 billion per year in direct medical expenses between 2010 and 2019 (Wong, McQuillan, Hutchinson, & Poynard, 2000). Clearly, HCV continues to be an important public health concern for the future as well as a significant economic burden on the health care system.

Reducing the number of HCV infections and impact of HCV-related disease in the United States requires implementation of primary prevention activities to reduce the risk for contracting HCV infection and secondary prevention activities to reduce the risk for liver and other chronic diseases in HCV-infected persons (CDC, 1998). Due to the common risk factors with HIV, the initial recommendation for HCV containment was that comprehensive programs be developed and implemented. These programs would be aimed at conducting surveillance, preventing new cases, ensuring early detection, counseling infected individuals and providing care, just like the programs currently in place for HIV (Birkhead et al., 2007). Unfortunately, these HCV prevention

interventions, modeled after current HIV interventions, are simply not working (Crofts, Aitken, & Kaldor, 1999; Vlahov, Fuller, Ompad, Galea, & Des Jarlais, 2004; European Centre for Disease Control and Prevention, 2011).

Interventions that currently prevent HIV may not prevent HCV infection mainly due to HCV's high prevalence. HCV prevalence is 3.2 million in the U.S. vs. HIV prevalence of 1.2 million (Birkhead et al, 2007; CDC, 2008). Several HCV prevention programs are available, however their effectiveness has not been tested, and as of today, targeted, comprehensive HCV prevention strategies are still needed (Crofts, Caruana, Bowden, & Kerger, 2000; Hagan & Des Jarlais, 2000; Edlin & Carden, 2006; Birkhead et al., 2007). Unlike HIV, HCV also lacks a large, active advocacy group, and resources are yet to be made available in order to sustain a viable public health effort (Edlin & Carden, 2006; USDHHS, 2001). Finally, while the majority of HIV behavioral programs to date intervene at the individual level, most HCV interventions have yet to utilize that methodology (Herbst et al., 2007).

Risky injection practices are by far the most significant risk factors for HCV (Matheï, Robaeys, Van Damme, Buntinx, & Verrando, 2004). In addition to sharing needles, there is growing evidence that HCV infection may also be possible through the sharing of other injection materials such as spoons (cookers), filters, and rinse water (Matheï et al., 2004).

Sexual behavior is a relatively understudied risk factor for HCV, but has been found to be associated with HCV infection as well (Burt et al., 2007). A history of sex work, prior history of sexually transmitted infection (STI), high-risk sexual behaviors among men who have sex with men (MSM), and a history of multiple sexual partners

have been associated with HCV infection (Burt et al., 2007; Matheï et al., 2004; van de Laar et al., 2007; Armstrong, Wasley, Simard, McQuillan, Kuhnert, & Alter, 2006; Lavanchy, 2002; Wu et al., 2006).

Demographic factors such as race and age as well as lower educational attainment have also been associated with HCV infection (Burt et al., 2007; Operskalski et al., 2008). While to date there are no studies that specifically examine age and gender risks of HCV infection in Hispanic/Latino groups, studies in Montreal show that younger age (mean was 32 years) and male gender (70%) were strong predictors of injection equipment sharing, which is hypothesized to be a strong predictor of HCV infection (De et al., 2009). Studies among intravenous drug users (IDUs) in New York City showed a mean HCV prevalence of 47% in men (versus 44% in women) and a mean age of 26.1 years (Hagan et al. 2007). Only one study showed women were more likely to test positive for HCV (42% versus 27% in men; Neaigus et al., 2007). It is important to note that the latter study's participants were 81% white, non-Hispanic.

*Why do Hispanics/Latinos present a unique problem with HCV?*

Recently arrived Hispanics/Latinos to the U.S. bring with them their own customs, which have been found to keep this group healthier than U.S. born Hispanics/Latinos, despite a lower socioeconomic status (Smith, 2006). As their length of residence in the U.S. increases, the protective effect of their original customs wanes because they adopt more unhealthy behaviors in their new environment (Abraido-Lanza, Chao, & Flórez, 2005). Length of residence in the U.S. among the Hispanic/Latino population has been correlated with higher fat intake and lower fruit and vegetable consumption, higher risk of obesity, and increased risk of psychiatric and substance use

disorders, including adoption of HCV risk behaviors (Neuhouser, Thompson, Coronado, & Solomon, 2004; Gordon-Larsen, Harris, Ward, & Popkin, 2003; Trooskin et al., 2010).

Minority populations have been disproportionately affected by HCV (Trooskin et al., 2010). This disparity has been primarily documented in Mexican-Americans (2.1% vs. 1.5% in non-Hispanic Whites) in the U. S. (Rodriguez-Torres, 2008; Armstrong et al., 2006). Mexican-Americans comprise approximately 67% of the Hispanic/Latino population in the U. S. while the rest of the Hispanic/Latino population is comprised of numerous groups from the Caribbean, and Central and South America. Specific incidence and prevalence rates for Hispanic/Latino groups other than Mexican Americans are not available in the literature (U.S. Census Bureau, 2011; Trooskin et al., 2010; Rawls & Vega, 2005).

The natural progression of HCV among Hispanics/Latinos is not well defined (Rawls & Vega, 2005). Hispanics/Latinos with HCV have been shown to have higher liver enzymes (alanine transaminase, aspartate transaminase, and bilirubin) as compared to other racial/ethnic groups (Jamal et al., 1999; Celona, Yu, Prakash, Kuo, & Bonacini, 2004). HCV infected Hispanics/Latinos have also been shown to progress faster with liver fibrosis than African Americans or whites (Bonacini, Groshen, Yu, Govinarajan, & Lindsay, 2001). Data are not available in the literature regarding response to therapy among Hispanics/Latinos (Trooskin, 2010).

Lack of access to healthcare has also been shown to increase HCV prevalence among Hispanic/Latino IDUs. Research has shown that, in general, minorities are less likely to receive medical treatment than their white counterparts (Epstein et al., 2000, Fiscella et al., 2000). This disparity has been attributed to provider racism as well as

patient distrust of medical research (King, 2003). For example, many patients who actively inject drugs are deemed "ineligible for treatment" by the healthcare provider (Grebely, Genoway, Raffa, & Dhadwal, 2008). IDU patients may not follow their physicians' advice, are less likely to fully and truthfully disclose their IDU use and associated behaviors, and/or fail to keep their appointments (Kresina et al., 2005). Healthcare providers caring for drug users often experience these behaviors as frustrating and are more likely to refer the patient to addiction specialists or a drug treatment facility, unintentionally denying caring for IDUs (Kresina et al., 2005).

Research has also demonstrated that health beliefs differ based on race and ethnicity (Talavera, Elder, & Velasquez, 1997). Beliefs about health may influence whether a participant complies with physician recommendations as well as the utilization of routine health screenings, and may also lead to avoiding participation in research interventions, particularly for a disease that was likely acquired through illegal activity (Nelson, Geiger, & Mangione, 2002). Only one study to date has demonstrated that HCV knowledge varies between races and that overall, HCV knowledge in minorities is poor (Buffington, Damon, Moyer, & Culver, 2000). Differences in knowledge about disease processes overall may also differ within different Hispanic/Latino subpopulations (Loue, Cooper, & Fiedler, 2003). This finding could be the case for HCV as well. Research has found that knowledge about a particular disease may depend on the level of acculturation of the patient (Harmon, Castro, & Coe, 1996). This research underscores the many barriers that Hispanics/Latinos face when it comes to overall healthcare and HCV infection in particular.

Given the evidence at hand: 1) high HCV prevalence in the IDU population, 2) disproportionate effect of HCV infection in Hispanics/Latinos, 3) little knowledge of Hispanic/Latino groups, and 4) currently no extant comprehensive and effective HCV prevention strategy/program, this study will lay the foundation for understanding the risk factors that affect Hispanics/Latinos (with emphasis on groups other than Mexicans) with regards to HCV infection. The main purpose of this study is to identify risk factors for HCV infection and identify the strength of association between the identified HCV risk factors and HCV infection in a group of Hispanic/Latino IDUs in Miami-Dade County, Florida. Identification of these behaviors may serve as a basis for targeted interventions to help reduce the prevalence rate of HCV infection in these Hispanic/Latino groups of IDUs. By identifying the circumstances and characteristics that are associated with infection, progress towards HCV infection prevention will be made (Hagan et al., 2007).

*Research Aims, Questions and Hypotheses*

In order to address the various issues presented in this proposal, the following aims, research questions, and hypotheses have been formulated:

Research aim #1: To identify the risk factors for HCV infection in Hispanic/Latino intravenous drug users.

Research aim #2: To calculate the strength of association between the identified risk factors and HCV infection in Hispanic/Latino IDUs.

Research aims #1 and #2 will be achieved via the following research questions/hypotheses:

- Research question #1: Are demographic factors associated with HCV infection in Hispanic/Latino IDUs in Miami-Dade County, Florida?

- Hypothesis #1a: In comparison with HCV negative individuals, HCV positive individuals will be more likely to be unemployed (*employment*, *income*) as well as be less likely to be educated (*education level*) and have familial stability (*marital status, residency*).
- Hypothesis #1b: In comparison with HCV negative individuals, HCV positive individuals will be older (*age*) and will be more likely to be male (*gender*).
- Hypothesis #1c: In comparison with HCV negative individuals, HCV positive individuals will be more likely to have resided in the U.S. for a longer period of time (*number of years in the U.S.)* and be born in the U.S. (*born in the U.S.).*

- Research question #2: Is there a relationship between sexual behaviors and HCV infection in Hispanic/Latino IDUs?
  - Hypothesis #2: HCV positive individuals will be more likely to engage in high-risk sexual behaviors than HCV negative individuals as measured by sexual history (*age at first sexual encounter*) and number of sex partners (*number of sex partners in last 3 months, number of sex partners in a lifetime*).
- Research question #3: Is there a relationship between different drug use behaviors and HCV infection in different Hispanic/Latino IDUs?
  - Hypothesis #3a: HCV positive individuals will be more likely to engage in high-risk injection behaviors than HCV negative individuals, as measured by utilization of shared injection paraphernalia (*cooker, cotton, rinse water, syringes*) and injection frequency (*weekly injection frequency, daily injection frequency*).

- Hypothesis #3b: HCV positive individuals will be more likely to have a larger percentage of IDUs in their personal network than HCV negative individuals (*IDUs in network*).

Research aim #3: To utilize the knowledge gained from the study and develop a targeted, theoretically based HCV prevention program for Hispanic/Latino IDUs in Miami-Dade County, Florida aimed at specifically targeting individuals in any stage of behavior change and systematically moving them to a new stage via a series of activities designed to change participants' health behavior.

Research aim # 3 will be achieved by synthesizing the knowledge gained from the study. Utilizing the transtheoretical model (TTM) as a theoretical basis, a comprehensive, tailored HCV prevention intervention will be developed. The main goals of this intervention will be the primary prevention and reduction of transmission from HCV-infected individuals to non-infected individuals in the Hispanic/Latino IDU community.

*Theoretical basis*

The TTM is a process-oriented paradigm that views intentional behavior changes as a progression of several stages (Prochaska & DiClemente, 2005). The TTM hypothesizes that individuals move through a series of five stages (pre contemplation, contemplation, preparation, action, maintenance) in the adoption of healthy behaviors or cessation of unhealthy ones (Prochaska et al., 2008). The five stages are summarized below with their specific applications to Hispanic IDUs and the risk factor "*use new needles*" used as an example.

- Pre contemplation. The participant is unaware that change is needed or does not see the problem (*The participant has no intention of using new needles at every injection session in the next six months*).
- Contemplation. The participant recognizes the need for behavior change, but is not confident on his or her ability to do so (*There is an intention to use new needles at every injection session in the next six months*).
- Preparation. The participant is close to making a behavior change but may need new skills for making change (*Intend to use new needles in the next 30 days or already using new needles but not consistently*).
- Action. Behavior change has been accomplished (*New needles used at every injection session but for less than six months*).
- Maintenance. Behavior change has continued for an extended period of time (*Consistent new needle use at every injection session for at least six months or more*).

The TTM has also been used for a variety of health behaviors, including readiness to change blood-borne virus transmission behaviors (Ko, 2010; Gasiorowicz et al., 2005). An often-cited advantage of the TTM is that it very flexible and can be applied to a range of situations (Armitage, 2009). The TTM, along with information gained from the data analysis from the current study will be used to develop an intervention aimed at reducing HCV infection in Hispanic/Latino IDU's. The TTM makes no assumption about how ready an individual is to change and recognizes that different individuals will be in different stages and therefore appropriate interventions must be developed to reflect this individuality (Velicer, et al. 2004). It is also acknowledged that not one single path of change process can be applied to every health behavior (Hasler et al., 2003).

Research conducted on behavioral change using the TTM show that interventions become more effective when tailored to the current stage of change of the individual (Levesque, Prochaska, & Prochaska, 1999). By using more cognitive-affective processes (person, situation and their interaction) throughout each stage of change, an educator/counselor cultivates motivation; if, however, the educator uses more behavioral processes of change he or she may be met with more resistance (Levesque, et al., 1999; Rosen, 2000). Other studies show that a combination of cognitive-affective and behavioral interventions is most effective and varies by health condition (Rosen, 2004). Since there is little agreement, therefore on intervention strategies with this population, a pilot stage of the intervention is proposed (prior to it being used in the general population) in which the use of both cognitive-affective and behavioral interventions will be measured and carefully calibrated to maximize results.

In a study of 322 African American male street addicts in Texas, Stephens et al. (1993) reported that after counseling delivered by a professionally trained health educator, the percentage of participants who reported injecting frequently decreased from 92% to 71% at a 3-month follow up. In addition, it was also reported that needle-sharing behavior in this particular group declined from 67% to 24% of respondents (Stephens, et al., 1993). The proposed study will have counseling sessions delivered by trained outreach educators to a group of Hispanic/Latino IDU's (analogous to the African American IDUs in the Stephens et al. article).

Des Jarlais et al. (1992) studied the effects of teaching safe injection practices to a group of heroin users (both sniffers and injectors) in New York in order to determine if, 1) the rate of users transitioning to injecting heroin from sniffing would decrease, and 2)

the rate of injection risk behaviors were reduced in already injecting users. At a 9-month follow up, there was a significantly lower level of injection in the groups. After the education intervention, 15% of follow up respondents were injecting frequently versus 33% in a control group (Des Jarlais, et al., 1992). The proposed intervention will build on this finding by utilizing the safer injection practices and "AIDS 101" curriculum as utilized by Des Jarlais and colleagues.

Utilizing the few extant examples of successful individual and group level interventions for IDUs, the proposed intervention builds on those by introducing interventions that are culturally targeted to the Hispanic/Latino IDU.

*Summary*

The purpose of this dissertation is to determine whether known HCV risk factors in the overall IDU population, such as demographic, injection, and sexual risk factors, differ not only from the overall IDU population, but also within Hispanic/Latino populations. In addition, this dissertation lays the groundwork and proposes a community based intervention program aimed at reducing HCV infection in Hispanic/Latino populations based on any differences in risk factors learned from the initial part of the study. The remaining sections of this dissertation will, 1) examine the factors related to HCV transmission that have been explored in the literature, 2) determine whether there are any statistically significant risk factors (demographic, injection and sexual) within the Hispanic/Latino population, and using that information, 3) propose a targeted, theoretically based HCV prevention intervention.

# CHAPTER II

# LITERATURE REVIEW

## *HCV Transmission*

Hepatitis C is one of six known hepatitis viruses (Chen & Morgan, 2006; CDC, 2008). It was initially discovered in 1989 when it was isolated from an individual with non-A, non-B hepatitis (Chen & Morgan, 2006). This finding led to the discovery that approximately 90% of all non-A, non-B cases were HCV infections (Chen and Morgan, 2006). There are six identified HCV genotypes and over 100 subtypes (Chen & Morgan, 2006; Chevaliez & Pawlotsky, 2007, American Public Health Association [APHA], 2008). Approximately 70% of HCV cases in the U. S. are genotype 1, the majority of those being subtype 1a (CDC, 1998).

The evidence for transmission of HCV via pathways other than IDU remains unclear (Division of Viral Hepatitis and National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention, 2009). Blood transfusions accounted for a large proportion of HCV infections in the late 1980's (CDC, 2008). In the 1990's, HCV infection from blood transfusions was virtually non-existent, although the risk was never zero (CDC, 2008). The risk was so low that the Center for Disease Control's (CDC) sentinel counties in their viral hepatitis surveillance system were unable to detect any cases (CDC, 2008). Today, however, the CDC considers HCV infection from blood transmissions as "intermediate risk" and recommends testing for anybody who has received a blood transfusion (CDC, 2008a).

The most efficient means of transmission of HCV occurs through percutaneous exposure to HCV infected blood (APHA, 2008). Other documented means of

transmission include sharing of contaminated needles or equipment for drug use, receipt of infected blood, blood products and organs, vertical transmission, needle sticks in health care settings, sexual contact with an HCV infected individual, sharing of personal items (such as razors or toothbrushes), invasive health care procedures, tattooing, body piercing and acupuncture (Alter, 1997; Burt et al., 2007; CDC, 2008; CDC, 1998; Rhoads, 2003; Solomon et al., 2011; Hand & Vazquez, 2005). IDU however, is by far the most reliable factor for HCV infection (Hagan et al, 2011). HCV is identified as the most common infection affecting IDUs, and injection drug use has been identified as the main mode of transmission (McMahon, Pouget, & Tortu, 2007).

*Epidemiology of HCV infection*

The National Center for Health Statistics (NCHS) at the CDC estimated that between 1999 and 2002, 1.6% of the non-institutionalized, civilian U.S. residents ages six and older were HCV positive (Armstrong et al., 2006). During the same time period, 79.7% of these were considered to be chronically infected (Armstrong et al., 2006). This equates to a prevalence of approximately 1.3% or 3.2 million individuals aged six or older in the U.S. living with chronic HCV (Davis et al., 2003). Overall, the demographic group with the highest anti-HCV antibody prevalence was non-Hispanic black males between the ages of 40 and 49 (CDC, 2008). Acute HCV infection, however, is primarily found among persons aged 20–49 years, and males have a slightly higher incidence rate (Deacon et al., 2011).

HCV has had a pattern of disproportionate impact among Hispanics/Latinos, but statistics are hard to find for a number of reasons (Birkhead et al., 2007). First, Hispanics/Latinos are chronically underrepresented in clinical trials (Fleckenstein, 2004).

Part of the problem lies with the different terms Hispanic vs. Latino. These two terms are often utilized interchangeably in the literature, and leads to the impression that any person who speaks Spanish may be grouped into one homogeneous group with the same customs, beliefs and risk factors for any particular disease (Blessman, 2008; Zambrana & Carter-Pokras, 2010). There are many groups within the larger Hispanic/Latino group in the U.S., each with their own cultural background and health beliefs. As a consequence, each subgroup has its own risk factors for any health outcome. This un-acknowledged diversity leads to difficulty in searching the literature, as ethnic groups are not well defined in research (Blessman, 2008). Second, only approximately 75-85% of HCV cases are actually reported. This is probably due to the fact that many people with HCV may actually be asymptomatic, and may not seek medical care because they do not know they are infected (CDC, 2008). Also, HCV infected individuals may be more likely to be a member of marginalized groups that may not have access to basic medical care.

Standard public health efforts seek to identify host, agent and environmental factors and manipulate them in order to control exposure and transmission of the disease (Heymann, 2004). Unfortunately for the IDU population, multiple factors enable infection and reduce the opportunity for identification (Hagan et al., 2007). In countries where at least some effort to combat HCV exists, those efforts largely focus on harm reduction (Madden & Cavalieri, 2007). The fact that no country has been successful in preventing large numbers of new cases has led many researchers to question the effectiveness of the harm reduction approach to HCV infection (Hagan, 2007; Mateu-Gelabert, et al. 2007; Madden & Cavalieri, 2007).

*Human Immunodeficiency Virus (HIV)/HCV co-infection*

HIV and HCV share many risk factors (e.g., injection and sexual behaviors). Alberti and colleagues (2005) found 30-50% of HIV-infected patients are co-infected with HCV. There are approximately 300,000 co-infected individuals in the U.S., which represents 15-30% of HIV infected individuals and 5-10% of HCV infected individuals (Andersson & Chung, 2006; Mayor et al., 2008, Strader, 2005). Gonzalez & Talal (2003) found HIV/HCV co-infected individuals are likely to not have access to treatment for their HCV because of medical contraindications, such as active alcohol or substance use, past or current history of psychiatric disorders, advanced progression of AIDS, HCV genotype, HCV viral load or other comorbidities. In addition, HIV/HCV co-infected individuals are generally older, male, and are IDUs (Backus, Boothroyd, & Deyton, 2005). There are considerable data indicating that HIV/HCV co-infection has a negative effect on the natural course and response to antiviral therapy for both types of infections (Alberti, 2009). One of the most significant problems with HCV however, is that HCV is estimated to be at least 10 times more infectious per unit of blood than HIV, hence requiring less exposure to reach the current high prevalence (Paintsil et al. 2010). There is no available published research study or information about the impact of HIV/HCV comorbidity in a U.S. urban population (Alberti, 2009).

Given these rates and the evidence at hand, there is a need to deliver HIV/HCV prevention programs in conjunction, with the important caveat that existing HIV programs must be revamped as well. This point is discussed further in the discussion section of this dissertation.

*Risk factors for individuals of Hispanic/Latino origin*

According to the U.S. Census Bureau, Hispanics/Latinos are the fastest growing and the largest minority group in the U.S. (Cheung, 2005). Approximately 40 million people of Hispanic/Latino descent reside in the continental U.S. (Cheung, 2005). Little is known about HCV prevalence and transmission rates in non-Caucasian populations (Azócar, 2003). A study conducted by Azócar (2003) on 235 participants of Puerto Rican ancestry found that within the inner-city Latino population, the HCV seroprevalance rate of 8% was strikingly higher than that previously found among the general population. According to Azócar, this difference most likely reflects different behavioral patterns. The participants of this study resided in a densely populated area with a high unemployment rate, unstable marital status and high rates of incarceration (Azócar, 2003). Azócar's study found the following significant associations with an increased risk of HCV infection: (1) using intravenous drugs, (odds ratio [OR]=30.4), (2) using inhaled drugs (OR=26.44), (3) using drugs (injected, inhaled, or smoked) during sex (OR=18.67), (4) sharing objects (in this case, sharing of cutting edge objects such as nail clippers, scissors and razors, etc.; OR=13.75) and (5) having a history of STDs (OR=4.59).

In another study looking at a sample of HCV-positive Hispanic/Latino patients in the Texas/Mexico border region, researchers discovered that tattooing was the single most important independent risk factor for 84% of the sample (Hand & Vasquez, 2005). The authors concluded that the higher prevalence of HCV infection in Hispanics/Latinos might be due to unique risk factors such as tattooing and other high-risk behaviors among Hispanic/Latino IDUs (Hand & Vasquez, 2005).

A study conducted by Cheung (2005) found that Mexican-Americans had a higher anti-HCV antibody positivity rate than Caucasians (2.1%; 95% CI=1.7, 2.6), and were more likely to be viremic (73.6%; 95% CI=66.8, 81.2). However, this study found that after adjusting for other risk factors, ethnicity and race were not independently associated with HCV infection. It also found that Hispanics/Latinos, when compared to Caucasians, were more likely to be co-infected with HIV (20.4 % vs. 3.9%; Cheung, 2005).

Since Hispanics/Latinos are the most rapidly increasing minority group in the U.S,. more research is needed in order to determine barriers to initiating antiviral therapy as well as reasons for early treatment and to investigate any potential differences between various Hispanic/Latino populations (Cheung, 2005). Being of Hispanic/Latino ethnicity alone does not automatically double or triple chances of HCV infection, but being a Hispanic/Latino IDU does seem to carry a disproportionately increased risk for HCV infection compared to White, non-Hispanic/Latino IDUs (Estrada, 2005). In addition, several other risk factors converge on Hispanic IDUs, essentially increasing the infection risk considerably.

*Demographics*

It is theorized that several socio-demographic and lifestyle factors such as race and ethnicity, income, educational status and marital status may be strongly associated with HCV infection; some of these factors have been associated with more serious hepatitis C outcomes (Dev et al., 2006; Fujita et al., 2006; Hezode et al., 2003; NIH, 2002, Scognamiglio et al., 2007). Current theories do not address race and ethnicity differences between Hispanics/Latinos of different countries of origin. Research question #1 seeks to expand the current research in this area by examining whether individuals of

different Hispanic/Latino ethnic backgrounds follow the same pattern of associations as other, broader studies (such as studies looking at HCV infection in the overall IDU population, not just among Hispanics/Latinos).

To date, there are few studies that look exclusively at demographic factors and their association with HCV infection (Lopez et al., 2007). Trooskin (2010) utilized a cross sectional design to study 503 Hispanics/Latinos in the Philadelphia area and assessed their risks for HCV. Trooskin found that individuals who made more than $15,000 per year were more likely to have an HCV risk factor (not HCV infection) than people making less than $15,000 (OR=2.3; 95% CI=1.2, 4.5). Country of birth was also identified as being strongly associated with having an HCV risk factor, with U.S.-born Hispanics/Latinos being more likely than non U.S.-born Hispanic Latinos to have an HCV risk factor (OR=3.4; 95% CI=1.9, 6.0; Trooskin et al, 2010). Finally, being age 41 or older was significantly negatively associated with having an HCV risk factor compared to those aged 18-24 (OR=0.5; 95% CI=0.25, 0.99). It is important to understand that Trooskin examined whether these demographic factors were associated with having an HCV risk factor, not being HCV infected.

Being male as well as younger may also be associated with an increased risk of being HCV infected. Siddiqui et al. (2008) examined very limited demographic factors in a large cohort of urban HCV patients in Detroit. Of the 2,739 HCV positive patients in the study, most (65%) were males (Siddiqui et al., 2008). In addition, most risk factors were reported by patients in their 20s (Siddiqui et al., 2008). It is important to know that this study only included 2.1% “Hispanics and Asians” (Siddiqui et al., 2008). Despite this

however, this study offers some evidence that males of younger age are more likely to be at risk for HCV infection.

*Personal networks*

The IDU personal network is an important factor that requires attention. An IDU personal network includes people an IDU may have a social relationship with: an injecting partner, a sex partner, a family member, etc. Changes in the personal network of an IDU have been shown to cause changes in the individual's risk taking behavior (Costenbader, Astone, & Latkin, 2006). To date, there are no studies that examine the risk factors associated with IDU networks and HCV infection, but there are many studies that study HCV infection and personal networks. These studies shall serve as a proxy for the contribution of personal networks on HCV infection.

Wylie, Shah, and Jolly (2006) found that the likelihood of exposure to blood borne pathogens is a multifactorial process, primarily dependent on the risk behaviors an individual practices and the likelihood that a susceptible individual will come into contact with an infected individual, essentially increasing or decreasing the risks associated with a risk behavior. Infected individuals are brought into contact with one another in the context of personal networks (Wylie et al., 2006). The rate of pathogen spread through these networks may be affected by the overall structure and size of the network (Treolar et al., 2011).

Research among IDUs and their networks have identified many variables that may be associated with transmission risk (Wylie et al., 2006). Variables identified include the number of network members, the presence of family members or spouses within the network, higher network density, the setting where injection takes place,

turnover of network members, and the pooling of financial resources within networks for the purpose of obtaining drugs (Treolar et al., 2011). Racial/ethnic differences in HIV prevalence have also been at least partially explained by taking into account the differing network characteristics of different ethnic groups (Mayor et al. 2008).

An individual may have a set of risk factors that contribute to HCV infection. Within the context of a personal network, there is a different set of risk factors that emerge. Studying this hierarchy of risk factors is an important step that must not be ignored (Wylie et al., 2006). Both individual and network level concepts assist in characterizing and comparing the transmission of HCV, and determining the underlying patterns that drive the social connections between individuals that may favor or hinder transmission of HCV infection (Wylie et al., 2006).

Several studies have examined IDU personal network relationships on sexually transmitted infections, risky sexual behaviors and injection drug use behaviors (Rothenberg et al., 1998; Latkin, Forman, Knowlton, & Sherman, 2003; Latkin, Hua, & Forman, 2003; Latkin et al., 1994; Latkin et al., 1995; Latkin et al., 1996; Suh et al., 1997). For example, in a study examining the relationship between network characteristics and sexual risk behaviors, Latkin and colleagues found that increased network size increased the odds of exchanging money or drugs for sex and having multiple male partners (Latkin et al., 1994). Network density defined as networks with more connected relationships, was inversely associated with exchanging money or drugs for sex (Latkin, Hua, & Forman, 2003). In another study assessing the association between network characteristics and frequency of injection drug use, absence of a partner, size of drug network and network density were significantly associated with

injecting at least once a day in the adjusted analysis (Latkin et al. 1995). Larger drug networks were also shown to influence the likelihood of injecting in shooting galleries as well as a higher likelihood of sharing needles (Suh et al., 1997). This has also been shown in other studies where large networks were associated with frequent needle sharing, and being more central (or linked with more people) in a network is associated with needle sharing (Latkin, Hua & Forman, 2003; Mandell et al., 1999; Friedman & Aral, 2001).

*Sexual risk factors*

Sexual behavior has been theorized to be associated with HCV infection as well (Solomon et al., 2011). There are several cases on record where HCV infection could only be attributed to an HCV-infected sexual partner, as no other risk factor existed (Matthews et al., 2007). Most of this research was conducted in Europe, and to date there is no research that study Hispanic/Latino sexual risk factors for HCV infection exclusively, let alone study Hispanics/Latinos of different ethnic backgrounds. Research question # 2 would be the first attempt to examine sexual risk factors in Hispanic/Latino populations by different ethnic backgrounds in the U.S. This study would also be the first to investigate the strength of association of sexual risk factors within different Hispanics/Latinos as it pertains to their ethnic background.

Evidence continues to accumulate in support of the sexual transmission of HCV (Solomon et al., 2011). There are several cases on record where HCV infection could only be attributed to an HCV-infected sexual partner (Matthews et al., 2007). HCV RNA has been detected in bodily fluid samples (saliva and semen) of individuals who have are HCV positive, suggesting a potential sexual route of HCV exposure (Briat, Dulioust,

Galimand, et al., 2005; Liou et al., 1992). The infectivity of these fluids is unknown and studies have not been able to conclusively isolate exposure to saliva or semen as the cause of transmission of the HCV virus (Briat et al., 2005; Alary et al., 2005). Epidemiological studies examining an association between sexual contact and HCV transmission, conducted among various populations, including monogamous couples, where one partner is HCV positive and the other is HCV negative, HIV serodiscordant couples, heterosexuals, and men who have sex with men have been inconclusive but suggest risk may be positively correlated with the number of sexual partners and when the sexual partner was HIV/HCV co-infected (CDC, 2010; Leurez-Ville 2000; Nyamathi et al., 2002). Research with serodiscordant monogamous couples reveal that the rate of HCV transmission is low, ranging from 0.0-0.6% per year (Ghosn, Leurez-Ville, & Chaix, 2005; van de Laar et al., 2010). Infection risk is however slightly higher among heterosexuals who have multiple sex partners or are exposed to STDs, with rates ranging from 0.4-1.8% per year (Terrault, 2002; van de Laar et al., 2010).

MSMs are an example of a group where HCV incidence and prevalence is increasing, especially among HIV positive MSM (van de Laar et al., 2010; van de Laar et al., 2007; Danta et al., 2007; Gambotti et al., 2005; Fierer, 2010). For example, a study by van de Laar and colleagues (2007) documented HCV incidence among HIV-positive MSM to be 0.87 per 100 person-years (95% CI=0.28, 2.03), while the incidence among HIV-negative MSM was much lower (0.00 per 100 person-years [95 % CI=0.00, 0.05]). Another study looking at the sexual risk factors for HCV in MSM found that newly HCV infected HIV-positive MSM were significantly more likely to report unprotected receptive anal sex with ejaculation from their partner (Fierer, 2010).

It has been theorized that HCV sexual transmission may result from mucosal disruption during sexual contact (Danta et al., 2007; Filippini et al., 2001). MSM are much more likely to engage in these mucosally traumatic sexual practices ("rough" sexual techniques such as anal fisting, use of anal sexual devices and frequent group sex, all of which may cause lesions in the rectal tissues and possibly lead to blood contact), and could serve as a means for permucosal HCV transmission (Danta, et al., 2007; Gambotti et al., 2005).

Another dimension of sexual risk of HCV involves the combination of sex and drug use. People who engage in sexual activity under the influence of drugs (either injected or not injected) are more likely to engage in "risky sexual practices," such as lack of protection and "sexual transactions" (Floyd et al., 2010; Dunkle, Wingood, Camp & DiClemente, 2010). Sexual transactions occur as a means to procure drugs in the absence of money and are much more likely to result in lack of protection (Dunkle, Wingood, Camp & DiClemente, 2010).

As of today however, the evidence for the sexual transmission of HCV is still deemed "unclear" (CDC, 2010). New techniques, such as second and third generation anti-HCV assays that produce lower false positives, as well as more rigorous study methodology aimed at assessing the independent contribution of sexual activity in HCV infection will greatly enhance the ability to quantify sexual contact as a risk factor (Matthews et al., 2007).

The CDC collects detailed risk factor data for acute HCV infection through the Acute Hepatitis Sentinel County Surveillance System. Between 1995 and 2000, up to 18% of individuals with acute HCV infection reported sexual contact as their only risk

factor for infection (CDC, 2008). This statistic suggests that sexual transmission does contribute significantly to the total burden of HCV infection in the U.S.

*Intravenous drug use (IDU)/Drug paraphernalia*

IDU is the leading risk factor for HCV infection (Armstrong et al., 2006; Birkhead et al., 2007; Zule & Bobashev, 2008). Currently, IDU accounts for approximately 10-35% of the annual incidence of HCV cases in the U.S. through exposure to blood-contaminated drug injection equipment (Amon et al., 2008). Prevalence rates of 60% to 80% have been observed in the IDU population (Ministerial Advisory Committee on AIDS, Sexual Health and Hepatitis C Subcommittee, 2006; National Institutes of Health, 2002; Roy et al., 2002; Roy, Nonn, Haley & Cox, 2007). A substantial percentage of HCV infections, estimated at 60%, can be traced back to intravenous injection (Hellard, Sacks-Davis, & Gold, 2009; Grebely & Dore, 2011).

In 2006, injection drug use was responsible for up to 16% of new HIV cases in the U.S. (SAMHSA, 2009). This statistic however, pales in comparison with the percentage of HCV cases that may be attributed to injection drug use. Injection drug use is responsible for an inordinate number of HCV infections in the U.S. and abroad, approximating 90% worldwide and up to 60% in the U.S. (Hellard, Sacks-Davis, & Gold, 2009). Needless to say, IDU is an established, consistent and reliable predictor of HCV in all populations studied to date (Hagan, Pouget & Des Jarlais, 2011). Given the fact that Hispanics/Latinos from South America and the Caribbean are grossly underrepresented in the scientific literature, research question #3 seeks to answer whether different Hispanic/Latino ethnic backgrounds follow the same trends as reported in national

studies/surveys, and if differences are discovered, are those differences statistically significant.

Injection drug use puts the user at a very high risk for exposure to blood-borne pathogens such as HIV and hepatitis viruses (Substance Abuse and Mental Health Services Administration [SAMHSA], 2009). HCV can survive in a syringe for up to 63 days, demonstrating the viability of HCV and the prolonged duration of potential transmission through needle sharing (Paintsil et al., 2010). There is a broad base of literature that demonstrates elevated HCV risk in association with injection drug use, particularly among injectors who share injection equipment and have injected for long periods of time (Brewer et al., 2006; Hagan et al., 2006; Lert, 2006; De et al., 2007; Firestone Cruz et al, 2007; Morissette et al., 2007; Vickerman et al., 2007; Lee et al., 2008; Shannon et al., 2008; Oliveira et al., 2009). The risk for infection is further exacerbated by behaviors such as needle sharing, reusing unclean drug paraphernalia, sharing dirty water, backloading (sharing prepared drug by pulling the plunger from the back of the syringe), frontloading (sharing prepared drug by removing the needle from the syringe), jacking (drawing blood into the syringe then injecting a portion of the blood/drug mix and repeating), etc. (SAMHSA, 2009).

Drug paraphernalia have been proposed as a potential route of HCV infection (De et al., 2009; Hagan et al., 2001). Research into the links between shared drug use paraphernalia and HCV infection, particularly in the absence of injection with a contaminated syringe is a largely unexplored area of study (Hagan et al., 2001). Items such as cookers, cottons, and rinse water are commonly used by IDUs and sharing of this ancillary equipment has been shown to be a very common practice in the U.S. (Koester et

al., 1996, Gillies et al., 2010). In addition, studies have found viable HCV viruses on cookers, cottons, and in water (Crofts et al., 2000). It is theorized that due to the HCV virus' "hardiness," it can be deposited in these cookers via a contaminated syringe of one user, and be drawn up the syringe of another person who uses the same cooker, even if it is days later (Koester et al., 1996). The same can hold true for cottons, as they are used to wipe the injection site clean, as well as the syringe. If a dirty syringe is wiped with a piece of cotton and then that same cotton is reused by a separate person on a different needle, a pathway for infection has been created. Rinse water is also another potential vector for HCV infection, as a person can clean their syringe (potentially depositing the HCV virus) and then a second person may infect their needle due to the reusing of the rinse water either to rinse their syringe or to prepare the drug solution. With these three items, an HCV-infected IDU can still infect other individuals without a needle being shared between them.

In the late 1980s and early 1990s, needle exchange programs (NEPs) surfaced as a possible effective way to reduce infections (at the time, mainly HIV, but HCV soon thereafter) in the IDU population (Hagan et al., 1995; Hagan et al., 1999). Initial studies have shown that NEPs do not have any significant effect on the risk of HCV infection, even though the programs have had a significant positive effect in the reduction of HIV infections in IDU's (Hagan et al., 1999; Moss & Hahn, 1999; Heimer, 1998). Further studies have determined that the benefits of NEPs on HCV transmission are unclear (Mansson et al., 2000; Wright & Tompkins, 2006). It has been theorized that the difference in prevalence correlating with such prevention efforts may be due to discriminatory sharing of equipment and needles in which individuals choose with whom

they will share their instruments (Burt et al., 2007). Others propose that duration of IDU is a stronger risk factor for HCV infection and suggest the difference in prevalence rates may be associated with duration of usage rather than needle sharing behaviors (Diaz, et al., 2001).

*HCV Prevention Studies*

HCV prevention is still in its infancy. Although there is much work that has been done with regard to HIV prevention among IDUs, we still do not know how to successfully prevent HCV infection in this group (Mateu-Gelabert et al., 2007). HCV treatment programs for intravenous drug users have not been included as part of the efforts to reduce the impact of the HIV epidemic (Grebely et al., 2007). Whether as part of a combined HIV/HCV prevention program or a program specifically tailored to HCV alone, much work remains to be done, particularly in the Hispanic/Latino population. The high incidence and prevalence of HCV in IDUs makes prevention efforts a very difficult task (Shepard, Finelli & Alter, 2005). There are however, a few studies that attempted to study transmission of HCV in this population, none of them focusing specifically on Hispanic IDUs.

There have been only two studies in the past 10 years that examined the effect of behavioral interventions on HCV seroconversion among IDUs (Hagan, Puget, & Des Jarlais, 2011). Garfein and colleagues (2007) and Stein (2009) assessed the effects of peer education interventions (PEI) and motivational interviewing (MI) in cohorts of IDUs in multiple sites in the U.S. The Garfein study was a multi-site randomized controlled trial looking at PEI versus equal-attention controls over a period of six sessions in a cohort of IDUs (Garfein et al., 2007). The reported odds ratios for the peer education

interventions was 1.15 (95% CI=0.72, 1.82), indicating that there was no difference between the treatment group and the control group (Garfein, 2007). Stein (2009) also utilized a randomized controlled clinical trial utilizing MI in a cohort of IDUs in Providence, RI. The reported relative risk was 1.28 (95% CI=0.49, 3.35), also indicating that there was no significant difference between the groups (Stein, Herman & Anderson, 2009).

NEPs have also been studied as a potential intervention to reduce HCV transmission. Hagan and colleagues studied groups of IDUs in Tacoma (1995) and Seattle (2004). Utilizing an observational case-control study, Hagan compared participants that either ever participated in a NEP or never participated in a NEP. The reported OR was 0.14 (95% CI=0.03, 0.62), indicating that participating in an NEP had a significant, although small effect on HCV transmission (Hagan et al., 1995). Hagan and colleagues also looked at a cohort of IDUs in order to determine if using an NEP had any effect on HCV transmission. The reported hazard ratio (HR) was 1.4 (95% CI=0. 9, 1.9), suggesting that the results were not significant. Holtzman and colleagues (2009) obtained similar results when they studied a cohort of IDUs in a multisite study. The reported OR was 1.41 (95% CI=0.96, 2.01). NEPs may have some effect of the transmission of HCV in the IDU population, however NEPs are not legal in Florida, therefore this option would not be accessible to participants living in Miami-Dade County.

*Summary*

HCV has been identified as the most common blood infection in IDUs. Prevalence of HCV infection in this group is estimated to be as high as 75%. The main mode of HCV transmission is through percutaneous exposure to HCV infected blood or

blood products. As of today, the most common means of exposure to HCV infected blood/blood products is through IDU and the use of shared IDU equipment (needles, cookers, cottons, water). Although there is no concrete evidence for other infection pathways, unprotected sexual activity is quickly gaining attention as a potential alternate infection route, particularly among MSM who do not inject. Other risk factors for HCV infection include demographics and personal injection networks.

Given the fact that HCV seems to follow the same pattern of infection as HIV, and that between 30-50% of HIV-infected patients are also co-infected with HCV, it may be effective to deliver an HCV prevention program in conjunction with an HIV-prevention program. Unfortunately, there are certain physiological characteristics of the HCV virus (higher infectivity rate and "hardiness" of virus outside the human body) that may hinder these efforts and warrant a separate and focused intervention solely for HCV. Current interventions are in an infancy state and there has not been one intervention that has proven effective against HCV infection.

Hispanics/Latinos currently comprise the fastest growing and largest minority group in the U.S. In addition, several studies have found that Hispanics/Latinos have a much higher prevalence rate of HCV than Caucasians. Finally, Hispanics/Latinos are not well represented in the literature. Most studies group people of Hispanic/Latino background into large aggregate groups without considering different cultural aspects of their different nationalities (e.g., Cubans, Puerto Ricans, Dominicans, Mexicans), which could affect the reported HCV infection rates among Hispanics/Latinos and may differ among the groups.

# CHAPTER III

# METHODOLOGY

The main purpose of this study is to attempt to assess the association between identified risk factors for HCV infection in the Hispanic/Latino intravenous drug using (IDU) population and HCV infection. The sample selected for the proposed study was from Miami-Dade County, Florida. This study is based on an original CDC-funded study that primarily examined the HCV prevalence among Hispanic/Latino IDUs in South Florida (parent study). The current study is a secondary research analysis of data obtained from the parent study.

*Description of parent study*

This study utilizes data taken from an original CDC-funded study entitled "Prevalence of HIV, Hepatitis B & C Virus Infections, and Associated Risk Factors among Hispanic IDUs," CDC grant # U65/CCU423371. The main differences between the parent study and this supplemental study are, 1) the parent study did not calculate the strength of associations between risk factors and HCV infection *alone*, focusing primarily on comorbid individuals, and 2) the unit of analysis in the parent study was "Hispanic IDUs," whereas the unit of analysis in this study will be specific Hispanic/Latino ethnicities, specifically: Mexican, Central American (Belize, Costa Rica, El Salvador, Guatemala, Honduras, Nicaragua, and Panama), South American (Argentina, Bolivia, Brazil, Chile, Colombia, Ecuador, Guyana, Paraguay, Peru, Suriname, Uruguay, and Venezuela), Puerto Rican, Cuban, and Dominican individuals. Finally, the parent study did not develop the framework for a theoretically based, comprehensive HCV prevention intervention for Hispanic/Latino IDUs.

The parent study used a cross-sectional study design and collected information on the prevalence of selected diseases. There was no intent to educate the participants beyond providing them with standard information after the completion of the questionnaire. A total of 240 Hispanic/Latino drug injectors (both men and women, and both HCV positive and negative) across Miami-Dade County, FL were enrolled into the study and were surveyed. They were told that the study was investigating rates of HIV and hepatitis, as well as other issues such as alcohol abuse, sexual behavior, depression, and acculturation. The participants were selected utilizing a snowball sampling technique, utilizing participants as informants in order to gain access to other participants. This technique, while not providing a representative sample, proved to be the most productive given the study population. Given the high prevalence of IDUs in certain areas of Miami-Dade County, the targeted recruitment areas included: downtown Miami, North Miami, and Homestead.

Inclusion criteria for the main study included: injecting opiates and/or cocaine and/or amphetamines for at least three months, using substances at least weekly for the past 30 days, and being 18 years of age or older. After the participants were properly consented by study personnel pursuant to University of Miami IRB, they completed a computer assisted, self administered, in-depth survey (The Modified AIDS Risk Behavior Questionnaire) with 248 items that measured injection and non-injection drug use, alcohol use, sexual history, drug user networks, acculturation, information on HIV, HCV and other STIs, and demographic data (Chitwood, Comerford, Kitner, Palacios, & Sanchez, 2001; Weiss, Chitwood & Sanchez, 2008). This instrument required approximately one and a half hours to complete. This instrument been shown to be valid

and reliable in other drug using populations, with kappa coefficients ranging from 0.44 for nondichotomous variables to 0.72 for dichotomous variables (Ball, 1967; McElrath, Chitwood, Griffin, & Comerford, 1994; Stephens, 1972).

*Sample size calculation and power analysis*

Given that IDU was an original inclusion criterion, all original participants were eligible for this study. In order to ensure that there were enough participants to perform analyses, power calculations were conducted. An important factor in planning a scientific study is to identify as appropriate sample size to achieve sufficient power to detect the hypothesized effect.

The power of a study is defined as the probability of detecting a statistically significant effect (Purcell, Cherny, & Cham, 2003). Furthermore power calculations are useful to help determine if a study is underpowered, or if it is possible to find the smallest detectable effect size given the actual sample size. A requirement for computing power calculations is to make assumptions regarding differences about study effects. Several software tools are available to make power calculations practical, one of which is a Generic Power Calculator (Purcell, 2003). The Generic Power Calculator, which is a computational tool, was utilized to implement power calculations using quantitative traits on both HCV+ and HCV- subjects to determine if the study had enough subjects available to show statistically significant result. The result of the power analyses indicated that with a given *N* of 240, and a HCV prevalence of 75.8% in the sample, this study would have 80% power ($\alpha$=0.050, two-tailed) to reject the null hypothesis of zero correlation between the variables.

A minimum sample was calculated and considerations ensuring that multivariate models had sufficient ability to detect differences were made. Peduzzi et al. (1996) provides the following equation that provides guidance for a minimum number of cases and the maximum allowable number of independent variables that should be included in analyses, in this case, beginning with the univariate analyses:

$$N = 10\ k / p$$

In the above equation, ***N*** is the estimated sample size, ***k*** is the number of covariates (independent variables) and ***p*** is the proportion of positive cases in the population. The data reveal that the proportion of positive HCV cases (***p***) in the selected population is 0.758. There were 240 participants in the study (***N***), so in order for that number to be an adequate sample for this study, a maximum of 18 covariates (***k***) could be included in the model.

*Dependent variable*

HCV serostatus was the dependent variable in this study. The original study included serologic studies of all participants. HCV testing was performed at the University of Miami Hepatology Laboratory. HCV antibodies were detected by EIA (Anti-HCV 3.0 ELISA Test Kit Ortho Diagnostic Systems Inc., Raritan, NJ). HCV serostatus was operationalized as a dichotomous variable, which was coded: 0=negative, 1=positive. Correlations of demographic variables with HCV status are summarized in Table 1.

*Independent variables*

The independent variables used in this study are grouped in three overall risk factor profiles: demographic risk factors, sexual risk factors and injection risk factors. Demographics are always an important variable to include in this type of study,

particularly when very little information about the population as well as the incidence and prevalence rate of the selected outcome (HCV) is available. Risk may vary by location, age, gender, etc. The location of this study will not vary (Miami, Florida). Age and gender, however, have been captured as independent variables in order to study any fluctuation in risk given these two demographic variables. In addition, the data collected includes information on educational level, employment, income, marital status, and residency.

Sexual risk factors have been included in this study given the emergence of studies indicating that HCV may be transmitted via sexual contact (Terrault, 2002; van de Laar et al., 2007). Sexual risk factors that were a part of the original study are included in this study in order to ascertain their effects on HCV infection on this population. There is an emerging body of literature that suggests that unprotected sex may be independently associated with HCV infection (Terrault, 2002). As such, it is important to understand if and how sexual risk factors are associated with HCV infection in the Hispanic/Latino IDU population.

Injection drug use is the main mode of transmission of HCV. As such any variable associated with injection drug use was included in this study. Particular attention was paid to use of dirty needles (needle sharing), use of dirty paraphernalia, and frequency of injection. Personal networks are also an important risk factor for HCV infection and therefore information on networks were included in this study. As stated in the literature review, personal networks add another layer of risk and may influence the individual's own risk-taking behavior (Costenbander, Astone & Latkin, 2006). In order to

study the possible effects of the percentage of people who inject drugs in an individual's personal network, this variable has been included in the study.

The independent variables associated with the demographic risk factor profile are: gender, which can be male, female or transgender; age, which refers to the current age at the administration of the questionnaire as was dichotomized as "young" (18-24) and "older" (25 and older); education level, which refers to whether the participant has completed high school; employment refers to whether the participant was employed (either full-time or part-time) at the time the questionnaire was administered; income refers to the annual reported gross earnings for the participant at the time of the questionnaire; marital status refers to the current legal status at the time of the administration of the questionnaire; residency reports on the current reported living situation at the time of the questionnaire; Hispanic/Latino ethnic background refers to the self-reported Hispanic/Latino ethnic background. Some ethnicities were grouped as regions due to the fact that there were few participants who reported being from a specific ethnic background (i.e., "Peruvian" or "Costa Rican") and the group was not large enough to detect statistically significant results between all groups. Grouping ethnic backgrounds in this way produced several "small groups." Given that one of the aims of this study was to see if there were different risk factors in different ethnic groups, it was decided to leave the smaller groups intact to determine if they would produce statistically significant results. Number of years in the U.S. refers to the number of years continuously living in the U.S. at the time of the administration of the questionnaire; born the U.S. refers to whether the participant was born in the United States regardless of their ethnic background.

The independent variables associated with the sexual risk factor profile were: age at first sexual encounter, which refers to whether the participant reported age at first sexual encounter of younger than 14 or 14 and older. The age of 14 was the median age reported by the sample as the age when they first had a sexual encounter. Dividing the sample further by either using age as either a continuous or categorical variable with several groups produced very uneven groups that did not yield statistically significant results. Given this, the variable "age at first sexual encounter" was dichotomized. Number of sex partners in the last three months refers to the number of sexual partners in the 3-month period prior to the administration of the questionnaire; number of sex partners in a lifetime refers to the self-reported total number of sexual partners in the individual's lifetime. The variable "sex partners in the past 3 months" did have 66 missing cases, and those were treated as having no sex partners.

The independent variables associated with the injection risk factor profile were: use of a dirty cooker, which refers to the percentage of time the participant used a "dirty cooker" as defined by using it immediately after someone else had used it without it being cleaned/replaced with a new one; use of a dirty cotton, which refers to the percentage of time the participant used a "dirty cotton" as defined by using it immediately after someone else had used it without it being cleaned/replaced with a new one; use of dirty rinse water, which refers to the percentage of time the participant used a "dirty rinse water" as defined by using it immediately after someone else had used it without it being cleaned/replaced with fresh water; use of a dirty needle/syringe refers to the percentage of time the participant used a "dirty syringe" as defined by using it

immediately after someone else had used it without it being cleaned/replaced with a new one.

Several of the independent variables examined injection frequency. These variables were: weekly injection frequency, which measured the number of days the participant injected in the week prior to the administration of the questionnaire; daily injection frequency refers to the number of times per day the participant injected (the last time the participant injected) prior to the administration of the questionnaire.

Finally, there was one variable that examined the participant's personal injection network. The variable, IDU's in personal network, represented the percent of people in the participant's social network who currently injected any drug. The possible answers to all variables are summarized in Tables 1 and 2.

*Data analysis*

The data analysis used in this study included: 1) univariate (descriptive) analyses, 2) bivariate analyses, and 3) multivariate logistic regression analyses. Finally, in order to ensure that the final model included only the variables that contributed the most to the final model, ensuring that no further improvement is necessary, a backward logistic regression was performed. All of the analyses were conducted in SPSS version 19 (IBM, 2010).

The descriptive statistics (univariate analyses) in this study included frequency distributions as well as measures of central tendency. For the frequency distributions, the number and percentage of each occurrence were presented for all variables in the study. These included the HCV serostatus of the participants, as well as the study domains (demographics, sexual risk factors, and injection risk factors). Examining the

characteristic variables helped in determining whether each group (HCV + vs. HCV -) was equally represented in the study.

In the bivariate logistic regression portion of the study, HCV-positive and HCV-negative participants were compared in terms of demographic characteristics, sexual risk factors, and injection risk factors. The main purpose of this comparison was to ensure that the selected independent variable categories formed groups that were large enough for analyses. If the independent variable groups were not large enough or did not represent a hypothetical sample then the independent variables were recoded in order to more closely mimic a hypothetical population. Bivariate analyses were also performed to assess whether there were preliminary correlations among dependent and independent variables.

The Pearson's Chi square ($\chi^2$) was utilized for this particular analysis. A lower p-value informed us that the selected groups were distributed as expected and that true differences may be detectable between the groups. If a higher p-value was obtained, then the independent variables were recoded in order to maximize the correlation between the existing and expected (hypothetical) population. There were however, instances where the independent variables were recoded to be as large as possible (dichotomized), but a high p-value still existed. A higher p-value for the $\chi^2$ analysis however, did not cause the variable to be dropped from the overall analysis. Given that the selected variables proved to be significant in the literature review, they were still included in the initial logistic regression model.

The next step in the analysis involved determining the unadjusted odds ratios using logistic regression for every variable in the study. The dependent variable (HCV) was analyzed with each independent variable separately. The results of this analysis

showed the relevant odds ratios (unadjusted) and significance values for each independent variable with the dependent variable. This was an important step because this analysis assisted in further defining what independent variables were associated with HCV infection and essentially served to shorten the list of possible independent variables included in the multivariate logistic regression model. A generous p-value of $p < 0.20$ was applied and all variables significant at that level were included in the final logistic regression.

The independent variables included two sets that were very similar and possibly highly correlated. In the sexual risk factor profile, the *number of sex partners in the past three months* and *number of sex partners in a lifetime* could potentially inflate the odds ratios of other independent variables in the multivariate analyses. Similarly, in the injection risk factor profile, *weekly injection frequency* and *daily injection frequency* could influence the odds ratios as well.

The variable *number of sex partners in the past three months* also had a slight irregularity. As collected, the data show that only 174 participants answered the question "how many sexual partners have you had in the past 90 days?" A total of 66 participants left the question blank. In order to ensure equitable groups when performing all the analyses, it was assumed that a blank response meant that the participant did not have a sexual partner in the past three months and the variable was converted so that a blank answer equated zero.

This issue of multicollinearity was addressed by examining the calculated VIF (variance inflation factor) for these four variables. VIF is defined as an index of the amount that the variance of each regression coefficient is increased relative to a situation

in which all of the predictor variables are uncorrelated (Cohen et al., 2003). A VIF of 5 or less is normally deemed as an acceptable VIF before multicollinearity becomes a problem. In order to ensure that the interaction between these variables did not affect the odds of other variables in the multivariate analysis, the "collinearity" test (in SPSS) was performed on these variables prior to beginning the analyses. The calculated VIFs on these four variables were: number of sex partners in the past 3 months (VIF = 1.185); number of sex partners in a lifetime (VIF = 1.185); weekly injection frequency (VIF = 1.159); and daily injection frequency (VIF = 1.157). Given that all calculated VIFs were well below the suggested VIF of five, all four variables remained in the bivariate analyses and were included in the multivariate model.

In the multivariate analysis portion of the study, all significant variables (at $p < 0.20$) were included in a single logistic regression model. Final odds ratios and *p*-values were obtained and this analysis determined which of the original 20 variables, controlling for each other, had the most effect in predicting the HCV serostatus of the study population. At this point, the final model was produced and variables were categorized as either significant at the $p < 0.05$ level, or approached significance at the $p < 0.10$ level. Any variables in the multivariate model which were not significant at the $p < 0.05$ level were categorized as "not statistically significant."

Finally, a backward selection logistic regression analysis was conducted on the variables that were initially found to be significant in the preliminary bivariate analyses. With the backward selection method, only those independent variables that remained significant at the $p < 0.05$ were included in the backward regression model. For the backward selection method, a removal criterion of $p < 0.20$ was selected. This high level

was selected because the removal criteria should be more lenient, such that not every independent variable is removed from the model (Hosmer & Lemeshow, 2000). The backward selection method is utilized in order to ensure that the final multiple regression model is stable and does not have too many variables.

*Summary*

The current study is a secondary research analysis of data gathered under the parent study. The original study was entitled "Prevalence of HIV, Hepatitis B & C Virus Infections, and Associated Risk Factors among Hispanic IDUs," CDC grant # U65/CCU423371. The study was a quantitative cross-sectional survey. A total of 240 Hispanic/Latino drug injectors across Miami-Dade County, FL were recruited into the study. All 240 of the original participants were included in this current study, since the only exclusion criteria would have been no intravenous drug use.

For this study, HCV-positive and HCV-negative participants were compared in terms of demographic characteristics, sexual risk factors, injection risk factors, and their personal networks. Initially, all independent variables were analyzed using the $\chi^2$ (Pearson's Chi square) statistic. This allowed for the creation of statistically significant independent variable categories whenever possible. In addition, multicollinearity analyses were performed on variables suspected of measuring the same factor.

A univariate logistic regression was then conducted in order to determine the unadjusted odds for HCV infection for each independent variable. Independent variables significant at the $p < 0.20$ were included in a multivariate logistic regression and adjusted odds were obtained. All variables significant at the $p < 0.05$ level at this stage were then subjected to a backward logistic regression in order to ensure that the selected model was

stable. A removal criterion of $p < 0.20$ at this level was established, and any variables above this level would be removed from the final model. Utilization of the backward selection method ensures the most parsimonious model, where the fewest number of significant variables are included in the final model.

# CHAPTER IV

# RESULTS

Table 1 presents the frequency, percentages and $\chi^2$ values of the demographic risk factor profile. Most of the sample (75.8%) tested positive for HCV infection; the sample was majority male (87.5%) and most were unemployed (83.3%). In addition, the majority of the sample reported being unmarried (85%) and more than half of the sample identified themselves as Puerto Rican (66.7%). Finally, most of the participants surveyed stated that they were born in the U.S. (83.3%). The $\chi^2$ analyses on the demographic profile reveal that "Age", "Hispanic/Latino ethnicity" and "Born in the U.S." variables yielded significant findings ($p < .05$) when HCV+ and HCV- populations were compared. The variable "number of years in the U.S." approached significance at the $p = 0.10$ level.

Table 1

*Frequency, Percentages and $\chi^2$ Analyses of Demographic Variables*

| | Total N (%) | HCV (+) N (%) | HCV (-) N(%) | p-value |
|---|---|---|---|---|
| Age | | | | |
| 18 - 24 | 16(6.7) | 7(3.8) | 9(15.5) | 0.002 |
| 25 - older | 224(93.3) | 175(96.2) | 49(84.5) | |
| Gender | | | | |
| Male | 210(87.5) | 157(86.3) | 53(91.4) | 0.305 |
| Female | 30(12.5) | 25(13.7) | 5(8.6) | |
| Employment | | | | |
| Employed | 40(16.7) | 33(18.1) | 7(12.1) | 0.281 |
| Unemployed | 200(83.3) | 149(81.9) | 51(87.9) | |
| Income | | | | |
| None | 95(39.6) | 74(40.7) | 21(36.2) | 0.753 |
| < $5,000 | 46(19.2) | 32(17.6) | 14(24.1) | |
| $5,000 - $9,999 | 33(13.7) | 26(14.3) | 7(12.1) | |
| $10,000 - $14,999 | 19(7.9) | 16(8.8) | 3(5.2) | |

| | Total N (%) | HCV (+) N (%) | HCV (-) N(%) | p-value |
|---|---|---|---|---|
| $15,000 - $19,999 | 17(7.1) | 13(7.1) | 4(6.9) | |
| $20,000 or more | 30(12.5) | 21(11.5) | 9(15.5) | |
| Marital status | | | | |
| Married | 36(15.0) | 29(15.9) | 7(12.1) | 0.473 |
| Unmarried | 204(85.0) | 153(84.1) | 51(87.9) | |
| Residency | | | | |
| Own home/live with relatives | 114(47.5) | 83(45.6) | 31(53.4) | 0.298 |
| Hotel/motel/boarding house | 126(52.5) | 99(54.4) | 27(46.6) | |
| Education level | | | | |
| No high school | 96(40.0) | 70(38.5) | 26(44.8) | 0.389 |
| High school or GED | 144(60.0) | 112(61.5) | 32(55.2) | |
| Hispanic/Latino ethnicity | | | | |
| Mexican | 8(3.3) | 7(3.8) | 1(7.7) | 0.000 |
| South American | 8(3.3) | 8(4.4) | 0(0.0) | |
| Puerto Rican | 160(66.7) | 135(74.2) | 25(43.1) | |
| Cuban | 33(13.8) | 18(9.9) | 15(25.9) | |
| Dominican | 8(3.3) | 1(0.5) | 7(12.1) | |
| Central American | 4(1.7) | 1(0.5) | 3(5.2) | |
| Mixed | 19(7.9) | 12(6.6) | 7(12.1) | |
| Number of years in the U.S. | | | | |
| Less than 5 | 109(45.4) | 90(49.5) | 19(32.8) | 0.100 |
| 5-10 years | 52(21.7) | 39(21.4) | 13(22.4) | |
| 11-15 years | 27(11.3) | 16(8.8) | 11(19.0) | |
| 16-20 years | 21(8.8) | 14(7.7) | 7(12.1) | |
| 21+ years | 31(12.9) | 23(12.6) | 8(13.8) | |
| Born in the U.S. | | | | |
| Yes/Born in U.S. | 200(83.3) | 159(87.4) | 41(70.7) | 0.003 |
| No/Not born in U.S. | 40(16.7) | 23(12.6) | 17(29.3) | |

Hypothesis 1a proposed that in comparison with HCV negative individuals, HCV positive individuals will be less likely to be employed (*employment*, *income*) as well as less likely to be educated (*education level*) and have poorer familial stability (*marital status, residency*). Table 1 indicates that of the 182 HCV positive participants, most were

unemployed (81.9%). Of the 58 HCV negative participants, most were unemployed (87.9%) as well. In addition, none of the income categories showed a statistically significant relationship with HCV infection. These data suggest that in this sample HCV-positive individuals do not differ statistically from HCV-negative individuals in terms of employment, income and education level.

Furthermore, Table 1 indicates that 84.1% of the HCV positive participants and 87.9% of the HCV negative participants were unmarried. Of the HCV positive participants, 54.4% reported living in a hotel/motel/boarding house/homeless versus 46.6% of the HCV negative persons. The differences were not significant. Given these results, it is concluded that HCV positive participants in this sample do not differ from HCV negative participants in terms of marital status and residency status.

Hypothesis 1b proposed that in comparison with HCV negative individuals, HCV positive individuals will be older (*age*), will be more likely to be of the male gender (*gender*). The analyses did not reveal significant differences by HCV status with regards to gender. Age however, showed a statistically significant relationship in all analyses.

Table 2

*Frequency, Percentages and $\chi^2$ Analyses of Sexual and Injection Risk Factor Variables*

| | Total N (%) | HCV (+) N (%) | HCV (-) N (%) | *p*-value |
|---|---|---|---|---|
| Sexual Risk Factors | | | | |
| Age at first sexual encounter | | | | |
| Less than or equal to 13 | 98(40.8) | 73(40.1) | 25(43.1) | 0.686 |
| 14 or older | 142(59.2) | 109(59.9) | 33(56.9) | |
| # of sex partner in past 3 months | | | | |
| None or 1 | 145(60.4) | 118(64.8) | 27(46.6) | 0.013 |
| 2 or more | 95(39.6) | 64(35.2) | 31(53.4) | |

| | Total N (%) | HCV (+) N (%) | HCV (-) N (%) | *p*-value |
|---|---|---|---|---|
| # of sex partners in a lifetime | | | | |
| 10 or less | 50(20.8) | 41(22.5) | 9(15.5) | 0.718 |
| 11-25 | 63(26.3) | 47(25.8) | 16(27.6) | |
| 26-50 | 60(25.0) | 44(24.2) | 16(27.6) | |
| More than 50 | 67(27.9) | 50(27.5) | 17(29.3) | |
| Injection Risk Factors | | | | |
| Weekly injection frequency | | | | |
| Less than everyday | 39(16.3) | 18(9.9) | 21(36.2) | 0.000 |
| Everyday | 201(83.8) | 164(90.1) | 37(63.8) | |
| Daily injection frequency | | | | |
| Less than 4 times a day | 111(46.3) | 70(38.5) | 41(70.7) | 0.000 |
| 4 or more times a day | 129(53.8) | 112(61.5) | 17(29.3) | |
| Use of dirty cooker | | | | |
| Half of the time or less | 111(46.3) | 78(42.9) | 33(56.9) | 0.062 |
| More than half the time | 129(53.8) | 104(57.1) | 25(43.1) | |
| Use of dirty cotton | | | | |
| Half of the time or less | 140(58.3) | 101(55.5) | 39(67.2) | 0.114 |
| More than half the time | 100(41.7) | 81(44.5) | 19(32.8) | |
| Use of dirty rinse water | | | | |
| Half of the time or less | 149(62.1) | 110(60.4) | 39(67.2) | 0.353 |
| More than half the time | 91(37.9) | 72(39.6) | 19(32.8) | |
| Use of a dirty needle | | | | |
| Never | 103(42.9) | 69(37.9) | 34(58.6) | 0.006 |
| Sometimes | 137(57.1) | 113(62.1) | 24(41.4) | |
| IDU's in personal network | | | | |
| 25% or less | 17(7.1) | 13(7.2) | 4(6.9) | 0.870 |
| 26% - 50% | 28(11.7) | 21(11.6) | 7(12.1) | |
| 51% - 75% | 26(10.9) | 18(9.9) | 8(13.8) | |
| > 75% | 168(70.3) | 129(71.3) | 39(67.2) | |

In the sexual and injection risk factor profile (Table 2), weekly injection frequency, daily injection frequency, use of a dirty needle and number of sex partners in

the past three months were significant at the $p = 0.05$ level. These analyses suggest that the only drug paraphernalia variable that approached significance was "using a dirty cooker."

Hypothesis 2 stated that HCV positive individuals will be more likely to engage in high-risk sexual behaviors than HCV negative individuals as measured by sexual history (*age at first sexual encounter*) and number of sex partners (*number of sex partners in last 3 months, number of sex partners in a lifetime*). Table 2 indicates that 40.1% of the HCV positive participants had their first sexual encounter at age 13 or younger versus HCV negative participants (43.1%). The outcome was not significant.

With regards to number of sex partners in the past three months, it was initially analyzed as a continuous variable (mean=6.85, SD=17.77, range=1-100). As a continuous variable, number of sex partners in the past three months was not significantly associated with HCV infection in the bivariate analyses. The variable was then dichotomized as having "none or 1 sex partners" and "2 or more sex partners" and included in the univariate analyses. Unadjusted odds (Table 3) indicate that when compared to participants that have "none or 1 sex partners", participants with two or more sex partners are significantly less likely to be HCV positive ($OR = 0.472$, $p = 0.014$). When controlling for all other variables (Table 4), having two or more sexual partners in the past three months continued to be a significant protective factor against HCV infection.

Given the evidence, it is concluded that HCV positive participants do not differ statistically from HCV negative participants in terms of age at first sexual encounter and lifetime sexual partners. HCV positive participants do differ significantly from HCV negative participants in that participants having two or more sexual partners in the past

three months were less likely to be HCV positive when compared to participants that had only one sex partner or none in the past three months.

Table 3

*Unadjusted Odd Ratios for Hepatitis C Infection*

| Variable | Percent | OR | 95% CI | p-value |
|---|---|---|---|---|
| Demographics | | | | |
| Age | | | | |
| 18 - 24 | 6.7 | 1.000 | | |
| 25 - older | 94.3 | 4.592 | 1.627-12-956 | 0.004 |
| Gender | | | | |
| Female | 12.5 | 1.000 | | |
| Male | 87.5 | 0.592 | 0.216-1.626 | 0.309 |
| Employment | | | | |
| Employed | 16.7 | 1.000 | | |
| Unemployed | 83.3 | 0.620 | 0.258-1.487 | 0.620 |
| Income | | | | |
| None | 39.6 | 1.000 | | |
| < $5,000 | 19.2 | 0.649 | 0.293-1.434 | 0.285 |
| $5,000 - $9,999 | 13.8 | 1.054 | 0.402-2.767 | 0.915 |
| $10,000 - $14,999 | 7.9 | 1.514 | 0.402-5.694 | 0.540 |
| $15,000 - $19,999 | 7.1 | 0.922 | 0.272-3.127 | 0.867 |
| $20,000 or more | 12.5 | 0.662 | 0.264-1.660 | 0.379 |
| Marital status | | | | |
| Married | 15.0 | 1.000 | | |
| Unmarried | 85.0 | 1.381 | 0.570-3.43 | 0.474 |
| Education Level | | | | |
| No high school | 60.0 | 1.000 | | |
| High school or GED | 40.0 | 0.769 | 0.423-1.398 | 0.389 |
| Hispanic/Latino Ethnic Background | | | | |
| Mixed Ethnic Background | 7.9 | 1.000 | | |
| Mexican | 3.3 | 4.083 | 0.412-40.455 | 0.229 |
| Central American | 1.7 | 0.194 | 0.017-2.248 | 0.190 |

| Variable | Percent | OR | 95% CI | p-value |
|---|---|---|---|---|
| South American | 3.3 | 9.424 | 0.000-99.00 | 0.999 |
| Puerto Rican | 66.7 | 3.150 | 1.130-8.781 | 0.028 |
| Cuban | 13.8 | 0.700 | 0.220-2.226 | 0.546 |
| Dominican | 3.3 | 0.083 | 0.008-0.826 | 0.034 |
| Number of years in the U.S. | | | | |
| Less than 5 years | 45.4 | 1.000 | | |
| 5-10 years | 21.7 | 0.633 | 0.285-1.409 | 0.263 |
| 11-15 years | 11.3 | 0.307 | 0.123-0.765 | 0.011 |
| 16-20 years | 8.8 | 0.422 | 0.150-1.187 | 0.102 |
| 21+ years | 12.9 | 0.607 | 0.236-1.561 | 0.300 |
| Born in the U.S | | | | |
| Yes/Born in the U.S | 83.3 | 1.000 | | |
| No/Not born in the U.S. | 16.7 | 0.349 | 0.171-0.713 | 0.004 |
| Sexual Risk Factors | | | | |
| Age at first sexual encounter | | | | |
| Less than or equal to 13 | 40.8 | 1.000 | | |
| 14 or older | 59.2 | 1.131 | 0.622-2.058 | 0.686 |
| # of sex partner in past 3 months | | | | |
| None or 1 | 60.4 | 1.000 | | |
| 2 or more | 39.6 | 0.472 | 0.260-0.860 | 0.014 |
| # of sex partners in a lifetime | | | | |
| 10 or less | 20.8 | 1.000 | | |
| 11-25 | 26.3 | 0.645 | 0.258-1.614 | 0.349 |
| 26-50 | 25.0 | 0.604 | 0.240-1.516 | 0.283 |
| More than 50 | 27.9 | 0.646 | 0.261-1.160 | 0.345 |
| Injection Risk Factors | | | | |
| Weekly injection frequency | | | | |
| Less than everyday | 16.3 | 1.000 | | |
| Everyday | 83.8 | 5.171 | 2.508-10.662 | 0.000 |
| Daily injection frequency | | | | |
| Less than 4 times | 46.2 | 1.000 | | |
| 4 times or more | 53.8 | 3.856 | 2.036-7.314 | 0.000 |

| Variable | Percent | OR | 95% CI | p-value |
|---|---|---|---|---|
| Use of dirty cooker | | | | |
| Half of the time or less | 46.2 | 1.000 | | |
| More than half the time | 53.8 | 1.760 | 0.969-3.197 | 0.063 |
| Use of dirty cotton | | | | |
| Half of the time or less | 58.3 | 1.000 | | |
| More than half the time | 41.7 | 1.646 | 0.884-3.064 | 0.116 |
| Use of dirty rinse water | | | | |
| Half of the time or less | 62.1 | 1.000 | | |
| More than half the time | 37.9 | 1.344 | 0.720-2.507 | 0.353 |
| Use of a dirty needle | | | | |
| Never | 42.9 | 1.000 | | |
| Sometimes | 57.1 | 2.320 | 1.270-4.237 | 0.006 |
| Use of dirty rinse water | | | | |
| Half of the time or less | 62.1 | 1.000 | | |
| More than half the time | 37.9 | 1.344 | 0.720-2.507 | 0.353 |
| IDU's in personal network | | | | |
| 25% or less | 7.1 | 1.000 | | |
| 26% - 50% | 11.7 | 0.923 | 0.225-3.780 | 0.911 |
| 51% - 75% | 10.8 | 0.832 | 0.414-1.672 | 0.606 |
| > 75% | 70.0 | 1.006 | 0.680-1.489 | 0.977 |

Table 3 shows the unadjusted odds ratios (OR) for HCV infection by independent variables. The table shows the percent of the entire sample per categorical value, the associated odds ratios as well as the 95% confidence interval (95% CI) and significance value. At this step, the significance level of $p = 0.20$ was utilized to determine variables that approached significance and were included in the multivariate model (in Table 4).

Originally, age (mean=35.8, SD=9.2) was analyzed as a continuous variable (range=18-61). When included in the bivariate analyses with all the other variables, it was not significant. Age was then dichotomized as "younger age" which is 18-24 years

and “older age”, which is 25 years or older. In the bivariate analyses (Table 3), dichotomized age was a statistically significant predictor of HCV infection (*OR* = 4.592, $p = 0.004$).

Of all of the ethnic groups analyzed, being of Puerto Rican decent was significantly associated with HCV infection (OR = 3.150; $p = 0.028$). This however, could be reflective of the fact that there were a large number of Puerto Ricans in the study, when compared to all other groups. Both weekly injection frequency (OR = 5.171; $p = 0.000$) and daily injection frequency (OR = 3.856; $p = 0.000$) were significantly associated with HCV status. While not significant at the $p = 0.05$ level, using a dirty cooker (OR = 1.760; $p = 0.063$) approached significance as a risk factor for HCV infection. This finding may suggest that in future studies, with a sample that is more representative of the entire population, using a dirty cooker, or any other drug paraphernalia may be a significant risk factor for HCV infection among Hispanic/Latino IDUs.

This analysis also uncovered several protective factors for HCV at varying significance levels. Being born outside the U.S. (OR = 0.349; $p = 0.004$) was a significant protective factor, along with having two or more sex partners in the past three months (OR = 0.472; $p = 0.014$). Of all the ethnic backgrounds, being of Dominican decent (OR = 0.083; $p = 0.034$) was a significant protective factor for HCV infection. This finding however is suspect given the very small number of Dominicans in the study (n=8).

In order to address the significant factors with regards to “Puerto Rican” and “Dominican” ethnic backgrounds, two new variables were created. One variable was dichotomized “Puerto Rican/not Puerto Rican” and the other “Dominican/not

Dominican". Upon analyzing both variables in a bivariate model, these new variables were no longer significant and were not included in the multivariate model.

When compared with participants living in the U.S. for less than five years, participants who lived in the U.S. between 5-10 years were less likely to be HCV infected (although not significant). Participants living in the U.S. between 11-15 years however, were significantly less likely to be HCV infected (OR = 0.307; $p = 0.011$). In addition, as time in the U.S. increases, it appears that the protective effects begin to wane; this finding was not significant at the $p = 0.05$ level.

Hypothesis 1c stated that in comparison with HCV negative individuals, HCV positive individuals will be more likely to have resided in the U.S. for a longer period of time (*number of years in the U.S.)* and be born in the U.S. (*born in the U.S.).* Table 1 indicates that almost half of HCV positive participants (49.5%) actually have resided in the U.S. for less than 5 years. Table 3 shows that the only statistically significant result for number of years residing in the U.S. was for the group 11-15 years ($p = 0.011$), while the group 16-20 years approached significance ($p = 0.102$). The results were not significant at any other level. This result may suggest a waning effect as the number of years living in the U.S. increases.

In the unadjusted odds (Table 3), participants born outside the U.S. were significantly less likely to be HCV infected ($p = 0.004$). In the adjusted odds (Table 4), being born outside the U.S. continued to be a significant protective factor (AOR = 0.369; $p = 0.019$). These results indicate that HCV positive do differ statistically from HCV negative individuals when it comes to living in the U.S. for longer periods of time or being born in the U.S.

Table 4 (multivariate analyses) includes all variables that were significant at the $p < 0.20$ level in the bivariate analyses. The multivariate analyses show that when controlling for all other variables, injecting every day (AOR = 3.238; $p = 0.007$) as well as injecting four or more times per day (OR = 2.265; $p = 0.010$) were both significant risk factors for HCV infection. In addition, age (dichotomized) (AOR = 7.470; $p = 0.006$) was also a significant risk factor for HCV infection when controlling for all other variables. Drug paraphernalia variables: using a dirty cooker (AOR = 0.900; $p = 0.847$); using a dirty cotton (AOR = 1.270; $p = 0.665$); and using a dirty needle at least "sometimes" (AOR = 1.882; $p = 0.110$), were not significant at the $p < 0.05$ level.

Table 4

*Adjusted Odd Ratios (AOR) for Hepatitis C Infection*

| Variable | Percent | AOR | 95% CI | P-value |
|---|---|---|---|---|
| Demographics | | | | |
| Age | | | | |
| 18 - 24 | 5.0 | 1.000 | | |
| 25 - older | 95.0 | 7.470 | 1.790-31.170 | 0.006 |
| Born in the U.S. | | | | |
| Yes/Born in the U.S. | 83.3 | 1.000 | | |
| No/Not born the U.S. | 16.7 | 0.369 | 0.160-0.848 | 0.019 |
| Sexual Risk Factors | | | | |
| # of sex partner in past 3 months | | | | |
| None or 1 | 32.9 | 1.000 | | |
| 2 or more | 39.6 | 0.481 | 0.241-0.958 | 0.037 |
| Injection Risk Factors | | | | |
| Weekly injection frequency | | | | |
| Less than everyday | 16.3 | 1.000 | | |
| Everyday | 83.8 | 3.238 | 1.387-7.560 | 0.007 |

| Variable | Percent | AOR | 95% CI | P-value |
|---|---|---|---|---|
| Daily injection frequency | | | | |
| Less than 4 times | 46.2 | 1.000 | | |
| 4 times or more | 53.8 | 2.625 | 1.258-5.479 | 0.010 |
| Use of dirty cooker | | | | |
| Half of the time or less | 46.2 | 1.000 | | |
| More than half the time | 53.8 | 0.900 | 0.307-2.639 | 0.847 |
| Use of dirty cotton | | | | |
| Half of the time or less | 58.3 | 1.000 | | |
| More than half the time | 41.7 | 1.270 | 0.431-3.737 | 0.665 |
| Use of a dirty needle | | | | |
| Never | 42.9 | 1.000 | | |
| Sometimes | 57.1 | 1.882 | 0.867-4.083 | 0.110 |

Several protective factors for HCV infection did emerge from this analysis. Unexpectedly, having two or more sexual partners in the past three months (AOR = 0.481; $p = 0.037$) emerged as a significant protective factor against HCV infection. Additionally, being born outside the U.S. (AOR = 0.369; $p = 0.019$) emerged as a protective factor for HCV infection.

Hypothesis 3a stated that HCV positive individuals will be more likely to engage in high-risk injection behaviors than HCV negative individuals, as measured by utilization of shared injection paraphernalia (*cooker, cotton, rinse water, syringes*) and injection frequency (*weekly injection frequency, daily injection frequency*). Table 3 indicated that participants who injected every day were significantly more likely to be HCV positive when compared with participants who injected less than every day. Participants who injected four or more times a day were also significantly more likely to be HCV infected when compared to participants who injected less than four times a day.

With regards to drug paraphernalia, use of a dirty cooker, use of a dirty cotton, and use of a dirty needle were all associated with HCV infection. When adjusting for all other significant factors (Table 4), weekly injection frequency and daily injection frequency were both significantly associated with HCV infection. Use of a dirty needle approached significance ($p = 0.110$), but was not a significant factor in these analyses.

Based on the evidence, it is concluded that HCV positive participants are statistically more likely to engage in riskier injection practices as defined by more frequent weekly injections as well as more frequent daily injections.

*Backward regression*

In order to ensure that the model is stable and does not include too many variables, a backward regression was performed using only the variables significant at the

Table 5

*Backward Logistic Regression of Factors Affecting HCV*

| Variable | AOR | 95% CI | P-value |
|---|---|---|---|
| Age | 6.918 | 1.710-27.996 | 0.007 |
| Born in the U.S. | 0.365 | 0.163-0.816 | 0.014 |
| Weekly injection frequency | 3.737 | 1.631-8.563 | 0.002 |
| Daily injection frequency | 2.654 | 1.282-5.496 | 0.09 |

$p < 0.05$ level in the multivariate analysis (variables in Table 4). If any independent variable category was significant in the adjusted odds ratios, then it was included in the backward logistic regression. The results of the backward regression are included in Table 5.

The backward stepwise regression showed that age, being born in the U.S., weekly injection frequency and daily injection frequency, are all significant variables. Number of sex partners in the past 3 months was not significant in the backward logistic regression, so it was dropped from the final model. This indicates that introducing this variable in the model may make the model somewhat unstable, so care must be taken whenever utilizing "number of sex partners in the past 3 months" as a protective factor.

*Summary*

In summary, this analysis made use of secondary data to determine whether there was a significant difference between the HCV positive and HCV negative individuals in terms of the demographic profile as well as their sexual and injection risk factors. The unadjusted and adjusted odds ratios were used to determine which among the risk factors affected the dependent variable. Finally, a backward stepwise regression analysis was conducted to determine which among the significant risk factors identified through the bivariate odds ratio analysis significantly affected the dependent variable, HCV infection.

Among all of the studied risk factors, age, being born outside the U.S., weekly injection frequency and daily injection frequency were significant factors affecting the dependent variable, HCV.

# CHAPTER V

# DISCUSSION

HCV continues to capture the attention of the public health research community. For example, the CDC has made May 19th "National Hepatitis Testing Day" and has urged all "baby boomers" born between 1945 and 1965 to be tested for HCV, as this group represents the age sector with the highest percentage of HCV infection in the U.S. (CDC, 2012). While it is a relatively recent disease, the infectivity rate coupled with its correlation with HIV infections due to intravenous drug use continues to keep HCV in the spotlight of research (Choo et al., 1989).

This study is potentially the first that will lay the groundwork for successful prevention strategies for intravenous drug users who are currently HCV-negative. While it is customary to discuss the results of this study in the context of existing literature, the literature is admittedly still in its infancy (Mateu-Gelabert et al., 2007). There are many studies that will show associations between behaviors and HCV infection, but an attempt at differentiation and quantification of risk factors is still lacking in the literature. Moreover, the literature with regards to the varying risk factors of different Hispanic/Latino ethnicities is scarce.

Looking at the overall extant HCV literature however, allows us to compare the results of this study with other populations. This study did not find significant relationships between HCV and key demographic variables (gender, educational level, employment, income, marital status and residency status). This finding (or lack thereof) is not supported by national studies, particularly with regard to employment and income. According to data from the National Health and Nutrition Examination Survey

(NHANES), HCV is more prevalent in subjects who were below the poverty level (Alter et al., 1999). In this study, employment and income did not behave as predicted. Being unemployed served as a protective factor (not statistically significant), and income was inconsistent in its relationship with the odds of having HCV infection. It could be that unemployment may serve as a protective factor simply due to economics. Being unemployed means that there are no monetary resources to purchase drugs, and in turn, inject them (some shooting galleries actually charge an "entrance fee"). A potential confounder however is that in lieu of earning money to purchase drugs, a person may turn to illegal activities (burglarizing, robbery, etc.). Females (and some males) may turn to prostitution, which could help to explain the result found in some studies (discussed later) that men are less likely to be HCV infected. With regards to income, no specific pattern was obtained from the data, with the possibility of "illegal income" being a potential confounder.

Other demographic variables did behave as predicted, but the results were not statistically significant. It was hypothesized that not having a high school diploma/GED, being unmarried and living in a hotel/motel/boarding house would all be associated with HCV infection. The study results were consistent with those hypotheses, to a limited degree, though these results were not borne out in the adjusted analyses. Perhaps a larger sample size would assist in determining if indeed those results could potentially be significant.

Age did show a statistically significant relationship with HCV only when dichotomized as "younger" and "older". This could be due to high American acculturation in individuals who are in the U.S. for longer periods of time. It has been

shown that higher levels of acculturation are associated with an increased likelihood of unhealthy behaviors that may have an adverse effect on a person's health and a decreased likelihood of exhibiting health promoting behaviors (Ebin et al., 2001). However, with the decline of HCV infection due to blood transfusion in the present day, once a significant contributor to HCV infections in the U.S., there may be a potential confounder in this relationship (Sy & Jamal, 2006; van den Berg et al., 2007). Still, this potential finding is similar to a study linking older age (greater than 35) to an increased probability of HCV infection (Spradling et al., 2010).

Another important finding was that being born outside the U.S. is a potential protective factor when compared to being born in the U.S. While the HCV literature is lacking in this form of investigation, the HIV literature has examined the effects of place of birth and health (Delgado, Lundgren, Deshpande, Lonsdale, & Purington, 2008). Country of birth (U.S./non-U.S.) was significant in all analyses. This finding hints at the possibility that recently arrived immigrants may be healthier than Hispanics/Latinos who have been in the U.S. for a longer period of time (consistent with the "Hispanic paradox" theory). According to several studies, the longer Latinos stay in the U.S., the less healthy they generally become, with American acculturation associated with poorer health (Delgado et al., 2008; Lara, Gamboa, Kahrramanian, Morales, & Bautista, 2005).

The finding that being born outside of the U.S. could be a potential protective factor is consistent with studies that have shown that U.S. immigrants have better health outcomes than U.S.-born Americans in chronic noninfectious disease (Singh & Hiatt, 2006; Wei, Valdez, Mitchell, Haffner, Stern, & Hazuda, 1996). Unfortunately, HCV is an infectious disease and immigrants do not have the advantage in all diseases. For example,

a majority of recent U.S. immigrants are from the third world where the incidence and prevalence of many infectious diseases are higher than in the United States. For example, of all the tuberculosis cases diagnosed in the U.S. in 1999, 43% were from foreign born immigrants (CDC, 2001). Both hepatitis A and hepatitis B infections are more common in immigrants than in U.S.-born individuals (McQuillan, Coleman, Kruszon-Moran, Moyer, Lambert, & Margolis, 1999; Wasley et al., 2007). In addition, foreign-born Americans have been reported to be associated with a high risk of *H. pylori* seropositivity and *Toxoplasma gondii* infection (Everhart, Kruszon-Moran, Perez-Perez, Tralka, & McQuillan, 2000; Jones, Kruszon-Moran, Wilson, McQuillan,Navin, & McAuley, 2001). Along with this, the results of the present study show that participants living in the U.S. for 5-15 years have lower odds of being infected by HCV when compared to those living in the U.S. for less than 5 years; however, beginning in the 16$^{th}$ year (unadjusted odds) and after the 21$^{st}$ year (adjusted odds) the odds of infection increase. While these results are not statistically significant, it hints at the possibility that there may be some sort of dose-response relationship between number of years living in the U.S. (or possibly American acculturation, which can be hypothesized to increase the longer a person lives in the U.S.) and HCV infection. The "healthy immigrant" effect coupled with a higher incidence of infectious diseases in third world countries could essentially be cancelling each other out and possibly causing non-significant results when adjusting for other variables in the study.

When compared to females, males tended to be less likely to have HCV infection. This finding is contrary to what was hypothesized. Given the sheer gender difference in the sample (males accounted for 87.5% of the sample) it was assumed that statistically,

males would be associated with HCV infection, even if not statistically significant. This finding suggests the possibility that if the sample were equal in terms of gender, perhaps a significant result would be obtained. A suggestion for further research would be to oversample females in order to obtain a more equitable distribution and then analyze the results.

Many studies indicate that injection drug use is the main mode of HCV transmission (Rustgi, 2007). There is a need for the scientific community to understand what risk factors are shared between different Hispanic/Latino groups and the generally well-studied Caucasian, non-Hispanic/Latino population. Once the scientific community understands what risks are shared, then research can focus on what is different between not only Caucasians (Non-Hspanic/Latino) and Hispanics/Latinos, but what are the different risk factors within the Hispanic/Latino ethnicity. For example, while overall injection drug use is a risk factor for HCV infection, the risk may be differential depending on the race-ethnicity of the participant. For example, in some studies, Asian patients had a negligible risk of HCV related to IDU versus a very prevalent exposure in Hispanics/Latinos and African Americans (Celona et al, 2004). Unfortunately, this study did not have a large enough sample of other Hispanic/Latino populations in order to stratify analyses and examine HCV risk associated with injection behavior by different nationalities. Further studies should seek to perform those stratified analyses and attempt to ascertain if there are different risks by different Hispanic/Latino nationalities. Knowing this would help researchers design and tailor interventions to different groups depending on their risk level.

While the present study did show a positive association between injection frequency and HCV infection, knowledge of the infectivity rate of HCV informs the healthcare community that just one infected needle will be enough to infect the user. Given the high prevalence of HCV in the IDU community, every time a dirty needle or any paraphernalia is re-used, there is a very high probability of being infected with the HCV virus. While not significant in the adjusted odds ratios, use of a dirty cooker approached significance and should be studied further as a possible risk factor for HCV infection. This finding should be explored further as it has been shown that drug paraphernalia, particularly cookers, can transmit the HCV virus (Hagan et al., 2001).

An unexpected finding of this study was that having two or more sex partners in the past three months was negatively associated with HCV infection. Having more sex partners was not expected to act as a protective factor. To date, there is no known study that confirms this finding. One explanation for this may be that a participant with more sexual partners may be more likely to use barrier protection when compared with a participant with fewer sexual partners. The individual still may become infected through their injection behavior, therefore that sexual/injection behavior dynamic should be explored further. This particular study did not address condom use in this population, therefore a suggestion for further research would be to more closely examine the sexual habits of IDUs and determine if their infection status may lead to protective behaviors in certain areas, such as their needle sharing behaviors. Care must be taken when referencing this finding however, because this variable was not significant in the backward regression model, meaning that it could be a potential confounder. Further research is necessary in order to solidify this finding.

The debate with respect to the sexual transmission of HCV continues with evidence on both sides of the issue. Currently, the CDC considers HCV infection from sexual contact to be extremely low, and some may say that the evidence for HCV infection due to sexual contact is weak (CDC, 2008; Alary et al., 2005). Again, the literature is quite sparse in this area, possibly because of the CDC's determination. There is however, a rapidly growing body of literature, particularly focusing on the MSM population that is currently investigating sexual contact as a single risk factor for HCV.

*Study limitations*

Several study limitations are noted. First, the cross-sectional design of the original study did not allow a determination of whether HCV infection occurred before or after any injection behavior. True quantification of sex partner relationships and injection frequency could also not be known with certainty due to the original study's reliance on self-report and retrospective data. Given the selection criteria for the study (current IDUs, Hispanic/Latino origin), and the location of the study (Miami, FL), these findings cannot be generalized to other groups of IDUs or other cities in the U.S. Other limitations to this study include a small sample size (a larger sample would provide more power, adding to the significance of the results), lack of female participants in the study, as well as low numbers of participants from the ethnicities besides Puerto Ricans. In addition, the snowball sampling technique does not ensure that the sample is a representative sample of all Hispanic/Latino IDUs in Miami-Dade County, FL.

*Suggestions for further research*

As mentioned before, further research in this area should concentrate on the sexual habits of the IDUs and determination as to whether their sexual habits change due

to their HCV status. Additionally, there are no definitive studies that either support or refute sexual activity as a risk factor for HCV. Further research should determine exactly how much of a risk factor sexual activity presents. This type of research would allow a determination about whether to continue studying the behavior or refocus efforts on intravenous drug use.

Another suggestion for further research is to expand the current sample in order to ensure that there are large enough groups of participants that were underrepresented in the current study. For example, a future sample would include more women as well as more people who identify themselves as being of Hispanic/Latino ethnicity and are from groups that did not have large numbers in this sample (Mexican, Central Americans, South Americans and Dominicans). Given that targeted, individual-level HCV prevention strategies are still needed, there is a need to move from the theoretical realm and into the applied world, develop comprehensive prevention programs for HCV-negative IDUs and harm reduction programs for HCV-positive IDUs, and evaluate and refocus those programs for maximum efficiency (Birkhead et al., 2007; Herbst et al., 2007; Edlin & Carden, 2006).

Lastly, little research has been done on the effectiveness of interventions such as syringe exchange and harm reduction techniques associated with drug use paraphernalia in HCV-positive samples. To determine the effectiveness of such interventions, epidemiologic research would be invaluable. Research into the impact of care and treatment, in light of recent advancements should also be conducted.

The framework for HCV education exists today. Given that HIV and HCV follow the same trajectories in terms of epidemiology and routes of infection, HCV education

can be incorporated into current HIV educational programs. It is important to note that while the HCV education program could be incorporated into extant HIV programs, actual interventions against both infections may not be the same. As suggested by Mateu-Gelabert and colleagues (2007), the current HIV interventions retooled for HCV are practically non-existent and those that do exist are simply not working. Educational programs must first be instituted (with the help of current HIV education programs), but interventions must be created from the ground up in order to meet the challenges presented by HCV infection. This is especially important when designing interventions that are culturally tailored to the different Hispanic/Latino groups in the U.S. For example, HCV interventions should focus on IDUs, particularly the reduction in number of exposures by the user. This could potentially be coupled with a needle exchange program (even in light of the political obstacles to that approach). In addition, the reduction in exposure (injection frequency) will likely be achieved via a standard IDU prevention program but would be limited by the success of these types of programs.

It has been suggested that prevention programs reassess and refocus their efforts and improve their targeting, selection, and delivery of their prevention messages (Bertozzi, Laga, Bautista-Arredondo, & Coutinho, 2008). It is now time to do just that (re-assess, refocus, and target prevention programs), and strive for more efficiency in delivering these messages. This effort requires better understanding of the intricate dynamics and differences among IDUs, and the differences in their behaviors with regards to their ethnic background. Knowing these differences and targeting them will lead to better prevention programs.

*Conclusions*

The burden of HCV on the Hispanic/Latino population is high. It is entirely possible that even with all that is known in this area, not all HCV cases are reported, suggesting that prevalence and incidence rates may be even higher than reported. These realizations lend credence to HCV's unofficial title of "the silent epidemic" (Edlin, 2011; Mitchell, Colvin, & Palmer, 2010). HCV suffers from several issues that impede researchers. First, its asymptomatic nature does not seem to cause enough "urgency" in the population. More importantly, HCV simply does not benefit from the advocacy enjoyed by other diseases, such as HIV (Edlin & Carden, 2006; USDHHS, 2001). For example, in 2006, world governments committed themselves to scaling up HIV prevention and treatment responses (UNAIDS, 2007). Even so, while treatment access has expanded rapidly, the number of new HIV infections has not decreased (UNAIDS, 2007). HCV is going to need a commitment of that magnitude, and perhaps even larger, in order to reduce incidence and prevalence rates in the population. Resources are needed to strengthen and standardize the current infrastructure to best support identified and unknown infected cases. National funding should be increased so that new cases are prevented, and existing cases are identified and linked to care. The latter would prevent secondary transmission and disease progression to advanced stages, essentially saving healthcare dollars.

In conclusion, current research into HCV, its transmission routes, and effective, culturally adapted interventions aimed at reducing its impact on the Hispanic/Latino population is just beginning. The breadth of research required to fully understand the HCV epidemic will continue to be uncovered as more information emerges. This study is

one of hopefully many others that will add to the current body of knowledge that can be used to inform health policy and planning decisions regarding identification of risks, effective interventions and resource allocation.

# CHAPTER VI

# PROPOSAL OF A TARGETED, THEORETICALLY-BASED HCV PREVENTION INTERVENTION

There have been a few attempts at primary prevention of HCV within at-risk populations. In the past 20 years, only 18 studies have been identified that are interventional in nature and describe a primary prevention intervention targeting IDUs and aiming to reduce the incidence of HCV (Wright & Tompkins, 2006). Of the 18 studies identified in this time period, only four studies were conducted in the U.S. that included or possibly included Hispanics/Latinos (Hagan et al., 1999; Hagan, Des Jarlais, Friedman, Purchase, & Alter, 1995; Kapadia et al., 2002; Thiede, Hagan, & Murrill, 2000).

For the purposes of developing a targeted intervention aimed at reducing HCV infection in the Hispanic/Latino IDU population, individual risk factors that were found to be significantly associated with HCV infection will be targeted for behavioral intervention. The intervention will be tailored around 1) assessing the individual's readiness to change the selected behavior via an algorithm developed by Cabral et al. (2004), and 2) systematic activities aimed at moving individuals from one stage of change to another, with established outcomes needed to successfully move to each successive stage.

Given the results of the study, targeting IDUs who inject every day of the week would be the ideal group to target for this HCV prevention intervention. The following is a proposal for a targeted intervention that will attempt to change the injecting behaviors of the target population. In this particular case, the target behavior would be to reduce the

weekly injection frequency to a target of a maximum of three times a week versus every day of the week.

*Intervention Development*

There have been several studies that have looked at the TTM as an effective model for behavior change in IDU's (Appel, Ellison, Jansky, & Oldak, 2004; Booth et al., 1996; Booth et al., 1998; Neff & Zule, 2000, 2002). In addition, the TTM served as the basis for CDC's AIDS Community Demonstration Project, which is "A Successful Community-Level Intervention to Reduce HIV Risk" (CDC, 2007). There is also an abundance of research that has examined readiness to change as factors in substance abuse treatment retention and outcomes (Annis et al., 1996; Avants, Margolin, & Kosten, 1996; Carboni & DiClemente, 2000; Connors et al., 2001; DiClemente & Hughes, 1990; Goldbeck, Myatt, & Aitchison, 1997; Gwaltney et al., 2001; Longabaugh & Wirts, 2001; Maisto, Carey, & Bradizza, 1999; Prochaska & DiClemente, 1983; Prochaska, Velicier, DiClemente, & Fava, 1988; Ramsey et al., 2000; Reilly et al., 1995). No research was found however that covers Hispanic/Latino IDUs specifically. However, the supporting evidence shows that the TTM methodology is an effective intervention for this group (IDU's), and the TTM's flexibility allows it to incorporate cultural elements that may lead to better outcomes in drug treatment programs (Warner et al., 2006).

This proposed TTM intervention for Hispanic/Latino IDUs would focus on participants who report injecting at least once a day. The first step of the intervention would be to identify and recruit participants for the program. Trained community outreach workers, along with peer educators would disseminate materials advertising the intervention in the community. Potential participants would have the option of

anonymously contacting the project staff in order to request more information about the program. In addition, the program would benefit from a website where participants can learn more about the program as well as HCV infection. The website would also feature a simple algorithm aimed at assessing a participant's willingness to reduce their injection frequency to at least three times per week. The website will have an option for the potential participant to leave contact information and program staff may contact that participant at a later time or through real time chat sessions or personal contact. The use of the internet has been somewhat successful in providing information and surveying drug addicts, mainly methamphetamine users (Recovery and Treatment of Crystal Meth, 2012) as well as those with chronic diseases, and substance abuse problems such as nicotine and alcohol addiction (Copeland & Martin, 2004). It is theorized that the internet's interactivity, flexibility, relative availability and most of all, confidentiality will allow users to be more forthcoming, improving the reliability of responses (Copeland & Martin, 2004; Miller & Sønderlund, 2010). Participants who are not ready to be in an intervention can be redirected to a general informational site about drug use and HCV.

Another proposed outreach technique would be to arrive at a specific location every day at the same time in order to create awareness and an expectation by the potential participants. Finally, it would be important that the community outreach workers be as diverse as the population served, hence it would be important that the worker be of the same Hispanic/Latino background (preferably same country of origin) as the participants in the intervention.

Participants eligible for the program would include any IDU over the age of 18 who injects every day of the week. HCV seroprevalence will not be a factor in

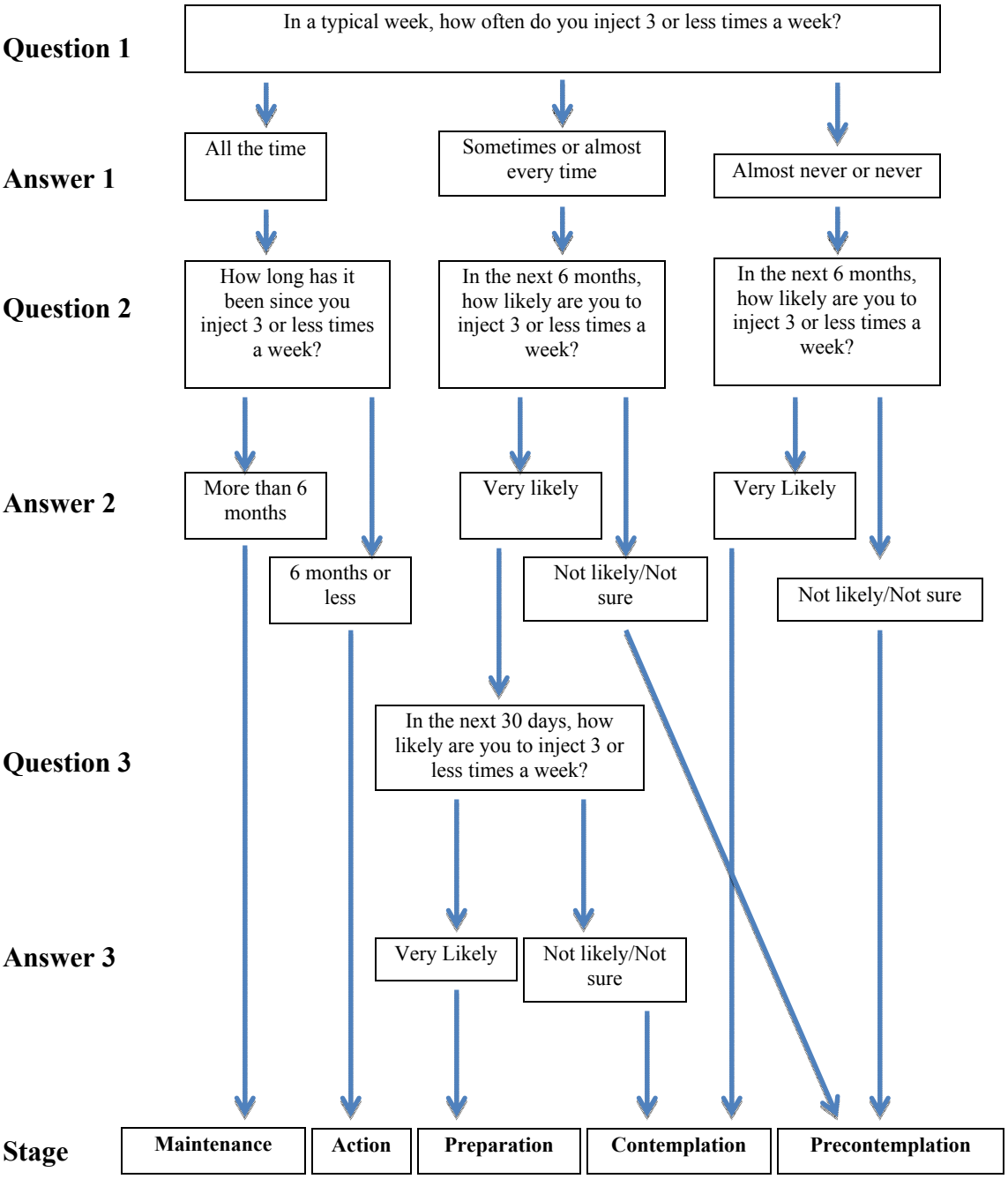


*Figure 1*. Algorithm for stage of change assessment. Adapted from Cabral et al. 2004.

determining whether a person may participate in the program. All interviews would normally be done in a group format, as it will be the most financially feasible format.

There is however, room for individualized consultations should it be deemed necessary by the counselors.

The next step in the intervention program would be to assess the stage of readiness for change in each potential participant. Utilizing an algorithm developed by Cabral et al. (2004), the participant's current stage of readiness may be determined by asking a series of questions. Depending on the answers given by the participant, the stage of readiness will be determined (See Figure 1).

There are three main staging questions that can be utilized to determine the participant's stage of change. The first question is "In a typical week, how often do you inject three or less times a week?" The second question is "How long has it been since you injected three or less times week?" OR (depending on the answer), "in the next 6 months, how likely are you to inject three or less times week?" Finally, a third question will differentiate between participants in the "preparation" or "action" stages. These questions could be asked as part of a focus group or as part of a one-on-one interview.

Once it is known in what stage the participant is in, then the tailored intervention can begin. Figure 2 shows all the different stages, their definition as it pertains to this intervention, the activities aimed at moving the individual from that particular stage and the minimum desired outcome.

*Precontemplation Stage*

Participants in this stage either have no intention of injecting three times or less in the next six months or are unaware that there is a problem with their behavior. Given that cognitive and emotional processes facilitate movement in these stages (Cabral et al., 2004), activities in this stage will be aimed at raising consciousness and self-reevaluation.

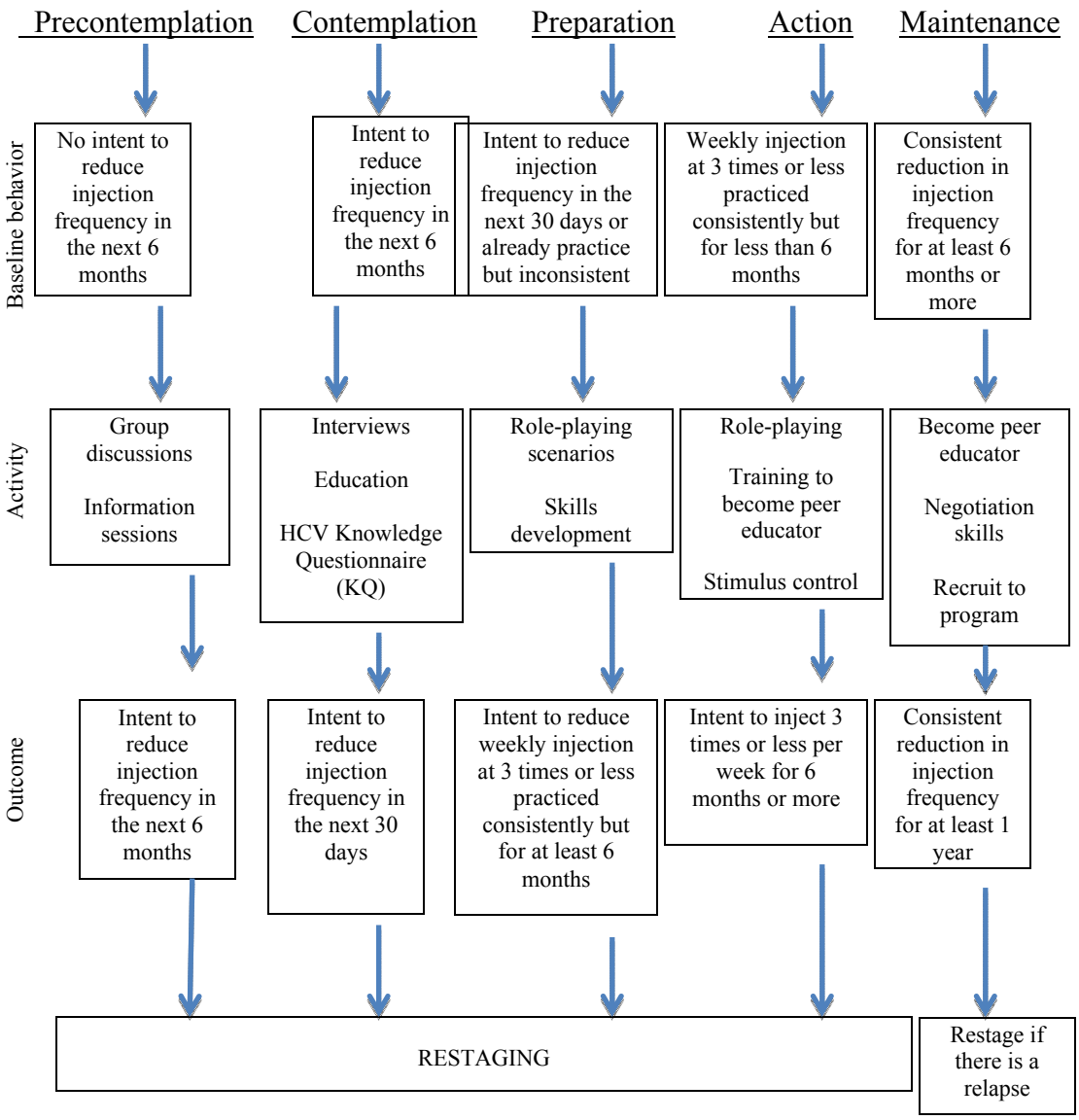


*Figure 2*. Intervention design for Hispanic/Latino IDUs

These interviews and education are aimed at clarifying with participants that it is their responsibility to make the decision about behavior change. A technique employed during interviews will be to identify and evaluate the pros and cons of their current behavior; the same process will be used for the behavior change. In addition, the participant is encouraged to identify and promote new and positive outcome expectations.

Overall, the purpose of these activities is raise awareness in the individual about their behavior. Once the individual is aware that their unhealthy behavior may be directly related to their health status, it is hypothesized that they may be ready to enter into another stage of readiness.

This process is designed to occur over 60 days maximum, at which time the participant will be once again assessed as to in which stage of change they currently find themselves. If the stage has not changed, individualized counseling sessions will be scheduled in order to more thoroughly raise the participant's awareness about HCV. If the stage has changed, then the individual will progress to the appropriate category. Successful movement by the participant from this category into the next category entails a solid commitment to reduce injection frequency in the next six months.

*Contemplation Stage*

Participants in the contemplation stage recognize the need for behavior change but either lack motivation or lack the skills necessary for action. In this stage, it is important to let the participant know that the decision to inject less frequently (three or less times a week) is theirs alone.

An effective tool that could be used at this stage is an HCV knowledge and attitudes questionnaire. While to date there are no valid and tested questionnaires that assess HCV knowledge among Hispanic/Latino groups, there are several baseline questions that may be asked (Evans, 2005). The HCV knowledge and attitudes questionnaire will be used as a gauge to determine if the participant is ready to move on to the next stage. It is very important to have a valid and reliable tool at this stage (as well as the preparation stage) because it is important that participants are not prematurely

moved to later stages of the program because the relapse rate may increase dramatically (MacMaster, 2004).

A good model for an HCV knowledge questionnaire (HCVKQ) could potentially be developed from the HIV Knowledge Questionnaire (HIVKQ) developed by Carey and Schroeder (2002). This is a brief (18 item) questionnaire that assesses a participant's HIV knowledge level. Higher scores (16-18) indicate a proficient understanding of HIV-related knowledge (Carey & Shroeder, 2002). An HCV knowledge questionnaire should be developed and would be a useful tool for this intervention. Attitude questionnaires have been successfully used for HCV behavioral interventions and could be combined with an HCV knowledge questionnaire and adapted for this population (Eassa et al., 2007).

Focus groups will also be utilized to obtain more thorough information about the participants' HCV knowledge. Utilizing the topics from the focus group, the counselor could lead informational sessions that target the participants concerns and educates them about HCV.

In addition to administering the HCVKQ, continuing educational sessions would be administered. These sessions are aimed at continuing to increase awareness and knowledge about HCV and the need to reduce injection frequency to three times or less per week. Motivational interviewing would also be utilized as one of the techniques that will move participants into the next stage. In addition, one-on-one interviews may be conducted in order to assess any potential barriers that may prevent the reduction of weekly injection frequency. During these sessions, techniques for overcoming these barriers will be discussed and practiced.

After a period of 60 days, the participant will once again be assessed for their current state of readiness. If participants remain in the current stage, then more individualized attention will be given to them in order to determine the barriers to change. If the participant regresses, then they will receive individualized attention in order to prevent further relapse. If the participant progresses, then they will move to the next stage of readiness. Successful movement by the participant from this category into the next category entails a solid commitment to reduce injection frequency in the next 30 days.

*Preparation Stage*

Individuals in this stage may need new skills for making change. Participants may have had some experience with behavior change and are generally "testing the waters." At this stage, it is important that the individual practices the desired behavior. Given this, role playing activities and negotiating skills will be the primary foci of this stage. The participant will be expected to identify obstacles and/or assist in problem solving. During this stage, the participant may also be required to identify and access social support.

Participants in this stage will also be shown that they may have underlying skills for behavior change. Through role playing and constant practice scenarios, the participant will be encouraged to take small steps to increase the desired behavior. This stage may be one that takes the longest, therefore assessment of the stage will occur monthly for three months in order to ensure that the behavior is being performed consistently.

If the participant regresses to a lower stage, individualized counseling along with more contact with peer educators will be conducted. If the behavior is found to be consistent over a period of three months, then counseling will continue until six months,

at which time the participant will once again be restaged. If the participant is found to have progressed and has maintained the healthy behavior for six months, the participant will progress to the next stage. Successful movement by the participant from this category into the next category entails attempting to reduce injection frequency to three times or less per week for at least six months.

*Action Stage*

Individuals in this stage have been practicing their behavior for less than six months. During this stage, it is important to continue reinforcing the desired behavior in order to avoid relapse. It is during this stage that role playing is done more frequently, with the participant assuming not only the roles of the person attempting to reduce their injection frequency, but also the person pressuring or avoiding reduction of weekly injection frequency. In addition, participants in the later stage can train to become peer educators. As a peer educator, they will be trained in the TTM, will learn to assess participants on their stage of readiness, and recruit participants into the program. Additionally, participants in this stage will learn stimulus control as part of their maintenance of healthy behaviors. At the end of three months, the participants will be assessed again. If they have relapsed, then more in-depth counseling will be performed. Specific "triggers" will be identified and coping strategies will be discussed in order to avoid further relapse. Participants who progress will be moved to the final stage. Participants who do not progress will remain in this stage with more individualized counseling. Successful movement by the participant from this category into the next category entails reduction of injection frequency to three times or less per week for six months or more.

*Maintenance Stage*

Individuals in this stage have been consistently performing the desired behavior for no less than six months consecutively. It is during this stage that participants make a commitment to program staff to continue the behavior for at least one year. Participants in this stage learn to focus on restructuring cues and to access social support whenever needed. During this stage as well, participants are taught to "reward themselves in healthy ways" and make those rewards reinforce their healthy behavior. During this stage, participants are also taught to deal with possible relapse and how to cope with that scenario.

Participants in this stage also have the option of becoming peer educators as well as outreach workers, will also be able to teach negotiation skills to other participants, and recruit participants. All of these activities are aimed at suppressing any triggers and continue the healthy behavior. Successful movement by the participant from this category into the next category entails successfully reducing injection frequency to three times or less per week for at least 12 months.

*Relapse*

Relapse is a concept that is dealt with early in the program in hopes of averting it completely. It is expected that a significant percentage of the participants will relapse to their unhealthy behaviors (in this case, more frequent injecting). A majority, up to 90% of IDUs who seek drug counseling services, are not in the action stage (MacMaster, 2004). If an individual experiences a relapse, the first thing that should be done is to evaluate the "trigger." Once identified, it would be easier for the participant to identify that particular trigger in future situations and be able to cope accordingly. At this point, peer educators

and case workers will work with the participant in order to reassess their motivation and identify any barriers they may be experiencing. Stronger coping strategies will also be discussed. At the end of each cycle, participants will be restaged in order to make sure they are not relapsing. If they are relapsing, then appropriate and more aggressive measures will be taken in order to have participants stay in the program. Another reason for restaging after every stage is that risk behaviors are dynamically interacting with each other, and IDUs may circle between stages of behavior change several times before achieving a successful change (Prochaska and Velicer, 1997).

*Discussion*

Prochaska and DiClemente (1982) categorized change processes into verbal (cognitive-affective) and behavioral, indicating that each set of strategies were more appropriate during certain stages of the model. These processes of change were defined as the strategies that assist the change process and include consciousness raising, self-reevaluation, self-liberation, counterconditioning, stimulus control, reinforcement management, helping relationships, dramatic relief, environmental reevaluation, and social liberation (Petrocelli, 2002; Prochaska & DiClemente, 1982). Each change process is thought to elicit a specific change behavior, thus initiating the movement to the next stage, as outlined in the TTM (Petrocelli, 2002).

Studies show that behavior change is a gradual process (Cabral et al., 2004). Cabral (2004) measured effects for two years after an intervention, and cautioned that sustained intervention may be necessary past that time. In addition, several techniques have been identified that make this intervention work: use of theory; integration of programs in the community; use of culturally adjusted role model stories and counseling

activities; use of peers as educators and outreach workers; repetition of the messages through multiple outlets; and multiple contacts with project staff have been identified as markers for success in a program such as this one (Cabral et al., 2004).

In addition, it is imperative that a program evaluation be conducted to ensure that the intervention is doing what it was designed to do. In order to achieve this, data should be collected as part of the program. When participants enter the program, their current state of readiness could be recorded. After a period of three years, when enough time has passed to allow for several cohorts to complete the program, participants could be re-assessed as to their current state of readiness reduce their weekly injection frequency. A significant positive result would be the finding that more people in the sample are at later stages of readiness compared to the baseline.

If the program does not produce desired results, then it will be reworked, with input from the community to assess where the program is failing and how more individuals could be moved into a maintenance stage of less frequent weekly injection. Finally, this progran could be one of many, for example with a second program aimed at reducing injection frequency to just once a week and eventually no injections at all.

*Possible barriers*

While the advantages of this program have been discussed as well as the theoretical framework utilized, there are admittedly several drawbacks. First, no single theoretical model can account for the diversity in behavior. However, reviews of journal articles published in the past two decades across a broad range of health behavior topics have revealed that along with the Health Belief Model (HBM) and the Theory of

Reasoned Action (TRA), the TTM is a popular and effective theoretical framework to use in many cases (Glanz & Bishop, 2010).

Second, moving individuals from one stage of change to another may take a long time. Individuals may drop out or move, leading to loss of the program's ability to conduct follow-up. Loss to follow-up may potentially be a significant challenge in this program, since most of the intervention consists of repeat visits to seminars and focus groups. Since the program will be tailored to different Hispanic/Latino nationalities, there must be a cultural component included. Unfortunately, the cultural component will be as varied as the different nationalities. This variety will not be known until there is a pilot phase and it is understood what type of cultural component works best with the selected population. There also is no "brief" version of the program, and HCV educators must be aggressive in getting participants to stay for the entire length of the program. Finally, to date there is no comprehensive HCV knowledge questionnaire that could serve as a measure for assessing baseline knowledge of HCV by potential participants.

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APPENDIX 1

Selected items from The Modified AIDS Risk Behavior Questionnaire

1. What is your date of birth? _____
2. That makes you how old? _____
3. Gender of Respondent

   -Male

   -Female
4. Where were you born? _____
5. How many years have you lived in the U.S.? _____
6. Do you consider yourself to be Hispanic or Latino?

   -Yes

   -No

   -Refuse to answer
7. Which of the following best describes your ethnic background? Please check all that apply.

   -Mexican

   -Central American

   -South American

   -Puerto Rican

   -Cuban

   -Dominican

   -Spaniard, from Spain

-Refuse to Answer

8. What is the highest level of education you have completed? (Choose one)

   -8th grade or less

   -Some high school (9th to 11th grade)

   -High school graduate (12th grade) or GED

   -Some college or technical training

   -College graduate or higher

   -Refuse to Answer

9. What was your total household income from all legal sources last year? (Choose one)

   -Less than $5,000

   -$5,000 - $9,999

   -$10,000 - $14,999

   -$15,000 - $19,999

   -$20,000 - $24,999

   -$25,000 - $29,999

   -$30,000 - $34,999

   -$35,000 and above

10. Which one of the following best describes your work situation in the LAST 3 months? (Choose one)

    -Regular full-time work (30 or more hours a week)

    -Regular part-time work (Less than 30 hours a week)

    -Labor pool work

    -Occasional work (daily)

-Unemployed (actively seeking for a job)

-Retired

-Unable to work – disabled

-Homemaker

-Student

-Other: (Specify)_____

11. What is your current marital situation? (Choose one)

-Single

-Officially married

-Divorced

-Widowed

-Refuse to answer

12. Where were you living during most of this 3 month period? (check all that apply)

-Your house or apartment

-Spouse's house or apartment (if you do not consider this your own home)

-Girlfriend/boyfriend's house or apartment

-Parent's house or apartment

-Other relative's house or apartment

-Friend's house or apartment (not a sex partner)

-A hotel

-A rooming or boarding house

-A halfway house

-A shelter

-A welfare boarding home

-Abandoned building

-On the streets (a vacant lot, park, car)

-Jail/prison

-Some other place I haven't mentioned (SPECIFY) _____

13. In a typical week that you inject drugs, how many days do you inject at least once a day? (Choose one)

-1 day per week

-2 days per week

-3 days per week

-4 days per week

-5 days per week

-6 days per week

-7 Everyday

14. On the days that you inject, how many times do you inject? _____

15. Of the times you injected in the past 3 months, how often did you inject using a needle or syringe that had been used by somebody else to inject? (Choose one)

-Always

-Almost Always

-More than half the time

-About half the time

-Less than half the time

-Rarely

-Never

-Refuse to Answer

16. Of the times you injected in the last 3 months, how often did you use a cooker with someone or after someone else used it? (Choose one)

-Always

-Almost Always

-More than half the time

-About half the time

-Less than half the time

-Rarely

-Never

-Refuse to Answer

17. Of the times you injected in the last 3 months, how often did you use cotton at the same time or after another person used it? (Choose one)

-Always

-Almost Always

-More than half the time

-About half the time

-Less than half the time

-Rarely

-Never

-Refuse to Answer

18. Of the times you injected in the last 3 months, how often did you use rinse water with

or after another person drew up water or rinsed their syringe in it? (Choose one)

-Always

-Almost Always

-More than half the time

-About half the time

-Less than half the time

-Rarely

-Never

-Refuse to Answer

19. How old were you when you first had sex? _____

20. Since you became sexually active, how many different sex partners have you had?

_____

21. How many different sex partners did you have in the last 3 months? _____

22. Of the people you currently know, how many inject drugs? (Choose one)

-None

-A few

-About 25%

-About half

-About 75%

-Almost all

-All

# VITA

## ARTURO E. RODRIGUEZ

| | |
|---|---|
| February 26, 1977 | Born, Bayamón, Puerto Rico |
| 2001 | B.A., Anthropology<br>University of Miami<br>Coral Gables, Florida |
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| 2008-2012 | Doctoral Candidate in Health Promotion and Disease Prevention<br>Florida International University<br>Miami, Florida |
| 1998-2001 | Research Staff Assistant<br>University of Miami School of Medicine<br>Miami, Florida |
| 2001 | Administrative Research Assistant<br>Mount Sinai Medical Center<br>Miami Beach, Florida |
| 2002-2004 | Grants and Contracts Manager<br>University of Miami School of Medicine<br>Miami, Florida |
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PUBLICATIONS AND PRESENTATIONS

Rodriguez, AE. (2009, November). *Hepatitis C Related Risk Factors Among Hispanic IDU's in Miami, Florida*. Poster session presented at the annual meeting of the American Public Health Association, Philadelphia, PA.

Rodriguez, AE. (2012, October). *Injection Drug Use (IDU) Paraphernalia and Hepatitis B and C Infection Associations in a Cohort of Puerto Rican IDUs in Miami, Florida*. Poster session presented at the annual meeting of the American Public Health Association, San Francisco, CA.