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# Hepatitis C Virus (HCV) and Human Immunodeficiency Virus (HIV) Opt-out Testing in a Southern Federally Qualified Health Center (FQHC)

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## ABSTRACT

### HEPATITIS C VIRUS (HCV) AND HUMAN IMMUNODEFICIENCY VIRUS (HIV) OPT-OUT TESTING IN A SOUTHERN FEDERALLY QUALIFIED HEALTH CENTER (FQHC)

By

LEAH MICHELLE PINHOLSTER

APRIL 29, 2019

**INTRODUCTION** The CDC recommends one-time HCV screening of all baby boomers and those at high risk for infection. Despite HCV being the most common blood-borne virus in the US, routine HCV testing is not uniformly practiced.

**AIM** To evaluate the prevalence of HIV/HCV screening prior to and following the implementation of a dual routine opt-out program, the linkage to care practices for positive patients, and the demographic characteristics of positive patients in a southern FQHC.

**METHODS** We conducted a retrospective, cross-sectional study using electronic health record data from patients receiving care at SMC in Atlanta.

**RESULTS** *Pre-implementation:* Of the 68 HIV+ patients, most were linked to care (97.05%), African American (95.59%), non-Hispanic (98.53%), and male (62.50%). Of the 89 HCV+ patients, most were African American (67.42%), non-Hispanic (97.75%), male (53.93%), and baby boomers (72.02%). There were 3 co-infected patients. *Post-implementation:* Of the 232 HIV+ patients most were African American (82.33%), non-Hispanic (93.53%), and male (58.19%). The linkage to care rate was 96.98%. Of the 274 HCV+ patients, 52.92% were African American, 94.89% were non-Hispanic, 55.84% were male, 79.71% were linked to care, and 77.38% were baby boomers. There were 13 co-infected patients.

**DISCUSSION** These results reflect the population SMC serves: non-Hispanic African Americans. The age distribution of the HCV+ patients matched the trends seen nationwide for the 1945-1965 birth cohort. There was a 286% increase for HIV tests. The increase in HIV/HCV testing and high linkage to care rates may partly be due to the hiring of an Infectious Disease specialist in 2015.

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TESTING IN A SOUTHERN FEDERALLY QUALIFIED HEALTH CENTER (FQHC)

by

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B.S., UNIVERSITY OF GEORGIA

A Capstone Submitted to the Graduate Faculty  
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APPROVAL PAGE

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## Author's Statement Page

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Leah Pinholster  
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## Chapter I. Introduction

This chapter will cover the following topics: hepatitis C, the similarities between HCV and HIV and the complications that arise from co-infections, an overview of Federally Qualified Health Centers, opt-out testing, HCV screening, and HCV treatment. This will inform a broader understanding of the need for routine opt-out testing in primary care facilities, the burden of HCV on the healthcare system, and the emerging HCV epidemic as a whole.

### Hepatitis C Overview

Hepatitis C virus (HCV) is a contagious infection that attacks the liver. It can begin as an acute infection, but in some instances the virus remains in the body, resulting in chronic disease and long-term liver problems. While there are vaccines for other viruses in the hepatitis family, there is no vaccine for HCV.<sup>1</sup> HCV is the most common chronic blood-borne pathogen in the US and a leading cause of complications from chronic liver disease.

Initial HCV infection is classified as an acute infection, often symptom-less, which the body can clear on its own in some cases. However, approximately 75-85% of those infected develop chronic infections due to the virus remaining in the body.<sup>1,2</sup> Chronic HCV can progress to chronic liver disease, cirrhosis, and hepatocellular carcinoma.<sup>23</sup> Progression rates to these complications vary, with one study approximating that 10-20% of patients will develop cirrhosis over 20-30.<sup>46</sup> For people who develop cirrhosis, the annual risk of HCC and hepatic decompensation is 1-5% and 3-6%, respectively. Once hepatic decompensation has occurred, characterized by the development of ascites and varices, a patient's risk of death in the subsequent year is between 15-20%.<sup>23</sup>

HCV is primarily transmitted when a person is exposed to infected blood. Past or current injection drug use (IDU) is the most common risk factor for HCV infection, with most studies reporting IDU as a factor in more than 50% of cases.<sup>10</sup> Other transmission pathways of HCV include needle stick injuries in the medical field, blood transfusions, being born to a mother who has HCV, organ transplants, hemodialysis, and sexual contact with an infected person. The risk of contracting HCV from sexual contact with an infected person increases for those who have multiple sex partners, those who have a sexually transmitted disease (STD), those who engage in rough sex that could cause bleeding from the penis or

vagina, and those who are infected with HIV.<sup>1</sup> Sharing items such as razors or toothbrushes and non-hygienic practices with tattoos and piercings are less common modes of transmission. Before 1992, HCV was most commonly spread through blood transfusions and organ transplants due to the lack of blood screening. Equipment-related transmission, whether IDU paraphernalia or other, is especially hazardous, as the virus can survive outside the body at room temperature, and on environmental surfaces, for up to 3 weeks.<sup>1</sup>

### Hepatitis C Epidemiology

There are an estimated 3.2 million people living in the U.S. that have hepatitis C.<sup>1,2,3</sup> About 75% of those affected are unaware of their infection.<sup>1</sup> Due to the often symptom-less nature and slow progression of HCV, those infected may not be aware of their infection until complications from the disease have reached severe levels and available treatment options have become limited. IDU is the predominant mode of transmission, and co-infection with HIV occurs in a significant amount of those with HCV.

From 2010-2015, reported cases of acute HCV infection increased more than 2.9-fold, rising annually throughout this period. The increase in acute HCV case reports reflects new infections associated with rising rates of injection-drug use. The increase may also be due to improved case detection.<sup>1</sup> The Centers for Disease Control and Prevention (CDC) estimated that in 2015 there were 33,900 new HCV infections.<sup>1</sup>

For the state of Georgia from 2011-2015, the reported rate of acute HCV cases ranged from 0.5 to 0.8 per 100,000 populations.<sup>4</sup> These rates are calculated from newly reported cases of either present or confirmed past HCV infection per standard population of 100,000.

Nationwide, mortality among HCV-infected persons-primarily adults aged 55-64 years increased during 2006-2010 and HCV-associated deaths reached an all-time high of 19,659 in 2014. A study by Ly et al. found that the annual HCV-related mortality in 2013 surpassed the total combined number of deaths from 60 other infectious diseases reported to CDC.<sup>5</sup> These infectious diseases included HIV, pneumococcal disease, and tuberculosis.

The CDC's Division of Viral Hepatitis reports the number of death certificates nationwide listing HCV as a cause of death for each year as part of the HCV statistics and surveillance system. An HCV-related cause of death is defined as the primary cause of death

or one of the multiple causes of death with the International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) diagnostic codes B17.1 and B18.2 In 2010 the number of death certificates was 16,627. The number increased each year and in 2014 the total number was 19,659. The CDC notes that these numbers represent only a fraction of deaths that can be attributed wholly or partly to chronic HCV.<sup>2</sup> The majority of people who died of HCV-related causes were aged 55-64 years old, were American Indian/Alaska Native, and male.

HCV infection disproportionately affects several groups in regards to age, sex, race/ethnicity, and socioeconomic status. Baby boomers, those born between 1945 and 1965, males, people of color, people who inject drugs (PWID) and those of a low socioeconomic status have higher rates of HCV infection.

Baby boomers represent 75% of those infected.<sup>10,11</sup> This disproportion may be due to unsafe medical procedures conducted in the US in the years after WWII.<sup>15</sup> If baby boomers received an injection or blood transfusion during this time, they could have been exposed to HCV. Without a diagnosis and thus no treatment, they would have been at an increased risk to infect others.

Men have higher rates of chronic HCV than women. Baden et al found that women have a higher chance of spontaneously clearing HCV and those who do not clear the infection have a slower progression to liver disease.<sup>44</sup> A study by Franco et al found that men were less likely to utilize healthcare and more likely to partake in unhealthy behaviors, like smoking and alcohol abuse. Men were also found to be less likely to participate in preventative care and to view disease risk as less severe than women.<sup>11</sup>

Studies have shown that minorities have higher HCV prevalence. A study by Coyle et al found that there were more non-Hispanic black patients with current HCV infection than any other racial/ethnic group.<sup>12</sup> Between September and December 2009, a sample of 466 IDU in metropolitan Atlanta was surveyed to monitor behaviors associated with transmission of HIV.<sup>13</sup> The African American PWID had the highest percentages of both HIV and HCV. These survey results show the extent that these infections disproportionately affect different races. The Office of HIV/AIDS and Infectious Disease Policy released a compilation of facts focusing on HCV and African Americans in 2015.<sup>45</sup> Data from the National Health and Nutrition Examination Survey (NHANES) showed that between 1999

and 2002, African Americans had a prevalence rate of HCV that was more than twice that found in non-Hispanic whites. This increased rate may be due to higher rates of sickle cell disease and the subsequent need for blood transfusions during a time when blood screening was not as rigorous as it is today. In addition to infection rates, African Americans also have the highest rates of mortality from HCV.<sup>45</sup>

In recent years, a new wave of acute HCV cases has been developing in people who inject drugs.<sup>15</sup> Young, white people living in rural and suburban parts of the Midwest and Eastern US with a history of IDU were the predominant demographic of these new infections. This increasing population of young PWID has led to a doubling of reported acute cases since 2010.

Those who are uninsured or underinsured are also disproportionately affected by HCV.<sup>11</sup> Additionally, those who live in households with annual incomes <\$25,000, have a history of incarceration, are homeless, or are poorly educated show higher HCV prevalence than those who live in households with greater annual incomes, those without a history of incarceration, those who have stable housing, and those who are educated.<sup>8</sup> These populations of low socioeconomic status are also more likely to engage in risky behaviors such as drug use and less likely to have access to health care due to disproportionate placement of medical facilities.<sup>8</sup>

HCV does not occur evenly throughout the various geographic regions of the US. A 2017 study by Rosenberg et al., found that HCV infection has most impacted the western and southern regions of the US, with the west having the highest region-specific prevalence (2.14%), and the South having the highest number of persons testing positive for the presence of HCV antibodies (n=1561600).<sup>18</sup>

### Hepatitis C Virus (HCV) Burden

The increasing number of people in the US who are living with HCV, coupled with 75% of those infected being undiagnosed and unaware of their infection, puts a considerable burden on the healthcare system and on healthcare spending. If diagnosed early, patients can utilize treatments that are highly effective for the majority of infections and last two to three months.<sup>6</sup> Acute HCV infection can be symptom-less but some people experience fever, fatigue, dark urine, clay-colored bowel movements, abdominal pain, joint

pain, nausea and vomiting. However, when those infected do seek treatment it is often once the infection has become severe enough to indicate that there has been damage to the liver. At that point, the treatment options for severe liver-related conditions are limited and those that are available are costlier and more intensive than interventions used to treat acute HCV infection.

One of the groups at highest risk of HCV is the baby boomer population, those born between 1945 and 1965. As this population ages, HCV-associated morbidity and mortality rates are projected to increase over the next few decades.<sup>7</sup> This includes new cases of cirrhosis from HCV (by over 30% as of 2020), HCC, liver de-compensation, and liver-related deaths.<sup>3</sup> Currently annual direct costs are estimated to be \$1.1 billion, and indirect costs are estimated to be \$7.5 billion. Because so many infected people do not know they are infected, annual direct spending is expected to exceed \$10.7 billion between 2010-2019.<sup>7</sup> HCV and its associated complications have a significant impact on healthcare resource utilization and costs.

#### HIV/HCV Comorbidity and Epidemiology

HCV and HIV have many epidemiological similarities including risk factors, transmission routes, and disproportionately affected groups. Deaths due to HCV have exceeded deaths related to HIV/AIDS nationally since 2007.<sup>1,2</sup> Although HCV is a considerable burden on the healthcare sector, funding for HCV prevention and research continues to be less than funding for HIV efforts. In the 2017 FY request, \$39 million was proposed for viral hepatitis as part of CDC's HIV/AIDS, viral hepatitis, STI, and TB prevention programs, compared to \$788 million for domestic HIV/AIDS prevention and research.<sup>19</sup>

An estimated 20% of those infected with HIV are co-infected with HCV.<sup>12</sup> For people with HCV/HIV co-infection, the chance of liver-related morbidity and mortality is higher, even when the HIV infection is well controlled.<sup>22</sup> Continued effort for these federally funded programs is needed as the incidence of hepatocellular carcinoma increases in HIV co-infected patients. Co-infected patients account for 93% of hepatocellular carcinoma cases and studies have reported a 10-fold increase in mortality for these patients. Antiretroviral therapy and HCV therapies benefit co-infected patients and improve

prognosis.<sup>23</sup>

In 2016, Platt et al. conducted a systematic review and meta-analysis on studies that reported on HCV and HIV co-infection. The prevalence of HIV-HCV co-infection was found to be 2.4% in the general population, 4.0% in the pregnant population, 4.0% in the heterosexual population, 6.4% in men who have sex with men (MSM), and 82.4% in PWID. People living with HIV were six times more likely to have HCV co-infection when compared to their HIV-negative counterparts.<sup>15</sup>

In patients with HIV, the progression to cirrhosis is more rapid than in mono-infected patients. In the US, about 20% of HIV-infected patients are also co-infected with HCV. Across the world, patients with HIV are 6 times more likely to be infected with HCV than the general population. PWID are most likely to have co-infection, and in the US, 50% to 90% of HIV-infected PWID are also co-infected with HCV.<sup>24</sup>

Co-infection results in accelerated liver fibrosis, higher HCV loads, and poorer responses to interferon-based therapy when compared with HCV mono-infection. In the absence of HIV, about 25% of those infected will spontaneously clear HCV infection.<sup>25</sup> The rest will have persistent infection marked by ongoing viremia, a virus being present in the bloodstream. In HIV co-infection, the rate of spontaneous clearance ranges from 5-24%. In co-infection, the viral set point is increased in HIV infection with an HCV load more than 1 log higher than those who are HCV mono-infected. In chronic HCV infection, HIV-positive men are more likely to shed HCV RNA in semen than their HIV-negative counterparts. Some have suggested screening high-risk populations with HCV-RNA testing, as the humoral response to HCV appears to be delayed in HIV infection.<sup>43</sup>

As HIV-related mortality and morbidity have declined, HCV-related liver disease has increased. The availability of highly active antiretroviral therapy (HAART) has improved outcomes for those infected with HIV, however HIV/HCV co-infected patients continue to face hurdles in the treatment of their infections. HAART can lead to a decline in HCV liver-related mortality, but it can also increase risk of hepatotoxicity. Combining other drugs, such as pegylated interferon with ribavirin, has led to improved treatment outcomes; however, HIV continues to accelerate HCV liver-related conditions.<sup>26</sup>

Funding efforts for the treatment and prevention of HIV have had great success in combating the HIV epidemic. Due to the similarities between HIV and HCV and the rates of

comorbidity between the two infections, the model used to promote funding that addressed the HIV epidemic could also be used to address the emerging HCV epidemic. HCV-targeted funding would improve the lives of those living with HCV infection, as well as those at risk and those with HIV co-infection.

### Federally Qualified Health Centers

Federally Qualified Health Centers (FQHC) are an important part of healthcare, especially for those who are underserved and uninsured. FQHCs provide primary and preventive care including health services, oral health services, mental health services, and substance abuse services to anyone, irrespective of their insurance status. FQHCs are community health centers that are reimbursed by the Bureau of Primary Health Care and the Centers for Medicare and Medicaid Services of the US Department of Health and Human Services.<sup>32</sup>

In many areas of the south, community health centers are key players in the healthcare system and community health centers like Southside Medical Center provide care and support to communities that are underserved in healthcare; communities who also are most burdened by diseases such as HIV and HCV.<sup>33</sup>

Southside Medical Center (SMC) was founded in 1967 in southeast Atlanta and is one of Atlanta's largest FQHCs. A private, non-profit FQHC, SMC's mission is to serve the medically underserved and impoverished communities in metropolitan Atlanta.<sup>33</sup> The population around Southside consists of high rates of no insurance (16%) and poverty (24% of the population live below 200% of the federal poverty level).<sup>34</sup> Southside's client population is overrepresented in these aspects, 56% lack health insurance and 56% live below 200% of the federal poverty level. Southside Medical Center has 11 clinic sites in and around the Atlanta area. Clinics are located in the following counties: Fulton (4), Clayton (2), Henry (2), Butts (1), DeKalb (1), and Spalding (1). Southside serves over 30,000 patients each year. The majority of these patients are black (89%), female (68%), living below 200% of the federal poverty level (56%), and uninsured (56%).<sup>33</sup>

SMC has a unique position in the community in that it provides comprehensive care to all patients in both urban and rural settings, regardless of insurance status. This comprehensive care includes adult medicine, pediatrics, OBGYN, dentistry, optometry,

podiatry, mental health and substance abuse treatment, infectious disease, and an onsite pharmacy. Patients benefit from multiple specialties being housed in one site.

In June 2012, routine, opt-out HIV screening was implemented for all patients 13-64 years of age. Prior to this, routine screening was performed in the women's health clinic and at the behavioral health clinic.<sup>33</sup> In the 12 months prior to the start of the routine program, 812 patients were screened and 1.6% of those tested were HIV positive. 21% of eligible patients were screened for HIV from May 2013-April 2014. During this time, 0.7% of those screened were HIV positive and 99% were linked to care within 90 days of diagnosis. In the most recent 12 months of the screening program there were 6767 HIV tests conducted, 44 (0.7%) of which were positive. Routine HCV opt-out testing began two years later in March of 2014. Routine HIV/HCV opt-out testing at SMC was funded by Gilead's FOCUS Program.

The burden of HCV is clear; however, routine HCV screening is not implemented nationwide. Even when HCV and HIV testing occurs, the decision to test is mostly based on a patient's risk level, despite the CDC's 2012 recommendations.<sup>12</sup> Due to the similarities of both infections, dual HCV/HIV opt-out screening is one way to relieve some of the burden of these diseases. This study of Southside Medical Center's dual HIV/HCV opt-out testing aims to measure the impact of increased screening measures on patient health outcomes.

### HCV Screening

Screening and early detection are not only beneficial for patients, but are also cost-effective long-term. If screening were implemented broadly, the complications of HCV could decrease by 16-42%.<sup>3</sup> Furthermore, identification of HCV infection before the onset of long-term complications is shown to be cost effective and prevents transmission of HCV.<sup>8,9</sup> Despite HCV being the most common blood-borne virus in the US and the substantial scale and burden of the disease, routine HCV testing is not uniformly practiced.<sup>7</sup>

Screening for HCV leads to early diagnosis and thus earlier access to treatment, more treatment options of a chronic infection, prevents the development of HCV-related complications.<sup>27</sup> Implementation of screening programs leads to reduced mortality and improved outcomes overall.<sup>9</sup> Screening strategies include opt-out universal screening, opt-in testing, and risk-based testing. Choice of a testing strategy is likely influenced by the

perception of disease prevalence and budget limitations.<sup>27</sup> For diseases that are considered rare, risk-based testing would be less costly than opt-out testing due to the small number of cases in a population.

There are two tests used to detect HCV, an antibody test and a confirmatory test. The antibody test (anti-HCV or HCV Ab) detects HCV antibodies present in a patient's blood, which indicates the person has been exposed to HCV but hasn't necessarily developed a chronic infection. The confirmatory test detects the presence of HCV ribonucleic acid (RNA), which conclusively identifies those actively infected.<sup>7</sup> An estimated 30% of those testing anti HCV+ never receive an HCV RNA test to confirm current infection. This leaves them undiagnosed for chronic infection.<sup>40</sup> The U.S. Preventative Services Task Force (USPSTF) has determined that an anti-HCV antibody test and subsequent RNA test accurately detects chronic HCV infection.<sup>10</sup>

### HCV Treatment

Treatment for chronic HCV infection entails regular medical assessments by a primary care provider, and can involve specialists such as a hepatologist, gastroenterologist, oncologist, infectious disease specialist, and a primary care provider.<sup>7</sup>

Treatment of HCV has changed greatly since the first treatment, interferon, was approved by the FDA in 1991. Interferon injections boosted the immune system, rather than targeting the virus. The cure rate was 6%. A combination of interferon injections and ribavirin pills were used in the following years, and cure rates were about 50%. Treatment duration could last for a year, and side effects resembled those from chemotherapy. In 2011, cure rates increased to 70% when protease inhibitors, antiviral agents, were combined with interferon and ribavirin. Since 2013, the cure rate has exceeded 90% due to new antiviral agents. These new therapies consist of one-pill regimens and 3-pill regimens and are taken for 8-24 weeks. These medications have fewer side effects, are easy to take, and have an increased chance of cure for those who take them as prescribed.<sup>28,29</sup>

For those with an HIV/HCV co-infection, a specialist who has the expertise to select HIV and HCV therapies that do not have interactions will be needed.<sup>24</sup> People with chronic infection may also require continual access to a pharmacy, help with medical insurance issues, and emotional and psychological support, linkage-to-care coordinator, counselor,

on-site social worker, certified application counselor to complete the insurance process, and a bridge counselor or patient navigator.<sup>11</sup> Thus, a fundamental aspect of continuing treatment is linkage to care. When a patient is linked to care, he/she is provided access to these many facets of continued treatment, which increases the likelihood of better health outcomes.

Linkage to care does not have a universal definition. Generally, linkage to care is defined as attendance of a medical visit following a diagnosis within a specific time frame.<sup>30</sup> Linkage to care often falters, as it relies on infected individuals to be diagnosed, to be made aware of and have an understanding of their diagnosis, and to have access to care continuously over a period of time. There are several barriers to successful linkage to care because of the patient population and the natural progression of the disease. Franco et al found that substance abuse and psychiatric disease were prevalent in the cohort (37% and 30%, respectively) and that substance abuse was associated with LTC failure ((OR, 1.91; 95% CI, 1.17–3.11;  $P = .01$ ). Moreover, the strongest independent predictor of LTC failure was lack of insurance. These barriers have a significant impact on LTC, as it is estimated that more than 60% of individuals who have received a diagnosis are not engaged in care.<sup>11</sup>

### Opt-Out Testing

Opt-out testing occurs after a patient is notified that the test will be done. The test is carried out unless the patient refuses consent. Opt-in testing requires patients to specifically ask their healthcare provider to have the test.

In 2006, the CDC gave the recommendation that opt-out testing for HIV should be implemented for the general population.<sup>3</sup> In 2012, the CDC revised HCV screening recommendations to include one-time testing of all baby boomers and screening for those who are at high risk for infection (outlined above).<sup>11</sup> A downside of risk-based screening is that risk assessment is largely based on self-reported factors and thus reliant on a patient's cooperation and honesty. Patient reluctance to disclose risk behaviors and sensitive information can diminish the ability to reliably assess risk and can lead to a gap in risk behavior detection.<sup>8</sup> Because risk-based screening uses self-reported risk as a proxy for prevalence, it is difficult to accurately identify all modes of transmission. In facilities that utilize risk-based testing, reliance on self-reported risk factors is shown to limit case

finding.<sup>8</sup> Another downside to risk-based testing is that up to 45% of those infected do not know how they contracted virus.<sup>7</sup>

Routine testing at a primary care setting offers many benefits, however it is not commonly integrated into primary care. Primary care facilities are able to utilize reflex laboratory-based testing as well as support services necessary for patients to move from primary care to HCV care. Furthermore, a primary care provider known to and trusted by the patient can disclose test results as well as provide support and assist with the patient's treatment.<sup>7</sup>

Per the CDC's recommendations, a comprehensive prevention program incorporates testing for HCV, HCB, and HIV and rapidly links positive patients with appropriate medical care. For drug-related HCV positive patients access to substance abuse treatment as well as needle exchange programs will be needed.<sup>6</sup>

A 2014 study assessed the perspectives of primary care providers concerning HCV testing.<sup>31</sup> The providers who had not implemented the CDC's recommendations cited the increased amount of time needed to assess the patient's risk-factor history and to discuss sensitive, stigmatized behaviors. These providers were also concerned that health insurance would not completely cover HCV testing and treatment, and that patients would not receive the appropriate support needed for treatment.

## Chapter II. Literature Review

Of the available literature examining the implementation of HCV screening programs, only a few were focused on the efforts of primary healthcare settings and federally qualified health centers. Other available literature examined HCV testing in emergency departments or prisons and jails. While these models yield valuable information, the methods and diagnostic standards are not comparable to community healthcare settings. There continues to be a need for in-depth research into routine opt-out testing in primary care.

A 2016 study by Crumby et al. examined SMC and another FQHC in the south, Central Care in Houston, Texas. Like SMC, Central Care also implemented a comprehensive program for routine HIV screening and linkage to HIV care. The study reviewed medical record data to analyze patient-level health outcomes, the number of HIV screening performed, the number of positive HIV tests, and successful linkage to care for the 12 months before and after the start of the programs.<sup>33</sup> The results showed that out of the 52,437 eligible patients at SMC, 80% were offered an HIV test and 27% of those were tested. Among those screened, 0.7% were positive. Ninety nine percent of patients testing HIV positive were linked to care within 90 days. Compared to the 12 months prior to the start of the program, there was a 733% increase in conducted HIV tests, and a 238% increase in patients who tested positive. The majority of patients who received an HIV test were female, aged 23-40 years, non-Hispanic, and black. The majority of patients who tested positive for HIV at Southside were male, aged 31-50 years, non-Hispanic, and black.

Of the 22,658 eligible patients at Central Care, 48% were offered an HIV test and 91% of those were tested. Among those screened, 0.5% were positive. Seventy nine percent of those testing HIV positive were linked to care. Compared to prior to the start of the program, there was a 618% increase in conducted HIV tests, and a 600% increase in patients who tested positive. Non-Hispanic black females between the ages of 13-30 years represented the majority of the screened patients. The majority of those testing positive for HIV were black males aged 41-50 years. This study demonstrated the effectiveness of implementation of routine HIV screening programs that can dramatically increase testing volume and linkage to care. This model is beneficial to other community health centers

considering routine opt-out testing for HIV, as well as any primary care center interested in beginning other screening programs.

Two 2016 studies by Coyle et al. aimed to increase rates of HCV testing, disease detection, and linkage to care in FQHCs in Philadelphia, Pennsylvania.<sup>7,12</sup> The first study incorporated a routine HCV testing model into primary care at five FQHCs and assessed the effects of the model on testing rates, case identification, and linkage to care. From October 1, 2012 to June 30, 2014, an integrated HCV opt-out testing model was implemented at five primary health care centers, two of which specialize in treating HIV patients and HCV patients, using several strategies: modification of electronic health records, revision of clinic policies, and education of staff members on topics such as HCV etiology and epidemiology. A medical assistant initiated the opt-out testing program for each patient, which was followed by laboratory-based testing supported by grant-funded laboratories for patients without insurance. Staff members were trained in regards to the shared EHR, project goals, and the overall plan for the model. In order to determine the more efficient testing method, the two health centers specializing in high-risk populations implemented a universal testing program, and the three health centers providing general primary care implanted a risk-based testing program. Patients with risk factors included: those born between 1945 and 1965; those with a history of intranasal or IDU; recipients of a tattoo or piercing from an unlicensed location; recipients of a blood transfusion/organ transplant before 1994; women who had a cesarean section before 1990; HIV-positive patients without an HCV test in their medical chart; those on long-term hemodialysis, those with a liver condition, those with work-related exposure to infected blood, and those who are ever-homeless. HCV AB testing was provided to 4,207, with 11.6% testing anti-HCV positive. Of those testing antibody positive, 88.7% received a confirmatory HCV RNA test and 72.3% of these had a current HCV infection (overall prevalence=7.4%). HCV RNA-positive patients were further broken down into three categories: received HCV RNA-positive results (77.6%), referred to an HCV provider (58.8%), and successfully linked to care (38.7%). The results of this study illustrate the effectiveness of routine testing, whether risk-based or universal, in FQHCs to identify people having never received an HCV test, those currently HCV positive, providing awareness of their current HCV status and linking HCV-positive patients to care. This model provides a template for other primary

care or community health care centers in integrating HCV testing and linkage to care, as well as identifying potential barriers faced in implementation of a similar program.

The second study conducted by Coyle et al. built upon the already-implemented HCV testing model from the previous study and incorporated routine HIV opt-out testing in four of the five Philadelphia FQHCs. This study aimed to examine how a dual-routine HCV/HIV testing model impacts community health centers in terms of viability of program implementation, screening rates, case identification, and successful linkage to care.<sup>12</sup> The dual-routine HCV/HIV testing model was defined as: an opt-out HCV test for high-risk patients coupled with an opt-out non-risk-based HIV test for all patients.<sup>12</sup> Comparisons were made between the 9-month period with the routine HCV testing model and opt-in HIV testing, and the 9-month period with the routine HCV testing model and opt-out HIV testing.

The success of this dual-routine testing program in increasing HCV and HIV screening, improved case identification, and enhanced linkage to care shows that similar testing programs implemented in the primary care setting are feasible and yield positive results. Because HCV and HIV disproportionately affect poor and minority populations, community health centers that serve these populations could benefit greatly from this testing model. The testing model incorporated a multi-faceted strategy that included staff training sessions, system-wide health-care modifications for opt-out testing and laboratory requisitions, and changes to the EMR system such as daily queries in charts and reports used to track patients.

The results from the second study by Coyle et al. showed that the amount of tests given, the number of new diagnoses, and linkage to care increased during the dual-routine HCV/HIV testing model implementation compared to the routine HCV testing and HIV opt-in testing model. Dual-routine HCV/HIV testing resulted in a 23.7% increase in HCV tests and a 124.7% increase in HIV tests, a 44.3% increase in HCV case identification using HCV RNA tests, a 225.0% increase in HIV case identification, an increase in the percentage of HCV patients linked to care from 49.1% to 66.1%, and an increase in the number of HIV patients linked to care from 1 to 9.

Evaluation of opt-out testing for HCV is not represented in the current literature. Studies in FQHCs focus on screening practices already in place, increasing linkage to care

efforts, and educating staff. In 2015, several FQHCs in urban Alameda County, California, developed an initiative to expand hepatitis C treatment into primary care.<sup>35</sup> The four FQHCs collaborated to build a program that educated staff, increased capacity, discussed best practices, and facilitated training. The project measured HCV testing and linkage to care data. During the measurement period of 16 months, the number of patients who began HCV treatment increased by 538%. Of these patients, 96% have been cured. This capacity building initiative demonstrated how developing a site-wide program that educates, trains, and fosters collaboration among community organizations can expand access to treatment.

There were several studies available in the literature that examined multiple clinical settings. While these studies did not focus solely on community health centers or FQHCs, they are still of value in assessing routine opt-out testing across a wide range of healthcare sites. A study by Patel et al. examined several US sites to assess HCV birth-cohort testing and linkage to care from 2012-2014.<sup>37</sup> The 104 different clinical sites were comprised of emergency departments, FQHCs, community health clinics, STD clinics, and state health departments in cities in California, Colorado, Georgia, New York, North Carolina, Pennsylvania, Puerto Rico, South Carolina, Texas, and Washington, D.C. The testing population was previously undiagnosed people from the birth cohort, as well as those who reported HCV risk factors in accordance to the CDC recommendations. Three groups were analyzed according to their testing and results status: those who were anti-HCV positive, those tested for HCV RNA, and those who were HCV RNA positive. Demographic data and reported risk factors were included in the analysis. A total of 24,966 participants received Ab HCV testing. Groups with the highest frequency of testing were: those born between 1961 and 1965, those who were non-Hispanic black, and women. Of those tested, 11.6% were Ab HCV positive. Of the 2,900 people testing Ab HCV positive, 2,108 (72.7%) received testing for HCV RNA. A total of 1,497 people tested positive for HCV RNA and 938 were successfully linked to care. This study showed that birth-cohort testing could be successful in different healthcare settings. For successful and impactful engagement in the HCV care cascade, primary care facilities must champion testing initiatives and linkage to care.

The established HIV care continuum can serve as a model for developing a care continuum for HCV. A 2016 study by Seña et al. used this strategy to implement an HCV

testing and linkage to care program through the Durham County Department of Public Health from December 2012-February 2014.<sup>38</sup> HCV Ab testing with reflex RNA was offered through a sexually transmitted disease clinic, a county jail, community testing sites (including a residential substance abuse recovery program), and a homeless clinic. Positive patients were linked to care through an HCV bridge counselor who provided education, incentives, and transportation, and scheduled appointments with HCV specialists at nearby academic centers and on-site clinics. The study defined linkage to care for HCV using the definitions from the HIV care continuum: The process of assisting people diagnosed with chronic HCV infection with their initial visits with an HCV medical provider. The established provider networks and existing funding programs of HIV can facilitate similar networks and a coordinated system of care for HCV. In addition to showing the benefits of basing an HCV program on an already-established HIV program, the study found the following demographic trends: among those with current infection (241 people), 73.9% were men, 55.2% were born between 1945-1965, 62.2% reported ever injecting drugs, 2.5% were co-infected with HIV, and 51% were linked to care.

In October 2012, the Grady Memorial Hospital Primary Care Center and Grady Liver Clinic in Atlanta, Georgia began the Internal Medicine Trainees Identifying and Linking to Treatment for Hepatitis C (TILT-C). TILT-C aimed to conduct routine HCV screening with the goal of identifying undiagnosed persons, primarily African American baby boomers, and linking them to care. In 2016 Miller et al. published a report on the implementation of this program and the results from the first year.<sup>39</sup> This study conducted routine HCV screening to identify previously undiagnosed, primarily African American baby boomers with chronic hepatitis C infection and link them to care. To implement screening and linkage to care, TILT-C executed an electronic medical record prompt, held HCV educational sessions, and used a project coordinator to track testing outcomes and link HCV+ patients to care. This multi-faceted program yielded 201 HCV Ab+ patients (out of 2,894 tested), of which 86.6% received HCV RNA testing. Of those who received an HCV RNA test, 71.3% were positive; 98.4% of these patients were referred to care and 98.4% of those referred attended the first appointment. The total linkage to care rate was 96.8%.

The CDC developed the Hepatitis Testing and Linkage to Care (HepTLC) Initiative as part of the Viral Hepatitis Action Plan released by HHS. Between 2012 and 2014, the aim of

the initiative was to improve screening and linkage to care for those with chronic HCV. A total of 24 programs in geographically diverse US cities conducted HCV testing on different populations, including PWID. This initiative is the first step in developing a nationally coordinated effort to address viral hepatitis, and several studies assessed the impact of HepTLC as a means to inform future endeavors. The healthcare facilities chosen by the CDC to provide testing included community health centers, university hospitals, health departments, primary care centers, and public health clinics. People were tested at sites like homeless shelters, syringe service programs, methadone clinics, alcohol and drug treatment centers, and correctional facilities.

A study by Blackburn et al. reported findings from the hepTLC initiative from 2012-2014, and assessed how agencies with testing sites targeting PWID can improve testing, diagnosis, and treatment of HCV in this population.<sup>40</sup> The results showed that at 84 testing sites targeting PWID, the total number of people tested with HCV Ab was 15,274. Of those tested, 11,159 (73%) reported having injected drugs in their lifetime, 7,789 (51%) reported injected drugs in the past 12 months, and 3,495 (23%) tested anti-HCV positive. Of those with a positive HCV Ab test, 1,630 (46.6%) were tested for HCV RNA. A total of 1,244 (76%) were HCV RNA positive. Receiving both the Ab and RNA tests on the same day was associated with increased success: 601 of 2,465 (24%) anti-HCV+ people received an HCV RNA test when there was not a single testing event.

Although a few FQHCs have reported how they have implemented HCV screening, testing, and linkage to care initiatives, there remains a need for the evaluation of HCV opt out testing programs. Current data is most often cited in large, national studies of health departments, community health centers, and hospitals. Data specifically from FQHCs on opt out testing is lacking. Of the published literature, the program sites tend to be exclusively in urban cities, leaving out rural populations from the studies. Furthermore, there is limited evidence about integrating a robust HCV screening program and comprehensive HCV treatment into primary care.

Dual Opt-Out Testing for Human Immunodeficiency Virus (HIV) and Hepatitis C Virus (HCV) in Primary Care Centers: The Time Is Now

Introduction

There are an estimated 3.2 million people living in the U.S. that are infected with hepatitis C virus (HCV).<sup>7</sup> About 75% of those affected are unaware of their infection.<sup>1</sup> Due to the often symptom-less nature and slow progression of HCV, those infected may not be aware of their infection until complications from the disease have become severe and available treatment options have become limited. From 2010-2015, reported cases of acute HCV infection increased more than 2.9-fold, rising annually throughout this period.<sup>2</sup> Mortality among HCV-infected persons-primarily adults aged 55-64 years-increased during 2006-2010. In 2013, HCV-associated deaths exceeded the combined number of deaths with 60 other infectious diseases as underlying causes. Deaths due to HCV have exceeded deaths related to human immunodeficiency virus/acquired immunodeficiency syndrome (HIV/AIDS) nationally since 2007.<sup>1</sup>

Although HCV is a considerable burden on the healthcare sector, funding for HCV prevention and research pales in comparison to funding for HIV efforts, even though an estimated 20% of those infected with HIV are co-infected with HCV.<sup>12</sup> For those who are co-infected, the chance of liver-related morbidity and mortality is higher, even when the HIV infection is well controlled.<sup>22</sup> Co-infected patients account for 93% of hepatocellular carcinoma cases and studies have reported a 10-fold increase in mortality for these patients.<sup>23</sup>

In 2012, the Centers for Disease Control and Prevention (CDC) revised HCV screening recommendations to include one-time testing of all baby boomers and screening for those who are at high risk for infection.<sup>11</sup> Screening for HCV leads to early diagnosis and thus earlier access to treatment, more treatment options, prevention of the development of HCV-related complications, and higher linkage-to-care success rates.<sup>27</sup> Despite HCV being the most common blood-borne virus in the US and the substantial scale and burden of the disease, routine HCV testing is not uniformly practiced.<sup>7</sup> HCV screening rates are reported

to be as low as 54% and it is estimated that more than 60% of individuals who have received a diagnosis are not engaged in care.<sup>11,41</sup>

The existing literature is limited to only a few Federally Qualified Health Centers (FQHCs) and the implementation, development, and evaluation of their HIV and HCV opt-out testing programs. Opt-out testing is done after the patient is notified that the test will be performed. Opt-out testing infers that a patient consents to being tested, unless the patient specifically asks for the test to not be performed. The rationale for this type of testing is that it enables widespread testing that can identify infections earlier, increase the number of people who do not know they are infected, reduce stigma associated with HIV testing, and simplify testing because written consent is not required. These clinics represented in the published literature are in large, urban cities and the results are not generalizable to other locations and populations. This study of the HIV/HCV opt-out program of Southside Medical Center (SMC) adds to the prior literature by reinforcing the success of routine opt-out testing. Because SMC is an access point for over 30,000 people across rural and urban counties in Georgia, this study presents additional data that has not been thoroughly studied.

The aims of our study were to evaluate the prevalence of HIV and HCV screening prior to and following the implementation of a dual routine opt-out program, the linkage to care practices for positive patients, and the demographic characteristics of positive patients in a southern FQHC.

## Methods

We conducted a retrospective, cross-sectional study using electronic health record (EHR) data from patients receiving care at the Southside Medical Center (SMC) in Atlanta, Georgia. The EHR system allows patient-level data to be extracted across all clinic sites from 2012-2017. Medical records created prior to 2012 were not available for this study. Approval from the Georgia State University Institutional Review Board was obtained prior to study start.

Diagnostic codes from the 9<sup>th</sup> and 10<sup>th</sup> revisions of the International Classification of Disease, Clinical Modification (ICD-CM) were used to find cases. The use of ICD 9 codes first

began in 1979, and continued at SMC until September 30, 2015. The current coding system is ICD 10, which began on October 1, 2015.<sup>42</sup> Inclusion criteria for HIV+ patients were: 13-64 years of age, treatment at one of the 10 SMC clinics, and a diagnosis of HIV infection using ICD 9 CM diagnostic code 042 and ICD 10 CM diagnostic code B20. B20 human immunodeficiency virus (HIV) disease includes: acquired immune deficiency syndrome (AIDS), AIDS-related complex (ARC), HIV infection, symptomatic. Inclusion criteria for HCV+ patients were: 18 years of age and older, treatment at one of the 10 SMC, and a diagnosis of HCV using ICD 9 CM diagnostic codes 070.41: acute hepatitis C with hepatic coma, 070.44: chronic hepatitis C with hepatic coma, 070.51: acute hepatitis C without mention of hepatic coma, 070.54: chronic hepatitis C without mention of hepatic coma, and 070.7: unspecified viral hepatitis C, and ICD 10 CM diagnostic codes B17.1: acute hepatitis C, B18.2: chronic viral hepatitis C, and B19.2: unspecified viral hepatitis C. Inclusion criteria for co-infected HIV+/HCV+ patients were the same as the criteria detailed above. The year in which the case was counted depended on the earliest known date for the secondary infection. The earliest diagnostic dates for each of the infections were counted in the year in which they occurred, so that a co-infected patient was counted 3 times: as a case for the year in which an HIV+ diagnosis first occurred, as a case for the year in which an HCV+ diagnosis first occurred, and as a case for the year in which a secondary infection diagnosis first occurred.

Pre-HIV/HCV opt-out testing implementation was defined as a positive HIV or HCV diagnosis between June 2012 and February 2014. Post-HIV/HCV opt-out testing implementation was defined as a positive HIV or HCV diagnosis between March 2014 and July 2017. All-tested refers to all eligible patients who consented to being tested for either HIV or HCV. The patient-level demographic data that were collected included date of birth, age, sex, race, and ethnicity. The EHR data was de-identified and unduplicated prior to analysis.

Linkage to care was defined as a patient attending an appointment with a prescribing provider within 30 days of the diagnosis.

## Results

### *Pre-HIV/HCV opt-out implementation*

SMC conducted 9,906 HIV tests prior to HIV/HCV opt-out testing implementation. The number of HCV tests conducted during the pre-HIV/HCV opt-out testing implementation could not be analyzed, due to multiple software updates and a lack of documentation of HCV during this time.

There were 68 patients identified as HIV+. Sixty-six of these patients were linked to care (97.05%). Of the 68 diagnosed with HIV, 95.59% were African American, 98.53% were non-Hispanic, and 62.50% were male. Thirty-seven percent of these patients were aged 41-50, 25% were aged 31-40, 25% were aged 51-90, and 12.5% were aged 23-30.

There were 89 patients identified as HCV+. Of these patients, 67.42% were black/African American, 15.73% were white, 11.24% declined to answer, 1.12% were unknown, and 4.49% were Asian. The majority of patients were non-Hispanic (97.75%). 53.93% were male and 46.07% were female. The age range of HCV+ patients showed that most patients were 50-59 years of age or 60-60 years of age: 33.71% and 38.31%, respectively. There was no information about linkage-to-care nor data on HCV Ab total tested prior to March 2014.

There were 3 HCV/HIV co-infected patients identified prior to routine opt-out testing. All 3 patients were Black/African American and non-Hispanic. Two patients were male; 1 was female. Their ages were 35, 63, and 57 years old. Two of the patients had a primary diagnosis of HIV and a secondary diagnosis of HCV. The third patient was diagnosed with both on the same day. All three patients were linked to care with a referral to external organizations. This was due to SMC not having an Infectious Disease clinic at that time.

#### *Post-HIV/HCV opt-out implementation*

SMC conducted 38,283 HIV tests and 19,308 HCV tests after HIV/HCV opt-out testing implementation. There were 232 HIV+ patients identified during this time period. There was a successful linkage to care rate of 96.98%. Of the 232 patients diagnosed with HIV, the majority were African American (82.33%) and non-Hispanic (93.53%). Males comprised 58.19% of the population. Patients were nearly evenly distributed amongst the following age categories: 51-90 (28.45%), 23-30 (27.59%), and 31-40 (21.98%).

There were 274 HCV+ patients identified during this time period. Of these patients, 52.92% were Black/African American, 94.89% were non-Hispanic, 55.84% were male, and 79.71% were linked to care. 45.99% were 60-69 years of age and 31.39% were 50-59 years old. The other age groups were as follows: 9.49% were 40-49 years of age, 5.11% were 30-39 years of age, 4.01% were 18-29 years of age, and 4.01% were equal to or older than 70 years of age.

There were 13 co-infected patients identified during this time. Of these patients, 76.9% were male, 61.53% were Black/African American, 92.30% were non-Hispanic, and 61.53% were in the birth cohort. Five patients (38.46%) received both diagnoses concurrently. Four patients had a primary diagnosis of HCV, and four patients had a primary diagnosis of HIV. Eleven patients were linked to care.

## Discussion

The HIV and HCV patient populations remained consistent both before and after implementation in regards to demographic distribution. These demographics reflect the general population of the patients SMC serves: non-Hispanic African Americans.<sup>33</sup> The age distribution of the HCV+ patients at SMC matched the trends seen nationwide for patients belonging to the 1945-1965 birth cohort.

Comparing the amount of tests performed during the pre-HIV/HCV opt out testing period to the post-HIV/HCV opt out testing period, shows a 286% increase for HIV tests. The increase in HIV/HCV testing may partly be due to the hiring of an Infectious Disease specialist in 2015. Referrals to external organizations for HIV/HCV positive patients may take longer, require more work and coordination, and have poor follow up. Internal referrals to the infectious disease department happened the same day as the diagnosis, which some providers opting to personally call the infectious disease clinic to refer the patient.

SMC has fully incorporated infectious disease into the primary care environment. An infectious disease specialist works alongside adult medicine providers, pediatricians, pharmacists, OBGYNs, and counselors. There is an onsite lab at each facility that allows patients to see the provider and get lab work done immediately after. This comprehensive

system simplifies and lessens the burden put on patients to keep up with their medications, diagnoses, lab work, and appointments.

The linkage to care rates for HIV+ and HCV+ patients were higher than those of other studies and guidelines. The national HIV linkage to care goal, set by the federal government, is at least 85% of persons linked to HIV medical care within 30 days of diagnosis.<sup>43</sup> For HIV+ patients, the percentages were >95% during both time periods. The HCV linkage to care rate of the post-opt out period (79.71%) was also greater than those found in similar studies by Coyle et al. (38.7% and 66.1%).<sup>7,12</sup>

Several barriers were identified during implementation of the testing program and during analysis of the available data. The lack of access to digitized medical records prevented an in-depth look at the actual prevalence of HIV and HCV infection in the patient population during the years when paper records were used. Complete records are needed to fully demonstrate the significance of routine opt-out testing, and resources should be allocated to improve and update electronic health databases. In going forward with new EHR software, health centers should make it a priority that patient information not be lost when moving to a different program.

Additionally, patient contact information should be checked and updated at every visit to guarantee that the most up-to-date information is available for linkage to care efforts. Making patients aware of available transportation, prescription assistance programs, and sliding scale pay fees should also be of utmost importance during the initial visit. These changes require financial resources and additional staffing that many may not have access to. To mitigate this issue, FQHCs could train staff who work in medical records to transition the practice over to digital medical records.

SMC was able to successfully implement routine opt-out testing thanks to considerable efforts to initiate and support an Infectious Disease (ID) Clinic within the health center. Including a separate ID Clinic allowed providers and staff to give focused care to HIV and HCV infected patients in a smaller, more individualized setting. The unique one-stop shop method at SMC enables patients to receive primary care from their PCP, and then move to ID treatment with an ID specialist, then to the pharmacy for any prescription needs with ease. This setting limits the amount of trips one patient will need to make for

health care which alleviates stress and the hassle of keeping track of several appointment dates and times.

### Limitations

Our study had several limitations. First, the population receiving primary care at SMC is primarily Black/African American, low socioeconomic status, and uninsured and underinsured; thus, our results may not be generalizable to other populations. Similarly, SMC is a community health center located in Atlanta, a highly populated city in the southern US, and the results shown here may not apply to other cities or types of health services across the country. Second, due to high staff turnover, there is no way to know if providers are reliably moving through the opt-out prompts with the patients. There is a lag in opt-out training for the newly on-boarded staff, leading to inconsistent offering of opt-out testing. Third, due to SMC's variability of being a primary care facility for some and a walk-in clinic for others, some patients testing positive may have different primary care providers outside of SMC and thus could have been linked to care elsewhere.

### Conclusions

Southside Medical Center is in a unique position as a community health program located in Atlanta, a highly populated southern city facing the HIV epidemic. SMC's development and implementation of routine dual HCV/HIV opt-out screening programs should serve as an example to other health centers looking to improve care outcomes for patients living with and at risk for HIV and HCV, as well as the general population's healthcare as a whole.

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