INTEGRATION OF HEPATITIS C VIRUS TREATMENT MODULE WITHIN METHADONE MAINTENANCE TREATMENT PROGRAMS

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By

E. Clarke

Dr. Lynne Weissman, DNP, Program Director, and Chair Dominican College

Dr. Barbara Polowczyk, DNP, Faculty, and Capstone Mentor

Dr. Patty Furlong, DNP, Faculty, and Capstone Mentor

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List of Acronyms

American Association for the Study of Liver Disease…… AASLD
Agency for Healthcare Research and Quality…… AHRQ
Centers for Disease Control …….. CDC
Corona Virus Infection ……. ….. COVID-19
Direct Acting Agents ……... DAAs
Food and Drug Administration ……. FDA
Health Belief Model ……. HBM
Hepatitis C Virus ……..HCV
Health Insurance Portability and Accountability Act ……... HIPPA
Infectious Disease Society of America ……. IDSA
Institutional Review Board ……... IRB
Intravenous ……. .IV
Intravenous Drug Use …….. IDU
Methadone Maintenance Treatment Program ……...MMTP
New York City ……NYC
Outpatient Treatment Program…….. OTP

People who inject with drugs …… PWID
Substance Abuse and Mental Health Service Administration ……... SAMHSA
Social Determinant of Health …….. SDOH
Sustained Virological Response ……... SVR
The National Institute of Health ……... NIH
Treatment Improvement Program ……TIP
United States of America……. ……USA
US Preventative Service Task Force ……USPSTF
The World Health Organization ……WHO

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Abstract

Hepatitis C infection co-occurrence with opioid use disorder is a current public health crisis prevalent in individuals who are actively injecting or have a history of injecting drugs. Worldwide, a devastating 177 million individuals are affected by hepatitis C (HCV), most of whom are undiagnosed. Approximately five million Americans currently use illicit drugs, with an estimated four million newly diagnosed with HCV. Chiefly caused by the sharing of needles, straws, or contaminated blood, HCV impacts intravenous drug users, many of which are registrants in New York City's Methadone Maintenance Treatment Programs. Despite the high prevalence of HCV in this population, scant attention has been paid to housing an HCV treatment module within methadone treatment programs to address its coinfection with the opioid dependent population to facilitate uptake rates among people inject drugs. Public health efforts must focus on MMTPs and this marginalized population to achieve the national goal of HCV elimination.

Keywords HCV; MMTP; OTPs; co-location; integration; in-house

Section II Introduction

Statement of the Problem

Chronic hepatitis C virus is prevalent in patients registered in New York City's Substance Abuse and Mental Health Service Administration (SAMHSA) Methadone Maintenance Treatment Programs. Intravenous drug use is a primary risk factor for Hepatitis C Virus (HCV) and remains the preferred route for people who inject drugs. In the United States, a disproportionate number of people who inject with drugs are registered in methadone maintenance treatment programs (MMTP) and are co-infected with the hepatitis C virus. Although registered and receiving care for their opioid addiction, these individuals have inadequate treatment access and resources to hepatitis C care resulting in health care access disparities. This, despite the new and available improved direct-acting antiviral medication treatments. The disease, primarily acquired through the sharing of needles, straws, or contaminated blood products, causes liver disease, liver cancer, and premature deaths continue to increase. Incidentally, reports of over two-thirds of people acutely or chronically infected with HCV are intravenous (IV) opioid drug users. Often marginalized and stigmatized, individuals coinfected with HCV and opioid dependency have limited access and frequently are neglected by providers, insurance companies, and governmental agencies for improved access and treatment (Roncero, Ryan, Littlewood, Macias, Ruiz, Seijo, & Vega 2018). In view of this, to bridge the gap, SAMHSA recognizes the importance of MMTP programs providers on-site and operationally-equipped in screening and detecting HCV co-infected patients. Thus, integrating HCV treatment within MMTP is a crucial initiative to screening, treatment, and the eradication of the disease in this high-risk population (Kresina, Hoffman, Lubran, & Clark, 2017). The purpose of this evidence -based capstone improvement project is to improve an upsurge in

screening, testing, treatment, and cure for HCV within the co-occurring disease opioid use disorder. Rapid progress in the treatment of HCV infection has led to highly successful therapies leading to viral eradication and sustained viral response in more than 50% of patients. Despite these advances, the opioid use population is a recognizable stigmatized population to be experiencing HCV down-surge rates of screening, testing, and treatment modalities.

For nearly three decades, methadone hydrochloride (6-dimethylamino-4, 4-diphenyl-3heptanone hydrochloride) has been the primary means of treating opiate addiction. Approved by the Food and Drug Administration (FDA) in 1947 for analgesic and antitussive uses, methadone was shown to be effective in treating opiate addiction in the mid-1960s and was approved by FDA for this use in late 1972. Pharmacologically, methadone is a weak-acting opiate agonist (that is, it imitates the action of an opiate, such as heroin) that does not generate the euphoria of an opiate but does reduce symptoms of opiate withdrawal. Today, an estimated 115,000 individuals receive methadone treatment for opiate addiction, and thousands more have benefited from it in the past. (Rettig & Yarmolinsky, 1995). MMTP provides treatment for patients with opioid dependency, where the majorities of their patients have a history of IV drug use; or are currently active drug users infected with co-occurring HCV infection. Current practice is to refer HCV patients off-site to their PCP, to liver or disease clinics, or gastrointestinal specialists for treatment. Several studies supported the successful treatment of an HCV onsite opioid treatment program, specifically, Butner et al., (2017). In discussing the onsite treatment of HCV within a substance treatment program utilizing oral direct-acting antivirals, Butner et al, (2017) findings supported fundamental factors authenticating the purpose of this capstone project. The retrospective study highlighted the importance of implementing a co-integration HCV treatment

model within an opioid treatment program to increase screening, detection, intervention, and eradication of HCV in people who inject with drugs (Butner et al., 2017).

Keywords: Hepatitis C Virus treatment, Hepatitis C infection, Opioid Dependency, Opioid use disorder, People who inject with drugs, integration of care, co-occurring disease, onsite opioid treatment, Methadone Maintenance, and opioid treatment program.

Background and Significance

Background

The prevalence of HCV and its co-occurrence with opioid dependency in the United States has increased in recent years, threefold in 2016, creating a national public health epidemic (Campbell, et al., 2017). According to the Centers for Disease Control (CDC), approximately 71 million individuals worldwide are infected with HCV, of which an estimate of four and a quarter million reside in the United States (Centers for Disease and Control, 2019). Nearly three to four million new infections occur each year. HCV is a blood-borne virus infecting the liver. Patients with HCV have a higher risk of the disease progressing to liver disease, liver cirrhosis, liver fibrosis, hepatocellular carcinoma, need for liver transplant, and premature death resulting in immense health and economic burdens to families, communities, and countries globally. In Australia, there is an estimated HCV treatment cost of four and a half billion to approximately five billion Australian dollars. Yet, this is minute in comparison to the 900 to 1150 billion dollars expenditure in USA dollars (Scott, N, McBryde, Thompson, & Doyle, 2016). According to Edlin (2016), the 2014 approval novel direct-acting antivirals medication for HCV cost approximately 83,000 through 150,000 US dollars for a complete three month treatment course. Both private and public indemnity companies denied access to thousands of individuals infected with HCV unless diagnosed with end-stage liver fibrosis or liver cirrhosis (Edlin, 2016).

Injection drug use (IDU) is the leading risk factor for HCV transmission and opioid use disorder overdoses in the United States. HCV is transmitted through needle sharing, contact with contaminated blood, body piercing, tattoos, blood transfusion, infected blood, and needle exposures used in dialysis, and organ transplant. Needle sharing is a high behavioral risk factor associated with individuals infected with HCV and for the population of individuals who inject prescriptive or illicit opioids drugs. People who inject with drugs (PWID), accounts for the highest portion of acute HCV infection in the United States. Also included are men who have sex with men, individuals born between 1945-1965, transgender women, healthcare workers exposed to needle sticks, contaminated blood products, and body fluids. Individuals exposed to blood transfusion prior to testing, and individuals with persistently elevated liver enzyme levels are all at an increased risk of being infected with HCV (Ghany & Morgan, 2020).

Most individuals infected with HCV are unaware of the disease as symptoms may be insidiously dormant for years or decades. This finding is congruent with the work of Krans et al. (2016) retrospective cohort study of pregnant women registered in opioid treatment and infected with HCV. This cohort study reported many high-risk substances using females are asymptomatic and unaware of their HCV status (Krans, Zickmund, Park, Dunn, & Schwarz, 2016). Krans et al. (2016) went further and reported prenatal care is often one of the first opportunities for high-risk women of childbearing age, to be screened and identified with HCV infection.

Individuals infected with HCV can be classified as acute or chronic. The acute phase, approximately 20 percent of the cases, is defined as being infected with HCV occurring from the time of exposure to six months of the infection. In the United States an estimated 80 percent of people infected with acute HCV will develop chronic HCV, and 30 percent will develop end-

stage liver disease in the United States. Chronic HCV is defined as being infected with the hepatitis virus for more than six months (Li & Lo, 2015). Classified as a silent epidemic, HCV-infected individuals are unaware of their status. They are at an increased risk of developing hepatocellular carcinoma, the most common indication for liver transplant in the United States (Ditah, Bawardy, Gonzalez, Behnam, Ditah, Kamath, & Charlton, 2015). In a 2020 study, Field reports viral sequela of HCV includes abdominal pain, nausea, vomiting, loss of appetite, gray-colored stool, fever, fatigue, jaundice, dark urine, joint pain, and blood clotting disorders (Field, 2020).

Given most people are unaware of being infected with the HCV virus, most exhibiting symptoms occur during the chronic stage where the liver begins to fail, and liver cirrhosis develops. Liver cirrhosis accounts for significant morbidity and healthcare spending of about three billion dollars of direct cost and $10.5 billion of indirect loss in the United States. Despite HCV being without vaccination or a cure, educating the population on HCV prevention, treatment, and cure impacts the disease with early intervention as this can reduce the cost of healthcare of comorbidities associated with the disease.

Notably, in 1989 HCV was discovered by scientists led by Michael Houghton's team at the Centers for Disease Control and Prevention (CDC), and The National Institute of Health (NIH) when they isolated DNA from the blood of a person infected with non-A non-B virus. Aside from the HCV discovery, the team also isolated the viral RNA, which preceded the rapid development of the serological and virologic diagnostic tests. In 1998, the Center for Disease Control released screening recommendations based on exposure and risky behaviors to identify HCV infected individuals (Lynch & WU, 2016). Identification of HCV RNA enables the active assertion of the disease in the liver, in peripheral blood mononuclear cells, and blood serum. The

latter easily obtained by a blood draw. Therefore, the presence of HCV and the detection of HCV RNA in the serum identify individuals with an active infection. Individuals with anti HCV antibodies and undetectable HCV RNA are classified as exposed patients but cured of the virus. Those cured are characterized as having a sustained virologic response (SVR) (Lingala & Ghany, 2018).

Many studies over the last decade have examined an enormous amount of research to develop a cure for HCV. In 1991, the Food and Drug Administration approved the first drug treatment interferon -x for HCV. Initially, Interferon, an intravenous (IV) dosed medication of three million units, was used for its antiviral and immune properties as the primary treatment for chronic HCV. This work is congruent with the work of Liang, Rehermann, and Seeff (2000), who claimed the therapy required modification in response to results of combination therapy with Interferon and Ribavirin (Liang, Rehermann, & Seeff, 2000). In 1997, Pegylation, a weekly subcutaneous injection medication and Ribavirin, were developed, increasing the efficacy of therapy in addition to combination medication consisting of Ribavirin and Interferon. Despite this, initially, people who had a history of substance use disorder were not included in the clinical trials for Interferon and Pegylation for treatment of hepatitis C. However, these medications had numerous side effects, namely flu-like symptoms, diarrhea, nausea, vomiting, weight loss, headache, fatigue, anemia, joint pain, depression, and immune suppression. Aside from these side effects, the medications were expensive costing patients over twenty-four thousand dollars per treatment. Most insurance, including Medicaid and Medicare, rejected claims, and most patients could not afford to pay the thousands of dollars out of pocket required for treatment (Re, Gowda, Halladay, Brinkley, & Kostman, 2016). People who inject with drugs constitute the major group, account for the majority of new infections and were not only rejected

by insurance company but also striped of their right to receive treatment due to opioid addiction. Of the 15 million Americans who presently utilize illegitimate medications, an expected one to approximately two million inoculate them, and approximately 80 to 95 percent of inoculation drug clients have been infected with HCV. Despite this scale-up, an agreement articulation on the administration of hepatitis C, the National Institutes of Health suggested in 1997 that people who utilize illegitimate medications not be offered treatment for HCV contamination until they had halted all illicit drug use.

As a consequence, few substance use patients received HCV treatment. With the increased side effects, those who initiated treatment failed to complete therapy and remained infected. Over the last ten years, pharmaceutical companies finally developed effective, curative, well-tolerated, and short treatment duration oral antivirals inhibiting HCV medication that are both effective in curing all infected populates and cost-effective with minimal side effects. Chhatwal et al. (2015) estimate the new drugs will cost an additional $65 billion in the five years to treat eligible HCV -infected individuals in the United States (Chhatwal, Kanwal, Roberts, & Dunn, 2015). In spite of these newer rapidly improved HCV medication oral direct-acting agents (DAAs) therapy and cost, pharmaceutical company advertisements "promises of up to 95 % cure rate." Treatment suppression occurs with an increasingly high cost to the health care system (Falade-Nwulia, Irvin, Merkow 2019, and Malespin, Harris, and Kanar 2019).

Significance of the Problem

Hepatitis C is the most prevalent blood-borne infection in the United States, and IV drug users have the most increased risk of developing the disease. The World Health Organization (WHO) established goal to eliminate HCV between 2015-2030 targeting high-risk populations of people who inject drugs (WHO, 2017). As of 2017, there are an estimated 99,178 number of

active people living in New York State with chronic HCV, and 5308 newly chronic diagnosis representing a 62.2 % per 100,000 people increase indicating the need for education. Although HCV incidence is increased in PWID, less than ten percent with the positive RNA are untreated. Barriers to treatment include limited access to treatment, under or uninsured, stigma in health care settings, decrease provider knowledge, continued substance use, lack of PWID awareness, and a lack of health education literacy concerning available cures. Not to mention patient fear and traumatic stress from loss of family members or friends to initial HCV therapy (Falade-Nwulia, et al., 2019).

People with substance use dependency are at an increased risk of hepatitis C infection. In the United States, opioid addiction and HCV are essential public health threats and concerns, even more so, specifically in New York State. As a result, the Substance Abuse and Mental Health Service Administration (SAMHSA) of New York, the primary funding agency for MMTP, initiated new initiatives to treat the co-occurring diseases concentrating on integrating HCV services into substance abuse treatment programs. The first initiative created as "Hepatitis Education and Training at MMTP," provided training in the prevention, care, and treatment of HCV infection for outpatient treatment programs (OTP) and providers supported with funds from the American Association for the Treatment in Opioid Dependence utilizing Treatment Improvement Protocol (TIP) fifty-three (Substance Abuse and Mental Health Services Administration, 2020).

Treatment Improvement Program (TIP) fifty-three, created by the Centers for Substance Abuse Treatment, focuses on viral hepatitis in people with substance use disorder. Developed from evidenced-based practice and structured in two sections, TIP fifty-three provides HCV information and guidance for counselors, administrators, and medical providers providing

substance abuse treatment in written documents, web-based, and best practices guidelines supported by the American Association for the Study of Disease (Substance Abuse and Mental Health Services Administration, 2020).

Currently, the American Association for the Study of Liver Disease (AASLD), the Infectious Disease Society of America (IDSA), and the National Institute of Health (NIH) recommend HCV treatment guidelines for all persons, including PWID (Butner, et al., 2017). In the US, few types of research have been conducted in the field to investigate the range of advantages of the implementation of the onsite treatment of Hepatitis C Virus (HCV) within an opioid maintenance treatment program. Of those studies completed, in Australia and Spain, results show current or former PWID with HCV infection can successfully be treated for HCV at an onsite or in-house opioid treatment program, rather than referral to the off-site liver or infectious disease clinic (Chin, Hogan, & Nguyen, 2017). This study aims to test the feasibility of implementing an onsite HCV treatment module within the opioid outpatient treatment program population, within CMMC, a community-based outpatient treatment program in New York State, to increase HCV screening detection, increase compliance with treatment, and increase eradication of the disease within MMTPs. Opioid disorder users aside from being the largest co-infected HCV stratum, are also stigmatized at an increasingly disproportionately high rate compared to other individuals co-infected with other medical conditions. Subsequent to analyzing the reasoning for offering these scorned clients medical HCV therapy, ethical guidelines, public health practices, and accessible practitioners paved the way for a less prohibitive elective approach. The detection, treatment, and cure of HCV within this population are crucial in preventing chronic liver disease, serious hepatic complications, and mortality.

Target Population

Detecting Hepatitis C Virus

The Institute of Medicine (IOM) recommended federal, state, and local agencies expand their efforts to decrease the risk of HCV in people who inject with drugs, to include preventative guidelines for risk factor screening-detecting exposure or ascertaining immune status for hepatitis C virus, and referrals for medical provider management. (Colvin & Mitchell, 2015). In discussing the detection of HCV antigens and antibodies Warkad, Song, Pal, and Nimse (2019), postulated the lack of awareness to HCV and its treatment, access insecurity to an adequate medical provider, and screening desert for HCV infection contributed to the enduring 170 million global infection of hepatitis C virus and inauspicious to population, community and individual health (Warkad, Song, Pal, & Nimse, 2019). Treatment regimens for HCV dual-infected substance abusers are hard to persevere through and require a genuine responsibility by providers with respect to this stigmatized population. Adherence to treatment regimens among illicit substance users is regularly thought to be poor. Some may hence contend that treating illicit intravenous drug user's co-contamination with HCV is futile. Early detection, treatment, and curative intervention reduce the risk of morbidity and mortality in the transmission of the hepatitis C virus. While this may be true, presently, a vast amount of the opioid dependency population is unaware their HCV may result in liver cirrhosis, liver fibrosis, liver failure, and hepatocellular carcinoma. Subsequently, determining HCV infection requires screening the opioid population registered in methadone treatment programs for the presence of HCV antibodies, also known as anti-HCV using molecular assays or serological assays.

At the initial admission screening and at annual history and physical, OTP clients are advised and encouraged to consent to HCV screening and testing. It was while performing

annual history and physical, the DNP candidate noticed numerous patients were never tested for HCV, were unaware of their HCV status, and those who were aware of being infected failed to obtain access for treatment. Those who reported HCV history and treatment were not documented.

The ability to offer screening and testing choices with education, not only increase screening compliance, but also detects long-standing HCV and upscale testing. Once screened and consent is obtained, HCV is isolated, the molecular assay nucleic acid testing (NAT) isolates HCV RNA in blood and body fluid samples. Serological tests obtained from a simple blood draw detect HCV antigen in plasma and serum (Warkad, Song, Pal, & Nimse , 2019).

Following this further, the article claimed, the nucleic acid tests are more costly and an ineffective tool for rapid screening results for large populates. On the other hand, serology assays are more cost-efficient as it is designed for mass detection of anti- HCV antibodies, HCV antigens, efficacious, utilized for treatment monitoring, and for the virologic clearance confirmation. Besides, accurate and rapid diagnostic tests with the utilization of the high availability of efficacious, cheap, and well-tolerated direct-acting antivirals (DAAs) are crucial for mass screening and treatment of those co-infected with HCV to obtain sustained virologic clearance greater than six months after completion of therapy (Lee et al. 2018).

Target Location

The practice setting for this change capstone project is located in an urban community-based downtown neighborhood as a nonprofit outpatient treatment program that has been serving the community for over forty years and is located in New York State. The outpatient program, CMMC, focuses on providing treatment for opioid addiction with the dispensing of liquid methadone to the substance abuse population community it serves in compliance with its mission

statement. Established in the early 1980s, CMMC is an outpatient treatment program under the umbrella of a local nonprofit hospital network that provides medical care to low-income, Medicare, Medicaid, uninsured, and underinsured population in New York State. At its inception, CMMC housed 200 participants. In 2015, IHS treatment service, an established program upstate New York, closed its door after residents of the “elite" population complained about a methadone program in their neighborhood. Clients registered in methadone treatment programs require daily dosing. To prevent relapse in their treatment, 450 patients registered at IHS outpatient treatment program transferred to programs throughout Westchester and New York methadone treatment programs. In 2015, CMMC absorbed 250 clients from IHS treatment service lifting the census to four hundred.

Equipped to service 550 clientele, and due to its business nature where clients can freely “flow” within programs, CMMC currently provides service to 430 clients. In 2017 two fulltime family nurse practitioners (FNPs) were added. Henceforth, in 2018, one medical doctor transferred to the affiliated program, as the interim Medical Director , in the Queens New York network facility . Currently, the practice has one full-time medical doctor and two full-time FNPs. The clinic provides outpatient opioid methadone treatment for adult patients. The medical doctor, who is also the medical director, is primarily responsible for the initial screening, intake, admission, and initiation of treatment for all patients.

Additionally, the doctor is responsible for providing assessment for patients who express the need to be discharged against medical advice from the program. The FNPs are accountable for all patients’ initial history and physical, annual examination history and physical, episodic visits for methadone dose adjustments and reinstatements, approving the extension of take-home

medication privileges, and case conferences. There is a shared responsibility between the providers for interdisciplinary counseling management and reviewing of laboratory test results.

Patient-centered care, health promotion, disease prevention, and education are highlights of the family nurse practitioners' role. The inclusion of the FNP in the opioid arena is a great avenue to facilitate screening, educating, referring, and monitoring patients as recommended by the federal preventative health initiatives, CDC, Institute of Medicine (IOM), the USPSTF, and AASLD guidelines to assist patients in making better health choices and decisions. The FNPs were included to provide high-quality personalized care, increase patient satisfaction. The ultimate goal is to utilize the health care model framework to alter past nonadherence behavioral practices to increase HCV screening, encourage compliance, and the implementation of an onsite HCV module to promote the eradication of the HCV disease.

Evidence of the Scope of the Problem

Never has it been more imperative to address the co-occurrence of substance abuse and HCV in the Unites States. According to Ly, Hughes, Jiles and Holmberg, (2016), from 2003-2013, the quantity of HCV deaths has now overtaken 60 other notifiable blood-borne conditions (Ly et al., 2016). Annually, 15,000 people living in the Unites States die from HCV related disease: with PWID coinfected with HCV representing an astounding 60-70 percent (Safo, Batchelder, Peyser, & A, 2015). Notably, preventing deaths considering how knowledgeable clinicians can more readily utilize HCV screening and treatment for sickness recognition. Also to assess readiness to take part in HCV therapy among PWID who are thinking about antiviral therapy modalities.

Methadone treatment programs are expanding their services to increase programs provided to this marginalized population. Unquestionably, when MMTPs fail to effectively screen, detect, and treat PWID co-infected with HCV, treatment plans and patient outcomes are affected. Batchelder, Peyser, Nahvi, Arnsten, and Litwin (2015), semi structured qualitative interview study examined the psychosocial and behavioral transformation of clients enrolled within a combined HCV and MMTP program. Clients depicted mental, social stigma variation and disgrace related to HCV and opioid dependence, throughout the span of HCV treatment. They also reported increase HCV divulgence and self-care, decreases habitual substance use, and new longing to help other people who are living with HCV.

Affecting one hundred and seventy seven million people worldwide, endemicity hepatitis C virus currently affects approximately four million persons across America. According to the public OASAS website, in May 2017, HCV cases statewide topped to a long term fifteen year high amongst youthful grown-ups between the ages of 20-29 with IV drug use the common vector transmission denominator (Office of Addiction Services and Supports, 2020).

Market Analysis, Strategic Analysis, and Readiness for Change

Market Organizational

Identified as a global threat in 2015 by the World Health Organization (WHO), today, HCV continues to cause devastation loss to individuals, families, and communities. In 2016 the Global Health Sector Strategy assembly for 2016-2021 recommended the eradication of hepatitis as a public epidemic by 2030. Predicted to increase by 35,000 annually. HCV without proper screening, testing, and treatment will continue to multiply in the at-risk population. The evidence suggest HCV could be eradicated within MMTPs if providers could increase patient awareness,

increase screening to detect the virus and treat those affected within an integrated HCV co-occurring opioid dependency treatment program (Johnson, Aluzaite, Taar, & Schultz, 2019).

Persons who inject with drugs, the primary group for HCV transmission, who seek care for their substance use disorder within an opioid treatment facility, ideally are registered at a key location that can upscale screening, detection, and treatment for their disease under one roof. In 2017 family nurse practitioners joined the CMMC treatment team. With their vast knowledge base, which focuses on preventative medicine, an NP identified the gap in treatment and developed a plan of implementing a change project to increase screening, detecting HCV, and recommending treatment options for the eradication of the disease. Equally important the national benchmark recommends a one-time HCV testing for patients with risk factors. OASAS and SAMHSA recently mandated HCV screening for all clients, measured against national guidelines the gap analysis identified a low uptake of HCV screening. The goal of this project was to increase screening, detection and implementation of an in-house treatment site to treat patient co-infected with HCV who are opioid dependent. The change project will ultimately improve our patients' care and quality of life outcome. The upscale screening, detection, and treatment recommendations, having also impacted the change proposal, was then discussed with the medical director, program director, clinical director, and nursing coordinator.

PICOT Question

In their 2006-2013 review of incidence and prevalence of hepatitis C virus among people who inject with drugs, Jordan, Jarlais, Arasteh, McKnight, Nash, and Perlman (2015) found a 67 percent of HCV co-infected prevalence (Jordan, et al., 2015). The opioid dependency patients

who are co-infected with HCV prevalence remains increased, have a low uptake rate, and they are without treatment. Despite the increased co-occurrence of HCV and the opioid dependent population, no HCV infected clients registered at CMMC community MMTP in New York State are offered anti HCV therapy within our outpatient MMTP setting, creating a gap in treatment. Utilizing the PICOT research format, data will be gathered to critically appraise research and available evidence to guide the implementation of my capstone project. The population, intervention, comparison, outcome and timeline question designed to guide this project is: Will the implementation of an onsite hepatitis treatment module within a community based outpatient opioid treatment program, increase HCV screening, detection, client treatment compliance, and the eradication of the disease within four months? The global COVID-19 pandemic not only disrupted the day-to-day lives worldwide, its impact also affected this capstone project. In spite of the fact that the pandemic undermines everybody, it is especially grave to the large number of Americans with narcotic use problem who depend upon eye- to -eye dispensing of medication. The overseeing body SAMHSA gave rules to approve take- home methadone to decrease the patients and staff risk for COVID-19 exposure (Alexander, Stoller, Haffajee, & Saloner, 2020). In September 2020, the PICOT time frame was updated to nine months to reflect the impact of the COVID -19 monitoring of the project.

Conceptual Theoretical Framework

Risky behaviors of snorting, injecting, and non-injecting of drugs have increased the coinfection opioid-dependent and hepatitis C virus population in the US. Hepatitis C virus, if left untreated, infects the liver and is the leading cause of liver disease. Despite the fact HCV has a preventable disease sequela, screening, detection, and treatments are suboptimal. Regular surveillance, avoidance of risky behaviors, preventing complications, and early treatment all

encompass "decision-making choices," the major concept required to improve patient outcomes and quality of life. Upon completing the improvement of service need assessment, the Health Belief Model (HBM) framework was adopted to guide and support this project. Jones, Jenson, Scherr, Brown, Christy, and Weaver explained the Health Belief Model (HBM) is the most extensively used theory of health behavior (Jones, et al., 2015). Consisting of six constructs, the Health Belief Model, a psychological theories model, will be utilized to examine, explain, and predict people with coexisting HCV and opioid disorder behavior, decision making in a choice situation, promotes the patient's beliefs and the impaction on their ability to accomplish a certain task with participation with respect to HCV eradication. The Health Belief Model (HBM) will be appropriated to promote and implement the integration of HCV within a community based opioid treatment program. Using the Health Care Model as a guidance framework will enhance the understanding of health behaviors while including promotion, promoting modification of optimal behavior changes for providers, staff, and patients, and supporting the integration process to improve patient screening. The operating goal is upscaling HCV detection, enhancing treatment, and promoting a healthier lifestyle, and improving patient outcome. Equally important, the culmination and eradication of HCV for the co-infected patients at CMMC.

Rashrash, Maneno, Wutoh, Ettienne, & Draftary supported Jones et al. (2016) findings, citing the Health Belief Model has been one of the most broadly searched theoretical frameworks in healthcare research to explain public health behavioral changes (Rashrash, Maneno, Wutoh, Ettienne, & Draftary, 2016). The HBM was developed in 1950 during the initiation health literacy era of screening and preventative management of the disease. Social psychologists Hochbaum, Resenstock, and Kegal (1952) created the HBM framework to assist the US Public Health Service to grasp why people refuse to participate in disease prevention strategies and

preventative screening tests. The developers hypothesized that two component factors influence the health-related behavioral changes: change in behavior will avoid a threat or progression of illness, and compliance with treatment will eliminate the threat or cure the illness. According to Urich (2017), the framework has also been used to understand the patient's response to education, adherence to medical regimen, and perceived alterations in lifestyle changes to prevent chronic illnesses (Urich, 2017). The fundamental modification and course of action are contingent on the patient's belief and perception of the benefits and constraints related to the illness/disease. The HBM originated around six constructs: perceived ideology and a self-efficacy ideology, the concept of HBM influences subjective beliefs, perceptions, and behavior. Additionally, it utilizes the health belief theory for the risk or actual behavior, empowering clients with the co-occurring disease of hepatitis C and opioid use disorder who are enrolled at the community-based OTP to participate in HCV health promotion and complete therapy to improve health literacy and maximization of quality of life. The model is used to influence the patient's behavior to a perceived threat to illness, disease, or death; the failure or consequences to accept the recommendation and adherence to treatment. Four of the constructs were original to the HBM model and two were integrated as the model developed :Perceive susceptibility, perceived severity, perceived benefit, perceived barriers, cues to action, and self-efficacy (Appendix K).

Definition of Variables

Conceptual and Operational Definitions

Perceived susceptibility: This construct relates to the patient's own subjective belief and view of past behavioral risky practices for contracting or having the HCV such as a one-time intravenous or nasal use of illicit drugs. The HBM foresees the patient will recall the risky

behavior and will then agree for screening and avoid behaviors that will increase the risk of contracting the disease.

Operational behavior. Perceived susceptibility was measured after the patients were provided with educational written materials and verbal teachings regarding the new policy of one-time HCV testing for all patients.

Perceived seriousness of the conditions: This construct examines the patient's feelings on the severity of the progression of HCV if left untreated.

Operational definition: If infected with the HCV and the patient fails to screen to detect the. infection, or those with the infection, fails to initiate treatment therapy; the patient risks developing liver carcinoma.

Perceived benefits. Do perceived benefits sketch the positive feelings and beliefs of avoiding risky behaviors to prevent Infection or reinfection of HCV and adherence to treatment results in the eradication of liver disease.

Operational definition Perceived benefits of the action: Screening and HCV medication compliance effectively identifying and eliminating liver disease and carcinoma, which increase the patient lifespan.

Perceived barriers of the action: Perceived barriers paint obstacles, complications, negative ramifications, infliction of liver cancer, decreased quality of life and a shortened life span for failure to screen and be treated for HCV.

Operational definition. Will the patient's cessation of IV and nasal use of illicit drug and refusal of screening eliminates the HCV.

Cue to action: This is the trigger provoking question the patient will contemplate to spark and ignite the desire to be screened for HCV, initiation of treatment, and completion HCV therapy.

The desire for prolonged life, increase health, and improved quality of life to share with family and significant others are goals of the human race.

Operational definition: Information regarding unstreamed screening, in-house treatment, the ease of access to PCP, PCP monitoring, approval for medication by insurance companies, and medication with minimal side effects that provides healing for "my liver" and prevent liver cancer are interval conflicts that stimulate the activity of agreeance for testing.

Self -Efficacy: The belief the patient can avoid risky behavior, initiate testing or treatment, and maintaining compliance with treatment.

Operational definition the patient completes HCV screening, accepting the diagnosis and completing therapy accomplishing the desired behavior to increase the eradication of HCV providing increase quality of life and an extended lifespan with my family and loved ones

Both HCV and opioid use disorder are common chronic disorders. Registration and daily adherence within an opioid-dependent drug program require multiple lifestyle changes to receive treatment for hepatitis C virus effectively. Within CMMC, currently during intake and annual history, there is an increase prevalence of screening refusal and untreated HCV patients respectively within my area of practice. This DNP capstone project was formulated to increase screening, educate, and increase uptake of treatment by using the HBM theoretical framework.

AIM Statement

This capstone project will focus on people who inject with drugs, who are co-infected with opioid dependency, and registered in a methadone clinic. The essential aim of this quality improvement capstone project is to expand HCV screening, testing, and treatment to eradicate HCV among patients with a co-occurring diagnosis of opioid use disorder enrolled inside

MMTPs. With the emergence of the novel COVID 19 epidemic, the underlying objective goal for the implementation of the capstone project extended to the end of 2020.

Prior to the FNP provider partnership within the CMMC provider plan, existing practice HCV screening and testing protocol at CMMC was offered for symptomatic patients. With no symptoms, no prophylactic vaccine on the horizon, and the development of cost-effective, efficacious DAAs with treatment duration of 12 week, it is imperative to upscale screening in people co-infected with HCV. This capstone project will focus on people who inject with drugs, opioid dependent, co-infected with HCV, and registered in methadone outpatient treatment programs. Prior to FNP provider partnership within the CMMC provider plan, existing practice HCV screening protocol at CMMC was offered for symptomatic patients. Besides, with no prophylactic vaccine on the horizon, and the development of cost-effective, efficacious DAAs with treatment duration of 12 weeks, it is imperative to upscale screening in people co-infected with HCV and opioid use disorder.

Objectives

The purpose of this quality improvement capstone project was to develop and implement a toolkit for healthcare providers and patients to upscale screening, testing, detection, treatment, and eradication of HCV in patients with co-occurring opioid dependency registered at CMMC substance use disorder methadone clinic in New York City. The patient-centered quality improvement project main objects and after-effect markers driving the capstone project are to attain the targeted goal, which includes the following:

1) Conduct a gap analysis of CMMC to include an evaluation of current HCV and opioid use disorder literature on implementing a co-location treatment model within

MMTP to upscale HCV screening, testing and treatment to eradicate HCV within this marginalized population.

2) Implement HCV screening for all new admission and one-time screening for all registrants at the CMMP methadone treatment program by 100 percent.

3) Increase testing to determine the existence of HCV virus by 100 percent. 4) Increase detection to isolate to confirm or repudiate the presence of HCV at 100 percent.

5) Increase engagement in treatment to eradicate HCV in this marginalized population by 80 percent.

6) One hundred percent MMTP staff compliance with lifelong. HCV education of patients.

Section III. Critical Appraisal of the Evidence

Introduction

Hepatitis C Virus (HCV) infection has infected millions of lives across the world (2019). The Centers for Disease Control and Prevention (CDC) state there is no immunization against hepatitis C and no powerful pre-or post-exposure prophylaxis accessible. Studies led during 2013–2016 demonstrated an expected 2.4 million people (1.0%) across America were living with hepatitis C virus. Percutaneous introduction is the most effective method of HCV transmission and infusion drug use (IDU) accounts for more than half of people who become infected with HCV. Moreover, in 2017, an aggregate of 3,216 cases (1.0 per 100,000 populace) of positive HCV disease were accounted to the CDC. The detailed number of cases probably speaks to fewer than ten percent of the real number of cases as a result of down-scaled screening and under-reporting thus creating reservoirs and constant carriers if untreated (Schillie,

Wester, Osborne, Wesolowski, & Ryerson, 2020). According to the US Preventative Service Task Force (USPSTF) (2020), HCV is the most widely recognized ongoing blood-borne microorganism in the US and a main source of persistent sequela liver disease. The task force closes with recommending a moderate sureness that screening for HCV disease during birth and at ages 18 to 79 years has a generous net advantage (The US Task Force, 2020). Internationally, The World Health Organization estimates an expected 71 million individuals with persistent hepatitis C infection contamination, recognizing causative mode as a bit of blood introduction. Transference modes of the disease is through an unsafe infusion of needle drug use, hazardous medical services, tainted infected bonding of unscreened blood, and sexual practices that lead to an introduction of blood. With approximately two million infectious persons globally on, testing for against HCV antibodies with a serological test distinguishes individuals who have been contaminated with the infection (World Health Organization, 2020). Consequently, the opioid dependency population deserves execution improvement techniques with the aim to improve screening, testing quality, by making changes to the cycle, conventions, treatment, and suppression of the disease regardless of the disparaged narcotic use problems of the population co-infected with HCV. With no immunization on the horizon, HCV does not generally need treatment, as the insusceptible reaction in certain individuals will clear the disease. Notwithstanding, when HCV contamination becomes constant, treatment is fundamental. The objective of hepatitis C treatment is screening, treatment, and cure.

Search Strategies and Yields

Literature Review

A comprehensive electronic data search was conducted to examine evidence-based research articles supporting hepatitis C screening, treatment compliance, and implementation of

an onsite of HCV treatment program within an opioid treatment program. Additionally, a literature review was conducted to examine and determine the existence of stand-alone integrated methadone and hepatitis C treatment entity infrastructures within an opioid treatment program. In an effort to answer the PICOT question, the central electronic databases were accessed and searched for relevant articles published in English and published in the last five years: CINAHL, EBSCO, Medline via PubMed, Medline via Ovid, Centers for Disease Control and Prevention (CDC), World Health Organization (WHO), Journal of Substance Abuse, Substance Abuse Treatment, Prevention and Policy, SAMHSA, OASAS, Journal of the American Medical Association, Journal of Addiction Medicine, Hepatology, Science Direct, BMC Infectious Disease, National Institute of Health, and the United States Preventive Services Task Force. Accessed articles ranging from January 2015 through the current date were obtained through the college website and place of employment. Terms and phrases used included the following search terms, *Hepatitis C Virus, HCV, people who inject with drugs, opioid, opioid use disorder, opioid dependency, opioid addiction, methadone treatment programs, medication-assisted treatment, methadone maintenance treatment program (MMTP), outpatient treatment program* (*OTP), integration of HCV and opioid dependency, barriers to HCV within OTP, onsite HCW within OTP and HCV screening*.

The databases yielded over 2,000,000 articles, but when the research term was limited to HCV, hepatitis C, people who inject with drugs, opioid dependency treatment programs, integrated care, HCV co-location, HCV under-one-roof, and HCV onsite treatment, the results yielded approximately four thousand, articles. With limited US studies research articles available, worldwide research was included. Studies completed in non-English language were excluded, as well as duplicated items across databases, opioid uses in the age groups below

seventeen years, those addressing mental health and Hepatitis B virus, HIV, Hepatitis A virus, Buprenorphine, and Naloxone. Inclusion criteria included systematic reviews with meta-analysis, systematic reviews, case studies, cohort review, retrospective review, integrated models, simulation, quality improvement, and practice guidelines. Primary sources published in peer reviewed journals published within the past five years and based on their titles addressing HCV, people who inject with drugs, OTP with, or without the combination of onsite care, co-location, and integration of care were the main journal articles examined. Notably, once screened against inclusion and exclusion criteria, twenty-five studies were selected.

Evidence Rating Scheme

The articles were evaluated using the Oxford Level Classification of Evidence-Based Medicine (CEBM) Ranking Recommendations in Clinical Guidelines (Howick, et al., 2021). Geared to promote evidence-based decision-making for medical professionals and clinicians, the CEBM primarily focuses on preventative measures, treatment diagnosis, differential diagnosis, and prevalence of symptoms in healthcare. For straightforwardness and effortlessness, utilizing this scoring framework, which is dedicated to practice, is in the accompanying sections. The clinical trials show evidence of support by the Roman numeral I, II, or III. Roman numeral I was proof from in any event of one appropriately randomized controlled preliminary trial conducted. Roman numeral II is research evidence from at any rate one well-designed planned clinical preliminary study, without randomization, or from a cohort study or case-controlled logical investigations. Roman numeral III were clinically tested trials from assessments of highly regarded specialists/panelist in light of clinical experience, graphic investigations, or expert boards' reports. This rating scale examines the strength of the evidence for therapeutic intervention (i.e., Level one through five), the article grading, and the quality recommendations

of the evidence (A, B, C or D). Once screened against the inclusion and exclusion criteria, the twenty-five articles selected were predominantly rated CEBM evidence levels one through seven. The evaluating CEBM evidence table can be found in appendices E (page 111)

Review of the Evidence

People who inject with IV drugs face multiple challenges of homelessness, poverty, dysfunctional relationships, rejection, incarceration, mental health disorders, and the social and medical issues of hepatitis C infection. As of 2017, the New York State Department of Health reported 153,000 new lab reports, with females representing 56.7 percent and males 91.4 percent per 100,000 of those with acute and chronic HCV infections (Maxted, 2017). The results were predominately increased in young males, white, and non-Hispanic adults who inject with drugs.

The work of Jessop et al. (2020) supports that the hepatitis C virus (HCV) is a highly prevalent infection in current and former IV drug users (Jessop, Bass, Brajuha, Alhajji, Burke, Gashat, Wellington, Ventriglia, Coleman, D'Avanzo, 2020). Aside from this, the article, a randomized control trial (RCT) reports that over 70 percent of people registered in methadone treatment programs have HCV, but only 11 percent have initiated treatment despite the availability of new direct -acting antivirals (DAA), which incidentally are easily tolerated and can cure the infection in eight to twelve weeks (Jessop, et al., 2020). The RCT conducted a pilot trial, and the sample for this study consisted of 122 participants. Utilizing a "Take Charge, Get Cured" decisional treatment tool, data was collected by means of a tool-kit in which they were tested on, feasibility, acceptability, and promise of efficacy to participants was circulated via electronic tablet and participants responded to post-test questions. At three months, a follow-up survey was conducted. Ninety-three participants who received the Take Charge, Get Cured tool, representing 76 percent of the participants expressed the tool helped them with decision making,

intention to be treated for their HCV virus, and demonstrated more significant improvement in HCV knowledge. In comparison to participants who received no targeted decisional tool, these participants reported increased knowledge with intention to be screened, tested, and comply with HCV treatment (Jessop, et al., 2020).

With increased availability and the past decade of the availability of DAA, as a high priority, the US food and Drug Administration, and the National and State Health Departments have heightened their response by including DAA treatment modalities in the eradication of HCV. A retrospective review, drawing on the work of Trabut, Barrault, Charlot, Carmona, Bourdel, Brenslimane & Roudot-Thoraval, (2018) where 50 HCV participants in this study were selected from individuals with a history of addiction receiving treatment with DAAs (Trabut, et al., 2018). The subjects of this study consisted of forty-two males and eight females. Participants were asked to compare five DAA regimens. These regimens of varying weeks, sofosbuvir/ledipasvir for eight weeks (n= three), sofosbuvir/ledipasvir and Ribavirin for 12 weeks (N=19), and sofosbuvir/daclatasvir for 12 weeks (N=20) sofosbuvir/simeprevir (N=1) or sofosbuvir/ daclatasvir for 24 weeks (N=20) were utilized according to the European guidelines. The data analysis was based on univariate analysis. The results of forty-five participants achieved a 90 percent sustained virological response (SVR) rate with no significantly associated sociodemographic or viral characteristics treatment or socio environment, drug use, and adherence. The findings were reported as consistent with "the real world SVR rate of 90 percent" in improving the overall health and quality of life for participants' registered within OTPs. They the DAAs' were decreasing the risk of liver failure, liver cirrhosis, and liver-related deaths. Of greatest significance, providers will gain confidence in prescribing DAA, and patients will comply and remain registered in therapy for the eradication of the HCV infection. Also, with

improvement, some patients can be removed from the liver transplantation list and the compilation list developed at CMMC.

A Jordon, Cleland, Wyka, Schackman, Perlman, and Nash (2020) cohort study assessed the incidence of HCV among 8352 patients registered in substance use disorder program across New York City spanning from January 2013 to December 2016. The study found approximately forty-nine percent of first-time testers yielded a positive HCV result with an incidence of approximately seven percent active IV drug users. The researching findings suggested HCV occurrence was higher among those with lower MMTP daily compliance and lower among those accepting higher methadone portions, recommending satisfactory methadone dosages enhanced HCV engagement and treatment commitment thus supporting a co-integration of HCV module within MMTPs (Jordon, et al., 2020).

Australia has one of the highest HCV diagnoses in the world. Therefore, like other foreign organizations, Australia developed The Australian Society Hepatitis C Guidelines (2014) to upscale treatment (Thompson, 2016). The panel recommended testing and treatment with DDAs for all persons within their borders who shared or injected drugs infected with chronic HCV. Australia's National Hepatitis C Strategy (2014) guidelines identified people who inject drugs as a priority population (Butler, Day, Dietze, Bruno, Alati, Burns, 2015). According to Butler et al., in Australia, 90 percent of newly diagnosed HCV is acquired by people injecting drugs, and people living with HCV will experience an accelerated rate of liver damage, which will increase their risk of severe life-threatening liver disease (Butler, et al., 2015). The researchers' survey results found if healthcare providers were screening for HCV, the screening would prevent a missed opportunity, an increase infection rate would be identified, and

appropriate evaluation and treatment utilized, coupled with decreased cost, would be of great importance in preventing the progression of liver disease and the reduction of morbidity and mortality. These finding were echoed by Turner et al (Butler, et al., 2015) (Turner, Taylor, Hanson, Liang, Veerapaneni, Villarreal, Perez & Fiebelkorn, 2015).

During the investigation process, the DNP candidate was able to locate a superb resource titled " *High Priority for Hepatitis C Screening in Safety Net Hospitals: Results from a Prospective Cohort of 4582 Hospitalized Baby Boomers*" by Turner et al., (2015) . The article highlighted the importance of healthcare settings infrastructure, providing services to the low-income population, and linkage to HCV care. There is an increasing prevalence of HCV within this socio-economic population. The underpinning relationship between the low-income population and HCV infection in individuals born between 1945 and 1965 highlights the importance of HCV screening, diagnosing, and treating this cohort. Although conducted within a hospital setting in Texas from December 2012 through August 2014, the study showcased the importance of HCV screening, linkage to HCV treatment, and healthcare infrastructure supporting CMMC's role in implementing an in-house HCV dual treatment module. Approximately 4600 of the admitted patients to the Texas facility; upon screening and testing, ninety percent of the patient completed tested, and seven percent resulted positive for HCV. The result representing a doubling HCV increase of the national rate (Turner, et al., 2015)

In Spain, Roncero, Littlewood, Vega, Martinez-Raga, and Torrens (2017) carried out an extensive study involving 28 sources of relevant published pieces of literature of 300,000 individuals with a lifetime history of injecting drugs (Roncero, et al., 2019). Roncero et al. (2017) support the notion there is a high HCV prevalence in individuals who inject drugs

(Roncero, Littlewood, Vega, Martinez-Raga, & Torrens, 2017). Strictly speaking, Roncero (2017) expressed concerns that individuals in these groups are underserved, have a higher mortality rate, and when compared to the general public, experienced difficulties, if not a hardship, to access health care resulting in a wider public health problem in Spain. Roncero's 2017 study discussion of opioid use includes access to harm reduction, medication-assisted treatment, and openly acknowledge that 2500 specialist drug treatment clinics are "stand-alone" with psychiatrists and addiction expert physicians, psychologists, and nurses on site. The authors consulted with experts and shed light on PWID experience in obtaining access and completing hepatitis C therapy.

Aside from this, Roncero et al., (2017) also provided detailed information on the role of healthcare providers. The healthcare providers provided screening, but in reality, Roncero et al., argues engagement and retesting is not a routine practice. Besides, healthcare providers also lack awareness of the evolution of HCV, the development of new therapies while reporting these deficiencies limit increasing providers' knowledge, engagement, and advocacy for those infected. The study further identified patient characteristics impeding compliance, treatment, and engagement. Nonetheless, PWID lack motivation, have diminished health and social equity status, are underinsurance, fearful as they fear side effects of interferon-based treatment, and have decrease knowledge of evolving treatment modalities.

Furthermore, the article also reported a decrease in HCV awareness and decreased understanding of the sequelae of HCV were less viewed as common limitations. One of the central claims of this is, the limitations and challenges faced may be addressed by providing a supporting collaboration of drug treatment, developing a jointly shared protocol, and implementing HCV care protocols for HCV patients. Equally important are healthcare providers

and all stakeholders involved with the patient care and the endpoint providers' referrals at outpatient social services. More than anything else, the lack of insurance, no insurance or underinsurance, may decrease the benefits of screening for this population and identify them as asymptomatic HCV-infected individuals who are less likely to pursue downstream care (Ditah, et al., 2015).

Treatment of outpatient opioid users is predominately off-site, often operating as a stand-alone, corresponding to approximately 61 percent, followed by affiliation with a medical healthcare system or acute care hospital 16 percent (Jones, et al., 2019). In 2011, SAMSHA reported there are approximately 1500 OTP programs in the United State a number that is expected to increase. As stated previously, approximately 190 million people in the United States living with chronic Hepatitis C, which incidentally, is now the most common blood-borne infection, having surpassed HIV as a leading cause of death statewide (Frimpong & D'Aunno, 2016). A systematic review by Frimpong and D'Aunno, (2016) compared investigated characteristics of outpatient treatment programs substance use disorder (SUD) managers reporting there is a limited investigation in this area. This investigation draws from two influxes investigate studies conducted prior by the researchers in 2005 with a follow up in 2011 of the National Drug Abuse Treatment System Survey (NDATSS). NDATSS is a statewide review agency, which inspects the authoritative structures and working qualities of the country's outpatient SUD treatment programs. They reported these studies were selected due to the opioid user predominant use of the number one infectious cause IV use- transmission of HCV. The sample size of 187 OTP was selected from the National Drug abuse Treatment Survey (NDATSS), a nationally representative survey that examines substance use disorder (SUD) organization structures. Additionally, to decrease bias, 200 OTP's from SAMSHA, the licensing

and governing body for OTPS were selected, some of which were chosen randomly. The research design involved data collection through the use of a completed telephone survey on treatment practices and program characteristics. In discussing the role of program managers, Frimpong and D'Aunno (2016) hypothesized there are three vital traits of managers related to the utilization of their organizational implementation of HCV testing: The manager's educational completion, knowledge, and utilization of evidence-based materials and support for preventative treatment.

Programs offering opioid treatment already have multilevel interventions geared to supporting patients. The application of best practice for a population underserved and unaware of their HCV infection promotes patient engagement and breaks the cycle of underachievers. Increasing new enrollment HCV testing for all admission in substance abuse outpatient treatment programs could be helped significantly to decrease the majority of HCV infected people. Frimpong & D'Aunno, (2016) pointed out increased HCV testing and integration within an MMTP program where managers offer HVC testing and programs managers are African American, these managers were more likely to offer onsite HCV testing than other programs. The authors rationalized the association of African American managers are more inclined to be employed in higher minority programs.

In a randomized trial conducted in New York and San Francisco, a decision-analytic model was used to compare HCV screening, education, and care coordination to no screening utilizing a control group HCV screening and education (Schackman, Gutkind, Morgan, Leff, Behrends, Delucchi, Mcknight & Linas, 2018). In the second analysis, the randomized trial added a fourth variable, HCV screening, education for all, and care coordination for HCV mono-infected patients. Schackman et al., (2018), concluded HCV care coordination interventions that included

screening, eradication, and linkage to care in MMTP settings were much more likely to be cost-effective.

The authors recommended these interventions should be significant for the implementation of an integrated viral hepatitis C Strategy (Schackman B. , et al., 2018). Simply put, in recent years, researchers have become increasingly interested in the integration of the HCV module and opioid use disorders treatment program to formulate collaborative care setting to improve patient compliance and outcomes. This is due to the fact patients will have increase monitoring, increase timeliness, an active linkage of care, continuation of care, cost-effectiveness, increase in quality of life and, most importantly, increase DAA medication adherence. However, screening, testing, and treatment of people who inject with drugs are lower than the recommended guidelines. Aside from this, the article utilized the Anderson Behavioral Model to tabulate responses to the knowledge of HCV, attitude, and treatment towards the disease and choice facilities to treat the disease. The conclusion garnered from the results found and argues patients had a moderate health literacy of oral DAA and the minimal side effects of medication in the management HCV, suggesting healthcare providers provided limited education regarding the availability of new treatment.

Sacket et al, (2018) outcome were supported by Perlman, Jordon, Uuskula, Huong, Masson, Schackman, and Jarlais (2015) organizational structures assessment study. Perlman et al, (2015) openly acknowledge inter-associational factors obstruct the co-occurring HCV and opioid use group population integration platform (Perlman, et al., 2015). These findings heighten OTP inadequacies in effectively treating opioid use disorder, its primary care service platform is concerning. On further examination of the article, the following also greatly impact substance use treatment program integration of an onsite HCV model upstretched HCV treatment cost,

insurance dismissal of HCV and OTP treatment, and the patient admittance to continuing illicit opioid binging (Perlman, et al., 2015).

Improving access disparity and elimination numerous barriers play a pivotal role in HCV engagement to achieve curability, treatment package, and naivety of additional treatment gaps. Also, ninety-three percent of the participants believed the opioid provider should recommend HCV treatment to those infected and perceived failure to recommend treatment as not important. Aside from this, the participants reported barriers to their continued substance abuse, lack of treatment information, limited access to treatment, decreased confidentiality in completing therapy, stigmatization, and mistrust of the healthcare system.

According to the Substance Abuse and Mental Health Service Administration SAMHSA, today, tackling the substance abuse disorder is challenging. Lifetime substance abuse users affect males more than females and are a disorder that has quadrupled in the last decade in an arena where prescription drugs have risen steeply. In the United States, there is an increase of unintentional overdose death in people who inject with drugs. Despite this, there is an increase in registrants of the outpatient program and the people infected with HCV have increased. Kampman and Jarvis, (2015) argued that suboptimal treatment within OTP might likely contribute to the expansion of the epidemic. This, nevertheless, is concerning for ethical practices as few providers are willing to provide care in this setting. According to Kampman & Jarvis, (2015) staff educational training and team building are crucial. Additionally, patient engagement and support, increased confidentiality, and a non-judgmental arena will build a patient-provider rapport while increasing morale, thus promoting a successful integration of care. Despite PWID relapsing tendencies, eradication of HCV will improve patient and staff morale, increase personal lifestyle, and improve the economic and public health.

The work of Morris, Smirnov, Kvassay, Leslie, Kavanagh, Alexander, Davey, Williams, Gilks, and Najman (2017), demonstrates the feasibility and effectiveness of integrating HCV care within a methadone treatment maintenance program. In an observational study, in Australia, 127 patient charts were reviewed after the integration of an MMTP and HCV care. Treatment response data gathered indicated HCV screening, treatment, retention, and SVR which indicates eradication of the HCV disease, can be sustained within MMTP improving patients' engagement and employing trained providers. Also, Morris et al. (2017) also identified the following crucial information; counseling sessions and frequent patient visits to the MMTP were effective in maintaining ongoing assessment and monitoring (Morris, et al., 2017). In comparison to Butner et al., (2017) retrospective study, both studies demonstrated comparable SVR outcomes. Butner et al. (2017) also argues concurrent treatment within an MMTP has significant benefits, especially in the public health sector. Both studies supported onsite HCV treatment and facilitated effective adherence to concurrent HCV treatment.

Springer and Del Rio (2020), in their study also supports the co-location of HCV and the opioid dependency population. The article, a retrospective observational study, observed 100 HCV participants ages 18-24 years registered within an integrated HCV and OUD program who received DAA treatment for 24 weeks concludes it is not only important and effective to integrate HCV and opioid addiction service under one roof, but it is also elevating patient outcome (Springer & Del Rio, 2020). A Taiwan retrospective study by Tai, Yen Bair, Tseng, Chang, Huang, Yeh, Dai, Chuang, Yu and Huang found consistent trends in their HCV screening and treatment suppression. This article found increasing patient engagement and higher education attainment enhances treatment compliance. They also reported patients who completed HCV treatment are associated with treatment success. Interestingly, the study reports only 65

percent of those surveyed completed HCV treatment and for those who failed reported medication intolerance (Tai, et al., 2019). This article supported HCV and MMTP integration. Martin, Bosse, Wilson, Losikoff, and Chiodo (2018) expanded on integrating an HCV treatment model within MMTPs. Their article, a commentary, culminated by identifying effective barrier removals to enhance HCV uptake and treatment. The authors first, supported embedding HCV within OTPs, increasing access to the efficacious DAAs, and increasing therapeutic clinician engagement. The latter ensures practical patient assessment, increases patient motivation, and maximizing treatment adherence. The commentary also supports screening all registrants of MMTP. Of the 750 patients screened, Martin et al. isolated 25-30 percent HCV positive antibodies and 23 percent with chronic untreated HCV, and all were offered HCV treatment. Seventy-two percent accepted treatment onsite, 48 percent completed treatment, four were lost to follow-up, and two failed to complete treatment. The editorial found PWID and infected with HCV experience fragmented care, and MMTP's infrastructure is uniquely poised to incorporate HCV treatment or expand services to decrease HCV desert as a co-location treatment facility (Martin, Bosse, Wilson, & Losikoff, 2018)

An increase number of patients enrolled within MMTPs are assessed, screened, tested, or treated for HCV. In their plan to appraise an incorporated HCV tainted patient model within MMT registrant's clinic, the researcher noted patients' commitment on recommendation for treatment upsurge from fourteen percent to fifty -eight percent, of which PWID were included. Their finding found despite an increase in patients' engagement on being referred to a liver specialist, only a minority of MMT patients achieve successful treatment (Tai, et al., 2019)

Inasmuch as the hepatitis C virus, a major public threat is underappreciated, this lack of attention, screening, and awareness about the disease translates into missed health uptake,

detection, management, and preventative opportunities. Also, despite advanced technology, the availability of published peer-reviewed and evidence-based guidelines, healthcare providers, PCP's and APN's face challenges within their daily scope (Falade-Nwulia, et al., 2019). In the convenience sample data provided, Roncero et al. (2019), reported although 22 percent of PCPs agreed a provider should prescribe DAA, 84 percent were much more interested in HCV training, offering support, and admitted to minimum knowledge within the field. (Roncero, Littlewood, Vega, Martinez-Raga, & Torrens, 2017)

Results of study Taylor's 2020 expert peer-reviewed studied the role in the co-location of HCV within MMTP's models indicating integration improves patients outcomes. Taylor assessed the effectiveness of HCV co-location of care within MMTPs and identified PWID enrolled within MMTS; are already engaged in treatment; improves HCV retention in care, and infrastructure supports utilizing DAA's. Together with a multi-disciplinary supportive behavioral staff, and decrease in stigma bolster screening, testing, and treatment to accelerate the eradication of HCV (Taylor, 2020), solidifying CMMC's co-location aim.

Falade-Nwulia, Irvin, Merkow, Sulowski, Niculescu, Olsen, Stoller, and Mehta (2019) in their convenience sample outlined several significant barriers and facilitators of the co-infection of HCV and people who inject with drugs. In their discussion, Falade-Nwulia et al., (2019) report in the United States, HCV is a major public health issue among PWID and, as of 2014, was associated with more deaths in the US than all other reportable infectious diseases. Subsequently, people who inject drugs are disproportionately—impacted by HCV, with a prevalence rate of 50-80 percent (Falade-Nwulia, et al., 2019). The study's convenience sample consisted of 650 HCV co-infected participants with substance abusers enrolled at a drug treatment program at two participating OTPs in Baltimore, Maryland. At the programs, the participants received

counseling sessions, substance abuse education, relapse prevention, HCV/HIV risk reeducation education, sobriety planning, and risk education teaching. For HCV treatment, clients were referred out to hospital and community resources. Neither programs facilitated onsite HCV screening, rapid HCV screening, onsite HCV treatment, or primary care. Interested patients were selected to participate in a 15-20 questionnaire regarding HCV history, treatment, recommendation, HCV treatment by a provider, and HCV initiation. Pursuing this further, the researchers using a Likert scale of one through five, with five being the highest, list open ending response to the question regarding minimizing barriers in treating HCV as the next step for upscaling participation.

More tellingly, Perlman et al, (2017) supported Falade-Nwulia, et al., (2019) finding raising concerns and gaps in HCV treatment cost, insurance dismissal of HCV and OTP treatment claims, reduced access to care, stigmatization and marginalized engagement for individuals who self- reported continued IV drug abuse of narcotic illicit drugs. To increase global recognition and response, the researchers encouraged OTPs to utilize their platform to empower installing HCV treatment within OTP, viewing the integration as a vital component in eradicating HCV worldwide.

Of great importance, the cost of HCV treatment within an HCV housed within methadone. In a decision analytic model, Schackman and colleagues, (2018) found the cost - value of HCV, uptake, testing, and treatment connection within MMPTS as cost-effective. In discussing the cost-effectiveness of an integrated HCV and MMPT programs, Schachman's decision analytical model established a projected control group strategy linkage of HCV care of 35 percent within six- months. At which time at the completion of HCV therapy , 31 percent will achieve sustained viral load. In comparison to applying the integrated service, which resulted in

a 60 percent HCV diagnosis and 54 percent of patients achieving SVR, which translates to an upsurge of patients and an increase eradication of HCV. In comparing cost, no intervention yielded 76 thousand dollars comparison to an intervention cost of approximately 25,000 dollars. The study concluded MMTPs improves HCV care coordination mediation inside MMTPs settings and are likely financially cost-effective (Schackman B. , et al., 2018).

Concerning the 1997 National Institute of Health recommendation to withhold HCV in PWID using drugs until the PWID halted use for a half- year reports apportioning or limiting access to medical services is regularly practiced in medical services healthcare systems. The researchers ascribed apportioning to incorporate money saving advantages, investigation, and cost viability which they contrasted with moral multifaceted nature encompassing sickness, wellbeing, recuperation, and passing. More broadly, the researches concurred with the advancement of the new progressive DDA's to treat HCV. There is convincing evidence HCV treatment is effective and successful in treating PWID. Grebely et al, (2015) also recommended eliminating all limitations on access to new HCV treatment for those dependent on narcotic replacement treatment (Grebely, et al., 2015)

Today, numerous national guidelines, medical organization, and community assessment plans, are executing the National Viral Hepatitis Action Plan (U. S. Department of Health & Human Services, 2020). Incidentally, the plan recommends stakeholder collaboration, coordinating services, and developing learning opportunities to support HCV treatment and expanding HCV awareness within healthcare services. In a multisite observational ETHOS study to pinpoint treatment barriers Keats, Micallef, Grebely, Hazelwood, and Everingham (2015) gauged HCV co-occurring assessment and eradication techniques within MMTPs. Results of the study concluded peer support workers, a member of the interdisciplinary team,

facilitated increased engagement, education , HCV discussion, and treatment. It also allowed stakeholders to focus on the HCV continuum. However, instead of sustaining a HCV upsurge, the intervention produced low treatment compliance, isolated barriers for HCV eradication suggesting the need for further studies (Keats, et al., 2015)

Hepatitis C Treatment Guidelines

With no available vaccination to treat HCV, in 1998, the CDC released recommendation guidelines for the screening and testing of HCV. These guidelines were released to guide healthcare providers for HCV testing of individuals born between 1945 through 1965. In conjunction with the US Preventative Service Task Force (USPSTF), the committee recommended all Americans born from 1945 through1965 should receive one-time testing for HCV without prior ascertainment of HCV risk. HCV is a slow progressing insidious disease; therefore, recommendations were also made for primary care providers to obtain a complete hepatitis C screening for the baby boomers 1945-1965 cohort.

In 2013, the two major liver and infectious disease treatment specialist groups – The American Association for the Study of Liver Disease (AASLD) and Infectious Disease Society of America(IDSA)-combined forces and developed screening and testing guidelines for the management of HCV. The following recommendations were drafted: 1945-1965 birth cohort and other persons based on exposure, behaviors, and conditions that increase the risk for HCV infection: All persons recommended for HCV testing should first be screened and tested for anti-HCV using an FDA approved test with positive result confirmation performed utilizing nucleic acid testing for HCV RNA and recommendation for annual HCV testing for persons who inject with drugs and HIV seropositive men who have unprotected sex with men. Most importantly, the offering of periodic testing for ongoing risk of HCV exposure. The American

Association for the Study of Liver Disease (AASLD) and Infectious Disease Society of America (IDSA) also created direct educational mandates for HCV persons. These mandates , in 2013, stressed the importance of patient education about their disease and how to prevent further damage to their liver and the utilization of direct-antivirals.

In 2017, the CDC revised its guidelines for the birth cohort 1946-1965. Rewritten and updated the guidelines recommendations include offering a one-time HCV screening for all individuals born between 1946 through 1965 and screening all persons at high risk integrating the substance abuse populate and people who inject with drugs.

Section IV: Methodology and Implementation

Context

The theme and recommendations from the studies reviewed indicate the need for upscaling HCV screening, detection, and treatment utilizing an in-house HCV treatment module within opioid addiction treatment programs. This section will examine the strategy used to research the implementation of HCV screening and treatment within an MMTP program, the project's goal**,** tools, and variables used to measure the importance of upscaling HCV screening and treatment in opioid dependency stigmatized population. Besides, the HCV team and DNP candidate will discuss data collection procedures during the screening, testing, and treatment. It is important to protect the vulnerable opioid addiction population. The timeframe and its adjustment will also be examined as the COVID-19 pandemic continues its wave in New York City. In conclusion, the section will describe the project's sustainability incorporating SAMHSA advancement of methadone “take home bottles” in the MMTP population. The section will

conclude with the anticipated resources, budgets, and cost factors associated with implementing the project.

This quality improvement incorporates the HCV treatment model within an opioid treatment program to increase HCV screening, testing, and treatment to eradicate the hepatitis C virus in the opioid use dependency population.

Study Design

The capstone project intermingled with engaging staff on HCV improvement training standards and executing current OASAS and SAMHSA HCV guidelines to increase HCV testing, treatment, and elimination within the MMTP program. It is essential to look at the staff and implement, engage patient commitment, and address how to create and actualize frameworks to guarantee the staff's continued empowerment to facilitate order and drive to make changes in their workplace to enhance CMMC patient's well-being.

This project was created as a non-invasive intent-to-treat quality improvement quantitative design capstone project in an opioid use disorder maintenance program affiliated with a large hospital in Westchester, New York. With no comparison data, the design was fitting to examine and measure the increase in patients' HCV uptake, testing, treating, and cure rate within a substance abuse outpatient clinic. The AHRQ quality indicator tool-box will be used to measure the data. A substance abuse maintenance program was selected due to the current opioid epidemic and HCV upsurge in the US, which incidentally is associated with an increase in PWID (Zibbell J. , et al., 2018).

The project design guided the participants throughout the health care model stages from their perceived susceptibility of longstanding history of IV drug use HCV to the impact of HCV sequela and diagnosis of liver hepatocellular adenocarcinoma. The perceived benefits of an

increased lifespan, the perceived barriers of continued opioid addiction, and the ability to adhere to HCV treatment to prevent a life-debilitating disease utilizing along with improved HCV antiviral medications, is a goal which can be achieved in three months. For this project, all registered patients will be screened for HCV, tested for the virus, and an MMTP integrated model will offer treatment in-house to those with a positive HCV result. The patient's progress from screening to completion of therapy will be monitored. Therefore, the design's goal was to inspire behavioral changes in the opioid dependency population co-infected with HCV to be active participants and motivators in their cure of HCV. Frequent monitoring along the HCV cure continuum allowed for assessment, support, praise report, and modification of planned interventions to meet project goals, guidelines, mandated initiatives, and participants ' sustained virologic response. The latter is significant as it increases the participants' health, reduces the sequel of hepatocellular carcinoma, reduces mortality, and solidifies the importance of the opioid treatment programs' goal of providing exceptional care to a marginalized population (Ioannou & Feld, 2018).

Measurable outcomes

Noteworthy quantitative and qualitative data inferences were inferred from resulted data measures and applied to measure quality improvement outcomes. These are critical components required to make a difference in evaluating the actions taken to improve patient care quality and patient safety. The Institute of Health Improvement (IHI) recommends three types of measures: outcome, process, and balancing (Institute for Healthcare Improvement, 2020).

Outcome measures are those procedures that explain the system's impact on the patient's beliefs and their well-being. This also impacts the program's policies and procedures and ensures

compliance with SAMHSA and OASAS guidelines. Process measures evaluated the CMMC protocol as it achieves the intended results. Practice measures focus on evaluating how people are adhering to the established guidelines.

Project Plan

To facilitate the DNP capstone project planning process, the DNP candidate conducted an organization readiness by first discussing with the program's director the CMMC readiness for change. The implementation of the process change, upscaling HCV screening, testing, detection, and co-location treatment with the desired goal of eradication of HCV for CMMC client's proposal was endorsed by the program, clinical, and medical directors. The organization was adapting the strength, weakness, opportunities, and threat analysis to identifying any extenuating factors, both internal and external, which may influence or skew the data. Quality improvement programs require planning ahead, developing established goals and outcomes to drive the project, including assessment, evaluation of the change intervention as well as data collection, data storage, and analysis. The quality of the change impacts targets enhanced programs for end-users and is advantageous for those who participate. The hope is they will benefit from the improvement initiated as a result of receiving the program interventions.

People who inject with drugs exhibit behavioral risk factors associated with the upsurge in cases of acute/chronic HCV infection resulting in an increase in the opioid dependency cooccurring HCV disorder population registered in a methadone treatment program. It is critical to diagnose and understand the prevalence of behavioral disorders coexisting with opioid addiction. An enormous part of this population has never been screen, tested, or treated (Fadnes, et al., 2019). The project plan is two-fold. First, to upscale HCV screening for detecting, treating, and eradicating HCV and secondly to encourage the CMMP population on maintaining a life

altering behavior of abstaining from injecting with drugs to prevent HCV reoccurrence. These steps revealed the need for a simple, standardized tool to screen, test, detect, and treat opioid dependency patients co-infected with HCV.

With no cure for HCV on the horizon, the aim of implementing and integrating an HCV and opioid use disorder co-occurring disease treatment project is to simplify uptake, treatment, and cure of HCV infected clients registered in an opioid treatment clinic. Utilizing a Health Care Model that focuses on behavioral changes, engagement, and compliance, the cost effective method will ensure uptake of HCV screening, testing, treating, and eradicating HCV in the opioid dependency population. The achievement of this project was determined by the increase of screening, testing, and the sustained SVR in opioid dependency patients co-diagnosed with HCV.

The quality improvement DNP capstone project requires objectives and expected results that drive the task, including the assessment of the effect of the venture, which is just as important as information collection and examination of the data. Quality impacted targets allude to the CMMC program members and the advantages they will gain increase HCV knowledge, because of accepting the program HCV mediations treatment plan (Issel, 2004). Goals are explicit proclamations with respect to the possible effect of the well-being of the project's execution, expressed in quantifiable terms. The project also expects staff to be knowledgeable . Employees with widespread knowledge of HCV is essential to engage and motivate HCV screening and compliance with treatment. Primary care providers should be targeted to increase their knowledge of HCV practice treatment, guidelines, and educational interventions. The upsurge in HCV screening and testing is required to expand the HCV workforce and patient linkage-to-provider opportunities as we seek statewide HCV eradication (Samuel, Martinez,

Chen, Markatou, & Talal, 2018).

Market Sample

CMMC opioid methadone treatment program is a medium-sized healthcare system in Westchester County, positioned north of New York City in The Hudson Valley with major cities and towns comprised of Harrison, Jefferson Valley, Mount Vernon, Mount Kisco, Peekskill, New Rochelle, White Plains, and Yonkers with the population size of approximately one million. According to the New York State Department of Health (NYSDOH), New York State (NYS) faces a developing HCV epidemic with rising loss of life, and given the accessibility of recently exceptionally compelling and improved all-around endured corrective treatment, we can at this point avoid the delay in providing HCV treatment to increase our community's health to ensure compliance with 2017 the NYS Hepatitis C Elimination Summit agreement proclamation (New York State Department of Health, 2020). The Elimination Summit focused on the following five pillars:

1) Enhance HCV avoidance, testing, and linage to think about PWID, individuals who are detained, and the diverse populace affected by HCV

2) Expand HCV screening and testing tom distinguish individuals living with HCV who are ignorant of their status and connection them to the mind

3) Provide admittance to clinically fitting clinical consideration and moderate HCV treatment without limitations

4) Enhance NYS HCV investigation

5) Commit NYS government and political authorities, and HCV specialists to take responsibility for the plan to eradicate HCV (Garmon & Gaudino, 2019).

For nearly three decades, methadone has been the primary means of treating opiate addiction and the only service provided in the methadone treatment program. An open-access model for the quick enlistment of individuals with IV opioid use problem co-infected with HCV, yet most of the patients going through methadone maintenance treatment are neither screened nor treated for HCV disease (Tai, et al., 2019). The sample for this project was 485 patients currently admitted to the CMMC opioid treatment program. Prior to admission to the CMMC opioid treatment program, all patients are routinely screen for urine opioid, morphine, fentanyl, suboxone, marijuana, and alcohol. Upon admission, patients at CMMC are required to visit the program for medication administration and are mandated to complete admission labs consisting of a complete blood count, comprehensive blood, and screening for syphilis. For the patient of childbearing age, a mandatory pregnancy test is performed. However, at CMMC, HCV is not a mandatory test.

To ensure compliance with the National Hepatitis Compliance plan and the NYS HCV initiative, universal mandatory HCV screening was integrated at the CMMC program to increase screening, testing, detecting, and eradicating the HCV disease in the methadone opioid dependency population co-infected with HCV. But not all patients were screened at admission. The COVID-19 pandemic social distancing guidelines and the forestalling delayed.

Organizational Settings

The CMMC clinic is located in one of the most opioid infested communities in Westchester County, NY. The practice setting for this change capstone project is located in an urban community- based downtown neighborhood non-profit outpatient treatment program serving the community for over forty years and located in New York State. The outpatient program focuses on providing treatment for opioid addiction with the dispensing of liquid

methadone to the substance abuse dependent population in the community it serves in compliance with its mission statement of providing quality and excellent care for all. Initially, in the early 1970s, the practice consisted of two full-time medical doctors. However, in 2015, GGMMT closed its doors due to community complaints, and half of the participants transferred to CMMC, increasing their capacity to 500 registrants.

Besides increasing the CMMC census, the workload increased for the two resident providers and decreased throughput. So, as a result, in 2017, CMMC opened its door for two family nurse practitioner (FNP) providers to fill the gap. In 2018, one medical doctor transferred to the affiliated program in New York City. Currently, the practice has one full-time medical doctor and two practicing FNPs. The clinic provides outpatient opioid methadone treatment for adult patients. The medical doctor, who is also the medical director, is primarily responsible for the initial screening, intake, admission, and initiation of treatment for all the patients. Additionally, the doctor is responsible for providing assessments for patients who express the need to be discharged against medical advice from the program. The FNPs are accountable for all patients' initial history and physical, annual well examination history and physical, episodic visits for methadone dose adjustments, approval of an extension of take-home medication privileges, and case conferences. There is shared responsibility between the providers for interdisciplinary counseling management and reviewing of laboratory test results.

An important highlight of Advanced Practice Nurse training is the prevention of illness and diseases. The inclusion of FNP's in the CMMC opioid arena is a great avenue to facilitate screening, educating, referring, and monitoring patients as recommended by the CDC, the USPSTF, and AASLD guidelines. Of great importance, since the inclusion of the FNP into the practice, there is an expectation to deliver high quality, efficient, and evidence-based care. The

ultimate goal of implementing this capstone project is to alter the mindset and nonadherence behaviors of patients registered at CMMC in the screening and treatment of HCV, a modifiable disease, with the application of the Health Care Model framework.

Categorized as an outpatient clinic providing patient-centered services to the community's opioid dependency population, at present, the staff at CMMS methadone program are occupied and focused on persuading their customers on achieving and maintaining their opioid addiction sobriety.

The DNP candidate's recommendation to increase HCV screening and testing and the implementation of an onsite HCV treatment team to CMMC management will enhance treatment services provided to this opioid dependency population. Increasing patient service not only improves patients outcome, but also ensures compliance with the objective of adopting the OASAS, SAMHSA, CDC, and IOM initiatives for screening, testing, and treating individuals infected with HCV or linking patients to treatment providers. Applying the IOM endorsements, a systematic review conducted by Meyer, Moghimi, Marcus, Lim, Litwin, and Altice (2015), supported the capstone project objectives of HCV pre-screening, evaluation and treatment initiation, connection to treatment and treatment observance (Meyer, et al., 2015).

Barriers to Implementation

MMTP community environments are constructed to including factors such as neighborhood safety, knowledgeable medical, nursing, and clinician care providers, access to transportation, and ease of clientele transfer within programs . These qualities ensure the seamless integration of the capstone project. Previously, little research addressed PWID infected with HCV creating gaps in the literature, as these stigmatized populations encountered guideline exclusions, lack of consensus regarding HCV screening, and limited infrastructure for providing assessment and

treatment for hepatitis C treatment to the opioid dependent population. In their 2016 cross-sectional study Falade- Nwulia et al. claimed the social determinant of health (SDOH) limited access to a primary care provider as a barrier for HCV treatment although new HCV treatment modalities exist (Falade-Nwulia, et al., 2016).

These barriers and restrictions resulted in low HCV assessment, testing, and detection. In a retrospective study conducted by Williams, Bossert, Chen, Jaanimagi, Markatou, and Talal (2019), the researcher examined how SDOH impacts and influences patient outcomes. The articles concluded by isolating access desert, an SDOH, both positively and negatively impacts clusters of patients who failed to receive HCV treatment (Williams, et al., 2019). The consensus has changed with overlapping modes of opioid addiction and hepatitis C acquisition occurring among persons who inject drugs. In the above-stated research by Falade-Nwulia et al. (2016), the researchers concluded providers who have a high pervasiveness of HCV among their patient population and also having an existing clinical practice, reducing HCV could be achieved provider HCV training (Falade-Nwulia, et al., 2016).

The recent additional therapy of universal access to the new Direct Acting Antivirals (DAA) has advanced the efficacy and tolerability of hepatitis C treatments. According to Madden, Hopwood, Neale, and Treloar (2018), despite the addition of DAA and positive outcomes, there is a plateauing of treatment indicating more work needs to be done to identify and address barriers to hepatitis C access and treatment (Madden, Hopwood, Neale, & Treloar, 2018). The study's finding supported residual existing barriers addressed and identified as: a personal level where social priorities interfere with keeping medical appointments, limited knowledge of HCV, little knowledge of new existing treatment modalities, limited access to transportation, poor venous access, and multiple comorbidities. At the same time, the provider's management level of patient

stigma consisting of complex health issues, decreased knowledge, withholding treatment, patient ongoing substance use, poor adherence to therapy, and increased risk or reinfection, in conjunction with system level discrimination by insurance companies that rejected and refused to payout treatment requisitions.

Dillon, Lazarus, and Razavi (2016) in their study of Urgent action to fight hepatitis C in people who inject drugs in Europe in an MMTP, found a vast amount of PWID fail to be diagnosed and new models were needed to overcome barriers to HCV treatment and care (Dillon, Lazarus, & Razavi, 2016). As mentioned previously, (Roncero, Littlewood, Vega, Martinez-Raga, & Torrens, 2017) discussion on barriers and limitations openly acknowledges the lack of health care providers' awareness of HCV pathways and new treatment modalities (Roncero, Littlewood, Vega, Martinez-Raga, & Torrens, 2017). This was supported by Falade-Nwulia et al. (2019), who recommended MMTPs explore implementing a co-occurring treatment with HCV and peer support for PWID. This exemplifies the need for increased PCP awareness. Additionally, the following patient barriers were identified, PWID continued substance abuse, lack of treatment information, stigmatization, discrimination, inadequate linkage to treatment, minimal follow up, mistrust between provider relationship, fear of medication adverse reactions or death, and decrease confidentiality. Employee barriers increased workload and decreased HCV education were also identified. Patient barriers listed will affect the sustainability of the capstone project,

A convenience sample conducted at two opioid treatments in Baltimore by Falade-Nwulia, Irvin, Merkow, Sulkowski, Niculescu Olsen, and Mehta (2019) results yielded additional evidence of a high prevalence of HCV among opioid treatment program patients and the availability of effective treatment, despite effective and simple DAA treatment associated with

cure rates above 95 percent. Despite these encouraging signs, HCV treatment uptake among people who inject with drugs enrolled in these two opioid treatment programs remained low. PWID are disproportionally impacted by HCV (Falade- Nwulia, et al., 2019). The data provided convincing evidence among the 124 participants, showing 20 percent of the participants received testing at the drug treatment center, 91 percent expressed HCV was a major concern, 89 percent were aware of the new treatment, and new treatment cures most people. Also, the authors reported 20 percent of the participants were diagnosed at the treatment program, 34 percent at their PCP's office, more than 60 percent had seen a provider, and only 40 percent were recommended to a specialist, with only 20 percent initiating or completing HCV therapy (Falade-Nwulia, et at. 2019). The data provided implied PWID co-infected with HIV is a crucial component of being more likely to have been referred and treated for HCV.

Included in their 2019 study, Falade-Nwulia et al. openly acknowledge potential facilitators for HCV treatment include transport to and from appointments, having a friend report HCV treatment, information about HCV, and location where HCV treatment can be assessed. Most importantly, the article provided resounding evidence identified by PWID of the importance of implementing an HCV treatment at their OTP clinic. In an era of effective DAA, the increased risk of the overlapping danger for acquiring or transmitting HCV and treatment in an OTP, the opportunity to integrate HCV treatment within OTP where past, active, and current people who inject with drugs daily attend, this population can effectively be tested, treated, and obtain eradication of the disease.

The most noticeable barrier occurred after the first month of the implementation of the project. As previously mentioned, clients registered within MMTPs can freely transfer within OTP program or self-discharge against medical advice. This latter decision was made by two

clients, cohabitating partners who ruled in HCV positive and failed to act on the planned intervention. COVID19 impacted the timely HCV screening and detection of the virus as well as the project's implementation, timeframe, outcome, and treatment goals. Staff members voiced no resistance to the project.

Data Collection/Privacy

According to Moran, Burson, and Conrad (2020), data collection tools to capture information should be expansive enough to integrate the measurement of the desired outcome as well as pertinent independent extenuating confounding factors related to the outcome (Moran, Burson, & Conrad, 2020, pp. 167-180). Quantitative and subjective information assortment techniques will be used. The quality improvement ventures information assortment device to be used will comprise self-reports by means of individualized organized meetings, HCV planned logs, and HCV following-up sheets to follow ongoing information. A medical record review of all charts was completed, and patients who were screened, tested, diagnosed with HCV, received treatment, and refused screening or treatment was extracted and compiled in stratum utilizing AHRQ quality tool kit excel data analysis tool.

A double knot security system was devised to secure all patient data extracted. For increased security, to maintain confidentiality, the second initial of the participants first name and the last initial of their surnames were utilized as an identifier. The second security step formulated reversed the year of birth and coined both steps to develop the patient identifier number. Identifiers with the same formats were then assigned to the patient’s first initial. The information assortment instruments chosen are practical, savvy, result coordinated, amendable, and venture explicit.

Key Personnel/Stakeholders

Utilizing a multidisciplinary approach, the team consisted of the program's director, clinical director, medical director, NPs, nursing coordinator, registered nurses, licenses practical nurses, CASACs, program managers, and clerical staff. The diverse behavioral multidisciplinary team is prepared and committed to providing opioid addiction service to the population they serve. Equipped to servicing 500 clients, the CMMC MMTP currently provides service to a fluctuating weekly clientele census of 485 clients. The majority of the clientele are on Medicaid, receive daily methadone dosing, while others are approved for reduced daily visits and are required to pick- up their medication on a pre-approved schedule. With the COVID- 19 pandemic raging through New York, OTP agencies and federal guidelines approved further staggering take-home bottle doses to reduce the opioid dependency population risk of contracting a disease where there is no approved medicinal treatment in the pipeline (Davis & Lieberman, 2020). Although delayed due to COVID 19, CMMC continues to ensure optimal service and treatment of the HCV affected opioid dependency population served via telehealth (Leppla & Gross, 2020). Despite this, the quality improvement project goal is to incorporate and enhance HCV screening, testing, detecting, treating, and eradicating of the disease within the CMMC opioid addiction population

The Stakeholders recognized were the patients, patient's family, authoritative administration, Medical Director, chief clinical manager, NPs, advocates, peer trained professionals, intercessioner, and OHHOPE, the partnering medication treatment affiliation group at CMMC. Additionally, key personnel include CMMS Family Medical Health Center, Gastrointestinal Service of Westchester, and patients' private practitioners. The collaborating groups, maintaining an open-door policy, are available on location on Wednesdays during

operating hours, and patient drop-ins are monitored. The diverse internal and external stakeholders, although with different roles, all played a vital influence in the accomplishment of the evaluation and integration.

Institutional Review Board IRB

The level of respect, confidentiality, and security obviously decide if respondents choose to engage in the treatment, and the level of utilitarian proposes engagement in actions, and behavioral changes accomplish improve outcomes. The security rule under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) protects privacy rights, confidentiality, and patients' health information. Additionally, HIPPA sets limits on how healthcare facilities and providers utilize and disseminate patient healthcare history (HIPPA, 2013).

The confidentiality rule under the Health Insurance Portability and Accountability Act (HIPAA) establishes guidelines on health information sharing, testing, and treatment (Substance Abuse and Mental Health Services Administration, 2020). In adhering to HIPPA guidelines and protecting MMTP patient's rights, it is critical MMTP participants are provided with HCV educational literature, consent to treatment, and understand the therapeutic methodology, as well as educated regarding the risks and benefits of treatment. It is also important MMTP program directors and the medical team is cognizant of the lawful and moral issues about giving HCV treatment as healthcare organizations endeavor to optimize services to the population served. This capstone project is a quality improvement project. The patient and staff were provided with HCV educational literature, participated in HCV question and answer group gatherings, interacted with the treatment team and discussed risks, benefits, and refusal of HCV treatment with the NP and medical team. Obtaining consent from all participants and data confidentiality

was secured by employing a two-fold name and birth alterations date. Storage of the participants' private information was stored in the treatment team's offsite office.

The Internal Review Board is charged with protecting vulnerable research participants. Opioid dependency, a behavioral health disorder, is an addiction, proven as the most severe type of substance use disorder that has pulverizing results to people, families, communities, and society (Vilkow & Boyle, 2018). The quality improvement project conducted at CMMC ensured all patient information collected and tabulated as part of this project's influence, aggregately did not consist of potential patient identifier valuing. All-electronic files and documents comprising of patient identifiers were password protected utilizing two-time certifications. The Internal Review Board (IRB) was consulted to determine the need for approval for this project and provided the roster for review of all participants' affidavits consent for, acknowledgment of the disease process, and signed statement of knowledge including risk benefits of the treatment modality. The IRB reviewed the proposal and supporting documents of the quality improvement project and agreed the capstone project was not a research analysis, revealed no patient harm, but an improvement to the human subjects. They also determined no breach of confidentiality under HIPPA guidelines or federal regulations. They informed the CMMC management team and DNP candidate there was no need for IRB approval for the capstone project.

Planning the intervention

People who use drugs and specifically the individuals who inoculate drugs adds to high HCV occurrence and prevalence rates among individuals who enroll in opioid dependency maintenance program. Despite the newly available, improved, and short duration treatment, statewide, there are gaps in initiating and treating those affected with HCV, resulting in downscaled treatment for PWID registered in MMTP. According to Haley and Kreek (2015)

previous research shows under six percent of HCV positive PWID have ever been treated for HCV (Haley & Kreek, 2015). Patients with persistent HCV have an unsurprising decrease in primary provider access disparity (Falade-Nwulia, et al., 2016). The Affordable Care Act (ACA) and the enactment of Senate Bill S3842 on January 1, 2014, by Governor Cuomo, opened avenues for increasing access for HCV related healthcare. Bill S3842 mandates all healthcare providers and facilities to screen and offer HCV testing to individuals born during 1945-1965. Mandatory HCV screening, governmental regulations and testing encouraged the planning and intervention of this capstone project. Equally important, the quality improvement project was further enhanced by SAMHSA TIP 53, which recommends the following behavioral health programs initiatives:

- -increase HCV screening, testing, detecting, and treatment OTP integration
- -Expanding the study of viral hepatitis disease transmission among staff utilized in MMTP
- Raise medical services practitioners' information and awareness on HCV and accessible therapy
- Increase program directors and administration information on HCV (Substance Abuse and Mental Health Services Administration, 2020).

Methadone treatment programs operate under the auspices of OASAS and SAMHSA. The project aims to increase the uptake of HCV screening, testing, detection, and treatment of HCV. According to SAMHSA TIP 53, most people co-infected with opioid dependency and HCV are unaware of their co-occurring diagnosis, at which time the liver is quietly being harmed. The substance misuse therapy program providers are not all educated about viral hepatitis, accessible to its treatment, or enhance client compliance treatment by integrating

HCV treatment within opioid treatment programs. The Stakeholders identified were the patients, patients' families, administrative leadership, medical director, counselors, peer specialist, intercessioner, and partnering treatment team at CMMS. The DNP capstone candidate's role in this quality improvement process is to identify the clinical treatment gap, develop a practice change model using evidence-based data and present-day research in the literature. Aside from researching the topic of interest, the DNP candidate will also translate the evidence into clinical practice. The partnering teams are present onsite on Wednesday's. Other partners include CMMS Family Healthcare Center, Gastrointestinal Service of Westchester, and the patients' private treatment practitioners. Drug organization, Mavyret communicated interest in this undertaking and plans for HCV co-integration with CMMC.

In developing the HCV co-occurring opioid dependency disease management integration model, the project's groundwork started with the treatment gap identified and stated above. Next, the discussion for the proposed HCV quality care improvement project with the CMMC program director, clinical program director, medical director, NPs, and the nursing coordinator. Cohesively the group formed the HCV committee convening daily for one week in the scheduled face- to -face round table discussion to review SAMHSA HCV protocols. The team also reviewed HCV current testing, screening, and treatment tool, brainstormed ideas, and collaborated on developing educational sessions for patients and staff. Educational assemblies selected included online and in-house learning sessions for all stakeholders. The program clinical director provided educational handouts and HCV protocols from SAMHSA, and the NP and nursing coordinator formulated the HCV screening tool. The DNP candidate assumed the lead role of the project and conducted daily HCV huddles.

As the lead, the DNP applicant surveyed the partners' needs, investigated current HCV testing, screening, and tracking tools clarified misconceptions, developed objectives for the capstone project, and offered support. The DNP candidate then performed a Strength, Weakness, Opportunity, and Threat Analysis (SWOT)e to segregate possible threats and barriers. A survey of the clinic staff knowledge of HCV and staff engagement in lifelong HCV learning, completion of OASAS, and SAMHSA recommended HCV training log were also monitored and reviewed. A stakeholder network was initiated and established with Mavyret pharmaceutical company and with partnering OHHOPE treatment center. The gap analysis and literature review conducted, revealed the need to develop a standardized tool to merge with CMMC's current disease assessment tool and create a tracking HCV tool for improved retrieval and identification of missed clients. The NP discussed the findings with the committee.

The COVID 19 pandemic, the primary threat identified, played havoc with the project's planning and implementation. To add to that, the DNP capstone student's disengagement due to decreased knowledge and limited evidence-based treatment modalities to provide care to those inflicted and expiring from the novel COVID-19 virus led to further delays. The loss of a colleague further impacted the futility of the project. Potential weakness, a work stoppage at the program as our clientele continued their risky practices resulting in an increased opioid overdose (Slavova, Rock, Bush, Quesinberry, & Walsh, 2018). Despite these potential hindrances, the program remained open. With significant encouragement from the DNP chair and candidate's advisor, the DNP candidate resumed the project during the eye of hurricane COVID-19.

The resurgence of the project resumed with six emergency committee meetings to discuss how to continue, to best engage the MMTP population to participate in HCV educational sessions, increase screening, testing, and adhere, if required, to treatment. Staff motivation and

HCV education buy-in, with continued teaching sessions, while ensuring all participants' safety to limit COVID 19 exposure and adhering to the CDC and SAMHSA recommendation for educational sessions, were also discussed to ensure sustainability.

Project Implementation

A critical strategic method was developed to learn how to increase engagement of the HCV co-occurring opioid-dependent population during their daily medication dosing or approved medication pick-up at CMMC. A semi-structured qualitative interview conducted by Batchelder, Peyser, Nahvi, Arnsten, and Litwin (2015) signposted few methodologies to enhance and deliver services and reduce barriers to HCV patients receiving methadone daily dosing in substance use MMTP programs. Substance use prevention programs promote availability to treatment, education on curability, and a culture of nonjudgmental and supportive relationships. While implementing the new testing guideline, patients and families 'buy in" will increase with education on healing a damaged liver and increase of lifespan and quality life improvement. Death is a feared phenomenon. The majority of mankind with alter behavior to extend their life course, MMTP clients are no different. The MMTP patient engagement will encourage peer support, diminish HCV hindrances, and expand members engagement and commitment (Batchelder, Peyser, Nahvi, Arnsten, & Litwin, 2015).

The hepatologist association, along with the CDC, WHO, OASAS, and SAMHSA, continue to publish guidelines and recommendations to increase HCV screening, detection, and treatment. In collaboration with the medical director and the nursing coordinator, on admission, it was decided all patients will participate in an HCV education session with the NPs with data charted on the Agency for Healthcare Research and Quality (ARHQ) toolkit Excel spreadsheet. Educational sessions to increase engagement will discuss HCV, its effect on the liver,

reinfection, and new and improved medication management for 12 weeks. For staff HCV education and questions, and Wednesday morning huddles were implemented for HCV collaboration and discussion. All participants signed an attendance datasheet. Strategic HCV priorities identified and discussed during the education sessions were the importance of screening, testing, treating, monitoring throughout therapy to its completion, and obtaining the final SVR results. To a greater extent, consent and data security were emphasized. And most importantly, continuation of IV drug use as a continued act may potentially re-infect the liver. A chart review was conducted for the established patient, and all patients with HCV diagnosis tabulated monthly, and data recorded in an excel data analysis spreadsheet.

The patients were informed by their counselors, of the importance of meeting with the NP monthly on the second Wednesday of each month to discuss their disease process, screening, testing, and treatment options. Sign attendance sheets are used for data collection. Also, to close the gap, during the NPs mandated daily history and physical for the patient, HCV protocol and treatment were discussed, and engagement encouraged.

The Program director initiated contact with the Westchester pharmaceutical representative for Mavyret with four HCV treatment modality educational employee lunch sessions training, one per month one hour in length and the representative introduction to the DNP candidate. Additionally, speakers from the family health center and CMHOP center collaborated with the researcher to construct an onsite educational medication clinic to increase patient engagement. The DNP candidate initiated an email network bank for the external facilitators, supporting continued communication avenues using direct meetings or phone calls before educational sessions.

The interventions chosen by the DNP candidate were intended to isolate and treat IV drug use and acquired comorbid disease conditions, specifically HCV. The project service improvement will emphasize stakeholders' HCV education. Screening, detecting, and providing onsite linkage to care to increase knowledge, engagement, and eradication of HCV, although initiated in February, was short-lived. The project continued through the second week of March 2020, ceased, only to resume late September as COVID -19, as SAMHSA cessation of face-to-face meeting stoppage was lifted. In September, HCV co-joined sessions continued for one week, then ceased for three weeks in two successive sessions due to confirmed COVID cases within the program. Since the beginning of the second week in November, normalcy via telehealth has resumed.

This educational preparation gives members a comprehension of:

- The function of the liver.
- Hepatitis C infection, sickness, and indistinct symptoms.
- Ways to abstain from getting contaminated and infecting others.
- The screening test for hepatitis C infection.
- Vaccination against different types of viral hepatitis (A and B).

A survey of central issues toward the training meeting's finish will help guarantee members have understood the material and have had their inquiries answered. Participants were given informative HCV data in the best way to address any concerning questions, which will be addressed anonymously.

Other HCV engagement gatherings included informative sessions detailing data security, withdrawal options, and family interactive educational sessions in small interactive HCV support groups assembled two times a week in two sessions to increase engagement. The DNP candidate

developed a plan for continued engagement for patients who completed or graduated therapy. These patients were encouraged to participate in the weekly "voice your experience HCV treatment session," an increased engagement project initiative, which failed to launch as a result of the fluctuating and continued upsurge and down-surge of COVID-19 cases in New York.

Monthly, the program's 485 patients were screened and tested for the hepatitis C virus during the timeframe. Laboratory testing confirmation result slips were collected and secured in the clinical directors' office—the result of interest being positive. Monthly, the patients yielding a positive test result was tabulated in excel utilizing descriptive gender and age stratum. Positive patients were then referred to the HOHOPE HCV treatment team and followed throughout the HCV treatment continuum for compliance with liver scan screening, initiation of therapy, completion of HCV treatment, and final laboratory SVR viral load testing HCV eradication.

Evaluation/Analysis of Data

Data is meaningless unless it's analyzed utilizing the mode, median, and mean statistical analysis. CMMC data was collected by various means, quantitative and qualitative, interpreted, and tabulated. The NP reviewed the data collection forms, attendance sign-in sheet for patterns in trends, distribution, and frequency. Outliers were excluded in particular compared to modes and medians to prevent the inclusion of biases (Singh & Singh, 2015). The self-reported qualitative responses of CMMC registrants were placed in cluster themes to maintain their validity and reliability. Analyzed data can then be summarized to predict current and future trends, draw the inference, predictability of success or failure of the integration module being studied, which is represented in this project as HCV co-treatment within opioid uses disorder program. The purpose of this capstone project was to increase HCV screening, detection, treatment, and eradication among opioid dependency patients co-infected with HCV within CMMC MMTP.

The quality improvement project will increase staff engagement, HCV knowledge, and influence the development of a continuous HCV treatment plan sustainable by the client's engagement and education. Evidence of increased staff and patient engagement will manifest with a 100 percent increase in HCV uptake and testing, 100 percent detection of those infected, and 80 percent of those infected initiating and completing treatment. The clients will also self-report cessation of risky IV drug use and SVR.

Other evaluation of the project success and sustainability includes management and staff attrition and noncompliance with complying with governing bodies guidelines, costly implementation, extended timeline and an exorbitant amount of client voiced reports exiting the program after refusing to comply with mandatory screening. Additional poor selection of measurement tools, DNP bias, and closure of the program, participation will reflect the effectiveness of the project.

Measurement Tools

In order to measure the outcomes of this DNP project, the following tested, reliable, and valid quality improvement instrument toolkits by Agency for Healthcare Research and Quality (AHRQ), excel, and spreadsheet, designed to assess, monitor, and improve patient's quality of healthcare care will be used to determine the patients' HCV engagement for screening, testing, imitation of treatment, and therapy completion. The Institute for Healthcare Improvement (IHI) project planning form from their quality improvement toolkit (Institute for Healthcare Improvement, 2020) and AHRQ toolkits will also be used throughout the timeline of the project to monitor employees HCV education compliance, patient’s attendance to HCV educational classes, and signed in sheets. All data collected will be logged in the AHRQ Excel and

Spreadsheet toolkit. The toolkit was used to produce the appropriate scatter graphs, pie diagrams, and charts. The informatics team was consulted to gather the additional diagnostic tool. Recommendations are given; data collected were simple and required no p-value, t-test, coefficient analysis, or other analytical analysis.

Though COVID-19 interrupted screening, testing, intake, and treatment initiation, the data process collection, tabulation, and analysis continued; although delayed, the implementation project continued relentlessly. The candidate, nursing coordinator, and treatment team will serve to collect and tabulate data from completed laboratory slips, laboratory results, educational session log, initiation and completion of HCV therapy, and employee education logbook. Data collected was stored in the faculties' secured double authenticated computer program Excel and spreadsheet. Quantitative primary and secondary data were accumulated and tabulated to gain information and draw inference utilizing Excel statistical analysis spreadsheets.

Risk/Benefits and Cost Analysis

The cost and benefits analysis focused on the value of care, estimating the direct and indirect expenditure of planning, piloting, and integrating HCV treatment within CMMC outpatient methadone clinic was minimal. With a financial aim to reduce costs and avoid unnecessary expenses, the discussion succeeded in modifying laboratory panels and existing office space. Annually and at admission, all patients are mandated to complete the routine laboratory testing. The laboratory department added HCV testing to the panel without charges. Currently, SAMHSA and OASAS offer no-cost fees for educational HCV information and training to MMTPS and the program's registrants. CMMC now occupies the first floor of a three-story building with two available office space to house inpatient treatment. However, due to required diagnostic testing during the treatment process, for easy patient accessibility and

compliance, the decision was made to house the treatment location in our partnering building at no added cost.

The CDC suggested screening all people conceived between 1945-1965 for HCV. According to The New York State Department of Health, roughly 150,000 New Yorkers are unconscious of their HCV status. Additionally, in 2014, Governor Cuomo signed into law Bill A.1286-A/S.2750, commanding HCV screening for all individuals while hospitalized and during PCP encounters. This in agreement with the CDC recommendation of individuals birth from 1945 through 1965. Additionally, ninety-eight percent of CMMC registrants are Medicaid recipients. With the bill's passage, Medicaid programs now include health insurance coverage for numerous HCV patients inflicted with opioid use disorder. However, for the drug sofosbuvir, prior authorization is required (Liao & Fischer, 2017). Still, patients inflicted with HCV have a significant opportunity to receive medical benefits, obtain access to healthcare, and initiate and complete HCV treatment, using the 95 percent proven DAAs HCV cure rate, which also promises minimal side effects. The eradication of HCV also increases the patients' lifespan, ensuring quality spent with loved ones and family. Also, the DNP candidate completed over 200 hours at no additional cost, loss, or gain of salary. Completing the capstone project while acquiring innovative HCV treatment modalities and increase knowledge facilitated future endeavors in the hepatology specialty. No additional cost incurred.

Ethical Considerations.

All participants were covered by the Health Insurance Portability and Accountability Act (HIPAA) 1996 which protects the privacy of a patient's health information (Colorafi & Bailey, 2016).

In discussing legal and ethical issues within substance abuse treatment programs, SAMHSA's Treatment Improvement Protocols (TIPs) support patient autonomy and recommend MMTPs obtaining informed consent from participants prior to HCV screening and administering of care without discrimination. Also, all MMTPs employees are mandated under the Health Insurance Portability and Accountability Act (HIPPA) to maintain patient confidentiality and privacy while disseminating information relating to the patients' treatment. Additionally, TIP 53 recommends program administrators acquire, distribute, and post up-to-date HCV education on current ethical and legal information pertaining to medical hepatitis care for all participants at the program to staff members (Substance Abuse and Mental Health Services Administration, 2020 p.71). TIPs 53 also recommends HCV screening at intake for individuals born between 1945 through 1965, all individuals who inject drugs, and individuals practicing risky behaviors. All clients currently enrolled at CMMC are presently at risk and are offered education on HCV disease process and transmission, the risk and benefits of testing, and, if results are positive, are referred to their PCP of choice of the provider of the family healthcare clinic.

In maintaining patient confidentiality, no patient's name will be mentioned. The program's name represents the medical practice operational name, and for additional privacy, the program location reflects its region in New York State. CMMC employees are in compliance with SAMHSA and OASAS guidelines, and no ethical dilemma/issues are identified for the preparation and implementation of an integrated HCV and substance use disorder model within the non-profit operated methadone treatment program. The HCV model's performance project is not a research study, but a non-research project to improve quality of service to the population served with the expectation of increasing knowledge for all stakeholders of the facility, participants inclusive. The quality service of this project will benefit the population served.

Driven by the facility's mission statement to provide quality, compassionate care, and the ethical principle of justice- advocating for a marginalized population, this DNP quality capstone project was presented to the CMMC leadership team. The proposed integrated quality capstone DNP project was approved by the CMMC program key personnel, the program director, clinical director, and the program's Medical Director. Deemed as a non-research integration project, with no ethical issues, conflict, or financial benefits to the team, the integration co-occurrence treatment model for HCV and opioid dependency patients at CMMC requires no prior approval from the IRB committee.

Evaluation of the Action Plan

This quality improvement project required additional time and was conducted for over ten months. The quality improvement tool used to evaluate the integration model's effectiveness was the Focus, Analyze, Develop, and Execute (FADE) model. The FADE model is a practical improvement evaluating tool utilized in healthcare to improve engagement, knowledge of the disease process, and treatment care. According to Moran and colleagues, 2020 FADE is one of the most well-known quality improvement instrument used by DNP candidates (Moran, Burson, & Conrad, 2020). The followings process in the FADE is summed up as follows:

Focus: In the focus step, the DNP candidate identifies and defines the quality improvement project as increasing HCV screening, testing, and treatment for the eradication of patients who are infected with HCV and registered in an opioid treatment program. A need assessment for the program's strengths, weaknesses, opportunities, and threats conducted, and staff contribution to improving patient quality of life resulted in the selection of HCV education for all stakeholders.

Analyze: During the analytical step, the DNP candidate reviewed, assessed, examined, and modified the current practice at CMMC. Currently, patients registered at CMMC are not routinely screened or tested. In October 2019, the DNP candidate proposed mandatory HCV screening and testing to the administrative directory on recognizing the treatment gap. For the patient who is found to be positive, the current management recommendations are referral to the patient's PCP or the facility family health center (FHC). On follow up, of the 102 patients yielded a referred 100 percent noncompliance with PCP or FHC assessment. The DNP's concerns were addressed with the CMMC program and clinical directors, and recommendations were made for care integration with OHHOPE. Substance abuse counselors' care plans were evaluated and to increase engagement modification made to engage their caseload and implement HCV screening, testing, and treatment goals. During counseling sessions, HCV preventative avoidance of IV drug use and education on the needle exchange program was discussed during counseling sessions.

Develop: During the developmental phase, the DNP candidate utilizes available standardized educational literature, educational and training classes available from OTP governmental agencies SAMHSA, OASAS, Department of Health, and AHQR for providers and patient and develop and identify educational materials for knowledge building. CMMC currently employees 24 employees. Educational teaching booklets from SAMHSA are printed and displayed at the entrance of the facility and placed in the conference educational room. The informatics department was contacted for computer operability and uploading educational classes and computer systems training, ensuring easy access and increased engagement. The next step is to modify CMMC's current HCV screening tool to incorporate consent for mandatory screening and testing; Develop consent for treatment and educational documents for patient and family. Daily screening, testing, referral to treatment, initiation of treatment, and completion of

treatment were charted using the AHRQ toolkit, log sheet, and excel worksheet updated weekly on Fridays.

To remain abreast of treatment modalities, the NPs also reviewed OASAS, SAMHSA, and the DOH hepatitis C guidelines and also engaged in the Providers Clinical Support System (PCSS) integrating HCV care into MAT clinic webinars.

Execute and Evaluate:

During this phase, the progress and achievement of all patients admitted to the program and existing clients who have attended HCV educational sessions, consented, screened, and tested were assessed. The HCV testing to treatment continuum was also evaluated. Those yielding positive results attended additional educational sessions with the pharmaceutical company and in-house treatment team. On a weekly basis, when permitted, the DNP candidate follow-up with each client on their progress in completing required laboratory testing, obtaining required ultrasound, or initiation of treatment. Also, open communication existed with the treatment team for the patients who failed to show, were lost to treatment, and those who adhere to treatment. Plus, weekly screening, testing, confirmed cases, initiation of treatment, and treatment completion were tabulated in the AHRQ toolkit Excel worksheet for evaluation.

All employees obtained access and were able to download HCV literature for supportive staff from OASAS and SAMHSA. To increase staff engagement, the counselors working at the top of their CASAC license were encouraged to complete HCV modules, review them monthly and engage, reinforce HCV teachings, their patient case, and update their HCV plan of care.

Project Management GANTT

The novel, COVID -19 virus delayed and disrupted the project's implementation, impacting the timeline for this project, hepatitis screening, detection, and eradication of the HCV

combined opioid dependency treatment within the CMMC MMT program. Although the initiative to implant the improvement was stalled, it remained streamlined. At CMMC, the advancement of clinical practice guidelines, policy implementation, education of patients, and staff promoting commitment while engaging stakeholders is key to successful integration. Initially planned to take place from January 2020 to March 2020, Covid19 interrupted planned milestones resulting in delays. The Gantt is a flow diagram used as an interface layered-view configuration displaying CMMC hepatitis C integration's directional flow within the MMTP project. But the developed and proposed GANTT chart formulated will demonstrate the adjusted structured timeline, ignited a renewed awareness on the importance of MMTP and HCV co-location service to screen, detect, and treat this marginalized population. The GANTT chart will be utilized to demonstrate to the project's team the different phases of the integration process, and the interactive provider encounters from HCV screening to the completion of treatment and the project.

Timeframe

Moran, Burson, and Conrad (2020) preempted impediments in meeting a well-judged timeline completion of the capstone project. Given this fact, the authors anticipated it was not extraordinary for the doctoral candidate project to travel a vainglorious undertaking prior to its completion (Moran, Burson, & Conrad, 2020). Admittedly, the timeline for implementing and evaluating this capstone project was projected for four months. By contrast, due in part to COVID -19 and continued risky behavioral practices of the project improvement population, this project timeline tripled.

In preparation for the capstone project, the DNP candidate, with the administrative staff's approval, led the morning huddle on February 5, 2020, introduced the HCV integration project

with the team, and encouraged participation and by-in. More broadly, it was agreed patient engagement and participation were paramount. The comprehensive chart review started on February 12, 2020 and continued to December 2, 2020. Mostly, in fact, on a weekly basis, patients are admitted to methadone treatment daily. To prevent missing opportunities to screen and test a prospective registrant, HCV consent and screening were initiated on February 6, 2020, for all admissions and testing obtained with initial admission labs. Data spreadsheets were also formed, indicating the onset of data collection. Staff and patient education continued throughout the duration of the project with bi-monthly follow-ups.

Sustainability

According to Silver, McQuillan, Harel, Weizman, Thomas, Nesrallah, Bell, Chan, and Chertow, (2016) to accomplish maintainability, organizational quality improvement activities should turn into another method of working as opposed to something added on to clinical consideration. These devices help support improvement, incorporates measure control board, performance sheets, and standard work guidelines (Silver, et al., 2016). The project's sustainability will be achievable as participants were providing with in-house educational group sessions, individual sessions, online education from SAMHSA, and OASAS offering HCV literature to support their specific language learning needs and assessing their baseline knowledge. They mandated staff competency skills, encouraging the necessary screening and testing for patients leading to improved HCV understanding, competence, and self-confidence. Plus, SAMHSA educational materials will also be mandated annually for the counselors and nursing staff. In March 2020, scholarly treatment models were offered for NPs upstate. A balanced scorecard and checklist will be utilized to monitor the patients' process from screening to HCV treatment completion and posted for the staff's view. The balanced scorecard is a visual

chart that enables stakeholders to identify current and desired goals. This, in turn, will help nurses improve their ability to provide safe and effective educational teaching that can decrease nonadherence of testing, screening, and treatment completion. The results of this study will be shared with the stakeholders, the leadership team, and CMMC community board planners.

Dissemination/Nursing Implications

The nursing profession is immovably grounded in the advancement of the nursing trade, compassionate care, patient advocacy, and evidence-based underpinning. The quality improvement project offers a stimulating opportunity for the DNP student to showcase leadership skills and engage stakeholders in the development and application of evidence-based practice to improve healthcare outcomes.

The DNP candidate intends to circulate findings obtained during the DNP project to the five MMTP within the Westchester cluster, and submit the capstone project for publication in an international peer-reviewed journal focused on quality improvement. Furthermore, the DNP candidate will contemplate presenting at local opioid dependency conferences and seminars. The DNP candidate also plans to present relevant information from this project to the Board of Directors of CMMC, showcasing the impact of MMTP on individual, community, and public health.

Budget

The capstone project intended to diminish cost by exploiting HCV training sessions offered by governmental agencies. The Substance Abuse and Mental Health and Department of Health, the Department of Health (DOH) and OASAS offer HCV training to providers,

healthcare personnel, patients and their families free of charge. Despite the no cost personal expense, most health care providers and patients fail to capitalize on lifelong HCV learning. Provider class preparation was completed onsite as staff invested and engaged in HCV training during working hours with no necessary staff replacements, and the cost structure for this task was basic. The preparation for educating our clients was likewise done during regular hours, wiping out the expense for any replacement or overtime time. Time was also assigned for leadership training. As the integrated service's primary features expanded, diverse strategical integration choices were recognized to achieve the essential objective of this informative workshop. By expanding mindfulness, inter-disciplinary collaboration, and the importance of knowledge building information to healthcare providers within CMMC, coordination of care through a partnership arrangement increased staff development, engagement, satisfaction, and increased the facility's preparation to address the down-scaled HCV screening and treatment of the population served. No extra financial cost was caused outside of resources allocated by the facility and governing bodies.

Strength, Weakness, Opportunities, and Threat (SWOT) Analysis

According to the Substance Abuse and Mental Health Service Administration TIPs 53 online guidelines, on referring people who inject with drugs who are co-infected with substance use disorder and HCV to primary care providers, multiple roadblocks are erected in securing appointments with HCV health illiteracy primary care providers (Substance Abuse and Mental Health Services Administration, 2020, p.64). A SWOT analysis of CMMC's municipal was constructed to isolate the community's external and in-house strengths, weaknesses, opportunities, and threats.

Strength

The most critical strength identified is the significant responsibility and engagement by the CMMC's leadership, interdisciplinary healthcare provider, and our partners. Above all is the tremendous commitment by the DC faculty in supporting, encouraging, and motivating the project's completion. DC provided and equipped the DNP candidate with an exceptional education as recommended by the American Association of Colleges of Nursing(AACN) quality improvement and Safety, Interprofessional Collaboration for Improving Patient and Population Health Outcomes and Population Health for Improving Health (American Association of Colleges of Nursing, 2011). More importantly, the no-cost educational material on the SAMHSA and OASAS website for all stakeholders, patients, and their families included. Last but not least, the patients, the end-users who graciously without manipulation acted on the challenge and trusted the dual cohort of HCV within "their opioid program" will self-actualize in the cure of their hepatitis C. As the COVID-19 pandemic exploded, SAMHSA recommended, as previously stated increasing take-home bottles to limit clinic dosing to decrease the spread of the disease for both employees and patrons.

Internal: Two major external strength identified, the relentless commitment of the staff to ensure the programs remained operative to serve the clients who continued their risky drug practice and implementing CDC recommended guidelines of use of a mask on CMMC premises for all patients, ensuring social distancing was adhered to and frequently supplying the patients with hand sanitizers. At the onset of the pandemic, these acts ensured no occupants, staff, or patients, when tested for the virus, resulted positive.

Weakness: Service change, lack of providers' knowledge of the new and improved DDA's for HCV treatment, continued use of paper charting in MMT programs, and opportunities

for top-level decision making the impacting diversion of methadone. Plus, the patient's limited access to cash flow to purchase the required lockbox for safe storage of their take-home medications are the weaknesses identified (Knopf, 2020).

Opportunities: This capstone project identified a vast number of opportunities within MMTP for both patients and interdisciplinary providers. The first opportunity identified is cost-free the lifelong learning modules and web-based educational materials available to all stakeholders. These learning modules provide up-to-date evidence-based practices. Despite previous access and treatment disparities, the increased knowledge coupled with improving HCV treatment service to MMTPs marginalized population free of cost and without restrictions, concomitantly with substance use disorder, is worthy of a year-long celebration. Another significant opportunity presented by this capstone project was the community outreach network to HCV patients who previously were denied treatment options toward eradicating HCV infection. Lastly, the dedication of CMMC healthcare providers to build aptitudes and knowledge in providing additional caring within an opioid treatment challenging and complex organization benefited their clienteles. The NPs were also offered to participate in the HCV treatment mentorship program to enhance their expertise.

Threats

As a result of the pandemic, MMT programs fearing closure, snowballing use of an illicit drug, and increasing street methadone, were a major threat to the community. A retrospective study conducted by Rodda, West, and LeSaint (2020) from January through April 18, 2020, concurred with Slavova et al. (2020) finding the COVID 19 pandemic disruption of MMTPs service delivery, heightening the prevalence of drug overdose in the opioid use disorder

population (Rodda, West, & LeSaint, 2020) showcasing the impact of COVID-19 on PWID and the riddance of HCV.

External: SAMHSA's mandate to grant patient's take-home dose and limit urine toxicology, although it decreased the frequency of the patient's daily program dose, but increased a patient risky opioid use behavior, the primary act which increased the upsurge in HCV. Moreover, according to Bach, Kondili, Aghemo, Cai, Dugan, Estes, Zeuzem and Craxi, (2020) the COVID -19 pandemic will result in approximately three percent of HCV infected patients who will not receive HCV treatment this year thus impacting the HCV elimination 2030 efforts (Blach, et al., 2020).

Internal threats: The major internal threat identified is the assumption of added treatment in a population who continue to practice their risky IV drug behavior, their manipulation traits, and unpredictable behavior. Also, safety concerns while in the communities that provide few open job opportunities for high-performance jobs, access to HCV treatment, and location within Yonkers high drug traffic rate sale of illicit drugs. In addition to gang violence, sex trafficking, and increased crime, it is potentially hazardous for a clinic to open its door primarily in the early morning with a limited security presence. Plus, resistance to change by employees, who on the other hand, have become complacent for years treating only opioid dependency within MMTPs.

Section V: Outcomes and Evaluations

Introduction of topic

Change is a process, and in healthcare, the bottom-up or top-down method both produces effective results. However, for change to occur, the organization must engage and demonstrate readiness for change. Stakeholder engagement, strategic planning, gap analysis, an

interdisciplinary change team all contribute to the development, measuring, and evaluation of the sustainability of new quality improvement projects cycle (Chartier, Vaillancourt, Cheng, & Stang, 2018). The chapter will describe the results of the increasing HCV screening, testing, and eradication of the virus. The most beneficial teaching tool to sustain the actual or potential benefits to MMTP and its community will be explored and discussed.

The capstone project's change objects included creating a toolkit for stakeholders that contains strategies to increase and monitor HCV screening, testing, treating to improve patient engagement along the HCV care continuum ensuring treatment compliance, and HCV eradication. The outcome measure includes completion of OASAS and SAMHSA HCV education for all stakeholders. A new admission who was screened, tested, and yielded a positive result but failed to complete the first thirty days on the addiction program were identified as outliers and excluded from all results.

Outcomes and Results

The outcome data related to the integration of service within CMMC were collated by the DNP candidate, the nursing coordinator, and the treatment team. The cumulative data was reviewed by the trio weekly, adjusted for outliers by the DNP candidate, and presented to the stakeholders monthly. At the same time, during case conferences, the counselors who gained the most clients' uptake, initiation, and completion of therapy were acknowledged. The interdisciplinary team encouraged them to continue engaging their clients.

The project's goal was to increase the HCV screening, testing, and treatment within OTP. The HBM framework was the driving force behind the NPs and nursing coordinators Hepatitis C educational class for the stakeholders, more specifically for the patients. As with any quality improvement project, stakeholder' education is fundamental (Samuel, Martinez, Chen,

Markatou, & Talal, 2018). Susceptibility of acquiring the disease, the seriousness of sequela for failure to screen and test, the benefits of treatment with the new improved DAA's and the importance of removing barriers to treatment were essential in creating the vision of HCV cure and thus improvement of the project.

Equally important, the project incorporated the FADE model to implement the change, observe the patients' enthusiasm for treatment initiation, experience the patients' " joy" of incompletion of their treatment, and monitor for the practice's improvement. The DNP candidate conducted a literature review to investigate the effectiveness of hepatitis screening, to testing, detecting, and a care linkage intervention within methadone treatment programs.

Before we analyze the data, it would be wise to say no comparative statistics data exist. We conducted all analyses using the Excel spreadsheet analytical toolkit. Extraneous variables were controlled by an excluding patient admitted less than one month to CMMC and for patients admitted while receiving HCV treatment. The results yielded some interesting findings. In the formative screening review, 100 % of the CMMC population (N=485) completed their HCV screening consistently. It is significant to note the 100 % screening engagement reflects the screening mandate implemented at the onset of the project. Tabulated returned laboratory testing slips and all HCV results received totaled 392 patients following through with being tested for the virus, representing approximately 81 % of those tested, a 19 % decrease from the projected goal. Of the 392 patients who tested, 287 patients were HCV positive, representing 59 % of the CMMC (N= 485) total population. Content analysis was further undertaken to quantify patients who initiated treatment, stopped treatment, completed treatment, and those who are currently receiving treatment. The outcome of interest is the number of patients who tested positive,

initiated therapy, and completed therapy. Of those who tested positive (N=287), the strata results are as follows:

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CMMC HCV TREATMENT FLOW CHART		
Initiation of treatment	205	71 %
Cessation of treatment	101	35 %
Currently enrolled in treatment	85	29%
Completion of treatment	30	10 %
Failure to start treatment	82	28%

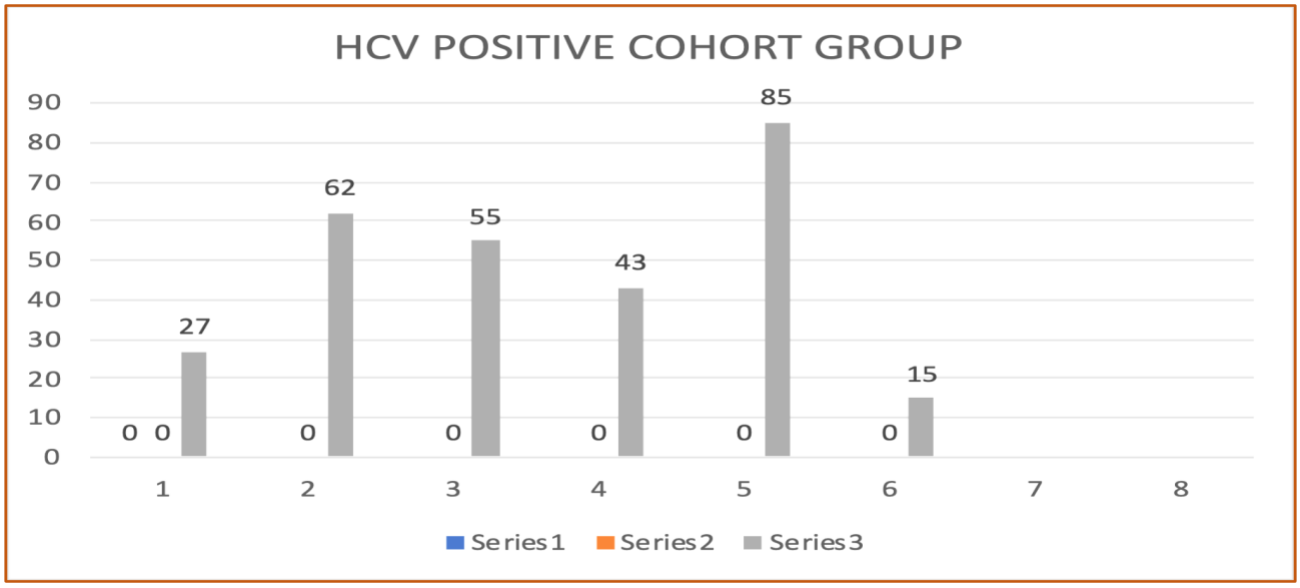
Of patients who initiated therapy (N= 205) and completed the program (n=30), the results yielded 14 %, an increase of four percent when comparing those who tested positive. On further analysis, when compared to all the patients who screen. (N= 485) 16 % of the CMMC population have currently eradicated the HCV. Compared to the projected goal of 80 %, this represented 64 percent decreases indicating greater effort is needed to engage PWID co-infected with hepatitis C and registered within MMTPs.

Of the eighty-two patients who failed to initiate treatment, the inference drawn may represent HCV's previous treatment with failure to disclose history to the medical team, HCV seroconversion, and fear of medication reaction, continued risky behavior, and insurance desert. Of the 82 nonresponding patients who failed to initiate treatment, various predictors or social determinants of health association may indicate a lack of access to healthcare, shame, economic instability, unemployment and/or religious beliefs. Primary care providers will need to develop

more creative and targeted educational engagement strategies to motive HCV treatment compliance.

Qualitative data collection and analysis included gender and patient's birth cohort. Of the 287 patients who tested positive, 218 were males representing approximately 76 percent, and 69 females, approximately 24 percent. The HCV data cohort is presented below.

➢ CMMC HEPATITIS C COHORT GROUPS in Years					
20-29	30-39	40-49	50-59	60-69	➢ 70
27	62	55	43	85	15



Employee Engagement

Throughout the extended timeline of nine months of the capstone project, the staff response to completing the mandatory OASAS and SAMHSA HCV education model was, for the most part, excellent. Labeled as compulsory, all staff members actively engaged in the HCV educational models, interacted with their clients, thus completing their treatment plans. The increased engagement resulted in all CMMC patients' participation in the HCV screening significant objective. As with any quality improvement projects with multi-stakeholder involvement, barriers, and limitations along with numerous strengths, weaknesses, opportunities, and threats were identified.

Impact

Admittedly the evidence reports former, and current IV drug users infected with HCV previously were denied treatment. Despite the upsurge in hepatitis C, and with new and improved DAA's, passage of the HCV Bill A.1286-A/ S.2750 by Governor Cuomo, and approval by Medicaid, this population continues to be underserved. The gap analysis revealed patients at CMMC would benefit from the capstone project's intervention to increase screening, testing, detecting, and treating those infected to eradicate the Hepatitis C virus in an HCV treatment co-location within an MMTP. Of the 485 participants, the results yielded 100 percent compliance. Two hundred and eighty-seven tested positive, and over 50 percent initiated treatment, and 30 (10%) of CMMC having SVR. Patient and staff heightened engagement and compliance improved HCV screening, and the co-location of the services upgraded access and service, resulting in improved patient outcomes. The integration of HCV treatment within MMTPs improved the patient's engagement registered at CMMC with 100 percent compliance

with screening and testing. Of note there was an increase in patients initiating treatment, as well as improving both staff satisfaction and patient outcomes.

Product

Many avenues exist in engaging and motivating healthcare workers and their antipode MMTP participants infected with HCV in managing their co-infected disease process. Models of service delivering an in-house co-location of HCV and MMTP service for sustainability requires a multidisciplinary team collaboration, HCV education, compliance with clinical guidelines, and funding.

Financial Funding

CMMC methadone treatment outpatient program is a non-profit organization. This program's current funding includes charity, religious, and awarded funds from the Office of Addiction Services and Support (OASAS). To retain funding from OASAS, CMMC continues to provide preventative, supportive, improvement, and recovery services to the community. Throughout the state, OASAS has awarded eight million dollars to addiction treatment throughout Westchester County. Annually, CMMC receives approximately two million dollars in the fund for the operations, financial overhead cost, faculty upkeep, and day-to-day operations.

Since the DNP candidate mentioned to the Program Managers' the interest in this venture as an assigned function, there was no additional expense to actualizing this undertaking. This quality improvement venture's advantages incorporate expanded knowledge for the patients, Program Managers, counselors, nurses, and NPs. To remain competent annually, all behavioral health employees are required to complete TIP 53, a SAMHSA hepatitis training with no incurred cost to employees. This instruction meeting preparation guide furnishes advocates and other clinical staff with a scripted arrangement to use in leading a hepatitis C training meeting

with patients in a social setting treatment group with their relatives. The training meeting depends on Treatment Improvement Protocol (TIP) 53, Addressing Viral Hepatitis in People with Substance Use Disorders, distributed by the Substance Abuse and Mental Health Services Administration (SAMHSA)

The TIPs 53 series draw on the experience and information from peer-reviewed clinical research, hepatologist, and regulatory specialists of different treatment types. Thus, implying a more grounded general well-being authoritative top-down guideline approach of which MMTPs adherence is warranted. This HCV treatment cycle's adherence and implementation will decidedly affect funding and, generally, well-being results in the program.

Results

Head-to-head patterns and problematic behaviors of repetitive or single IV injection or nasal ingestions of opioid and illicit drug users, MMTPs function on preventative management. Recovery from an intravenous drug infection is a personal journey that is structured on personal decisions, beliefs, choices, and commitment to changing lifestyle practices. Therefore, although registered and participating in an opioid treatment program, these individuals are on the path of recovery for opioid use but not for prevention or recovery of HCV. Participants in opioid treatment programs are medicated daily at MMTPs with liquid methadone, which is one of three medications used to treat opioid use disorder. Methadone is the longest-used drug for opioid addiction treatment and is classified as the Gold standard medication in treating opioid addiction. The evidence highlights providers who specialize in addiction medicine have limited knowledge on the management of HCV treatment and care. Compared to other chronic diseases, those affected with opioid dependency have sufficient access to treatment at MMTP for addiction

treatment with daily medication visits. But those infected with HCV have disjointed treatment modalities.

Despite MMTP infrastructurally equipped in providing HCV treatment services, addiction providers frequently refer these OTP clients to their PCPs. The PCPs, on the other hand, may have HCV health illiteracy and often refer their patients to liver specialists resulting in a delay in care, inadequate management, or patients' failure to follow up, resulting in insufficient accessibility of care. Currently, CMMC offers HCV testing for symptomatic individuals who consent to the HCV screen. Those who are optimistic are referred to their PCP for continued care, with minimal follow up creating a treatment gap within CMMC's treatment and mission statement in providing high-quality service and care to all within the community it serves.

Proponents of SAMHSA's s Treatment Improvement Protocol (TIPSs 53), which draws on topic-specific best -practice guidelines concluded for successful and effective integration of HCV model within MMTP, at least one change agent who advocates for the service will need to be on staff. Thus the current capstone developmental project. As a novel stakeholders at CMMC, the FNPs are frequently reviewing OASAS and SAMHSA regulations, both regulatory bodies of MMTPs, for integrating client services with existing MMTP services. With an established relationship with MMTPS clients, incorporating a co-occurring in-house treatment for HCV and substance use disorder was deemed feasible and in compliance with SAMSHA and OASIS recommendation to provide quality service to clients who are in need of treatment for hepatitis C virus. In a national survey of US opioid treatment programs (OTP), drawing on the work of Jones, Byrd, Clarke, Campbell, Ohuoha, and McCance-Katz (2019) , highlighted findings of a US national survey of 1605 OTPs utilizing an electronic 46 questionnaire and found approximately 96 percent of the programs offer methadone treatment for patients diagnosed with

opioid dependency. The results also isolated roughly 61 percent of the programs that provided viral hepatitis testing, of which 12.9 percent showed HCV treatment representing a continuous suboptimal treatment gap (Jones, et al., 2019).

Of greater importance, the evidence reviewed supports the implementation of the DNP capstone project to increase screening, testing and treatment to improve patient outcome. Results from the project was an overall success. A total of 485 participants participated in the project (N=485). In the hepatitis C screening and testing intervention, 100 % of CMMC clients engaged consistently in the implementation of the project. Two hundred and eighty-seven participants tested positive (59 %), of which 205 initiated treatment (71 %). CMMC reported ten percent of those who initiated treatment completed treatment with SVR (n=30). Staff engagement with the education mandate resulted in 100 % compliance and engagement.

Cost Analysis

The cost analysis estimating the direct and indirect expenditure of planning, piloting, and integrating HCV within CMMC outpatient methadone clinic was minimal. Annually, and at admission, all patients are mandated to complete the routine laboratory testing. The laboratory department added HCV testing to the panel without charge. Currently, SAMHSA and OASAS offer no-cost fees for educational HCV information and training to MMTPS and the program's registrants. The CDC suggested all people conceived between 1945-1965 be screened for HCV. According to The New York State Department of Health, roughly 150,000 New Yorkers are unconscious of their HCV status.

Moreover, in 2014, Governor Cuomo signed into law Bill A.1286-A/S.2750, requiring HCV screening for all individuals while hospitalized. During the patient and PCP assessment,

the CDC recommends HCV testing of individual birth during 1945 through 1965, strategic testing Governor Cuomo signed into law.

Additionally, ninety-eight percent of CMMC registrants are Medicaid recipients. With bill A.1286-A/S.2750 enactment, Medicaid programs now approve health insurance coverage for numerous HCV infected patients. Opioid use disorders, however, were included. However, for the drug sofosbuvir, prior authorization is required (Liao & Fischer, 2017).

Summary

In summary, the capstone project of increasing HCV screening, testing, detecting, and treatment of HCV to obtain SVR eradication and implementing a co-occurring treatment house for the marginalized opioid addiction patient infected with HCV has shown increased engagement and a positive outcome with staff and patients registered at MMTP approving of the HCV within. Staff and patient engagement promote success, sustainability, job satisfaction, patient satisfaction, and improved patient outcomes.

Section VI: Conclusion and Recommendations

Limitations

The major limitations to this project are the patients' failure to initiate treatment, insurance access disparities, failure to mandate, disclosure of an operable contact telephone number and address resulting in loss of contact, failure to follow up, transportation desert, continued risky practices, and the missed opportunity to treat substance use clients co-infected with HCV. An additional limitation is a failure to incorporate other demographics such as CMMC clients socioeconomic status, insurance, education, as well as social and community context.

AACN Essentials of Doctoral Education

The goal of this evidence-based practice project was to improve HCV screening and treatment of patients co-infected with HCV and opioid use dependency within an opioid dependent treatment program and to improve HCV knowledge of the interdisciplinary behavioral staff members at CMMC. The DNP capstone project was a prerequisite for the fulfillment of the DNP degree. The HCV treatment execution inside the CMMC MMTP program was a quality improvement capstone project that showed parts of the DNP fundamental abilities as characterized by the American Association of Colleges of Nursing.

Fundamental I*: Scientific Underpinnings for Practice.* This competency requires the DNP student to select, assess and analyze evidence-based information and data from various sources to improve public health. The DNP Candidate showed this by advancing a literature review and implementing the proposed project.

Fundamental II: *Organizational and System Leadership for Quality Improvement and System Thinking.* This capstone project is relevant to the American Association of Colleges of Nursing (AACN) essentials of the positional statement, which identifies the significance of emphasizing interprofessional collaboration as a critical component for improving patient, family, community, and population health outcomes. The position statement also addresses the importance of DNP graduate's proficiency in quality improvement policies and incorporating scientific and population health for improving health.

Fundamental III*: Clinical Scholarship and Analytical Methods for Evidence-Based Practice.* The third DNP fundamental require the DNP candidate to exhibit the capacity to interpret pertinent peer-reviewed research articles for reliability, sustainability, dependability, security, and quality. The DNP student showed this fundamental ability and achievement through

a worldwide exploration of documented evidence-based research, commentaries, HCV specialists, expert panel, and governmental regulators. The candidate then effectively executed an HCV treatment module inside CMMC MMTP

Fundamental V: *Health Care Policy for Advocacy in HealthCare*. This fifth essential criterion requires the DNP candidate to implement healthcare policy created through governmental actions to facilitate and address population health. This competency requires the DNP candidate to assume a leadership role on behalf of the nursing profession and the public to implement healthcare policies to improve public health. the DNP candidate displayed this skill by implementing bill A9124-A/ S6781 enacted by Governor Cuomo to reduce HCV barriers to screening, testing, and linkage to care to improve population health in an MMTP setting

Fundamental VI*: Interprofessional Collaboration for Improving Patient and Population Health Outcomes*. The six DNP essentially requires the DNP candidate to demonstrate interprofessional collaboration with the CMMC team to promote quality healthcare for patients and communities served. The DNP student displayed the ability in this skill by participating and engaging the interdisciplinary clinicians within the project team to identify educational webinars from OASAS and SAMHSA for staff and CMMC co-infected registrants

Fundamental VII**:** *Clinical Prevention and Population Health for Improving the Nation's Health*: Essential seven highlighted the importance of the DNP candidate's focus on a targeted population and utilizing evidence-based practices to improve and achieve an enhanced health state within a safe environment. The DNP competitor showed the skills needed in this fundamental through coordinated multidisciplinary planning.

Fundamental VIII**:** *Advanced Nursing Practice*. The six DNP essentially requires the student to demonstrate advancing the nursing practice in a specialty area. The DNP student displayed this ability

in Opioid addiction, a marginalized population often outcast by society. Practitioner dessert exists within MMTPs, and OASAS and SAMHSA are encouraged to employ advanced practice nurses to fill this gap to treat this stigmatized population.

Section VI: Conclusion and Recommendations

Conclusion

Hepatic C virus, internationally, is a well-documented infection affecting people who inject with drugs. The literature studies' critique has demonstrated the importance of hepatitis C screening, testing, and treatment as effective in diagnosing the silent liver-damaging hepatitis virus.. Additionally, aside from co-integration within MMTP, HCV screening, testing, and treatment, it was deemed as fundamental care coordination within other healthcare providers, psychological well-being practices, and community clinics. Therefore, HCV screening and treatment can successfully prevent HCV and its sequel or distinguish and treat people with viral hepatitis. People who inject drugs are on the top of the chart for contacting HCV and transmitting the infection. The strong association cure rate between HCV, PWID, MMTPs, and DAAs can greatly reduce the prevalence of chronic HCV, its sequela, and manage difficult to treat patient in obtaining SVR in this marginalized population. The burden of this sequela is sustainable from MMPT's screening process though admission, treatment, and graduation of the program.

During the admission process, all patients admitted are required to complete a history and physical. Improved HCV testing within methadone treatment programs is an essential general well-being methodology in combat against the HCV upsurge. Improved access to methadone is a crucial public health strategy in confronting the HCV. Thus, identified people who inject drugs are a priority population for HCV treatment to reduce HCV prevalence and

prevent reinfection. The strategy calls for developing programs to test and educate people who use drugs and are at risk for viral hepatitis and link those who are positive for HCV to viral hepatitis care and treatment. Studies have demonstrated coordination or including viral hepatitis prevention and care services with other physical health, mental health, and social administration can effectively prevent infections or identify and link individuals with viral hepatitis into care. An association exists between the organizations providing public health services, clinical care, substance use disorder services, and the upscaling of HCV detection and treatment.

In conclusion, this capstone project to implement the co-occurring HCV treatment model within an opioid-dependent treatment program improves the substance use population health outcomes and will combat and reduce the death toll of HCV by 2030. The co-location treatment model is advantageous to the nursing profession for describing how EBP is incorporated successfully into the behavioral outpatient care setting. The project also highlighted future growth areas between outpatient behavioral healthcare organizations, healthcare workers, and the community in promoting improved patient outcomes Consequently, investigation of diverse treatment protocols of PWID registered in MMTP and incorporating hepatitis C treatment modalities within OTP harm reduction services is not only recommend but is also achievable..

Section VII :Other Information

Funding

This capstone project did not receive any financial funding, assistance, sponsorship, awards, religious donation, or contribution from any private or public organization, public or private entities, political affliction, commercial organizations, pharmaceutical companies, or affluent figures. The CMMC staff, patients, or the DNP candidate did not contribute financially to the integration of this quality improvement project.

Also, recognizing and realizing the long-term investment of CMMC patients' quality of life, the capstone project did not intend to produce an increase in investment. Despite the organization incurring no additional costs, it prides itself by improving the morbidity, mortality, and patient outcome of those serviced. Additionally, with improved DAA medication availability, managing HCV treatment within MMTP is harder and emotional loss associated with the morbidity or mortality associated with failure to treat our clientele where in doing so promotes the organizational values and goals.

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Section IX: Appendices

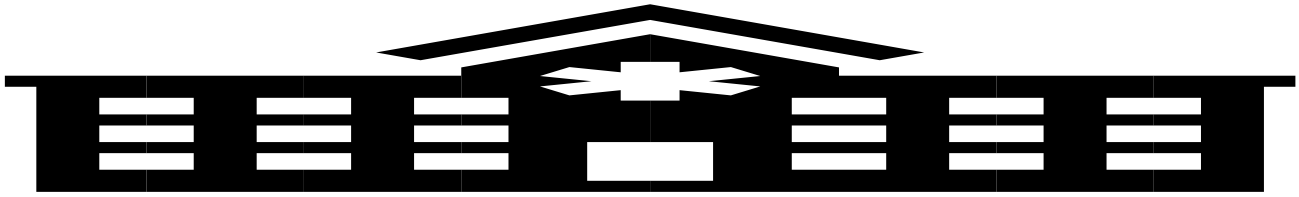
Appendix A. Oxford Level of Evidence

CENTRE FOR EVIDENCE -BASED MEDICNE CEBM LEVELS	
Level 1	Experimental Study, randomized controlled trial (RCT) or meta-analysis of RCT
Level 2	Quasi-experimental study
Level 3	Non-experimental study Systematic review of a combination of RCTs, quasi-experimental and non-experimental studies, or nonexperimental studies only. With no
Level 4	Opinion of nationally recognized experts based on research evidence or expert consensus panel (systematic review, clinical practice guidelines case series
Level 5	Opinion of individual expert based on non-research evidence Including case studies, literature reviews, personal experience , organizational reviews eg clinical expertise, quality improvement projects
CEBM STRENGTH OF RECOMMENDATION	
A	Great evidence to help suggested proposition of study for use. Should consistently be used
B	Moderate evidence to help a proposal for use, ought to for the most part be utilized
C	Moderate to Poor evidence to help a proposal for use; discretionary use
D	Poor evidence to help a proposal against use; ought to commonly not be cited
QUALITY OF EVIDENCE	
I	Evidence from at least one properly and appropriate randomized, controlled trial
II	Evidence from at least 1 well-designed clinical trial, retrospective cohort without randomization from group or case controlled analytic studies (preferably from more than once center or cite
III	Evidence from opinions of respected specialists, panels based on board clinical experience, descriptive studies, or reports of expert committees

Appendix B. Gap Analysis

Gap Analysis							
	Task	Current State	Expected outcome	Projected d Start Date	Strategies	Risk k	Completed
1	Downscaled	HCV Screening for symptomatic client	Mandatory HCV screening for all client	2/2020	Develop and implement screening tool with consent		Yes
2	Downscaled	HCV testing on request or patient is symptomatic	One time mandatory baseline HCV testing for clients and as needed	2/2020	Develop and implement testing tool with consent		Yes
3	Under-utilization of HCV panel	Lab panel for HCV testing downscaled	Upscale HCV lab panel	2/2020	Include HCV panel with lab		Yes
		No HCV educational poster displayed at facility	Display HCV educational poster and distribute HCV pamphlet on availability of DAAs	2/2020			Yes
5	No cost availability of Lifelong Educational modules and webinars	Minimal discussion between clinicians and client regarding the availability of DAA		2/2020	Encourage and mandate staff utilization of OASAS and SAMHSA HCV educational modules and webinars		Yes
	Increase use community involvement/services						

Appendix C. Letter of Support



CMMC BEHAVORIAL MMTP OUTPATIENT TREATMENT PROGRAM
COMMITED IN PROVIDING EXCELLENT CARE TO OUR COMMUNITY

February 22, 2020

To whom it may concern,

This letter of support signifies Ms. E Clarke is authorized to complete her Doctor of Nursing Practice capstone project at CMMC Outpatient Methadone Treatment Program in Westchester, New York. The executive management and leadership team grant her permission to implement her project here and use CMMC's facility in her final outpatient behavioral health treatment quality improvement project assignment.

M Bellows

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Appendix D. Hepatitis C Precentorship Program

Hepatitis C Preceptorship Program

Substance Use Providers and Addiction Specialists

Erie County Medical Center, Buffalo, NY

The New York State Department of Health AIDS Institute is partnering with Erie Country Medical Center (ECMC) to host a hepatitis C (HCV) preceptorship program targeting Substance Use Providers and Addiction Specialists. This program aims to increase capacity in substance use treatment programs to provide on-site HCV treatment to those most likely living with the disease. The lead provider for this preceptorship, Dr. Anthony Martinez, is trained in addiction medicine and hepatology. He is also an HIV specialist.

The HCV preceptorship will allow for training in the clinical evaluation and management of patients with HCV and co-occurring substance use disorders in a high risk, urban clinic. The multidisciplinary team at ECMC's Hepatology Clinic is comprised of physicians trained in both the management and treatment of HCV and addiction medicine and social workers specialized in serving people with HCV and addiction. Patients are provided services for polysubstance dependence with a special emphasis on opiate dependency, and HCV.

The preceptorship will allow Substance Use Providers /Addiction Specialists to shadow Dr. Martinez in his clinic, interact with his multidisciplinary team and learn about the latest HCV treatments. **ECMC will cover all travel related expenses for participating providers.**

Preceptorship Learning Objectives:

1) Increase knowledge of current HCV medication therapy for patients with HCV and/or HCV/HIV co-infection.
2) Develop skills for the management of HCV infection among persons with co-occurring substance use disorders.
3) Describe the management of addiction disorders, particularly opiate dependency; and
4) Identify key elements of a multi-disciplinary team to manage persons with HCV and substance use disorders.

About Dr. Anthony Martinez:

Anthony Martinez, MD is an Addiction Specialist and a Hepatologist. He serves as the Medical Director of Hepatology at Erie County Medical Center (ECMC) in Buffalo, NY. Dr. Martinez cares for patients with liver disease, including HCV, alcoholism, and fatty liver disease. He also evaluates and treats patients with HCV and HIV coinfection. Dr. Martinez conducts research to improve HCV treatments in populations disproportionately affected by HCV, including injection drug users, and patients with psychological disorders, as well as developing novel modalities to deliver care. Dr. Martinez is also co-investigator on numerous clinical trials related to new therapeutic agents for HCV and fatty liver disease. In addition, he lectures nationally about HCV with an emphasis on opiate dependence and special populations.

Register today!

There is open enrollment for this preceptorship.

To register, contact Angela Dieter. adieter@ecmc.edu

716-395-8860

Appendix E : Table of Evidence

#	Author/Article/Title Year	Study Design	Sample	Method	Setting	Analysis/ Results	Conclusion /Limitations	Evidence Level
1	Akiyama, Norton, Arnsten, Agyemang, Heo, Litwin (2019). Intensive Models of Hepatitis C Care for People Who Inject Drugs Receiving Opioid Agonist Therapy	Randomized Control Study	Sample Size N= 150	Unblinded stratified randomization assignment of participants to three groups who received HCV treatment according to AASLD/IDA guidelines. The participants responded to surveys and retrieved from chart reviews.	Participants are co-infected with HCV and opioid use disorder registered in three opioid outpatient programs in Bronx, New York, from October 2013 through April 2017. All partakers consented to treatment.	**Analysis**: Utilizing multivariable analysis, the study found: - Participant characteristics analysis by the percentage of frequencies - Linear models SAS for adherence to therapy -Autoregressive covariance for longitudinal correlation SAS Proc Logistics to test strata's -Bonferroni correction *P* to completion of therapy -Fisher exact test to compare groups	-At all on-site HCV care models delivered to PWID in the Bronx opioid use disorder programs, there was an increase in SVR despite the participants' continued drug use. - Participants directly observed in treatment was associated with greater adherence than self-administered intervention Limitations: Outcomes may not be generalized to PWID not enrolled in OTP programs	Level: 1 Grade: A Quality Rating: Strong

2	Batchelder, Peyser, Nahvi, Arnsten and Litwin (2015). "Hepatitis C treatment turned me around:" Psychological and behavioral transformation related to hepatitis C treatment. *Drug and Alcohol Dependence*	Convenience Semi structured qualitative design	Sample size: N=31.	Semi-structured interview by a qualitative interviewer for 45-90 minutes in a private room at the methadone clinic between June 2011- March 2013	Methadone – maintained treatment program patients enrolled in an integrated MMTP clinic in Bronx, NY.	**Analysis**: Use of thematic analysis and grounded theory **Results**: Participants expressed psychological and behavioral transformation throughout treatment, specifically reduced in internalized stigma, shame related to HCV addiction, elevated HCV disclosure, reduced in substance use, and desire to help others inflicted with HCV	Substantial evidence concludes that treating patients with cooccurring HCV and MMTP can improve behavioral and psychological transformation in an opioid-dependent patient infected with HCV. This will eradicate HCV, decreased HCV-infected patients, and improved patient's indignity, self-care, and quality of life.	Level: III Grade: B Quality Rating: Good

							Limitation: None reported	

3	Butler, Day, Dietze, Bruno, Alati, & Burns (2015). The potential reach of opioid substitution settings to deliver HCV care to people who inject drugs in Australia. *Journal of Substance Abuse Treatment*	Cross-sectional non-probability	Sample size: N= 887	Structured interviewer administered survey for 40 minutes, and participants remunerated $40 Australian dollars for participation	Australia utilizing the national HCV monitoring system: The Illicit Drug Reporting System(IDRS)	**Analysis:** Assessment completed with IBM SPSS version 22. Descriptive statistics to compare opioid substitution treatment (OST) to non-OST. Chi-square is utilizing categorical data. Means and standard deviations for normal distribution of data and *t*-tests to assess variable differences, median and range for nonparametric and Mann-Whitney *U*-test for distribution differences between nonparametric variables. **Results:** Within OST**,** two-thirds of the participants (65%) self-disclosed opioid as their drug of choice **have** an increased chance of testing positive for HCV (75%)	Conclusion: Limitation: Although similar to other PWID sample traits, Australia's population parameters are unidentified. Additionally, skewed memory recalls via self-report may play havoc by the recall and social remuneration desirable bias.	Level: III Grade: B Quality Ratings: Good
4	Butner, Gupta, Fabian, Henry, Shi,& Tetrault On-site treatment of HCV with direct-acting antivirals within an opioid treatment program (2017). *Journal 0f Substance Abuse*	Retrospective Study	Sample size: N=4326. The researchers were evaluating only the first 75 registrants	HCV and HIV testing offered to all patients enrolled within OTP	HCV infected client who injects with drugs enrolled within MMTP. Assessed Clients occurred during a routine clinic visit. Those with previous HCV positive	Analysis: Analysis done with Results: Ninety-eight percent completed treatment, ten patients lost to follow-up, and an undisclosed amount failed to initiate treatment. Additionally, 23 percent continued	Conclusion: Treating PWID infected with HCV enrolled within MMTP is achievable and beneficial; Continuous engagement increased co-occurring compliance of HCV and MMTP treatment.	Level: II Grade: A Quality Ratings: Strong

			from 20132015. Exclusion: Decompensated Liver cirrhosis		serology offered testing opt-out. They provided those infected with HCV education on the disease epidemiology. Providing Family involvement also increased engagement. Patient registered in treatment	drug use which did not alter the study's outcome. Female = 27% Male = 73 % Rapid virologic response (RVR)= 83 % SVR = 98%	Also, it is essential to upscale HCV treatment to decrease the HCV epidemic Limitations: - Single institution -small sample size -retrospective design - data collection during routine clinic care -- selection bias, as the first 75 participants selected did not represent the total clinic population -Patients with decompensated liver disease were excluded from the sample -limited replication due to differences in Medicaid approval **Recommendations** 1) Limited data exist, and additional studies are warranted on the achievability of treating HCV with DAA among PWID. 2) Investigation of diverse treatment protocols of PWID registered in MMTP	

5	Butsashvili, Kamkamidze, Kajaia, Gvinjilia, Kuchuloria, Gamkrelidze, Nasrullah, Averhoff (2019). Hepatitis C Treatment Integration With Harm	Convenience Sample	Sample Size: N= 358 participants	The survey conducted at five OTP and HCV co-location centers and four non-harm	Four Harm Reduction Center within OTP in Georgia USA selected to implement colocation hepatitis	**Analysis:** Intent-to-treat pre-treatment diagnostic algorithm **Results:** At the HCV treatment site, approximately 51 % received HCV treatment	Incorporation of hepatitis C within OTP harm reduction services is achievable.	Level: Grade: A Quality ratings: Strong
	Reduction Services in Georgia: Preliminary Findings. *International Network on Health and Hepatitis in Substance Users*			reduction sites in Georgia USA	C treatment within oral substitution therapy	-At the non-harm reduction site, about 49 % received HCV treatment. -Majority of the patients reported receiving HCV education and expressed secured confidentiality.		

6	Fadnes, Aas, Vold, Ohldieck, Leiva, Chalabianloo, and Johansson (2019) Integrated treatment of hepatitis C virus infection among people who inject drugs: study protocol for a randomized controlled trial (INTRO-HCV). *BMC Infectious Disease*	Randomized control test (RCT), Multicenter	Sample size N=200. Eligibility: -PWID registered in MMTP -HCV -Consent For treatment Exclusion Criteria: a) HIV coinfection b) severe HCV Decompensate-ated liver disease c) current HCV Rx	Screening, Assessment, and diagnosis of HCV. All favorable patient randomized treatment location a) treated on-site with DAA by nurse and provider or b) referral to an outpatient for 12week treatment centers.	PWID diagnosed with HCV and registered MMTP in Bergen and Stavanger, Norway	-Analysis: two-sided alpha (α) -CONSORT and SPIRIT guidelines - Descriptive data utilizing 95 % confidence levels -$p < 0.05$ -time-to-event analysis and linear models logistic regression -Markov model -Results cost per QALYs	**Conclusion:** Cooccurring treatment of PWID infected with HCV and registered win MMTP increases adherence to HCV treatment utilizing DAA improving patients quality of life	Level :1 Grade: A Quality ratings: Strong
7	Falade-Nwulia, Irvin, Merkow, Sulkowski, Niculescu, Olsen, Stoller, Thomas, Latkin, and Mehta (2019). Barriers and facilitators of hepatitis C treatment uptake among people who inject drugs enrolled in opioid treatment programs in Baltimore.	Convenience sample	Sample N=124	Self- report 50-item Questionnaire July –November 2016	PWID co-infected with HCV registered in two MMTP clinics in Maryland, Baltimore	-Univariable analysis -multivariable analysis	Testing participants at their PCP office, MMTP program, emergency room, or prison can is feasible. Female = 44% Male= 56%. Patients tri-infected with HCV, HIV, and	Level: III Grade: B Good

	Journal of Substance Abuse Treatment. Pp 45-51				The United States from July – November 2016		MMTP more likely to receive HCV treatment and less likely to be treated for continuous opioid use within six months. Despite the efficacy of DAA, patients coinfected with HCV and substance use disorder registered in MMTP treatment uptake remain low. HCV treatment provided at opioid treatment programs increases the likelihood of patients engage in HCV treatment.	
8	Frimpong,& D'Aunno (2016). Hepatitis C testing in substance use disorder treatment: program managers' role in the adoption of testing services. Substance Abuse Treatment Policy11,13 (2016). https://doi.org/10.1186/s13011016-0057-2	Investigation of the association between Program Directors of OPT and HCV testing	2005 N= 187 2007 N= 196 Total N= 383	Investigating association of Program Directors characteristics And HCV testing. Controlled variable: OTPs and client population	Opioid treatment programs	Multivariate regression model to examine HCV adaptation and testing correlations	In OTPs, where program managers were African American, onsite HCV screening and testing were up-scale in and the staffs were supportive of deterring HCV.	Level: III Grade: B Quality ratings: Good

9	Grebely, Tran, Degenhardt, Dowell-Day, Santo, Larney, Hickman, Vickerman, French, Butler (2020). Association Between Opioid Agonist Therapy and Testing, Treatment Uptake, and Treatment Outcomes for Hepatitis C infection Among People Who Inject Drugs: A Systematic Review and Metanalyses.	Systematic Review and Meta-analysis	Sample Size: N= 22 sample selected from 9877 articles	Review of bibliographic databases and conference presentation showcasing the association between OTPs testing, treatment, and treatment outcome for clients treated for	OTP located in Thailand, Australia, North America, and Europe	Results: Severe risk of bias identified in 21 studies -Modest bias identified in one study - Four of studies yielded antibody testing 1.80 Odd ratio result with 95 % confidence interval - In two studies, HCV RNA testing for HCV	**Conclusion:** OTPs have the capability to increases HCV linkage to care, upsurges HCV uptake, and enhance HCV treatment for people who inject with the drug which are registered in opioid agonist treatment programs	Level:1 Grade: A Quality ratings: Strong
	Clinical Infectious Disease			HCV in Thailand, Australia, North America, and Europe		antibody yielded an odds ratio of 1.83 with a 95 % confidence level		
10	Jessop, Bass, Brajuha, Alhajji, Burke, Gashat, Wellington Ventriglia, Coleman, & D'Avanzo (2020). "Take Charge, Get Cured": Pilot testing a target mHealth treatment decision support tool for methadone patients with hepatitis C virus for acceptability and promise of efficacy. *Journal of Substance Abuse pp 23-33*	Randomized Study	Sample Size : N= 122	A randomized Pilot study utilizing questionnaires in conjunction with an electronic decisional tool and three post follow-up questionnaires	At four OTP clinic located in Philadelphia Pennsylvania using a mHealth mobile decisional tool targeting MMTP patients co-infected with HCV. Partakers randomly selected and administered questionnaires on an electronic tablet and follow-up after three months.	**Results**: After three months, 93 partakers (76%) expressed intent to receive HCV treatment and increase HCV knowledge -There was no change between the groups to initiate HCV treatment	**Conclusion:** The utilization of an educational health tool effectively encourages PWID co-infected with HCV and registered within OTPs to seek HCV treatment.	Level: I Grade: A Grading ratings: Strong

11	Jordon, Cleland, Wyka, Schackman, Perlman, and Nash (2020). Hepatitis C virus Incidence in a cohort in Medication-Assisted Treatment for Opioid Use Disorder in New York City. *The Journal of Infectious Diseases ppS322-S334*	Cohort study	Sample Size: N= 8352	Open cohort study examining the efficacy and preventive HCV measures in an MMTP	HCV infected registrants of the OTP program in New York between January 2013 through December 2016	Person-years observation (PYO)	-Approximately Forty – nine percent of the total participants tested positive for HCV - Approximately 30 % t tested HCV negative (n= 2535). - per person-years (PYO) observation = 2.25/100 -HCV incidence 6.70/100 per PYO reported IV drug uses. - Females IV drug users experience lower retention in OTP and HCV seroconversion.	Level: III Grade: A Strong
							-Participants with decrease OTP attendance displayed higher HCV infection and higher methadone doses. -Participants on methadone less than 60 mg displayed decrease time to acquire HCV - The risk of HCV is higher in a participant receiving high methadone doses - The evidence supports in house co-treatment	

12	Litwin, Soloway, Cockerham Colas, Reynoso, Heo, Tenore, and Roose (2015). Successful Treatment of Chronic Hepatitis C with Triple Therapy in an Opioid Agonist Treatment Program *International Journal of Drug Policy pp 1014-1019*	Retrospective Observational Study	Sample Size: N= 3200 with results reported on 55 -Telaprevir N=42 Boceprevir N=8 in combination with Pegylated Interferon and Ribavirin	A retrospective review of patient's chart registered in Opioid Agonist Treatment Program receiving on-site DDA treatment with Telaprevir, Boceprevir in combination with Pegylated Interferon and Ribavirin between January 21, 2011, through April 2, 2013, to establish SVR, adherence, recent drug use, and effect of size	Three large Methadone Maintenance Treatment clinics in Bronx, New York	Analysis. -Date related to SVR analyzed utilizing chi-square and Fisher exact test -Odds-ratio for components of the effect of size -Multivariate models for measuring the relationship of prior medications and medication use during treatment	In general, 70% finished treatment, with 62 percent accomplishing SVR. Twelve percent failed to complete therapy/ Adherence to treatment 84 %. Received telaprevir and 16 % received boceprevir resulting in 90 % (< 90 % vs ³ 90 %). Five participants failed to complete therapy. There was no relationship between late medications use, and SVR and 62 percent supported SVR	Level: III Grade: B. Quality ratings: Good
	Author/Article/Title Year	Study Design	Sample	Method	Setting	Analysis /Results	Conclusion/Limitations	Evidence Level

13	Martin, Bosse, Wilson, Losikoff, and Chiodo (2018). Under one roof: identification, evaluation, and treatment of chronic hepatitis C in addiction care. *Addiction Science & Clinical Practice .pp 1-4* https://ascpjournal.biomedcentral.com/articles/10.1186/s13722018-0111-7	Pilot Study	Sample Size: N=740	Pilot study screening all patient for HCV at CleanSlate OTP offering treatment for HCV within outpatient opioid treatment program	Pilot Study of CleanSlate Addiction treatment Center in eight States From 2016 through 2017	Intention to treat analysis Dual location of HCV treatment within OTPs reduces HCV testing, linkage of care, initiation of therapy, and SVR eradication.	People with chronic HCV received disjointed care, and OTPs are matchlessly located to utilize their setup to expand services to enhance HCV treatment. Of the 740 clients screened, 25-30 percent prevalence of HCV. The authors found 75 with chronic HCV, approximately 23 percent found with chronic HCV and all offered treatment, 72 % received treatment at the program, and 28 % received referrals to the community. Forty-eight clients opted for treatment on-site, lost four to follow-up, and two failed to complete treatment. One patient experienced failed completion—the reported cure rate was 85 % with 98 % with SVR. Success attributed to: - An expert infectious disease specialist experienced in addiction and HCV care listed as part of the	Level: V Grade: A Quality ratings: Strong

							-multidisciplinary team. -client education -and advance interdisciplinary skills.	
14	Morris, Smirnov, Kvassay, Leslie, Kavanagh, Alexander, Davey, Williams, Gilks, and Najman (2017). Initial outcomes of integration community-based hepatitis C treatment for people who inject drugs: Finding from the Queensland injectors Health Network	Observational study	Sample size N=127 Male =69% Female =31%	Treatment responses and data collection by hepatology FNP	Clients registered with the QulHN Hepatitis C treatment and Management Program in Australia's Townsville, Brisbane, Sunshine Coast, and The Gold Coast. Utilizing hepatology FNP, medical providers and RNs	Participants evaluation completed sustained virologic response (SVR) -End of treatment response (ETR) Undetectable HCV RNA results computed on participants who completed 90 % of DAAs. who completed treatment analysis completed with Intent-to- treat -Logistic Regression is used to unadjusted. All data analyzed with Strat Version 14.0 with p statistical significance $p < 0.05$	Of the total 127 participants, 122 completed therapy, of which three percent took less than 90 % of the prescribed doses, two percent discontinued treatment Analysis.	Level: III Grade: A Quality ratings: Strong

15	Norton, Akiyama, Zamor, Litwin (2018). Treatment of Chronic Hepatitis C in Patients Receiving Opioid Agonist Therapy: A Review of Best Practice (2018). *Infectious Disease North America*	Comprehensive Retrospective–Cohort Review	Sample Size: N= Review of six Drug Efficacy treatment plans	Comparison of the following treatment modalities within OTPs -Peg/IFN/RBV -DAAs -Phase II/III Clinical trials HCV GT - Real-World Clinical Data	Clients registered within OTP and receiving treatment in the following colocation settings: -Peg/IFN/RBV -DAAs -Phase II/III Clinical trials HCV GT	Method: Data analyzed and interpreted by content analysis	HCV remains elevated in individuals who inject with drugs. With the new and improved DAA treatments, limited studies exist in persons who actively use drugs and are registered within OTPs. Increased screening, testing, and on-site OTP treatment with	Level: II Grade: B Quality ratings: Good
				_ Diverse PCP Models of Care -Group Treatment Direct Observed Therapy	- Real-World Clinical Data _ Diverse PCP Models of Care -Group Treatment Direct Observed Therapy		new and improved DAAs will increase the cure rate in this population. To enhance the success of HCV eradication, OTPs should implement comprehensive screening, increase patient HCV education, and educated on the importance of harm reduction	

16	Robaeys, Christensen, Lucidarme (2017) Chronic Hepatitis C Treatment in Patients with Drug Injection History: Findings of the INTEGRATE Prospective, Observational Study *Infectious Diseases and Therapy. Pp 265-275.*	Prospective Observation-al Study	Sample Size: N=46 participants	Forty-six participants enrolled at an opioid treatment clinic. The authors using comparative effectiveness of DAA's – Telaprevir combined with peg-interferon and Ribavirin as interventional medication to treat participants with co-occurring HCV clients registered within OTP	Six countries Belgium (six sites), France (three areas), Germany (four locations) Netherlands (one place), Switzerland (one spot) Kingdom(three regions) with the drug Peg-IFN/RBV	Results: Intent-to-treat participants of a multicenter, noninterventional, single arm study of telaprevir with Peg-IFN/RBV individuals opioid dependent individuals chronically infected with HCV GT1 with a medical history of IVDA and fibrosis of the liver cirrhosis -80 % opioid disorder -57 % completed therapy -43 % discontinued treatment with 17 % loss to follow-up, and 13 % experienced a reaction. **Statistical Analysis :** Clopper-Pearson formula R	**Conclusion:** Individuals who inject with medications should be considered for HCV, even though they oftentimes stop treatment. Improvement in this populace should be upscaled to improve HCV treatment, forestall reinfection, and abatement transmission	Level: III Grade: A Quality ratings: Strong

17	Roncero, Ryan, Littlewood, Macias, Ruiz, Seijo, Palma-Alvarez, and Vega (2019). Practical steps to improve chronic hepatitis C in people with opioid use disorder. *Hepatic Medicine: Evidence and Research pp 1-11*	Literature Review	Sample Size: N= 57 articles	The researchers used an organized, structured approach to organize literature reviews describing patients' journey from the initial admission at MMTP through engagement, screening, testing, and treatment interventions	Global Literature review of PWID infected with HCV from Canada, Portugal, Netherlands, USA, and the UK. The DAA medication became available in 2012, and data restricted to publications after their release. Also, to capture current data, the authors used relevant recent scientific expert releases.	Method: Data analyzed and interpreted by content analysis The conclusion is drawn from an expert clinician's review of the evidence.	**Results**: Internationally, People who inject drugs infected with HCV face an uphill battle and multiple barricades in securing HCV treatment. These individuals face reduced social determinant health and health access ….. Useful avenues recommended include providing integrated services, easy access, increased medication approval, patient engagement to improve compliance, standardized clinical pathways for the treatment, and " one stop" screening and treatment co-locations. -Unremitting counseling sessions promoted compliance with therapy. **Limitation:**	Level: II Grade: A Quality ratings: Strong
18	Schackman, Gutkind, Morgan, Leff, Behrends, Delucchi, McKnight, Perlman, Masson, & Linas (2018) Cost-effectiveness of hepatitis C screening and treatment linkage intervention in US methadone maintenance treatment program.	Randomized Trial	Sample Size: N=489	The researchers used the primary control Linking HCV care coordination interventions MMPT effective include screening, testing, education, and active care is	A randomize trial Conducted in New York City and San Francisco from February 2008 through June 2011. The researchers compared the	The two alternative scenarios were evaluated. The first evaluate how the cooccurring HCV within MMTP treatment impacted the participants' quality-of	Linking HCV care coordination interventions MMPT effective include screening, testing, education, and active care is achievable and cost-effective. Results: Non- Control participants 35 %	Level: I Grade: A Quality ratings: Strong

	Drug and Alcohol Dependence pp 411-420					life in comparison to the general public. The		

				likely to cost-effective theme to compare no intervention , HCV screening, testing and education along with care coordination to explore alternative strategies to linking HCV participants coinfected opioid use disorder	cost-effectiveness of a coupling HCV screening and instruction in an MMTP site with 244 and – the intervention group with no MMPT the control group 245 participant	second situation assessed the quality-of life estimator. Society benefits from co-linking therapy by $975,000 Measurement was through one-way sensitivity analysis. Both group received educational sessions and motivational interviewing	linked to care with 31% SVR -Lifetime linkage to care 42% with 43 % achieving SVR -MMTP intervention linkage yielded 60 % with HCV resulting in 54 % SVR Lifetime results 67% **Cost-effective: Control group** variable yielded a discounted $ 139, 000 per person and QALYs of 7.299 Conclusion: MMTP coinfected HCV participants will benefit from care coordination which includes screening, testing, education, and linkage to care as these settings are likely to be cost-effective	

18	Socias, Karamouzain, Parent, Barletta, Bird and Ti (2019). Integrated models of care for people who inject drugs and live with hepatitis C virus: A systematic review	Systematic Review and Meta-Analysis : Empirical quantitative studies inclusive of experimental and observational	Sample Size: 46 articles studies conducted in high-income countries	A narrative synthesis of the study's characteristics based on patients entry points - HCV facilities - OTP facilities - Co-location treatment	A systematic review of International patient enrollment in high-income HCV facilities, OTP facilities, co-location HCV and OTP and testing/treatment plus other services	Preferred Reporting Items for Systematic Reviews (PRISMA) utilizing inclusion criteria - ³ 18- years-old -PWID -Living with HCV infection	- **Findings**: The articles propose increasing patient engagement along with the HCV continuum care between individuals infected with HCV and Opioid use disorder patient colocation of at OTPS. HCV is prevalent among PWID -HCV Uptake is low as a low amount of PWID	Level 1 Grade: A Quality ratings: Strong

				To reduce risk, randomized clinical trial (RCT) Cochrane RoB tool for RCT utilized			are referred for HCV treatment - Increase the role of " one-stop" models for substance abuse and HCV models to increase access to HCV -Diverse setting may be successful in improving HCV infected participants Limitations: The article focused on only co-location of HCV and OTP services -Eighty partial abstracts were excluded -Short term DAA were excluded impacting if integrated models were sustainable Heterogeneity of integration limited extrapolation of data - One study used for comparison for integration versus noninteraction	
19	Scherz, Bruggmann, and Brunner (2018) Direct-acting antiviral therapy for hepatitis C infection among people receiving opioid agonist treatment or heroin-assisted treatment. *International Journal of Drug Policy pp74-77.*	Retrospective Study	Sample Size: N=64	Utilizing a retrospective chart review of patients registered in an outpatient opioid treatment center in Zurich Switzerland	Outpatient opioid treatment program in Zurich, Switzerland focusing on participants substance use, and treatment traits	Analysis: By means of intent-to-treat and modified -intent-to-treat	**Results.** All participants participated, with 59 of them completing therapy resulting in 92 % SVR. Three participants were lost in follow-up, and two sustained virological failure. The study concluded people who inject with	Level III Grade: A Quality ratings: Strong

							Conclusion: SVR rates are improved in people who inject with drugs, co-infected with HCV, registered in OTP while receiving treatment with DAA's. OTP clinics should offer coordinated HCV treatment to their patients	
20	Tai et al. (2019). Integrated care for methadone maintenance patients with hepatitis C virus infection. *Kaohsiung Journal of Medical Science*	Retrospective Study	Sample size: N=390	All OTP Patients with HCV Positive Serology Test	MMTP Participants: HCV infected OTP clients between April 2015 through May 2017	Continuous variables represented by Standard Deviation (SD) ±SD. Categorical variables represented by percentages Two group comparison with t-test. Multiple logistic regression analysis Independent factors	Individuals infected with HCV and registered in OTP colocation displayed increase compliance with HCV treatment when care is integrated with hepatologists and psychiatry. However, few OTP patients successfully completed treatment. **Results** Integrated care patient engagement increased from 14.1% to 58 %. Approximately 42 percent refused treatment. The authors concluded a multidisciplinary team approach is effective in treating individuals infected with HCV who are registered in OTP	Level: II Grade: A Quality ratings: Strong

21	Springer and Del Rio (2020) Co-locating Opioid Use Disorder and Hepatitis C Virus Treatment	Retrospective	Sample N=100		MMTP in Connecticut USA	Intent to Treat	Conclusion: Hardly any Studies have assessed the viability of	Level III Grade A Level Strong
	Is Not Only Right, But It Is Also the Smart Thing To Do as It Improves Outcomes *Clinical Infectious Disease 1723=1725*	observational study					coordinating HCV and opioid use problem; It is not only important and effective to integrate HCV and opioid addiction service under one roof, but it is also elevating patient outcome. Limitation Participants treated with buprenorphine	
22	Taylor (2020). Colocalization in Hepatitis C Virus Infection Care: The Role of Opioid Agonist Therapy Clinics *Clinical Liver Disease pp 12-15*	Expert Peer Review	Sample size: 34 articles reviewed	Method: Review of Literature	International OTP with focus on Switzerland's primary care based addiction medicine institute. S	Method: Data analyzed and interpreted by content analysis. Switzerland is the primary nation to build up a broad government financing program for heroin treatment.	Conclusion: Utilizing DAAs and Coordinating HCV administrations with methadone support are critical advance in overall general wellbeing reaction to the HCV pandemic worldwide Hepatitis C To achieve HCV elimination, PWID must be engaged in care, and international guidelines supports upscaling HCV treatment within the opioid dependency population.	Level: V Grade: A Quality ratings: Strong

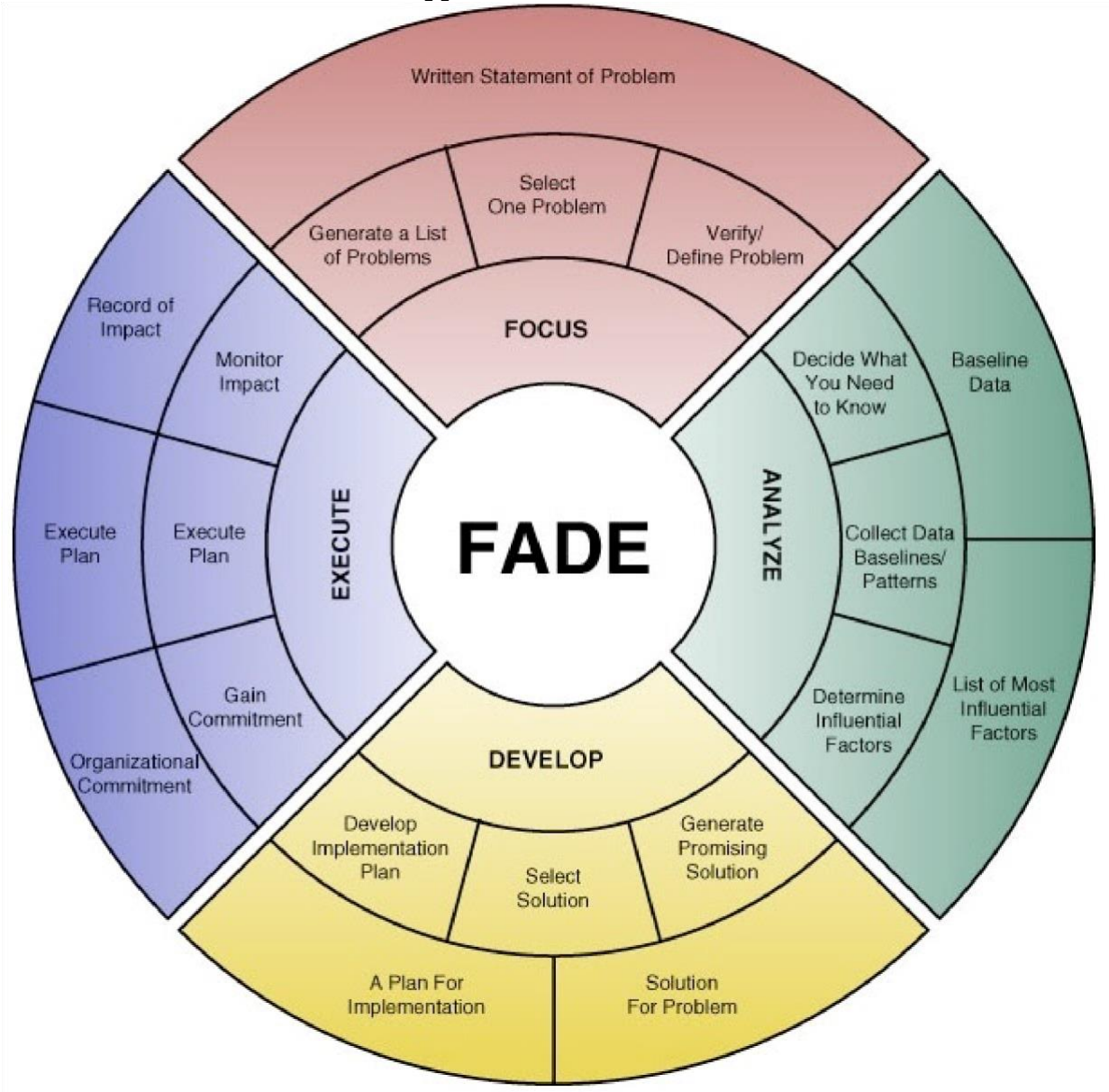
23	Thompson (2016). Australian recommendations for the management of hepatitis C virus infection: a consensus statement	Expert Panel Consensus	Non experimental. Seven expert Association panel	Consensus of seven expert panel in Australian: ------Australian Liver Association -------Australasian Hepatology Association		Consensus of seven expert panel in Australian treatment boards	Australian Consensus panel supports upscaling HCV treatment for all living HCV infected individuals to reduce the country's public health burden. The	Level: V Grade: C Quality ratings: Good

				-Viral Hepatitis and Sexual Health Medicine -Australian Society for infectious Disease -The Royal Australian College of General Practitioners - Hepatitis Australia Australasian Society for HIV			consensus citing recommendations for the development of innovated treatment models among which PWID and OPTs are highlighted	

24	Trabut, Barrault, Charlot,, Carmona, Bourdel, Benslimane, Francios, Hezode (2018). Integrated Care for the use of Direct-acting Antivirals in Patients with Chronic Hepatitis C and Substance Use Disorder. *Journal Of Addiction Medicine Pp346-352*	Retrospective analysis 32	Sample Size: N=50	Method: Retrospective study Employing the European HCV guidelines	Patients enrolled in hepatitis clinic within addiction services to examine the association with treatment difficult-to manage patients with a substance use disorder. Participants were asked to compare five DAA regimens	A review investigation of the 50 members who received treatment with DAAs as per the European rules	Results: Enrollees: 42 were males and eight females -Forty-five patients achieved SVR -68 % received opioid treatment Conclusion: In these hard to oversee patients with HCV and substance use problem, this present reality SVR rates 90% , an improvement, was like that in the nonaddicted populace. The results demonstrated improved treatment outcome of an onsite HCV within MMTP model	Level: III Grade: Quality ratings:

25	Tsui, Miller, Scott. Corcorran, Dombrowski, Glick (2019) Hepatitis C continuum of care and utilization of healthcare and harm reduction services among persons who inject drugs in Seattle. *Drug and Alcohol Dependence pp 124-120*	Retrospective study	Sample Size: N=513	Interviewer administered survey	The behavioral Surveillance system in Seattle and South King County, Washington from June through November 2015	Bivariate analysis using Gile Successive Sampling Estimator and survey data Strata SE 15. **Results:** 513 respondents screened for HCV - Approximately 60% HCV Ab+, 70 %. – - reporting the previous diagnosis - 56 % with confirmatory test results 17 % with last treatment -7% completed treatment	There is a considerable gap. between HCV screening and treatment among PWID in Seattle The outcomes issue the expanded admittance to HCV to this population by making treatment accessible in methadone facility a typical site of care for PWID. A future examination is required for compelling development and conveying HCV care to carry endeavors to the public objective of HCV end.	Level: III Grade: A Quality ratings: Strong

Appendix F. Fade Model



Appendix G. IRB

OTP RESEARCH TRANSFORMING THE FUTURE OF SUBSTANCE TREATMENT PROGRAMS

Date: February 2020

Subject: E Clarke OTP-MMTP

Title: Improvement on Prevention of Illicit Substance use or Service in OTP

Dear:

Ms. Clarke

As a Research Determination Official for the Methadone Maintenance Out -Patient Treatment Program, we have reviewed the documents submitted for the above mentioned project. The project does not meet the regulatory definition of research involving subjects as noted here:

[ ]
[X]

Not Research

The activity does not meet regulatory definition of research at 45 CFR.102(d)

§46.102 Definitions for purposes of this policy.

- ***Certification*** **means the official notification by the institution to the supporting Federal department or agency component, in accordance with the requirements of this policy, that a research project or activity involving human subjects has been reviewed and approved by an IRB in accordance with an approved assurance.**

-***Clinical trial*** **means a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health related outcomes.**

- ***Department or agency head*** **means the head of any Federal department or agency, for example, the Secretary of HHS, and any other officer or employee of any Federal department or agency to whom the authority provided by these regulations to the department or agency head has been delegated.**

- ***Federal department or agency*** **refers to a federal department or agency (the department or agency itself rather than its bureaus, offices or divisions) that takes appropriate administrative action to make this policy applicable to the research involving human subjects it conducts, supports, or otherwise regulates (*e.g.*, the U.S. Department of Health**

and Human Services, the U.S. Department of Defense, or the Central Intelligence Agency).

-(1) *Human subject* means a living individual about whom an investigator (whether professional or (2)

Identifiable private information.

Therefore, the project is not required to be reviewed by OTP Institutional Review Board (IRB**). This** determination is based on the information provided. If the scope or intervention of the project changes in a manner that could impact this review, please resubmit for a new determination. Also, you are responsible for keeping a copy of this determination letter in your project file as it may be necessary to demonstrate that your project was properly reviewed.

Sincerely

……*Ms. Flannergan***…**

Ms. M. Flannergan

OMB No. 0990-0473
Approved for use through July 31, 2023

U.S. Department of Health and Human Services (HHS)
Subpart C Certification Form

In compliance with 45 CFR 46.305(c), an institution that intends to conduct HHS-supported research involving prisoners as subjects must certify to the Secretary (through OHRP) that the IRB has made the seven findings required under 45 CFR 46.305(a), including the finding that the proposed research represents one of the permissible categories of research under 45 CFR 46.306(a)(2).

OHRP requires the electronic submission of Subpart C certification requests. Requests should be emailed to subpartc@hhs.gov. If an institution is unable to submit information electronically, please call 240-453-8141 to discuss an alternative submission process. Do not print and scan the certification form for submission. Fill the form out electronically and email a copy of the electronically filled-out form as an attachment. To submit a subpart C certification request to OHRP, the institution must submit a completed copy of this certification form in conjunction with a copy of the research proposal in order to determine whether the appropriate findings have been made. The term "research proposal" includes:

- the IRB-approved protocol, including consent forms.
- any IRB application forms required by the IRB; and
- any other information requested or required by the IRB to be considered during IRB review.

*Note: If an IRB considers the grant application during its review of the study, **only** submit the portions of the grant application relevant to subpart C review for the purposes of subpart C certification.*

Administrative Information

Name of Institution:	CMMC
Address of Institution:	Westchester New York
Contact Information:	*Name:* Click or tap here to enter text. *Title:* Click or tap here to enter text. *Phone:* Click or tap here to enter text. *Email:* Click or tap here to enter text.
Relevant Grant Number(s):	Click or tap here to enter text.
Funding Agency:	N/A
Granting Institution's Program Officer:	N/A
OHRP Assurance #:	Click or tap here to enter text.
IRB Registration # for Reviewing IRB:	Click or tap here to enter text.

Study Information

Study Title: Implementation of HCV treatment Module with CMMC OTP

Name of Principal Investigator(s): E. Clarke FNP

Brief Summary of Protocol: Implementation go HCV treatment model within MMTP
Click or tap here to enter text.

Date(s) of IRB meeting(s) in which protocol was considered, including the dates of initial IRB review and subpart C review: Click or tap here to enter text.

Permissible Categories of Research

This institution certifies that the IRB has determined that the research under review represents one of the categories of research permissible under §46.306(a)(2) or meets the criteria for use of the epidemiological waiver (45 CFR 46.305(a)(1) and 68 FR 36929):

Select One	Permissible Activity Description
	45 CFR 46.306(a)(2)(i): *Study of the possible causes, effects, and processes of incarceration, and of criminal behavior, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects*
☐	**45 CFR 46.306(a)(2)(ii):** *Study of prisons as institutional structures or of prisoners as incarcerated persons, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects*
☐	**45 CFR 46.306(a)(2)(iii):** *Research on conditions particularly affecting prisoners as a class (for example, vaccine trials and other research on hepatitis which is much more prevalent in prisons than elsewhere; and research on social and psychological problems such as alcoholism, drug addiction, and sexual assaults) provided that the study may proceed only after the Secretary has consulted with appropriate experts including experts in penology, medicine, and ethics, and published notice, in the FEDERAL REGISTER, of his intent to approve such research.*
☐	**45 CFR 46.306(a)(2)(iv):** *Research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or wellbeing of the subject. In cases in which those studies require the assignment of prisoners in a manner consistent with protocols approved by the IRB to control groups which may not benefit from the research, the study may proceed only after the Secretary has consulted with appropriate experts, including experts in penology, medicine, and ethics, and published notice, in the FEDERAL REGISTER, of the intent to approve such research.*

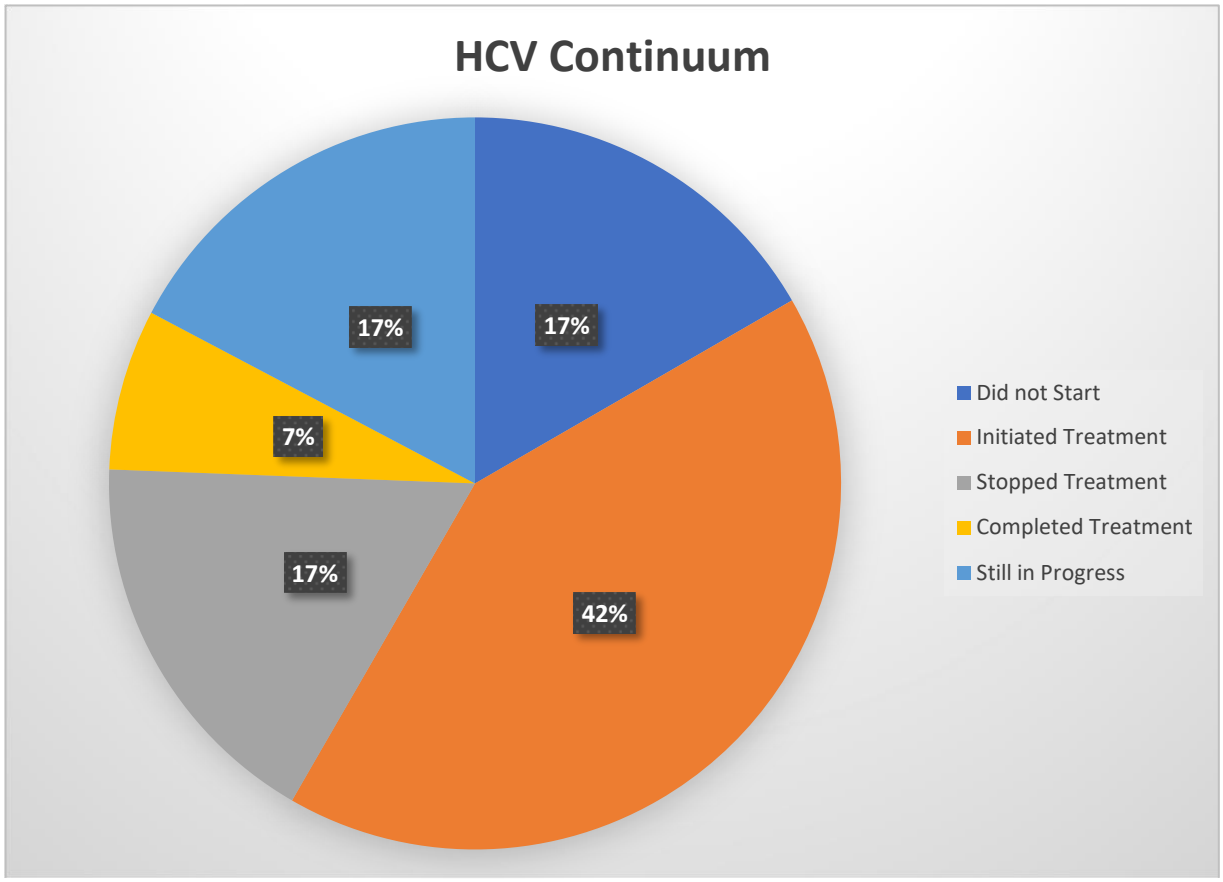
Select One	Permissible Activity Description

☐	**Epidemiological Waiver (68 FR 36929):** *Research conducted or supported by DHHS that involves epidemiologic studies that meet the following criteria:* *(1) In which the sole purposes are:* *(i) To describe the prevalence or incidence of a disease by identifying all cases, or* *(ii) To study potential risk factor associations for a disease, and* *(2) Where the institution responsible for the conduct of the research certifies to the Office for Human Research Protections, DHHS, acting on behalf of the Secretary, that the IRB approved the research and fulfilled its duties under 45 CFR 46.305(a)(2)–(7) and determined and documented that* *(i) The research presents no more than minimal risk and no more than inconvenience to the prisoner-subjects, and* *(ii) Prisoners are not a particular focus of the research.*

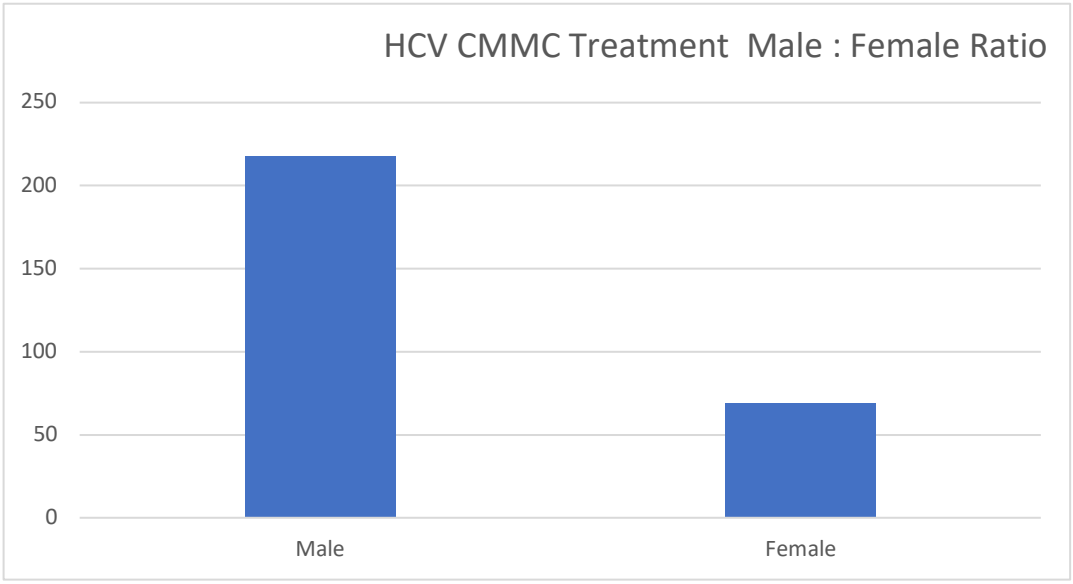
Certifications (both boxes must be selected before submitting this form) The institution further certifies the following:

Select	**Required Certifications Both**
X	That the research has been approved by an IRB that has adhered to all other responsibilities prescribed for Institutional Review Boards under subpart C (45 CFR 46.305(a)(1)).
X	That an IRB has made the determinations required by 45 CFR 46.305(a)(2)-(7).

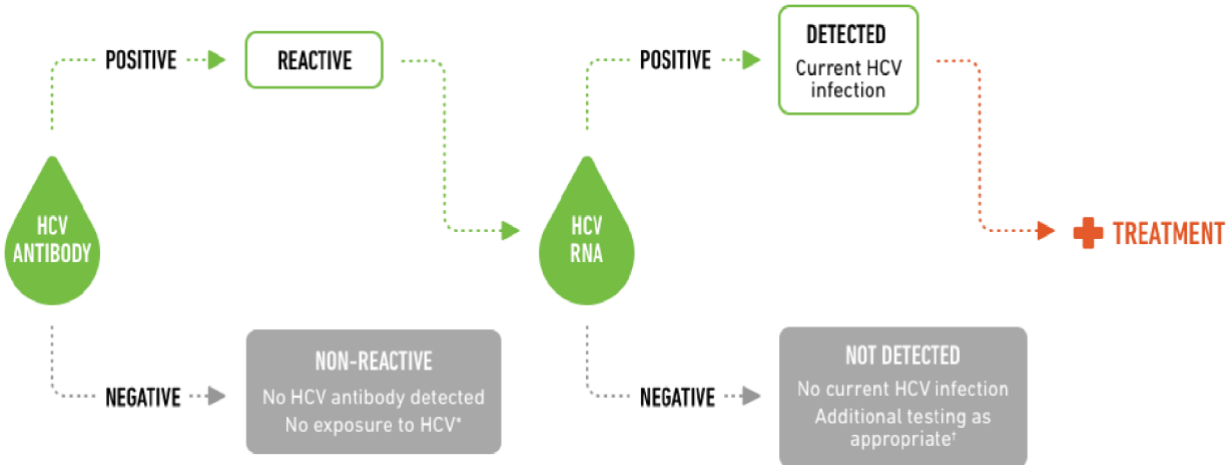
Appendix H
CMMC HCV Care Module



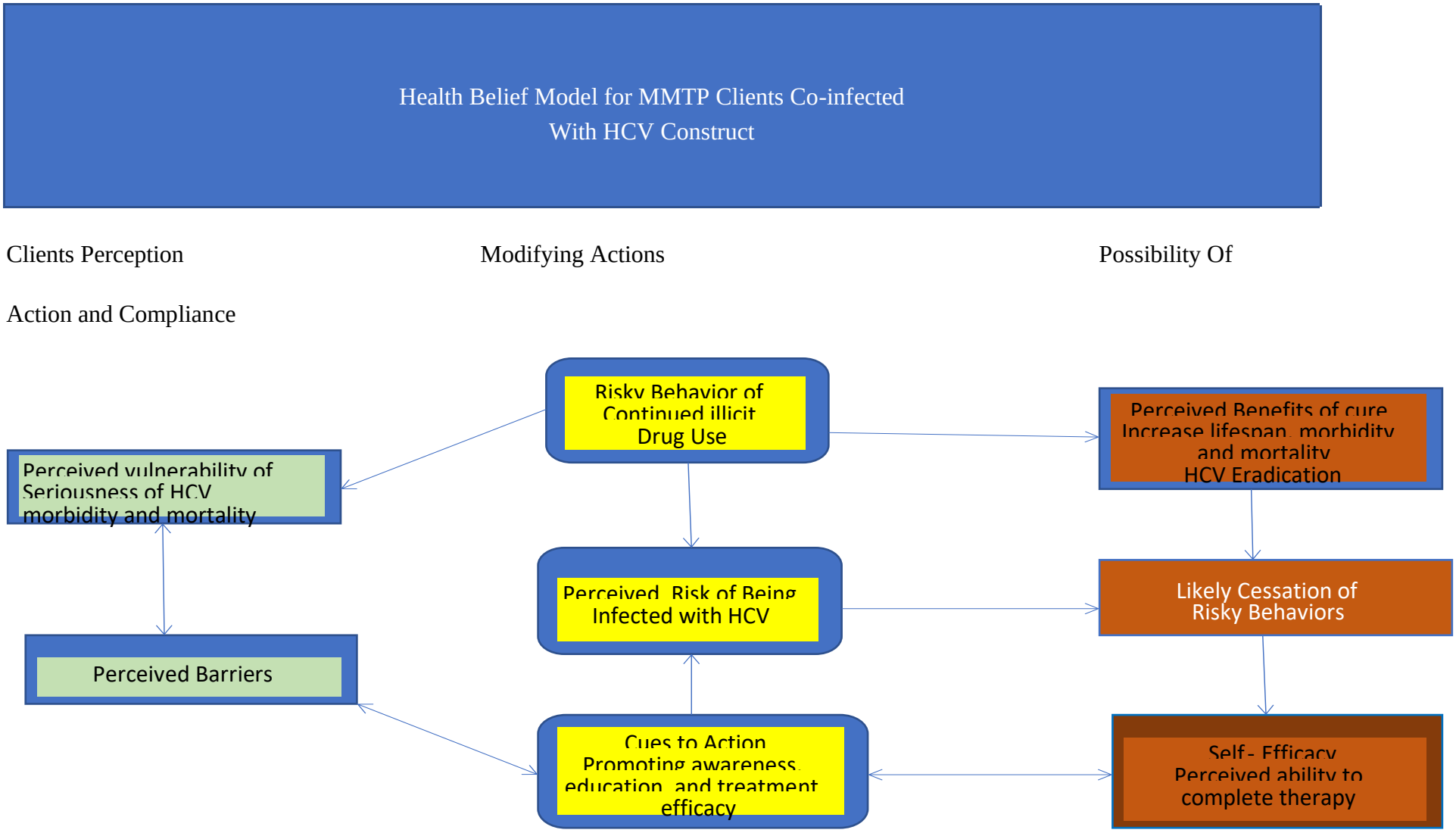
Appendix I CMMC Gender Ratio



Appendix J. HCV SCREENING STEPS



Appendix K Health Belief Model



Timeline

Implementing HCV integration within MMTP													
Project Concept													
	Identify gap in treatment	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
	Review SAMHSA and OASAS regulations												
	Literature Review												
	Discuss with leadership												
	Obtain project approval												
	Community HCV assessment												
	Identify Stakeholders												
	Project preparation												
Focus and Design													
	Focus on HCV need assessment												
	Identify program's strength												
	Identify available education for stakeholder's												
	Review design strategies												
	Review clients chart												
	Review OASAS and SAMHSA Education HCV content												
	Review Lab Panel												
	Create implementation committee												
	Identify HCV need assessment												
Analyze Current Practice													

	Modify screening tool												
	Modify lab panel												
	Initiate screening for all client												
	Collect and evaluate data on all positive clients												
	Continuing HCV education for stakeholders												

Key	
	COVID 19 Cessation
	Capstone In Progress
	FADE Module

Appendix M. SWOT Analysis

INTERNAL	**STRENGTH**	**WEAKNESSES**
	• Excellent Leadership • MMTP Infrastructure • Multidisciplinary team Staff engagement and willingness to improve clients outcome • Patient engagement • Support from funding organization • New and improved DAAs • Insurance Approval • Expansion of NP's role	• Limited HCV testing and services • Inadequate evidence-based research articles • Lack of mandatory MMTP HCV treatment • Limited provider HCV treatment within MMTP • HCV and MMTP stigma • Insurance disparities • Decrease provider knowledge
EXTERNAL	**OPPORTUNITIES**	**THREATS**
	• Increase MMPT provider • Improved client outcome • Increase governmental Funding • Increase use of community service • Lifelong learning opportunities	• Staff complacency • Client decrease engagement • Clients continued risky behaviors • Community mistrust of MMTPs • Limited MMTPs providers • Increase patient loitering • Increase illicit drug availability and sale • Medication reactions • Failure to complete therapy • Under or uninsured

Appendix N. CDC HCV Interpretations Lab Results

Interpretation of Results of Tests for Hepatitis C Virus (HCV) Infection and Further Actions

TEST OUTCOME	INTERPRETATION	FURTHER ACTIONS
HCV antibody nonreactive	No HCV antibody detected	Sample can be reported as nonreactive for HCV antibody. No further action required. If recent exposure in person tested is suspected, test for HCV RNA.*
HCV antibody reactive	Presumptive HCV infection	A repeatedly reactive result is consistent with current HCV infection, or past HCV infection that has resolved, or biologic false positivity for HCV antibody. Test for HCV RNA to identify current infection.
HCV antibody reactive, HCV RNA detected	Current HCV infection	Provide person tested with appropriate counseling and link person tested to care and treatment.†
HCV antibody reactive, HCV RNA not detected	No current HCV infection	No further action required in most cases. If distinction between true positivity and biologic false positivity for HCV antibody is desired, and if sample is repeatedly reactive in the initial test, test with another HCV antibody assay. In certain situations,§ follow up with HCV RNA testing and appropriate counseling.

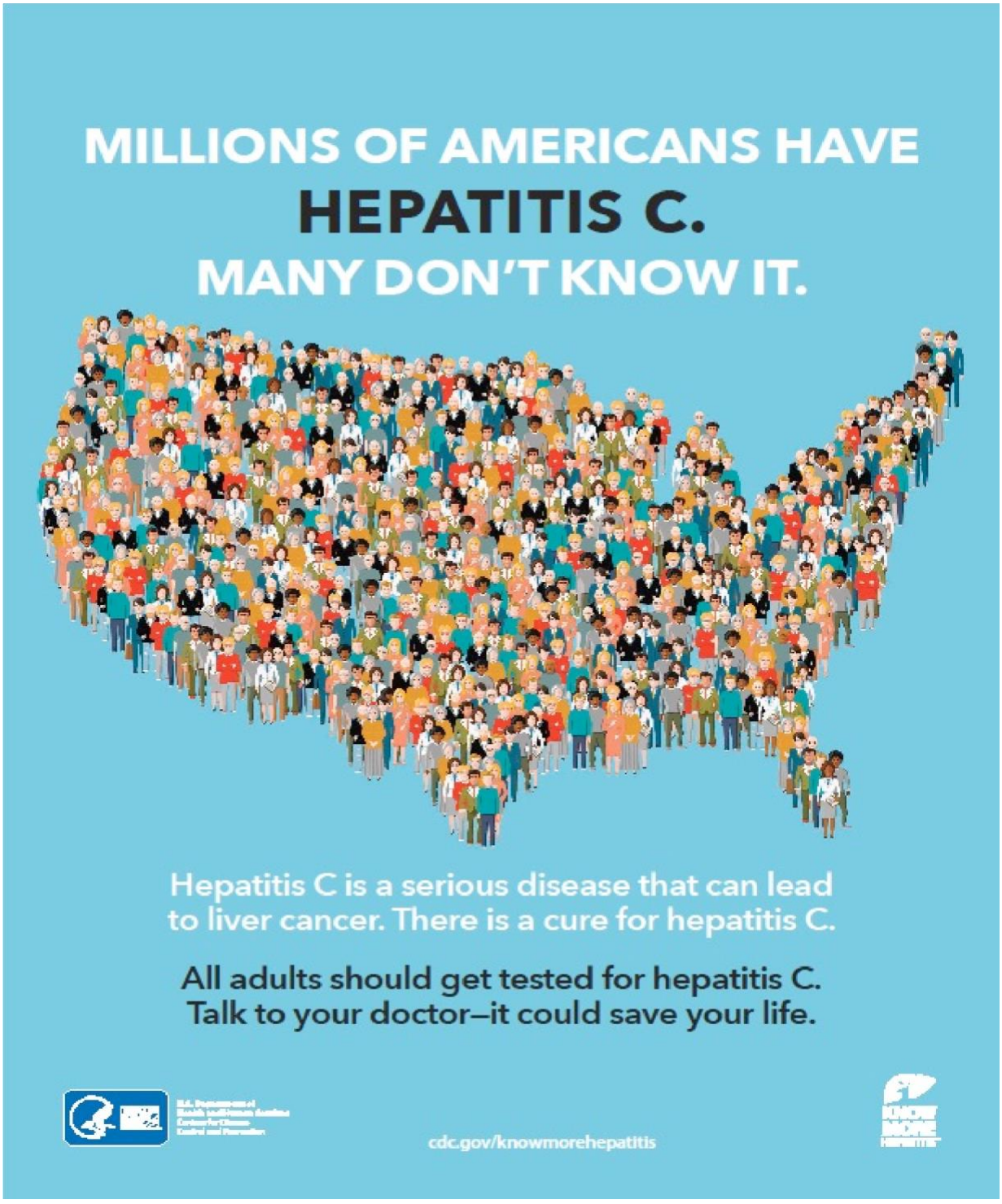
* If HCV RNA testing is not feasible and person tested is not immunocompromised, do follow-up testing for HCV antibody to demonstrate seroconversion. If the person tested is immunocompromised, consider testing for HCV RNA.

† It is recommended before initiating antiviral therapy to retest for HCV RNA in a subsequent blood sample to confirm HCV RNA positivity.

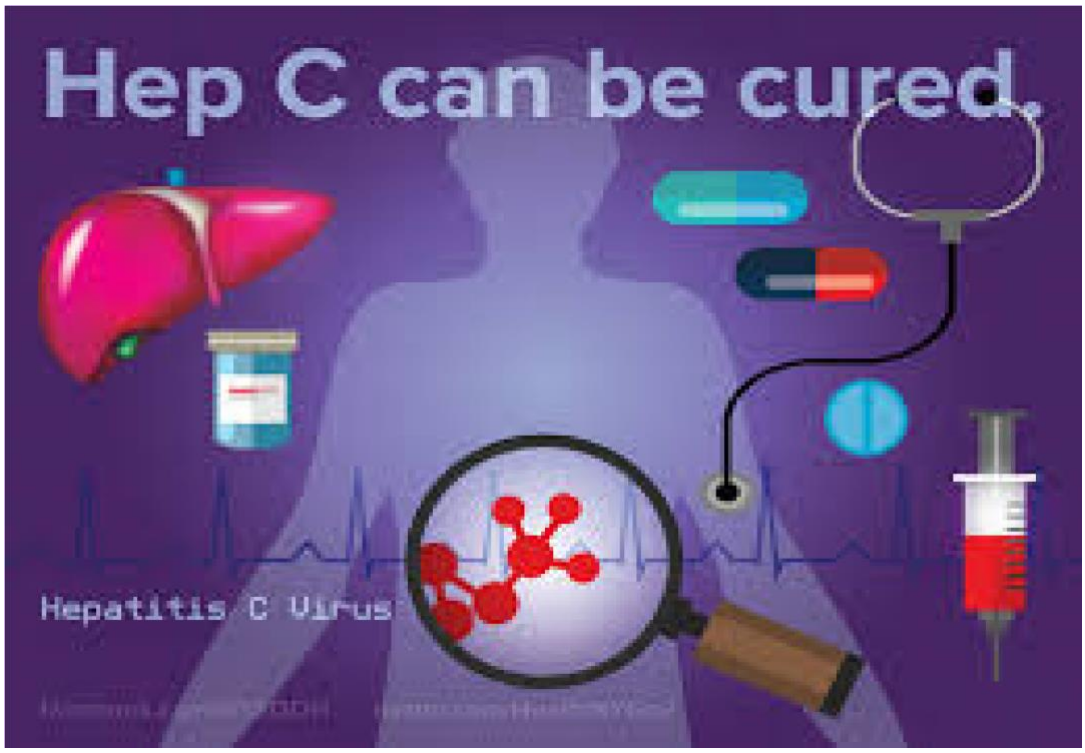
§ If the person tested is suspected of having HCV exposure within the past 6 months, or has clinical evidence of HCV disease, or if there is concern regarding the handling or storage of the test specimen.

Source: CDC. Testing for HCV Infection: An update of guidance for clinicians and laboratorians. MMWR 2013;62(18).

Appendix O. CDC HCV Map CMMC Display



Appendix P. Hepatitis C Poster Display



Appendix Q. SAMHSA TIP 53 HCV Improvement Protocol and Educational Guide