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Hepatitis C Treatment: A Community-Based, Multidisciplinary Approach to Increase Access and Improve Health Perceptions

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HEPATITIS C TREATMENT: A COMMUNITY-BASED, MULTIDISCIPLINARY
APPROACH TO INCREASE ACCESS AND IMPROVE HEALTH PERCEPTIONS

Elaine A. Leigh

A Dissertation Submitted to the Faculty of
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In

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DEDICATION

HEPATITIS C TREATMENT: A COMMUNITY-BASED, MULTIDISCIPLINARY APPROACH TO INCREASE ACCESS AND IMPROVE HEALTH PERCEPTIONS

This project is dedicated to the individuals with hepatitis C living in western Michigan and around the nation. Collaborative efforts are ensuring improved access to quality hepatitis C care. Special thanks to Bruce Olson MD who provided consistent mentoring and strongly promoted an evidence-based approach to program development.

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HEPATITIS C TREATMENT: A COMMUNITY-BASED, MULTIDISCIPLINARY APPROACH TO INCREASE ACCESS AND IMPROVE HEALTH PERCEPTIONS

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ABSTRACT

HEPATITIS C TREATMENT: A COMMUNITY-BASED, MULTIDISCIPLINARY APPROACH TO INCREASE ACCESS AND IMPROVE HEALTH PERCEPTIONS

Hepatitis C is a major international health care dilemma, occurring frequently in populations who suffer from other health care disparities. Hepatitis C is the most common blood-borne infection and the leading cause of liver disease in the United States (U.S.), causing 10,000 –12,000 deaths per year. According to the Centers for Disease Control and Prevention (2008), up to 3.9 million people are affected with the hepatitis C virus (HCV) within the US. Estimates suggest that 75% of those affected with the HCV are unaware of their diagnosis, and of those, only one in four people are offered treatment. Some researchers suggest that all US residents born between 1946 and 1970 be screened for hepatitis C over a 5-year period.

The HCV carries an estimated financial burden of \$10.7 billion nationally, and \$377 million in Michigan alone. Barriers to treatment include the lack of qualified healthcare providers and treatment programs; rigorous treatment regimens and significant medication side effects; psychosocial challenges include mental illness; addiction; stigmatization; and insufficient healthcare coverage. The purpose of this project was improve access and care for individuals with hepatitis C in an underserved area.

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CHAPTER 1

INTRODUCTION

Hepatitis C is a major international healthcare dilemma and occurs frequently in populations who suffer from other healthcare disparities. According to the Centers for Disease Control and Prevention (CDC, 2008), up to 3.9 million people are affected with the hepatitis C virus (HCV) within the United States (US) and this number rises to 170 million world-wide (World Health Organization [WHO], 2012). Hepatitis C is the leading cause of liver disease and is the number one reason for liver transplantation, according to the National Institutes of Health (NIH, 2002). Hepatitis C is the most common blood-borne infection in the US and it carries with it an estimated financial burden of 10.7 billion nationally (Wong, McQuillan, McHutchison, & Poynard, 2000) and 377 million in Michigan alone (Michigan Department of Community Health [MHCH], 2010).

Wong et al. (2000) forecasted that the greatest burden of the HCV would occur between 2010 and 2019. Their projections were based on data trends in the National Health and Nutrition Examination Survey III (NHANES, 1998). These estimates will likely become a reality if guidelines for age-based screening for the HCV are adopted. McGarry et al. (2011) suggest screening for hepatitis C for all US residents born between 1946 and 1970 over a 5-year period. Among the 102 million people 40 to 64 years of

age, as many as 1.3 million are infected with HCV but remain undiagnosed. With appropriate birth-cohort screening, this population could be captured. In contrast, current risk based screening would identify only 427,000. This means that an additional 742,000 person with HCV could be diagnosed and treated if current screening reflected existing knowledge. The cost saving of age-based screening occurs with early detection of advance liver disease to reduce the numbers of individuals progressing to decompensated liver disease, liver transplantation, or death.

Although national guidelines exist for the treatment of the HCV, the lack of qualified healthcare providers and established treatment programs limit the numbers of individuals receiving therapy. Estimates in the US today suggest that only one in four people affected with hepatitis C are offered or receive treatment (Yawn, Rocca, & Wollan, 2008). Before receiving treatment, those with hepatitis C will face rigorous eligibility criteria, the probability of worsening liver disease, and stigmatization.

Current healthcare systems are not meeting the needs of many of the individuals with the HCV (Tait, McIntyre, McLeod, Nathwani, & Dillon, 2010). The complexity of treating hepatitis C needs to involve an integrated approach to care with several healthcare disciplines collaborating to address the many barriers associated with treatment. The Extension for Community Healthcare Outcomes (ECHO) is one such program developed by the University of New Mexico Health Sciences Center (UNM HSC). This project was designed to specifically address the needs of patients with HCV in rural areas where there is a lack of qualified providers to manage complex treatment regimens (Arora et al., 2010). This program was developed initially to improve healthcare outcomes for individuals with hepatitis C and is now being implemented in

programs to manage a variety of chronic illnesses (Arora et al.). This approach to care involves professionals from a variety of healthcare disciplines who collaborate and coordinate recommendations prior to and during hepatitis treatment.

Evidence-based Scholarly Project

Improving healthcare outcomes can be enhanced by applying an evidence-based approach to current gaps in practices. For this project, the approach required a thorough review and critical synthesis of research on specific healthcare initiatives related to hepatitis C. The critique of this research then became the foundation for clinical guideline development and practice change (Coopey et al., 2006).

In an effort to improve care for individuals with hepatitis C in a shoreline community in West Michigan and the immediate surrounding rural areas, solutions to improve access to HCV treatment were sought by applying an evidence-based practice (EBP) approach. A five-step model guided project development and included the following: clear identification of the problem; systematic retrieval of existing research; critical appraisal of the evidence; application of results, and evaluation of the practice innovation (Johnston & Fineout-Overholt, 2005). The goal of this project was to improve access to HCV treatment by providing comprehensive programming that could address the multitude of health burdens faced by individuals diagnosed with hepatitis C. Ultimately, a multidisciplinary, community-based HCV treatment clinic was developed and implemented.

The Chronic Care Model (CCM) was used as the conceptual framework to guide this project. This model seeks to improve chronic illness management with cohesive and collaborative partnerships (CCM, 2010). This model offers strategies to manage chronic

illness by focusing on interventions targeted on six specific components: community resources and policies; healthcare organizations; self-management support; delivery system design; decision support; and clinical information systems. In managing health-related needs of patients with hepatitis C, the chronic care model was fully implemented but specific clinic programming focused on the components of self-management support and decision support in an attempt improve long-term HCV outcomes.

Background

Infection with the HCV is complex and individuals who have hepatitis C can remain asymptomatic for extended periods of time, making accurate prevalence rates difficult to estimate. As prevalence rates currently exist, reported numbers may not reflect incarcerated, mentally ill, or homeless populations. HCV exposure results in a chronic infection in approximately 85% of individuals, and of those, 10-20% will develop cirrhosis (Wise, Bialek, Finelli, Bell, & Sorvillo, 2008). The presence of chronic HCV increases the risk for developing hepatocellular carcinoma and the subsequent need for liver transplantation (Dolder, Wilhardt, & Morreale, 2002). As a health burden, chronic hepatitis C accounts for 8,000-10,000 deaths per year (Geppert & Arora, 2005; Shehab, Sonnad, & Lok., 2001).

Hepatitis C is primarily a percutaneous transmitted infection (Flamm, 2003) with the highest prevalence rates in people 30-45 years of age (Baldo, Baldo, Trivello, & Floreani, 2008). Individuals from vulnerable and disadvantaged populations are at the highest risk due to the prevalence of risk factors in these populations. The majority of persons affected with the HCV have acquired it from non-sterile intravenous drug use (IVDU) practices (Paterson, Backmund, Hirsch, & Yim, 2007). As many as 95% of

intravenous drug users have positive HCV virology (Geppart & Arora, 2005). It is believed that 20-30% of persons with mental illness are infected with the HCV which is significantly higher than the rates in the general population of 1-2 % (Rifai, Moles, & Short, 2006). Other populations at risk for the HCV include the incarcerated where 27-54% may be affected with the HCV (Pradhan, Horwell, Jones, Ramsey, & Cassidy, 2005); 22-42% of homeless persons (Nyamathi et al., 2002), and 2.6% of the approximate 5.6 million military veterans (Veterans Health Administration [VHA], 2010).

Further identifying people at risk for HCV infection requires clear knowledge of routes of transmission, some of which are not related to risky behaviors. For example, individuals were at increased risk of hepatitis C exposure during blood transfusions prior to 1991 when routine HCV screening was initiated for blood products. Additionally, healthcare workers exposed to contaminated needles or equipment remain at increased risk for contracting the HCV. Other risk behaviors include having sex with an infected person; sharing personal hygiene items such as razors and tooth brushes; tattooing or body piercing using non-sterile practices; sharing intranasal drug paraphernalia; or, although less likely, a vertical transmission from mother to child (Baldo et al., 2008).

Elements of Hepatitis C Virus and Treatment

Hepatitis C was first detected in 1989 (Choo, Kuo, Weiner, Overby, & Houghton, 1989). The HCV is diagnosed through specific ribonucleic acid (RNA) blood testing and can appear in the blood post-exposure anywhere from 14-180 days after transmission (Al-Saden, McPartlin, Daly-Gawenda, Connor, & Zelenka, 1999). Symptoms develop in 10-

15% of acute hepatitis C infections and include malaise, anorexia, jaundice, urticaria, weight loss, and elevated liver enzymes (Al-Saden et al.)

Hepatitis C viral genome is not found consistently in saliva or semen which may explain the infrequent transmission of disease in close or sexual contacts (Fried, Shindo, & Fong, 1992). The HCV can be identified as one of six genotypes and further classified in more than 50 subclasses (CDC, 2012). Genotype 1 accounts for 70-75% of all the HCV infections in the United States and is associated with lower response rates to treatment (NIH, 2002). Genotypes 2 and 3 are more frequently linked to IVDU (Hamlyn, 2005). While some individuals will spontaneously clear the hepatitis virus, it is estimated that up to 85% of people will develop chronic HCV which is generally asymptomatic (Herrera & Roveda, 1999).

The primary goal of HCV treatment is sustained eradication of the virus, reduction of the progression to hepatic fibrosis, minimization of the development of decompensated cirrhosis, and lastly, reduction of the incidence of carcinoma of the liver (Santos, Kontorinis, & Dieterich, 2005). According to existing HCV guidelines, genotype is the dominant determining factor in the course of treatment which can vary from 6 months to more than a year (Ghany, Strader, Thomas, & Seeff, 2009; National Digestive Diseases Information Clearinghouse [NDDIC], 2010; Woods & Herrera, 2002). For all genotypes, therapy for hepatitis C involves daily oral dosing of ribavirin and weekly injections of a pegylated interferon. In addition, new treatment options are available for those with genotype 1, such as triple therapy including pegylated interferon, ribavirin, and direct-acting antiviral (DAA) therapy with Boceprevir or Telaprevir. These protease inhibitors have markedly improved sustained viral responses (Ghany, Nelson,

Strader, Thomas, & Seeff, 2011). Regardless of treatment regimen, there is significant management and monitoring required by the healthcare provider and considerable patient accountability for accurate dosing and surveillance. Non-optimal success rates and time intensive work load for providers are two suggestions provided by Brok, Gluud, and Gluud (2010) as to the reason that only 25% of people are currently being offered treatment.

Population of Interest

The community of interest for this project is located along the shoreline of western Michigan. It is an area characterized by economic depression, high unemployment rates, and populations at risk for variable healthcare access. According to the Community Research Institute (CRI) of a neighboring metropolitan area, the population of this community was 172,188 in 2010 (CRI, 2010). Of those living in the community at the time, 77% were white, 14% Black, and the remaining were of various racial backgrounds. Males and female residents were nearly equal. With regard to age, the largest cohort is 45-64 year olds (21.9%) with the next largest cohort 5-17 year olds (20.7%). Less than 27% of the community residents are educated beyond high school. With an unemployment rate of 17.6%, nearly 12% of residents live in poverty. The community itself lies in an urban setting and all counties north of this area are rurally designated. It is well known that those residents living in rural areas may face extraordinary challenges in accessing healthcare (Goins, Williams, Carter, Spencer, & Solovieva, 2005). In Michigan, approximately 1.8 million (18.9%) people live in designated rural communities. Yet, out of the 140 hospitals in Michigan, 59 of them are located in rural areas (Rural Assistance Center, 2012).

Between 2006 and early 2011, 827 individuals had confirmed hepatitis C diagnoses with an additional 221 probable cases (those with positive HCV antibody but lacking confirmatory testing) according to the Michigan Disease Surveillance System, 2012. The estimated prevalence of hepatitis C for the community of interest ranges from 2157 to 2714 (L. Stegmier, personal communication, July 12, 2011). These numbers are calculated from estimates as the CDC (2011) has reported that 1.6-1.8% of the overall population has been infected with hepatitis C. Using those same calculations, two of the counties north of the community of interest have the following estimated rates of hepatitis C: County A, 342 to 430; County B, 640 to 760 (L. Stegmier, personal communication, July 12, 2011).

In sum, based on the estimated prevalence of persons infected with hepatitis C compared to those confirmed cases reported, roughly one third of people believed to have hepatitis C have been diagnosed. Furthermore, the issue of HCV treatment is heightened when constraints are imposed by specialty providers and concerns by primary care providers because of the perceived lack of appropriate local HCV care. In addressing this multifaceted healthcare concern, attention been drawn to the senior leadership from the local hospital system and federally funded healthcare agencies.

Barriers to HCV Diagnosis and Treatment Access

Barriers and Access to Care

A number of healthcare disparities exist for residents of the central shoreline of western Michigan that contribute to their vulnerability. The greatest obstruction to appropriate care for individuals who suffer from the HCV in this community is limited access to adequate care.

Goins et al. (2005) describe the perceived barriers to healthcare access among rural older adults. They depict barriers to healthcare access in three ways: entry, structural, or cultural. The investigators report financial issues as the leading entry barrier to healthcare access and cite issues with individuals who are uninsured, underinsured, or lack prescription coverage. Structural concerns refer to lack of qualified specialists or testing facilities in rural communities requiring most residents to travel for specialty care. For those living in the community of interest, limitations to care are posed by existing local medical specialists. As a result, people with hepatitis C lack consistency in follow up. Lastly, cultural practices and norms among ethnic minority populations or groups may lead to an underuse of services or have additional challenges associated with language barriers.

Goins et al. (2005) also reported on five common themes that emerged when assessing access needs, specifically those in rural areas: transportation difficulties; limited healthcare supply; lack of quality healthcare; social isolation; and financial constraints. The challenges in accessing adequate healthcare, specifically for individuals with hepatitis C treatment living in rural areas, was one of the main driving forces in establishing a dedicated hepatitis C treatment clinic. Because transportation challenges were the highest reported barrier and were especially aggravated by poor weather and road conditions, the location of the shoreline clinic intentionally reduces the travel for these patients. Next, the limited healthcare supply refers to the lack of qualified providers practicing in rural communities. Additionally, Goins et al. suggested that when there is limited availability of diagnostic testing coupled with provider disinterest, illness management is hindered. The fourth category of barriers describes the social isolation

felt by rural adults. This may lead to a lack of understanding of available healthcare services at the local level. Finally, financial constraints include travel expenses, diagnostic testing, and prescription medications. These concerns are exponentially heightened when individuals are either underinsured or uninsured.

Geppart and Arora (2005) provide expert opinion on five clinical-ethical arguments surrounding the availability of HCV treatment. These investigators reported justice, compliance, cost-effectiveness, balance of risk and benefit, and discrimination as issues that limit the access to HCV treatment. As such, these authors suggest there may be a professional and social obligation to further explore clinical-ethical arguments in vulnerable populations.

Stigmatization as a Barrier to HCV Treatment

Stigma is a complex social phenomenon which is subjective and variable (Butt, 2008). Stigma has been associated with many chronic infectious diseases such as leprosy, tuberculosis, and human immunodeficiency virus (HIV) (Butt), yet there is little exploration into the social and psychological implications of being diagnosed with hepatitis C according to Hopwood and Southgate (2003). Discrimination, fear of transmission, and self-loathing are only a few of the negative consequences associated with the HCV (Hopwood & Southgate). Persons living with these infectious diseases may avoid healthcare services, fail to disclose their diagnosis for fear of ridicule and discrimination, and have strained interpersonal relationships (Paterson et al., 2007). Persons who have contracted the HCV through IVDU are especially vulnerable as the association of drug use and infection is viewed as a self-inflicted condition caused by

irresponsible behaviors (Paterson et al.). Individuals may describe themselves as having a “dirty disease” (Butt).

Hepatitis C stigma was examined in an analysis of 30 studies completed over a 12 year time frame (Butt, 2008). Stigma was most frequently, but not perceived exclusively, as a negative consequence of the HCV and occurred in a variety of settings. In a study by Moore, Hawley, and Bradley (2007), stigma was reported to occur most often in healthcare settings or the home setting. They suggest that over time, stigma can result in a lack of trust for health professionals or family and can cause a cascading effect for a sense of hopelessness and isolation which can cause depression and anxiety. This may be compounded for persons with the HCV who are already vulnerable to discrimination, loneliness, and despair (Fraser & Treloar, 2006). For some, disclosure issues arise when individuals share their HCV diagnosis with others out of sense of obligation to protect them. This may be followed by those same individuals ridiculing or discriminating against them (Fraser & Treloar).

Acknowledgement of the issue of stigmatization by health professionals is imperative for improved quality of life for persons with the HCV. Interventions geared toward reversing social perception of infectious diseases can be initiated through changes in *binary* thinking, according to Fraser and Treloar (2006). The authors believe this is accomplished through education on what appears to be negative consequences and by focusing on the positive. Concepts of “*health/illness*,” “*clean/contaminated*,” “*well/sick*,” “*good/bad*,” and “*before/after infection*” can all be presented in such a way that allow for a more optimistic outlook. Fraser and Treloar further described the advanced practice nurse (APN) as a qualified professional to counsel individuals with

hepatitis C by first establishing a trusting relationship. Through individual or group sessions, the APN can give accurate information on transmission risks, manage treatment options, and advocate for those with the HCV. Their findings suggest that improved education for persons with hepatitis C can ultimately reduce their vulnerability to stigmatization.

In sum, hepatitis C is an infectious disease and it can be acquired through *innocent* means, although most infections continue to occur by IVDU (CDC, 2011). Severe psychological, social, and emotional responses can occur in those who are diagnosed with the HCV. Persons with hepatitis C are vulnerable to stigmatization and discrimination by healthcare professionals, family, friends, and co-workers.

Quality of Life and HCV

Quality of life indicators are infrequently reported in the literature in persons with hepatitis C (Zickmund, Ho, Masahiro, Ippolito, & LaBrecque, 2003). Reported studies focus on treatment options and necessary surveillance but few report interpersonal challenges faced by those infected (Cotler et al., 2000). Published findings on stigma and chronic hepatitis C indicate a negative impact on health outcomes and reduced quality of life (Butt, Paterson, & McGuinness, 2007). The decision to treat hepatitis C forces patients to tradeoffs between the negative attributes of treatment (medication side effects and rigorous treatment regimen) and the long-term health gains of eradicating the HCV (Schackman, Teixeira, Weitzman, Mushlin, & Jacobson, 2008). Common side effects to treatment include mild flu-like symptoms, nausea, itching, rash, headache, irritability, and alopecia (Holcomb, 2008). Cotler et al. describe how medication side effects can significantly reduce the person's ability to function in the work environment or within the

home. Financial securities may be compromised because of the potential limited capacity to fulfill employment responsibilities. Successful treatment can result in improved quality of life (Schackman et al.).

Hepatitis C Screening

For the last three decades, *Healthy People* has identified initiatives in the detection and treatment of the HCV. Healthy People 2020 released its objective to increase the percentage of people aware they have chronic hepatitis C infection (Healthy People 2020). In support of this initiative, researchers attending the annual Digestive Disease week (McGarrey et al., 2011) suggested a one-time birth-cohort screening for *baby boomers*, those born in the US between 1946 and 1964 over a 5-year period. Because individuals with hepatitis C typically have no symptoms, they may not be diagnosed with the virus for 20 years or more. The suggested age-based screening will increase the numbers of people aware they have the HCV and will be cost-effective according to Rein et al. (2012).

Leverence, et al. (2009) examined the HCV screening practices of primary care providers (PCPs) and found a wide variety of contradictions among the four major scientific national guidelines. PCPs reported the HCV as being serious and important (68%) but neglected to obtain necessary information regarding risk behaviors of IVDU (54%) or exposure risk from previous blood transfusions (28%). The study heightened the awareness of increased PCP education regarding HCV screening and improved consistencies in national guidelines as mechanisms to improve care. Conclusions in this study were supported in a qualitative study by Shehab et al. (2001). In their study, investigators developed a survey to review the HCV screening practices of PCPs within

the Primary Care Multiethnic Network (PRIME Net), focusing on medically underserved communities. Only 59% of PCPs in the study reported asking about HCV risk factors. This raises concern for underdiagnosis of the HCV by “gatekeepers” who are essential for early diagnosis and treatment. In this study, predictors of screening behaviors included age, gender, specialty, years of practice experience, and experience with HCV patients. Participants of this study practiced in rural, suburban, and urban communities. No significant differences were found in their attitudes towards screening and actual screening practices among the four provider networks participating.

As discussions of secondary prevention for hepatitis C continue, it is important to know that currently no vaccine exists (CDC, 2011). Vaccination for both hepatitis A and hepatitis B are recommended for individuals with hepatitis C and also for those with known liver disease (Wilkins, Malcolm, Raina, & Schade, 2010).

Populations at Risk

The highest rates of hepatitis C are reported in persons with psychiatric illness and those with addictions to alcohol and/or IV drugs (Abou-Saleh & Foley, 2008). At the same time, individuals in these particular populations are the most common group deemed ineligible for treatment in spite of the fact they remain most likely to acquire the disease. Abou-Saleh and Foley (2008) suggest the dilemma of improving HCV outcomes is daunting because of the increasing prevalence of hepatitis C among this at-risk population and the limited healthcare resources available to them.

Psychiatric Illness

Individuals with psychiatric illnesses continue to be one of the most vulnerable populations who lack adequate healthcare. This is especially true for those with hepatitis

C and mental illness because it is estimated that 20-30% of those who have mental illness also have the HCV. The dilemma of treating people with mental illness is of national interest due to the large financial burden and societal obligation to reduce healthcare inequalities. Healthcare disparities occur when persons with mental illness attempt to navigate numerous barriers in access to care. Barriers may include stigmatization from the providers of care, lack of access to services and social support, and lack of finances for services or recommended pharmaceuticals.

Unfortunately the healthcare challenges faced by the mentally ill are sometimes rooted in ignorance and apathy by the healthcare industry. The magnitude of the issue prompted the Institute of Medicine (IOM) to formulate a committee to address healthcare disparities for those with psychiatric illness. The committee on *Crossing the quality chasm: Adaptation to mental health and addictive disorders* was developed in part to investigate and understand the gap between patients who could receive healthcare and those who do receive healthcare (Pincus et al., 2007). In this report, the expanse between these two groups is described. With this understanding, the committee was charged with making recommendations to reduce these disparities. The proposed framework to improve healthcare delivery was focused on six important criteria: patient-centered, effectiveness, equity, safety, timely, and efficiency (Pincus et al.).

HCV Treatment and Psychiatric Illness

The National Institutes of Health suggest that HCV treatment be considered for persons with psychiatric illness on a case-by-case basis (Mistler et al., 2006) because of the profound risks associated with treatment. Psychiatric co-morbidities include a diagnosis of depression, personality disorders, psychotic disorders, anxiety, post-

traumatic stress disorder, or other mental disorders (Yovtcheva, Rifai, Moles, & Van Der Linden, 2005). Neuropsychiatric side effects are well known with interferon therapy (Strinko, Di Bisceglie, & Hoffman, 2004). One third of persons receiving HCV treatment will exhibit neuropsychiatric side effects and individuals struggling with mental illness can experience devastating consequences (Crone & Gabriel, 2003). Depression is the most common reported neuropsychiatric side effect along with “panic and anxiety, emotional lability, irritability, anger, aggression, hypomania and mania, confusion and disorientation” (Silverman, Kim, & Freudenreich, 2010, p. 2). In a cross sectional study by Zickmund et al. (2006), physical, mental, and social complaints of patients undergoing HCV treatment helped to identify practice needs for providers. In Zickmund et al.’s study, physical side effects were reported by 80% of the participants while 38% reported depressive feelings. Suicide and death have been reported in persons with unrecognized and untreated psychiatric side effects (Crone & Gabriel).

Research studies on the benefits of interferon usually exclude individuals with psychiatric illness based on physician reports of depression and not on a professional psychiatric assessment (Mistler et al., 2006). In fact, in a study by Alfandre, Gardenier, Federman, and McGinn (2009), over 75% of persons with documented hepatitis C, who were medically eligible for HCV treatment, did not have therapy initiated. Psychiatric illness was reported as a reason why failure to initiate treatment was so significant. Individuals in this population may have lower levels of health literacy and lack understanding of the HCV and modes of transmission (Alfandre et al.). Lack of insurance, low levels of literacy, and limited access to healthcare serve as further barriers to successful HCV treatment (Gardenier, Neushotz, & O’Connor-Moore, 2007). Crone

and Gabriel (2003) reported that quality of life indicators are impaired for persons with chronic hepatitis C and are especially significant for those with psychiatric illness. Social isolation, impaired interpersonal relationships, and socioeconomic constraints in individuals with psychiatric illnesses lead to non-compliance with appointments, testing, and psychiatric medication which contribute to further ineligibility for HCV treatment.

In contrast, Weiss and Morgello (2009) described survey results from specialty providers who service individuals with psychiatric illness and the HCV. Depression was the most common side effect of HCV treatment medication. However, the majority of providers acknowledged that treatment needed to be stopped less than 20% of the time because of worsening symptoms. In this study, 65% of patients with psychiatric illness achieved a 20-60% sustained viral response from treatment which is the average treatment success for persons without mental illness. The investigators concluded that stabilization of psychiatric disease is incredibly important prior to the starting of therapy in order to reduce the neuropsychiatric side effects (Weiss & Morgello).

Mistler et al. (2006) and Quelhas and Lopes (2009) completed systematic reviews examining HCV treatment for individuals with mental illness. The 2006 review explored 30 research studies as compared to the 2009 review which investigated 13 studies. Both systematic reviews suggest that patients with psychiatric illnesses are commonly excluded from clinical research on hepatitis C. Three of the studies included in the Mistler et al. report, concluded that the majority of individuals completed therapy with low drop-out rates, adhered to treatment guidelines, and had limited side-effects when aggressive psychiatric management and close monitoring was used. The bulk of the data reviewed were from small studies and overall conclusions support positive outcomes in

treating patients with mental illness and hepatitis C. This suggests that controversy and inconsistencies are common over whether or not mental illness should be an absolute exclusion for HCV treatment.

HCV Treatment and Substance Abuse

Historically, substance abusers or those addicted to either alcohol or drugs, have been deemed ineligible for HCV treatment based on several factors (John-Bastiste et al., 2009). This may include lack of readiness, perceptions that harms of treatment outweigh benefits, poor compliance, and treating the HCV has low priority when compared to other health concerns. (John-Bastiste et al.). Because IVDU remains as the greatest risk factor in acquiring new virus (Armstrong et al., 2006), new treatment strategies need to be considered for these at-risk populations. Care challenges may be further compromised because there are greater numbers of IVDU among individuals who are positive for HIV, which accelerates the progression of HCV-related disease (Bica et al., 2001). In fact, these authors report end-stage liver disease from the HCV as the primary cause of death in this HIV-seropositive population. One strategy reported in the literature has been a comprehensive needle exchange program implemented in New York that has substantially reduced the HCV prevalence in that community (Birkhead et al., 2007).

The effect of alcohol has been closely studied as it pertains to epidemiological and histological indicators associated with the HCV. Hepatitis C infection is found in nearly 40% of patients with alcoholic liver disease and this leads to rapid development of liver fibrosis in patients admitting to ingesting >40gms per day of alcohol (Degos, 1999). Because there is an impaired response to interferon in individuals who use alcohol, greater morbidity and mortality contribute to poor outcomes (Blackard, Yang, Bordoni,

Sherman, & Chung, 2004). As a result, there is an extraordinary need for comprehensive programming focused primarily on individuals with psychiatric illnesses and those addicted to drugs and/or alcohol that also have hepatitis C.

HCV Treatment Guidelines and a Multidisciplinary Approach

Ghany et al. (2009, 2011) authored an extensive review on guidelines for diagnosis and treatment of hepatitis C. These published guidelines were approved by the American Association for the Study of Liver Diseases (AASLD), the Infectious Diseases Society of America, and the American Society of Gastroenterology. This report clearly states that “interferon and ribavirin can be safely administered provided there is comprehensive pretreatment psychiatric assessment, a risk benefit analysis is conducted, and there are provisions for on-going follow up of neuropsychiatric symptoms during antiviral therapy by a multidisciplinary team” (Ghany et al., pg. 1362). The National Institutes of Health suggests that persons with substance abuse and/or mental illness be treated on a case-by-case basis (Mistler et al., 2006). The complexity of treating individuals with hepatitis C and other co-morbidities may require input from professionals in a wide variety of disciplines. The benefits of a multidisciplinary approach in treating hepatitis C was presented by researchers at the annual AASLD (2011) showing improved compliance, lower costs, higher sustained viral response, and increased quality-adjusted life years (Garcya-Retorillo, 2011).

Relevance for Nursing

Advanced practice nurses (APNs) and registered nurses (RNs) play a crucial role in the care of individuals with hepatitis C and are poised to have an even greater role in the future (Olson & Jacobson, 2011). Development and implementation of most models

of care for individuals with hepatitis C involve the nurse as a central caregiver. Several articles have been published on the benefits of nurses in lead roles in the management and support of individuals with the HCV (Ahern, 2006; Cheng, 2010; Clark & Ghalib, 1999; Ehsani, Vu, & Karvelas, 2006; Fahey, 2007; Ford & Cheong-Lee, 2007; Gardenier et al., 2007; Grogan, & Timmins, 2009, 2010; Johnson & Holman-Speight, 2005; Leone, 2002, Lewis, Allen, & Warr, 2010; Olson & Jacobson, 2011; Poll, 2007, 2009; Shutt, Robathan, & Vyas, 2008; and Van Zandt, D'Lugoff, & Kelley, 2002).

However, of the literature on benefits of nurses in lead roles, only five attempted to study specific improvements in care outcomes managed by APNs (Ahern, 2006; Ehsani et al., 2006; Grogan & Timmins, 2009, 2010; and Shutt et al., 2008). Ahern (2006) studied improvements in outcomes of quality of life indicators and treatment outcomes between nurse practitioners and physicians. While there were marginal differences in quality of life indicators by provider groups, nurse practitioners overall provided as equal care when compared to physicians. Grogan and Timmins (2009, 2010) studied the most common side effect reported with HCV treatment and whether patients were satisfied with the care received by a nurse specialist practice. Fatigue, sleep disturbances, and weight loss were the highest reported side effects and patients rated high satisfaction with the management of complaints by nursing services. In a qualitative study completed by Ehsani et al., key stakeholders were surveyed on the need to have nurses play a central role in HCV treatment. Those surveyed agreed that nurses were crucial for education, side effect management, counseling, and treatment compliance when managing HCV treatment. Lastly, Shutt et al. (2008) conducted a retrospective case study looking at how the addition of a clinical nurse specialist (CNS) impacted HCV

referral, assessment, and treatment between 2003 and 2006 and compared it to care provided in the earlier years (1999-2003). The investigators reported that the rates of those receiving treatment doubled during the timeframe with the CNS with improved follow up including an increased number of essential liver biopsies performed. Because of these findings, the United Kingdom passed mandatory requirements that CNSs be involved in assessing and treating HCV (Shutt et al.).

The remaining literature relative to nursing and HCV treatment focused on APN functioning at their fullest professional capacity. By definition, “nurse practitioners are registered nurses educated to function autonomously and collaboratively in an advanced and extended clinical role” (Cheng, 2010, p.6). According to several investigators, registered nurses can fill the gap in accessibility to HCV care by providing necessary management and support services (Clark & Ghalib, 1999; Johnson & Holman-Speight, 2005; Van Zandt et al. 2002). As an example, the Wald Model is community-based care delivered by nurses for those who are economically and socially underserved (Van Zandt et al.). This model of care focuses on identifying the barriers to accessing care and navigates these barriers by evaluating community resources, improving health education, advocating for patients, and involving families. Conclusions from this model suggest that nursing care working in collaboration with a HCV treatment centers could increase access to therapy by reducing the burden of side effect management with careful follow up.

Poll (2007, 2009) explored the important role of the community nurse in the prevention, diagnosis, and management of individuals with hepatitis C. In this study, nurses took the lead role in educating on transmission risks of the HCV and identifying

persons at highest risk. Improved screening protocols assist in diagnosing greater numbers of persons with the HCV who might otherwise remained undiagnosed. If eligible for treatment, a clinical nurse specialist manages medication dosages and side effects, laboratory monitoring, and supportive care for patients and families.

The link between successful completion of HCV treatment and rigorous side effect management was clarified in a study by Leone (2002). Side effects include muscle aches, flu-like symptoms, fatigue, sleeplessness, loss of libido, nutrition concerns, and headaches (Leone). Because of the profound side effects, compliance with treatment regimens is difficult when treatment courses range from 24-48 weeks.

The remaining studies describe the role of nurses in managing hepatitis C in difficult populations (Fahey, 2007; Ford & Cheong-Lee, 2007; Gardenier et al., 2007; Lewis et al., 2010). A case study reported by Gardenier et al. described the use of a medical/psychiatric co-management model with nurse practitioners. Historically, individuals with active substance use and psychiatric comorbidities have been ineligible for HCV treatment. This study sought to remove those restrictions on eligibility. Findings suggest appropriate use of case management can reduce barriers to HCV treatment. Similarly, a model of care involving the addition of a viral hepatitis clinical nurse specialist on a drug and alcohol team was reviewed by Fahey (2007). In this model, education and risk assessment care occurred in conjunction with drug and alcohol support groups. This model also includes nurses performing basic diagnostic testing and immunizations.

Ford and Cheong-Lee (2007) reiterated the need for hepatology nurses to have a central role in managing HCV treatment. The establishment of the Canadian Association

of Hepatology Nurses (CAHN) in 1999 has improved the ability of nurses to network and discuss the ongoing challenges of managing HCV patients. Authors suggest that managing patients who have serious mental health problems and hepatitis C can be especially difficult to manage (Lewis et al., 2010). In fact, persons with mental illness have the highest rates of hepatitis C infection yet are least likely to access care. To improve long-term HCV health outcomes in two United Kingdom communities, the development and implementation of HCV protocols were initiated. The involvement of a clinical nurse specialist improved care in this especially at-risk population by applying case management monitoring.

In sum, APNs exist in multiple settings and nurses are the most consistent healthcare professional in contact with patients. They are in an ideal position to advocate for improved access to HCV treatment and monitoring. Nurses can improve long-term health outcomes by reducing the health disparities among those most vulnerable. By establishing guidelines or protocols for HCV care, APNs are a central partner in collaboration of care, education, counseling and support, and advocating for improved HCV programming.

Summary

This chapter reviewed several important factors pertaining to the magnitude of hepatitis C as a national, state, and local healthcare dilemma. The complexity of hepatitis C treatment is multifaceted and involves significant barriers to improved care. This includes inadequate HCV screening practices leaving the majority of individuals unaware of their hepatitis C diagnosis. For those who have been diagnosed, there are limited numbers of qualified healthcare professionals and treatment programs available in the

community of interest. To further complicate the issue, patients face rigorous eligibility criteria prior to starting treatment. Psychiatric illnesses, substance abuse, and co-morbidities continue to be barriers for individuals seeking HCV treatment. Additionally, social issues of inadequate healthcare coverage, lack of social support, and lack of services for those living in surrounding rural areas are barriers to HCV treatment.

The dilemma of hepatitis C is on the rise and expected to be at its greatest impact this decade. This quandary will be heightened if healthcare providers adopt the recommended birth-cohort screening for *baby boomers*. Researchers and clinicians are charged with finding solutions to the challenges associated with screening and treatment of hepatitis C. It is imperative that innovative approaches to HCV care address barriers and limited access issues.

In response to this dilemma from local, state, and national healthcare agencies, a hepatitis C initiative was proposed and initiated as a doctor of nursing practice (DNP) project to improve the care for individuals with hepatitis C along the shoreline of western Michigan. In order to provide an evidence-based approach to this project, the next chapter will present current findings in literature on models of care to improve health outcomes for individuals with hepatitis C.

CHAPTER 2

LITERATURE REVIEW

The purpose of this chapter is to review the literature relative to models of care for HCV in community-based clinics. This review will encompass common barriers to treatment as they relate to models of care identified in the literature. To thoroughly explore current literature focusing on models of care for individual with hepatitis C, the following databases were reviewed: CINAHL; Cochrane Reviews; Medline; PubMed; and PsycINFO. Key words or phrases for this review included hepatitis C; approach to treatment; multidisciplinary; integrated care; nursing; nurse practitioner; barriers to treatment; collaboration; and community. In addition, the reference lists of all retrieved literature were reviewed for potential inclusion.

The absence of randomized controlled studies or comparative analyses of HCV models of care was a notable finding in this review and identified by two study groups (Ho et al., 2008; Knott et al., 2006). This suggests a growing interest in developing evidence-based care for persons the hepatitis C. Due to the lack of consensus on HCV treatment models, an attempt was made to review all relevant literature pertaining to current HCV models of care. To adequately develop a comprehensive treatment program for persons with hepatitis C, investigating existing programs and reviewing those elements that contributed to successful treatment was deemed necessary. The ultimate

goal of this review was to allow the literature to guide and support what type of programming would contribute the greatest outcomes. Because of the early stage of query, literature reviewed included references that were empiric and consensus based as well as those reporting expert opinion.

Three approaches to HCV care were identified in databases including multidisciplinary, integrated, and shared care models. The existing literature was reviewed and compared to obtain insight into the challenges associated with treating individuals with hepatitis C. The existing literature reviewed was compared by study design, methods, theoretical framework, study setting and participants, inclusion and exclusion criteria, variables, scales and statistical tests, findings of the study, and lastly, limitations and implications for clinical practice.

Multidisciplinary Models

For the purpose of this review multidisciplinary refers to healthcare providers from different professions who work together to collaboratively provide diagnoses, assessments and treatment, within their scope of practice and areas of competence. In contrast, interdisciplinary refers to the blending of two or more academic, scientific, or artistic disciplines (Merriam-Webster, 2011). Thus, when describing models of care for hepatitis C treatment, multidisciplinary care in this project constitutes the collaboration of several health disciplines including primary care providers, infectious disease physicians, hepatologist/gastroenterologists, nurse practitioners, pharmacists, addiction specialists, psychiatric providers, and social workers. This model was selected to address common complexities seen in patients with hepatitis C. Because most patients with hepatitis C are from high-risk populations (C. Everett Koop Institute, 2012), they encounter significant

barriers in healthcare. Instituting a multidisciplinary approach to HCV treatment assists patients in navigating barriers and allows healthcare professionals to provide an expert focus within their discipline.

Ten articles reported specific use or recommendations for multidisciplinary programming in the treatment of hepatitis C (Arora et al., 2011; Dolder et al. 2002; Grebely et al., 2007; Grebley et al., 2010; Guadagnino et al., 2007; Koff, 2001; Nazareth, Piercey, Tibbet & Cheng, 2008; Pozza, 2008; Shehab, Sonnad, Gebremariam, & Schoenfeld, 2002; Van Thiel, Anantharaju, & Creech, 2003). Four of the nine articles specifically report on findings of research studies employing a multidisciplinary approach to HCV treatment.

Arora et al. (2011) conducted a prospective cohort study comparing the outcomes of hepatitis C treatment with individuals who were under treatment using the Extension for Community Health Outcomes (ECHO) treatment protocols in a university setting with those treated by primary care providers in 21 rural ECHO sites. The treatment sites included prisons systems in New Mexico. The approach used teleconferencing allowing a multidisciplinary team to collaborate with local primary care providers trained to provide treatment. Of the 146 individuals treated for hepatitis C at the University New of Mexico (UNM) HCV clinic, 84 (57.5%) achieved sustained viral response compared to the 152 (58.2%) in the ECHO sites. Interestingly, reported rates of serious side effects were higher in the UNM site (13.7%) compared to (6.9%) the ECHO sites. This study suggests benefits in treating individuals with hepatitis C in typically underserved communities using a multidisciplinary approach and health technology.

Guadagnino et al. (2007) designed an observational, prospective study to explore the benefits of a multidisciplinary approach in six infectious disease centers in collaboration with 11 Italian drug detoxification units (DDUs). All participants underwent psychological testing to identify underlying mental illness. Of the 53 subjects studied, 54.7% achieved sustained viral response. Team members were available for pre-treatment counseling and during treatment evaluations and management. Weekly consultation at the DDU allowed for continuous monitoring and encouragement from the team members. In this particular setting, all team members had an active role in assisting patients. The relatively small sample size and type of drug treatment programming were recognized as limitations of this study.

Grebley et al. (2007, 2010) focused most of their work on the benefits of support groups for individuals with hepatitis C receiving directly observed HCV therapy. In this study, weekly support groups served as a mechanism for patients to receive education and social support. In the 2007 prospective study, 80 subjects were referred to the support group over a period of 80 weeks. Of those, 18 patients who were illicit drug users enrolled in the study and initiated HCV treatment. In total, 8 achieved end of treatment response (HCV RNA <50ml/IU) despite some patients having to discontinue early. These findings support the feasibility of HCV treatment for individuals practicing IVDU by integrating a multidisciplinary approach and a peer support group. The usefulness of this study is limited by the small study size and lack of clarity in reporting.

The 2010 study by Grebley et al. used a retrospective approach and was an extension of the 2007 study. In total, over a 3-year period (2005-2008), 204 individuals were referred to the weekly support group within the multidisciplinary program. Of the

109 assessed for treatment, 57 of those referred received treatment successfully. There was a significant association between attendance at the first four weeks of the support group and the patients undergoing treatment for hepatitis C. Both of these studies report success in treating individuals with current or former IVDU and hepatitis C by integrating a multidisciplinary care approach and a weekly support group.

A study by Dolder et al. (2002) reported outcomes for veterans in a San Diego Veterans Healthcare system. Their study examined access and cost of HCV treatment by utilizing either a high intensity HCV treatment model involving a multidisciplinary team or a low intensity (traditional) approach where gastroenterologists diagnosed, treated, referred, and managed all cases. The high intensity approach was found to treat a greater number of veterans more efficiently versus that of the low intensity model. The cost comparison found the high-intensity treatment model totaled \$33,318 compared to \$38,082 for the low-intensity model. This study was one of few to focus on the financial burden of hepatitis C. The authors described the cost of liver transplantation as exceeding \$240,000 with an additional cost burden of \$23,488 per year thereafter for follow up care. Updated estimates by the American Liver Foundation (ALF, 2007) for liver transplantation suggest a total cost of \$300,000 for hospitalization, physician fees, and pre/post-operative testing. This study further describes the importance of pretreatment education and counseling as a means to increase completion rates. Implementing a multidisciplinary (high intensity) program increased the numbers of veterans who were able to successfully complete therapy. Conclusions reported in this study were based primarily on expert panel opinion and estimated therapy completion rates were based on those seen in clinical trials.

The cornerstone of implementing a multidisciplinary approach is the participation of professionals from a variety of specialty practices. To better understand the components of the multidisciplinary model, studies were reviewed to compare the medical specialty of the lead provider in the care of patients with hepatitis C. Infectious disease physicians were considered the lead provider in three studies (Grebley et al., 2007; Grebley et al., 2010; Guadagnino et al., 2007), while hepatologist or liver specialists were considered the lead provider in another three studies (Dolder et al., 2002; Koff, 2001; Nazareth et al., 2008). Two studies referred to physicians in both infectious disease and hepatology as the primary leader of the healthcare team (Arora et al.; Pozza, 2008). Additionally, three studies examined the benefits of the addiction specialists in the multidisciplinary model for individuals undergoing HCV treatment with a current or former history of IVDU (Grebley et al., 2007; Grebley et al., 2010; Guadagnino et al., 2007).

In most of the literature regarding the use of a multidisciplinary approach, nurse practitioners/nurses played a central role in coordinating HCV therapy. Nazareth et al. (2008) and Pozza (2008) described the role of the nurse practitioner (NP) in managing patients undergoing HCV treatment with ancillary collaborative partners from other professional disciplines. Nazareth et al. (2008) introduced the Nurse Practitioner Model of Care in an Australian study. This study describes how trained hepatology nurse practitioners provide increased opportunities for disease management, assess lifestyle factors associated with the HCV, and increase the range of healthcare settings in which individuals could be screened or treated for hepatitis. Pozza (2008) reported specific benefits of the nurse practitioner in treating the HCV in a study examining clinical

evaluation and management in co-infected (HIV/HCV) populations. In this study, NPs provided education and support in therapy and effective side effect management. These studies suggest patients can be successfully treated with a multidisciplinary approach and collaborative efforts between physicians, NPs, and other health disciplines (Pozza).

In sum, the literature reviewed pertaining to the use of a multidisciplinary approach to hepatitis C treatment suggested increased rates of treatment success. Collaboration among professionals from a variety of health disciplines ensures appropriate assessment of comorbidities with an improved chance of patients completing treatment. Limitations of this review include the lack of controlled studies describing a multidisciplinary approach to hepatitis C treatment. This includes the inability to generalize the use of a multidisciplinary approach in open access settings as most of the literature focused on vulnerable populations challenged with a specific treatment barrier.

Integrated Care Models

The term “integrated” is defined as “combining or coordinating separate elements as to provide a harmonious, interrelated whole” (Dictionary, 2011). This type of care model for the HCV attempts to assure collaboration of services for vulnerable populations. In this review, integrated models of care for HCV treatment reduced fragmentation, improved communication among providers, and increased coordination of care. Incorporating the professional services of a variety of health disciplines was similar for both the multidisciplinary model of care and integrated care models. Yet, the integrated approach in the literature review directed care more often to the patient’s specific barrier to successful treatment.

Eleven articles were reviewed involving integrated care strategies in HCV treatment. Four reports suggest an integrated approach to HCV treatment for individuals with current or former illicit drug use (Birkhead et al., 2007; Fahey, 2007; John-Baptiste et al., 2009; Sylvestre, 2007). One study reported the benefits of an integrated approach for psychiatric illnesses and treating hepatitis C (Knott, et al., 2006), and two studies described the use of an integrated approach with persons who were co-infected with HCV/HIV (Palepu, et al., 2006; Stringari-Murray, Clayton, & Chang, 2003). Lastly, three articles (Garrard et al., 2006; Hill, Butt, Alvarez, & Kraiden 2008; Ho et al., 2008) explored the advantages of an integrated care model. Two articles discussed the benefits of integrated care in generalizations and not within specific vulnerable populations (Garrard et al.; Hill et al.), and the third examined care for veterans with or without psychiatric illness or substance abuse (Ho et al.).

As they exist, integrated care models support collaboration among professionals in addiction treatment, psychiatric evaluation and treatment, and infectious disease. Successful HCV treatment is often dependent on comprehensive pre-therapy evaluation and treatment of conditions that pose a risk to therapy outcomes. Historically most individuals with mental illness or substance abuse were deemed ineligible for HCV treatment. With informed support from integrated team members, some practices are changing and these conditions are no longer an absolute contraindication for treatment (Birkhead et al., 2007). To support these changes, the American Association for the Study of Liver Disease (AASLD) recommended HCV treatment guidelines so that treatment would not be automatically withheld from persons with current drug use suggesting treatment should be considered on a one-to-one basis (Ghany et al., 2009).

Important additional considerations when evaluating illicit drug users for HCV treatment include the risk of continued transmission should they not be treated, the risk of re-infection once treated, and compliance concerns regarding contraception requirements while on treatment.

Three of the eleven articles reviewed the incorporation of an integrated care approach in HCV treatment as a focus (Hill et al., 2008; John-Baptiste et al., 2009; Knott et al., 2006). These studies were done in Vancouver, British Columbia; Toronto, Ontario; and Minneapolis, Minnesota, respectively. Both Canadian studies used an integrated approach to HCV treatment in a community-setting; the American study was done in a community-based Veterans Administration (VA) facility.

Hill et al. (2008) examined the benefits of referring patients with hepatitis C to a local community-based program for educational programming and treatment. In this study, in just over a four-year period, 1795 individuals were sent for medical evaluation. Seventy-four percent of those referred received education but only 26% were deemed eligible for treatment. Of those, 363 initiated treatment with outcomes collected on 205 individuals. Sustained viral response was achieved in 61%. In sum, of the original 1795 individuals sent for evaluation, only 126 completed HCV treatment and achieved sustained response. However, this study reported success in integrating partnership between physicians and nurses leading to an increased number of people served.

John-Baptiste et al. (2009) completed a retrospective study looking at HCV treatments within Ontario Addiction Treatment Centers (OATC) using an integrated model involving hepatitis nurses, psychologists, an infectious disease specialist, and primary care providers. Pretreatment screening was performed by nurses over a series of

visits. Those deemed eligible for treatment were seen for at least one consultation by the infectious disease physician prior to starting therapy. Of the 4000 individuals seen at the OATCs during the study period of November 2002 and January 2006, it is estimated that 50% of those had hepatitis C. Of the nearly 2000 with the HCV, only 109 (<6%) received at least one interferon injection. Study outcomes concluded that HCV treatment can co-exist with addiction treatment with the support of additional specialty practice partners.

The remaining research study used an integrated approach to HCV treatment integrating the core elements of routine screening for psychiatric and/or substance use and the incorporation of a psychiatric clinical nurse specialist (PCNS) within the veteran's facility (Knott et al., 2006). Psychiatric screening tools were used to initially evaluate participants who were eventually divided into four categories: patients without positive screenings; patients with positive screening, who saw a PCNS (alone or in addition to a mental health provider outside the clinic); patients who had positive screening and saw only an outside mental health provider; and patients who had positive screening but declined mental health services. Of the 184 patients who underwent screening, 149 had at least one positive screen. Of those who started treatment, 34 were in the PCNS group, 8 were treated by mental health providers outside the clinic, and 6 received treatment after they opted not to accept mental health services. The importance of this study focuses on the integration of psychiatric services within the hepatitis clinic. As seen, mental health illnesses and substance use are barriers to successful HCV treatment and an integrated care model can support early interventions for those at risk.

The remaining literature regarding the use of integrated models of care for HCV treatment discussed the magnitude of challenges faced by people co-infected with the HCV and HIV. Garrard et al. (2006) reported barriers in use of integrated care included fragmented services systems; financial disincentives when psychiatric services are obtained outside of the treatment program; and dwelling on individual health barriers while other issues may be over looked. In contrast, Stringari-Murray et al. (2003) suggested benefits in an integrated approach for individuals suffering from both HCV and HIV. Their study described HCV services incorporated into an already established HIV/AIDS specialty clinic in Marin County, California. Recognizing that persons at risk for HCV/HIV are also at risk for acquiring other infectious diseases, true integrative services included appropriate screening examinations. Combining services was seen as a way to optimize healthcare resources. This study inconsistently described participant numbers and these discrepancies raised concerns regarding study validity. However, certain barriers such as alcohol and drug use remained high and a significant number of patients reported psychiatric illness. Additional barriers requiring further work up included lack of stable housing, inadequate insurance, and the presence of comorbidities. Developing partnerships with mental health services, establishing a case-management program, and most importantly, cultivating the role of the nurse practitioner with practice guidelines were suggestions posed by the authors.

In sum, the literature reviewed on integrated models of care support this approach to increase treatment availability for those with hepatitis C. However, there are discrepancies in the literature that support fragmentation of care with this type of model. This model focuses on integrating services of HCV screening and treatment in locations

where individuals are already receiving services for substance use or in community-care settings. The consistent benefit of nurse practitioners or clinical nurse specialists in the management of HCV treatment was highlighted.

Shared Care Models

Five articles were reviewed involving a shared care model approach to HCV treatment (Belfiori et al., 2009; Ewart, Harrison, Joyner & Safe, 2004; Hamilton, Gordon, Nelson & Kerbleski, 2006; Kontorinis et al., 2003; Tait et al., 2010). Three of the five studies were research studies that utilized the shared care model in treating hepatitis C (Belfiori et al., 2009; Kontorini et al., 2003; Tait et al., 2010). These studies were all conducted outside the U.S. specifically in Italy, Australia, and the United Kingdom respectively.

The shared care models in these studies examine the benefits of involving multiple disciplines in the management of HCV treatment. These studies provide insights to the advantages of “sharing” the work load when considering the intensive treatment regimens for patients and the time-intensive monitoring required by healthcare providers. By sharing responsibilities, increasing the availability of appropriate screening protocols and improving the management of side effects, increased compliance rates were noted.

Belfiori et al. (2009) studied 52 subjects in Italy in a drug maintenance program. This multi-centre, prospective, observational study was completed between 2003 and 2006. Of the 52 individuals who met inclusion criteria, 45 completed treatment and of those, 26 achieved a sustained response. The program included addiction specialists, specialists in infectious disease, and psychiatrists. Frequent monitoring by members of

the team allowed for early interventions and treatment modifications. This study suggested hepatitis C treatment success when treating IVDUs who were on methadone/buprenorphine was possible.

The shared care model reported in the prospective Australia study (Kontorinis et al., 2003) varied slightly in that surveillance monitoring was shared with the general practitioner. This approach included hepatologists, nurses, primary care providers, and specialists from other disciplines and offered psychiatric support. Hepatitis C treatment was initiated by the hepatology staff and followed with routine monitoring of blood work and monthly visits with the general practitioners. Of the 81 patients treated, 54 had previous failed attempts of HCV treatment. In this study, 40% of patients achieved sustained viral response and of those, 24% were genotype 1 and 58% were genotype 2/3. By using a shared care model for HCV treatment between general practitioners and nurse practitioners, these authors reported treatment regimen compliance rates of 98% and increased patient confidence.

The last research study reviewed for the shared care approach (Tait et al., 2010) to HCV treatment looked at Managed Care Networks (MCN) as a means to enhance access to hepatitis C treatment. The MCN added new pathways for referrals which included non-medical referral from addiction services, prisons, and outreach nurse-led clinics. Using this model, the access to HCV services in a 4-year period, in this study, rose from 61% to 82.4%. Tait et al. suggests these findings are congruent with previous reports that in-network collaboration significantly increases access for individuals in traditionally difficult to reach locations.

Two articles on a shared care model approach to HCV services addressed specific benefits with an increased role of the advanced practice nurse in the screening and management of hepatitis C (Ewart et al., 2004; Hamilton et al., 2006). These reports showcase the value of nurse practitioners in patient education, side effect management, surveillance of appropriate laboratory studies, and dose-adjustments, all of which fall within their scope of practice. In collaboration with liver specialists, pharmacists, psychiatric and addiction specialists, and primary care providers, nurse practitioners were able to appropriately manage HCV treatment.

In sum, the literature reviewed on the shared care model as an approach to hepatitis C treatment focused on improving access to treatment when limited specialists are available. Essentially, the model uses a multidisciplinary approach, often times with a lead nurse practitioner in collaboration with partners in other disciplines. In this study, MCNs offered added benefits to accessing care by reducing traditional barriers and extended wait times.

Conclusion

Three models of care have been reviewed: multidisciplinary, integrated, and shared care. All three addressed common barriers to treatment and proposed to improve access to HCV treatment. Psychiatric and substance use challenged the healthcare system to improve care delivery services. In many studies, these at-risk populations have the highest prevalence of hepatitis C and continue to be the largest group determined as ineligible for treatment. National guidelines now exist and encourage a change in policy by supporting efforts in individualized treatment evaluation. By instituting programs

which promote collaboration between specialties and primary care, patients with HCV have a significantly greater chance at completing treatment.

Scholarly Project

In order to improve the care for individuals with hepatitis C in a community along the shoreline of western Michigan, a scholarly project was initiated by incorporating knowledge gained from review of the literature. The design and development of this hepatitis C project focused on increasing access and addressing perceived barriers to treatment. Evaluating community support and perceived need for improved access to hepatitis C care was the first step in this project. Knowledge translation from the current literature guided the development and implementation of a community-based, multidisciplinary treatment program.

In this project, healthcare disparities for vulnerable populations with hepatitis C identified many biopsychosocial challenges. The magnitude of HCV as a healthcare dilemma was highlighted and peak prevalence was forecasted this decade. Comprehensive programming, using a multidisciplinary approach was established for individuals with HCV. This project used the principles of implementation science to translate research into clinical practice by developing and implementing an evidence-based approach to improved health perceptions for people with hepatitis C. By doing so, perceived barriers to HCV treatment were addressed and comprehensive HCV care was implemented in a cohesive, community model.

CHAPTER 3

CONCEPTUAL FRAMEWORK

The conceptual framework of the Chronic Care Model (CCM) was used to further understand the complexities of hepatitis C and the comprehensive programming necessary to adequately care for individuals with hepatitis C. The CCM is an evidence-based initiative aimed at reducing the gap between scientific underpinnings and quality patient care (Oprea, Braunack-Mayer, Rogers, & Stocks, 2009). The CCM has been used by individuals who seek to improve chronic illness management with cohesive and collaborative partnerships between patients and providers. Although the CCM was developed for use in primary care, it has been applied to a variety of healthcare settings and targeted populations (CCM, 2010). The CCM focuses interventions on six main components of care: community resources and policies; healthcare organizations; self-management support; delivery system design; decision support; and clinical information systems. Each component offers vital strategies to augment the care management of the chronically ill (CCM diagram, Appendix A).

The CCM can be implemented as a whole, or as individual components. Both approaches aim to improve care by coordinating treatment activities. The complete CCM has not undergone rigorous controlled testing; however, specific components have been used in well-designed studies. The greatest utilization of components of the CCM has

been in studies exploring congestive heart failure, asthma, and diabetes. In a systematic review of 39 studies by Bodenheimer, Wagner, and Grumbach (2002) examining diabetes care using the CCM, authors reported 32 studies showing improved outcomes using at least one process or outcome measure. In this review, no single component of the CCM was found to be more effective than the others. Additionally, the number of CCM components used was not a determining factor in improved outcomes.

The need to address chronic care management is highlighted by Bodenheimer and colleagues (2002) as they discuss a concept of “tyranny of the urgent.” This describes the anxieties experienced by patients who are more concerned about their acute physical complaints than they are in addressing on-going management of their chronic illness. Additional challenges in care delivery include incentives for efficiencies. This may include rushed appointment schedules; minimal to little time to review vital laboratory values; and inadequate education for patients on the importance of medications, diet, exercise, and follow up care. This phenomenon can be especially true for individuals who are newly diagnosed hepatitis C who may require more intensive education related to their disease. One example is the heightened anxieties experienced by individuals as they attempt to identify the source of their exposure to the HCV which likely occurred decades earlier.

Chronic care management takes place in three distinct, but often overlapping venues. Individuals receive care from resources in the community, healthcare institutions, and by a network of healthcare providers (Bodenheimer, Wagner et al., 2002). As the nation’s 65-year-and-older population increase, resources to manage chronic illness will be at its peak. *Baby boomers* challenge traditional approaches to care

and continue to show more interest in wellness and self-management strategies in their care (Bodenheimer, Lorig, Holman, & Grumbach, 2002). By applying elements of the CCM, patients are assisted in navigating the complexity of overlapping healthcare systems through development of collaborative practices.

Chronic Care Model Components

Community Resources and Policy

Advocating for changes in healthcare policies is an important step in redesigning how chronic care is delivered in the community. This involves diligent rethinking on the part of community, institutions, and government leaders. Reviewing and changing outdated healthcare delivery policies and avoiding duplication of services are examples of healthcare change that may help shape the future of chronic care management (CCM, 2010). These changes may efficiently reduce costs and encourage newer, innovative approaches to care. This may lead to improved coordination of care across organizations and encourage patients to participate in community chronic care management programming.

Healthcare Care Systems

One of the primary goals of the CCM is to create cultures, organizations, and mechanisms that promote safe, high-quality care (CCM, 2010). To accomplish this, senior leadership within organizations are now charged to engage in redesigning chronic care management, facilitating care coordination within and between organizations, coordinating communication, and sharing data across healthcare settings. Continual process improvement was deemed an essential step for healthcare systems as changes are made in response to errors or newly defined healthcare problems arise.

Self-management Support

Self-management support is one of the most important elements of the CCM. Regardless of the setting in which patients receive their care or by whom, the patients are held accountable for self-management of their chronic illness. Establishing collaborative partnerships with healthcare providers and patients changes the paradigm of “who is in control.” Self-management is highlighted in a contemporary format compared to traditional types of care where providers are in control (Bodenheimer et al., 2002). By working collaboratively and encouraging self-directed behaviors, patients can make more informed decisions about their care that will serve as further motivation for continual changes.

Collaborative care is clearly a driver in encouraging patients to take ownership of their illnesses (CCM, 2010). In traditional care delivery systems, physicians are the experts about diseases, give instructions on treatments, and evaluate outcomes based on compliance (Bodenheimer, Lorig et al., 2002). In collaborative care partnerships, there is mutual respect for providers as being the most knowledgeable about diseases but patients are recognized as the expert on themselves and their lives. Jointly establishing achievable goals in treatment and evaluating outcomes based on patient’s expectations, confidence, and motivation can ultimately invigorate sustained change. It is important to note in the CCM that the emphasis shifts towards the patient being the primary care provider with support and education augmented by healthcare providers (Bodenheimer, Lorig et al.).

Delivery System Design and Decision Support

Components of the CCM support the integration of evidence-based care in the healthcare system. As part of the delivery system design, defining team member's roles and responsibilities improve efficiencies and effectiveness of care delivery (CCM, 2010). Additionally, utilizing case management for complex patients and supporting evidence-based care supports higher-standards in care delivery and encourages appropriate follow up care. Collaboration between specialists and primary care providers offers continuity and reduces fragmentation among healthcare systems (CCM).

Clinical Information Systems

The last component of the CCM is clinical information systems. In the advancing world of electronic medical/health records in healthcare systems, pertinent data can be extrapolated to ensure comprehensiveness of treatment plans. Patient registries are a central component to the CCM (McEvoy & Laxade, 2008). These registries act as a means to track necessary surveillance testing and follow up schedules. By doing so, these registries encourage a proactive approach to chronic care management (Ortiz, 2006). Registries can be established without the availability of an electronic health record; most facilities have access to common software tools such as Excel where registries can be formulated (Ortiz). Electronic tracking encourages streamlining of care and communication patterns between providers of care (CCM, 2010). Ancillary referrals and correspondence between providers are examples where coordinated efforts are encouraged within this component of the CCM.

CCM and a Community-Based Hepatitis C Clinic

The Chronic Care Model provides a conceptual framework to further explore the complexities of treating individuals with hepatitis C. Several of the model components address explicit challenges in providing services to this population. The model serves to minimize the gap between research and practice by supporting the use of evidence-based practice and using a collaborative approach to care delivery. The CCM was used as a framework for program development for the community-based hepatitis C treatment clinic along the shoreline of western Michigan which was conceived as a DNP project. Although the model as a whole was used to guide this project, focus was placed on the self-management support and decision support components when developing the HCV treatment programming.

To improve chronic care management for individuals with hepatitis C in this community, initial steps of the project included increasing awareness of community resources. For example, one community agency seeks to solve healthcare issues related to inadequate healthcare coverage and lack of social services. The services offered by this agency encourage patients to participate in educational programs on disease management. Collaborative efforts established with this type of community agency can augment the services offered by the HCV treatment clinic.

As a healthcare systems component of the CCM, health literacy and cultural sensitivities were a major focus of this project. The highest rates of hepatitis C continue to be found vulnerable populations. It is imperative for the long term success of any HCV treatment program that providers and staff convey supportive, non-judgmental

attitudes on the “how, when, and where” people were infected. This reduces the stigmatization of hepatitis C and at the same time conveys sincere partnerships to improve health outcomes.

Self-management support was the primary component used for this project. The treatment regimens for hepatitis C are intense and require the patient to adhere to strict monitoring schedules. In addition, most patients face medication side effects which require self-management at home. This may include treating skin rashes, adjusting nutritional intake due to nausea, and/or reducing activity levels to reduce fatigue. Establishing strong patient-provider relationships encourage a collaborative approach to self-management as it relates to hepatitis C treatment. This includes vital education on the anticipated treatment regimens; medication side effects; expectations for adherence; and required follow up care.

Decision support was another essential component of the CCM when establishing this community-based hepatitis C treatment clinic. One of the most important aspects of this project was to develop an evidence-based, innovative approach to improve health outcomes. National guidelines and current literature supported the approach to care delivery established for this community-based hepatitis clinic. Collaborative partnerships were developed among several local professionals to gather the needed variety of healthcare disciplines. To provide for on-going education of patients and families relative to hepatitis C, written materials were reviewed for accuracy. Most importantly, patients were encouraged to be involved in decision-making whenever possible during their hepatitis C treatment.

Lastly, congruence among the clinical information systems in the community-based hepatitis C treatment clinic was challenging. Although the inpatient hospital units had complete access to electronic health records (EHR), the HCV clinic did not. Therefore, all documentation and communication was completed with paper copies or verbally by telephone. The quantity and coordination of paper documents proved to be inefficient and cumbersome. There was redundancy in paper charting in order to adequately establish registries for a monitoring system. As a new clinic in an already established ambulatory setting, multiple challenges were encountered including a lack of community awareness of hepatitis C services; shared physical space including phone lines and fax machines, poorly coordinated document exchange and miscommunication; and an unorganized process for scheduling patients.

Summary

The chronic care model can be used to improve the care management for chronic illnesses. This model encourages collaborative efforts by healthcare professionals in order to provide evidence-based care. Using the components of the CCM provided clarity and guidance in program development for this community-based hepatitis C treatment clinic along the shoreline of western Michigan. The CCM components of self-management support and decision support especially guided treatment programming to address known barriers to hepatitis C treatment. Ultimately, the quality of provider-patient relationship had a strong impact on the patients' ability to manage their chronic illness. Using the CCM, the project remained focused on increasing access and improving health perceptions for individuals with hepatitis C.

CHAPTER 4

METHODS

The purpose of this chapter is to describe the methods and strategies used to develop and implement a community-based, multidisciplinary hepatitis C clinic in an underserved area near the lakeshore of west Michigan. This project has been conceptualized in four intentional phases (a) evaluation of community need, (b) development and implementation of a community-based hepatitis C clinic, (c) early program evaluation including summary assessment of barriers to treatment, and (d) program outcomes as they relate to improved access to hepatitis C care. This project occurred between February 2010 and April 2012.

The need to improve care for individuals with hepatitis C in the west Michigan community of interest was a long-standing goal for healthcare providers. Community primary care providers sought solutions to the lack of adequate care for their patients with hepatitis C by first approaching senior administrators from the local hospital system. The urgency to find solutions occurred in the spring of 2010 after the sudden death of a local physician who was treating small numbers of patients and served as one of the few sources of care for persons with hepatitis C.

Establishing Hepatitis C Initiative

The Community HCV Initiative was a grass roots effort by interested professionals and the concept was presented to hospital administrative leaders in July 2010. With resounding support, a taskforce steering committee was comprised of a doctor of nursing practice (DNP) student; a local physician specializing in infectious diseases; the executive director of a community agency focused on services for the underserved; and the Vice President/Chief Medical Officer of the hospital. To adequately access the problem and determine the best evidence-based approach to program development, ample time was taken to review the current state of knowledge related to hepatitis C. The DNP student assumed responsibility to review literature on HCV treatment models and summarize existing guidelines on treatment management.

The review of literature on hepatitis C was limited relative to optimal models of care delivery for persons with hepatitis C. The review reflected a growing interest in HCV care and reflected the limited number of published studies on HCV models of care in the US. The review also included several studies from Australia and Canada describing particular challenges that were encountered as HCV-dedicated clinics were established in their local communities. Consistently, these findings suggested that a collaborative approach using expertise from multiple disciplines would be useful in HCV populations.

Congruent with the established timeline, members of the Community HCV Initiative steering committee met in January 2011 and reviewed the initial literature on models of care for individuals undergoing HCV therapy. A multidisciplinary approach was selected because of the dominance and success with this type of programming in the

literature. A multidisciplinary approach to HCV treatment was determined as the best clinical approach to address barriers faced by those diagnosed with HCV (Appendix C). Because of the success with other APN models in other countries, administrative leaders of the hospital requested a draft job description for a nurse practitioner (NP). The request included a definition of necessary education, experience, and a list of essential skills needed to manage HCV treatment in collaboration with an infectious disease physician. During this meeting, a list of potential community stakeholders was developed with the intent to bring these members together to discuss the HCV dilemma and explore opportunities for partnerships. For the purpose of the project, community stakeholders were defined as “persons who have direct or indirect influence on the quality of care for individuals with hepatitis C.”

Meanwhile, to better understand the needs of local primary care providers, a Community HCV Needs Assessment was developed. This survey was designed specifically to examine basic HCV screening behaviors of local primary care providers and to explore barriers, including access issues to HCV treatment. The survey was sent with an introductory cover letter (Appendix D) explaining the project to nearly 200 physicians, nurse practitioners, and physician assistants. Unfortunately, the email list included specialty practices and pediatric offices who were unlikely to refer patients for HCV treatment. The Community Hepatitis C Needs Assessment (Appendix E) was deployed electronically through *Survey Monkey* on March 18th 2011. Of the nearly 200 providers surveyed, 23 (11.5%) responses were collected. Although the survey response numbers were limited, the additional comments submitted by PCPs were helpful in delineating the need for comprehensive community programming.

The next step in the project was to meet with potential community stakeholders who might be willing to act as “partners in practice” (Appendix F). A taskforce meeting took place on April 29, 2011 and included members from the HCV Steering Committee; the local community public health department; pharmaceutical groups; interested community agencies; and healthcare disciplines to address the psychosocial barriers to HCV treatment. Physicians and leaders from local Federally Qualified Health Centers (FQHC) also attended in an attempt to network with key players involved in the HCV Initiative.

During this taskforce meeting, a short presentation on the dilemma of HCV, barriers to treatment, and a review of the literature on various HCV treatment models was shared. Additionally, the results of the Community Needs Assessment were reviewed and discussions ensued regarding the implementation of a community-based clinic using a multidisciplinary model.

As a result of the taskforce meeting, committees were formed to address the various subspecialty needs deemed essential for a dedicated HCV treatment clinic. Members of the various committees met with the DNP student and, when indicated, the collaborating infectious disease physician. The committees met at various times between April 2011 and April of 2012.

Multidisciplinary Partnerships

In order to establish multidisciplinary partnerships among the six subcommittees, the DNP student met with various members on 12 occasions to discuss collaborative efforts in improving care for individuals with hepatitis C and those undergoing treatment.

Appendix G is a complete listing of all potential multidisciplinary partnerships for the HCV clinic.

Psychological and addiction services. In January 2012, the DNP student presented to a group of nearly 50 community mental health case workers to describe the challenges of treating hepatitis C in individuals with mental illness. One main point of the presentation was to discuss the eligibility requirements for hepatitis C treatment and the need for evaluation on a case-by-case basis. Some case workers among this group of professionals voiced concerns as they acknowledged high rates of ineligibility among their patients with mental illness. The case workers were educated on the need for an extensive follow up regimen and common medication side effects for those deemed eligible for treatment. Likewise, appropriate screening tools for the initial HCV clinic evaluation, criteria for psychological referral, and the need for clear and consistent multidisciplinary communication were shared and discussed.

Community agencies. Members from community service agencies met to discuss resources available for the underinsured and uninsured individuals. This included information regarding assistance with prescription coverage and laboratory services. Options and resources for case management and assistance in locating primary care providers were also reviewed.

To address the requirements for reportable diseases, a nurse from the community public health department met with the DNP student to review policies regarding the importance of reporting communicable diseases and the dispensing of appropriate educational materials. The primary route of HCV reporting is from local laboratories to established databases. Nurses from the public health department attempt to cross-

referenced all patients from historical databases for permanent entry into the Michigan Disease Surveillance System (MDSS).

Pharmaceutical services. On multiple occasions pharmaceutical representatives met with the DNP student and physician to discuss issues related to HCV education and treatment. Pharmaceutical representatives provided information on patient assistance programs as well as provider and patient educational information. The medications for HCV treatment are extraordinarily expensive and often require prior authorization (PA). It was concluded that the filling of prescriptions might occur in a variety of ways. The service benefits of specialty pharmacies include tracking medications refills; assisting in the PA process; providing additional patient educational materials; and in some cases offering assistance in laboratory monitoring. Since the HCV clinic is housed in hospital ambulatory care center, the use of external services from specialty pharmacies may conflict with the local hospital pharmacy. The team recognized this as an issue and made careful communication a priority. Additionally, a hospital pharmacist was approved for part-time employment in the hepatitis C clinic although the details of this appointment had not yet been confirmed at the time of project conclusion.

Michigan Hepatitis C Advisory Taskforce. The DNP student met with the Adult Viral Hepatitis Coordinator from the Michigan Department of Community Health (MDCH) to discuss policy issues in the state of Michigan related hepatitis C. The coordinator chaired the Michigan Hepatitis C Advisory Taskforce from 2007 to 2010. This governor-appointed Task Force submitted 21 recommendations focusing on the following priorities: Increasing hepatitis C surveillance efforts/improving the quality of hepatitis C surveillance data; developing statewide needle exchange programming;

increasing syringe access; and providing other hepatitis C-related services to people who use injection drugs; and facilitating access to hepatitis C screening, testing, management and treatment (MDCH, 2010).

Educational offerings. To further develop their expertise, healthcare providers at the HCV clinic attended several seminar and educational opportunities. These offerings increased the knowledge and confidence of the providers in treating hepatitis C patients with Direct Acting Antiviral (DAA) in combination with interferon and ribavirin. Planned educational events by physicians from tertiary, research institutions offered expert insights on HCV treatment regimens and challenges. In addition, an infectious disease colleague from another community met with the DNP student and the collaborating physician to review treatment guidelines, discuss community referral options and reimbursement, and suggest strategies for monitoring. This opportunity allowed the providers to gain insights into hepatitis C treatment from the standpoint of a community-based clinic.

The DNP student spent immersion hours in another community-based HCV treatment clinic managed by a nurse practitioner and infectious disease physician. The experience allowed the DNP student to gain insights into patient processing, treatment protocols, monitoring strategies, and develop networking relationships with another collaborative team treating hepatitis C.

Collaborative Efforts with Federally Qualified Healthcare Clinics

To improve the care for individuals with hepatitis C in the community, members of local FQHCs, the DNP student, and the infectious disease physician met to discuss collaborative efforts to optimize access, outcomes, and reimbursement for services.

Because the majority of individuals with hepatitis C struggle with psychosocial challenges as well as health and financial concerns, it was assumed that a large portion of patients with hepatitis C may be established patients within the FQHCs. Therefore, collaboration between the FQHC healthcare providers and providers from the community HCV clinic was seen as important and a way to measure coordinated care.

Hepatitis C Treatment Program Development

The early phases of program development started in September of 2011. The DNP student completed over 400 hours of clinical immersion in an effort to develop community partnerships, plan and coordinate clinic programming, and obtain IRB approval for program evaluation.

Program Evaluation

Setting and Participants

The hepatitis C treatment clinic was established in a community hospital located along the shoreline of western Michigan. Early program evaluation was seen as essential to evaluate the effectiveness of HCV treatment in a multidisciplinary community-based setting. Clinic programming sought to overcome perceptions of barriers to care. The target population included all adults with HCV infection over 18 years of age who met inclusion criteria, agreed to participate, and signed appropriate consent (Appendix H) and HIPAA forms to allow select data extraction from their medical charts. All signed consent documents were maintained as part of the patient's permanent record. Further inclusion criteria included those individuals referred to the hepatitis C clinic for evaluation of treatment. Exclusion criteria included those who did not sign the informed consent and patients under the age of 18.

Instruments

Health perception survey. A Health Perception Survey (Appendix I) was developed to capture data regarding perceptions of available resources believed to impact successful hepatitis C treatment. Select demographic data was collected to determine commonalities and variability relative to patient characteristics to assist in further treatment programming. Demographics included age, gender, hepatitis C genotype, hepatitis C treatment history, and the county in which the patient resided. Data was also extracted on the types and frequency of community referrals to provide useful information for future programming and updates for interested stakeholders.

Survey collection steps. The survey was given to patients at five specific appointments; however, timeframes between surveys varied among patients due to their personal preferences in starting treatment and any necessary testing/consultations required between the various surveys.

Time 1. The first survey collection occurred after the patient received the Patient Information Handout (Appendix J) and was asked to complete the short 6-question Health Perception Survey. The survey could typically be completed in less than 5 minutes. Patients completed the surveys by marking an “x” along a 200mm line indicating their perception of the illness self-management questions. A potential discomfort for a patient may have included an inability to comprehend what the question was asking or an inability to read. In these cases, the clinic nurse was available to assist the patient with the survey. Completed surveys were dated and added to the patient medical record.

Time 2. The second survey was distributed prior to the physician consultation and completed after a brief review of the survey completion process. Again, the participant was asked to indicate with an “x” to reflect their perception of the illness-management question.

Time 3. The third survey was distributed at the time of the injection training and side effect management session and completed in the manner above.

Time 4 and Time 5. The fourth and fifth survey were distributed at the time of the first and second follow up (2 and 4 weeks after initiating treatment) and completed in a manner congruent with other surveys.

Informed consent collection. Informed consents were collected by the nurse(s) who assisted in the hepatitis C treatment clinic. Nurses were trained by the DNP student to explain the purpose of the project and to answer any initial questions. Prior to the time of data collection informed consent was requested from patients who were receiving treatment at the clinic, using a scripted approach (Appendix K). For those individuals who were no longer obtaining services at the clinic, nurses attempted to contact them to discuss the project and request consent. Patients were required to come in person to review and sign the consent if they agreed to allow access their medical record.

Institutional review board. A request for Exempt (Category 1-4) review was submitted and approved for by the Institutional Review Board (IRB) at Grand Valley State University and Mercy Health Partners, Muskegon, Michigan (Appendix L and M). This project involved extracting selected information from existing patient surveys to obtain program evaluation data for the community hepatitis C treatment clinic.

Data collection and evaluation tool. Data collection was accomplished by using a retrospective chart audit of existing medical records to examine selected demographic information and data regarding perceptions of available resources believed to impact successful treatment. Data was obtained from patients seen at the clinic between October 1, 2011 and March 15, 2012. A Hepatitis C Treatment Program Evaluation Tool (Appendix N) was created and used to obtain demographic and health perception information. To de-identify patient information, a corresponding sequential alphabet character was assigned to each participant. The DNP student only accessed the medical charts of those who agreed and provided written consent and only accessed medical records once unless validation of the data was required. The assigned character code was marked only on the program evaluation tool. A master list of participants was stored on a password protected computer in a secure site.

The results of the health perception questions were recorded by measuring the point where the patient has marked an “x” along a 200mm line. Quantitative results were determined by measuring this length from zero; thus, a 2mm interval equated to 1% in their responses.

Program Documentation

At the time of clinic programming development, electronic medical records were not accessible for the clinic areas within the hospital. This required creation of all paper assessments and monitoring documentation forms. The forms corresponded to the organization of the “paper chart” as directed by the physician. The documentation forms developed for the community hepatitis C clinic can be reviewed in Appendix O and include a *Problem List* with side effect management strategies; *Progress Notes*;

Medication Reconciliation; Pretreatment Testing Check List; Laboratory Monitoring Flowsheet which also documented vital signs for clinic visits and treatment medication dosages; *Intake Assessment History*; and *Laboratory Requisition*.

In addition to the forms for the medical record, standardized letters were developed to assist communication between clinic staff and community partners (Appendix O). These included correspondence to the ophthalmologist/optometrists for individuals requiring pretreatment eye exams and a letter to primary care providers informing them that their patient was seen at the clinic but required additional testing or referral. A specific letter was developed to the primary care providers addressing mental illness concerns and/or active alcohol use.

Development of an additional informed consent for hepatitis C treatment was completed. This informed consent addressed potential treatment side effects; need for medication and follow up compliance; and contraception information. Patients were asked to sign the consent before starting treatment regimens.

Clinic Service Coordination

Treatment Guidelines

One of the most important steps in developing the hepatitis C treatment clinic was to have a firm understanding of national guidelines for treatment. The most recent published guidelines exist as an addendum to those published previously (Ghany et al. 2009, 2012). These guidelines encourage patients to be assessed on a one-to-one basis for treatment eligibility. In this way former myths about eligibility requirements were avoided.

Clinic Protocols

Clinical protocols refer directly to the algorithm of how patients were referred and how they access services within the hepatitis C clinic. As with any new program, there was flexibility in these protocols until more knowledge was gained through experience.

Referrals. Patients were referred to the clinic in a variety of ways. The preferable method was a faxed or phoned referral from the primary care provider. Faxed referrals allowed patient information to accompany the requests; phoned referrals required the added step of sending appropriate patient records. The referrals received between October 1, 2011 and February 2012 arrived primarily from word-of-mouth announcing that the clinic was available for referrals.

HCV education. Adequate and accurate education was seen as imperative for patients with hepatitis C who were considering treatment (Birkel, Caldwell, Stafford-Fox, Casarico, & Benson, 2004). The design and development of the hepatitis C treatment program reflected models in literature and the design of the clinic played a key role in determining how patients would be educated and processed through the clinic (Larrey et al., 2011). As established, the program enhanced education of the patient on HCV; reviewed long term complications of HCV; described treatment and possible side effects; and counseled patients on the effects of alcohol and HCV. During the educational clinic visit, initial evaluations were made regarding HCV treatment eligibility and medical compliance concerns were addressed. In the future, patient education offerings may be scheduled in a group setting. Most importantly, the initial clinic appointment started the process of developing relationships between the patients, their families, and hepatitis care team.

Physician consults. Patients were scheduled for a physician consultation after they attended the education session. At the time of the visit, education was reinforced; a history and physical were completed; additional work up studies were identified; and patients were given ample time for their questions to be answered. Requirements to determine eligibility for treatment involved careful consideration of multiple factors including compliance issues, results of liver biopsy, imaging studies, blood work, eye exam, referral to psychologist or psychiatrist, or any other medical specialty such as cardiology, endocrinology, and gastroenterology.

Pretreatment testing. Before therapy could begin, all pretreatment testing was completed to determine underlying liver disease or existing co-morbidities that might alter treatment. This information, along with an accurate psychosocial evaluation ultimately determined treatment eligibility. Required pretreatment testing is shown in Appendix O.

Announcement Letter to Community Providers

A formal announcement introducing the hepatitis clinic to the community was mailed on February 3, 2012 (Appendix P). In this introductory note, it was clearly communicated that the clinic staff was first attempting to identify patient volume within the community and encouraged primary care providers to assist in the referral process by having their patients complete the required preliminary work up.

Hepatitis C Treatment Clinic Staffing

Estimating staffing needs for the clinic was difficult. Throughout the entire clinical immersion time the DNP Student (September 2011-April 2012) coordinated all hepatitis clinic services. One staff registered nurse was minimally involved in collecting

clinic referrals and laboratory monitoring. She also assisted in collecting informed consents. On a few occasions, a medical assistant was assigned to the HCV and roomed patients completing vital signs and weights, prepared charts, and assisted in making copies of chart documents.

In January 2012, a meeting was held with the collaborating physician, the clinic manager, and the chief medical officer to address staffing requirements for the clinic. After discussing the number of incoming referrals and the vigilance required for monitoring and management of hepatitis C treatment, the group agreed to move forward with developing a position for a nurse practitioner to work in collaboration with the infectious disease physician. At the time of project completion, a business plan was being formulated that would require eventual approval by the hospital finance committee. To secure continuous HCV clinic operations, a temporary position was posted in the hospital for a part-time nurse practitioner at the conclusion of the project.

Outcomes Evaluation

To evaluate improved access for hepatitis C treatment, healthcare providers in the community were surveyed at the completion of the project. Surveys were completed by providers who attended a *Grand Rounds* event on April 23, 2012. The survey (Appendix Q) mirrored the instrument used for the Community Needs Assessment in that information was gathered regarding HCV screening practices and perceived barriers to HCV care. Information reviewed at this seminar included magnitude of the HCV dilemma, known barriers to treatment, and expected benefits of the community-based hepatitis C clinic.

Summary

This project was developed with four key components in order to improve the care for individuals with hepatitis C along the shoreline of western Michigan. A community needs assessment was completed to provide the necessary data required to convene and convince institutional leaders to champion this cause. The project was then developed and implemented with knowledge gained from the literature review and guidance from components of the Chronic Care Model. Early program evaluation was completed by assessing the health perceptions of patients relative to common barriers to treatment. Lastly, an outcome assessment was collected and analyzed from primary care providers on their perceptions of the HCV clinic and meeting their patients' needs. This project took place over a two- year timeframe and involved dozens of community stakeholders. The community-based, multidisciplinary hepatitis C treatment clinic is now open for business.

CHAPTER 5

RESULTS

The purpose of this project was to increase access to hepatitis C treatment and report patient's perceptions of common barriers to successful completion of hepatitis C treatment. The project was developed in four phases (a) evaluation of community need, (b) development and implementation of a community-based hepatitis C clinic, (c) program evaluation as it relates to patient's perceptions regarding barriers to treatment, and (d) evaluation of program outcomes as they relate to improved access to hepatitis C care. The results reported reflect the findings of the community needs assessment, the hepatitis initiative outcome survey, and the health perception survey. Data analysis for the surveys was accomplished by using the Statistical Package for Social Sciences (SPSS) software.

Community Needs Assessment

Approximately 200 emails were sent to the healthcare providers in a healthcare network with an introductory note and link to an eight question provider survey. For the purpose of this evaluation healthcare providers included physicians, nurse practitioners, and physician assistants. Results of the survey are shown in Table 1. Of the 23 providers who responded to question one, the majority (56.5%) replied they had seen 0-5 patients with HCV in their practice in the last calendar year; 26.1% replied they had seen 6-10

patients; and 17.4% had assessed 11-20 hepatitis C patients. Questions 2-5 pertained to routine screening procedures. Most providers were *very likely* or *likely* (30.4% and 34.8%, respectively) to routinely ask patients about their IV drug history. The majority of providers (69.6%) would order a hepatitis profile if the patient disclosed their use of IV drugs. These findings support that most providers are aware of health risks associated with IV drug use, yet they need to be consistent about asking about risk behaviors. However, when inquiring about history of blood transfusion, only 39.1% of the providers were *somewhat likely* to ask patients about a previous transfusion, suggesting that this is an area where further education is needed.

Survey questions pertaining to referrals of patients with hepatitis C (Table 1) reported that 67% of the respondents were *very likely* or *likely* to refer patients for hepatitis C treatment, while 18.2% were *unlikely* to refer patients for treatment. Nearly half of the providers (47.8%) felt they were *very likely* to encounter barriers in getting their patients referred for treatment. Among respondents, 73.9% indicated they would be *very likely* to refer patients to a dedicated hepatitis C treatment clinic, while 8.6% stated they would only be *somewhat likely* or *unlikely* to refer to the hepatitis C clinic.

At the conclusion of the community needs assessment, healthcare providers were given the opportunity to submit additional comments regarding specific barriers to getting their patients treated for hepatitis C. In total, 15 providers responded and identified lack of access to specialists in hepatitis care, inadequate insurance, and psychological/social issues as barriers to treatment.

Table 1

Community Needs Assessment

Item	n	Very Likely n (%)	Likely n (%)	Somewhat Likely n (%)	Unlikely n (%)
Questions Pertaining to HCV Screening Practices					
2. How likely are you to ask a routine patient about a history of intravenous drug (IV) use?	23	7 (30.4)	8(34.8)	5 (21.7)	3 (13.0)
3. How likely are you to order a hepatitis profile should the patient disclose their use of IV drugs?	23	16 (69.6)	2 (8.7)	2 (8.7)	3 (13)
4. How likely are you to ask a routine patient about their history of blood transfusions?	23	7 (30.4)	3 (13.0)	9 (39.1)	4 (17.4)
5. How likely are you to order a hepatitis profile should the patient disclose a history of blood transfusion?	22	5 (22.7)	5 (22.7)	4 (18.2)	8. (36.4)
Questions Pertaining to Referrals					
6. How likely are you to refer a patient for hepatitis C treatment?	22	11 (50.0)	6 (27.3)	1 (4.5)	4 (18.2)
7. How likely are you to encounter barriers in getting your patients referred for hepatitis C treatment?	23	11 (47.8)	3 (13)	4 (17.4)	5 (21.7)
8. How likely are you to refer a patient to a local multidisciplinary hepatitis C treatment clinic?	23	17 (73.9)	4 (17.4)	1 (4.3)	1 (4.3)

Hepatitis C Initiative Outcome Evaluation

The Grand Rounds Lecture Series was attended by 49 providers on April 23, 2012 where the topic focused on the treatment of hepatitis C. Of those who attended, 34 completed the Hepatitis C Initiative Outcome Survey, 20 were primary care providers and 14 were providers from other healthcare services. Several minor changes were made to the Community Needs Assessment in attempt to clarify the volume of patients being seen by local providers, obtain information on screening procedures, and to identify those who might adopt the suggested age-based screening guidelines. A small revision was made to question one in an attempt to better identify how many were seen by providers in the community to offer insight into the provider burden to find adequate HCV care as well as how many individuals might be referred to the hepatitis C clinic. Of those who submitted a survey, 23(67.6%) providers had seen between 0-5 patients in the last year; three (8.8%) stated they had seen 6-10 patients; five (14.7%) had seen 11-20 patients within the last year; in that same time period, one provider (2.9%) had seen 21-30 HCV patients; and two (5.9) providers had seen over 30 individuals with hepatitis C. Questions 2-7 are reported in Table 2.

There was a wide range of responses when providers were asked about performing a risk-based HCV assessment (question 2). Once again, this indicates an area where further education might better inform primary care providers on the current HCV screening recommendation put forth by the U.S. Preventative Services Task Force (2004). The majority of providers (79.4%) would order a hepatitis profile if a patient disclosed risk(s) of acquiring a hepatitis virus. Over 20% still reported they would be *somewhat likely* or *unlikely* to order a hepatitis profile if the patient disclosed risk. Of the

34 providers who completed the survey, 67.6% reported they would *very likely* or *likely* adopt the age-based HCV screening recommendations. These changes in HCV screening will should lead to greater numbers of patients aware of the hepatitis C diagnosis and ultimately higher numbers of people being referred to the HCV clinic.

Of the providers who attended the Grand Round Series, 82.4% would refer individuals for HCV treatment. Only 17.7% reported they would be *somewhat likely* or *unlikely* to refer patients for HCV treatment. This indicates that at least some of the providers from other healthcare services would refer patients for HCV treatment.

Encountering barriers in getting patients referred for hepatitis C treatment (question 6) was reported in 55.9% of responders, 41.2% were *somewhat likely* or *unlikely* to encounter barriers, and one respondent, a urologist, did not answer the question. This data differs slightly from the Community Needs Assessment where over 60% of providers reported encountering barriers in getting their patients referred for HCV treatment. Most importantly, 91.2% of providers surveyed stated the community-based hepatitis C clinic would facilitate the care for their HCV patients. Of the two responders who reported the HCV clinic would not facilitate care for their patients, one identified himself as a surgeon, the other was not a primary care provider.

Table 2

HCV Screening and Outcomes

Item	n	Very Likely n (%)	Likely n (%)	Somewhat Likely n (%)	Unlikely n (%)
Questions Pertaining to HCV Screening Practices					
2. How likely are you to perform a hepatitis C Risk-Based Assessment?	34	8 (23.5)	9 (26.5)	10 (29.4)	7 (20.6)
3. How likely are you to order a hepatitis profile should the patient disclose their risk(s) for hepatitis C?	34	22 (64.7)	5 (14.7)	3 (8.8)	4 (11.8)
4. How likely are you to adopt the Age-Based hepatitis C screening guidelines?	34	13 (38.2)	10 (29.4)	6 (17.6)	5 (14.7)
Questions Pertaining to Referrals					
5. How likely are you to refer a patient for hepatitis C treatment?	34	19 (55.9)	9 (26.5)	4 (11.8)	2 (5.9)
6. How likely were you to encounter barriers in getting your patients referred for hepatitis C treatment?	33	8 (23.5)	11 (32.4)	5 (14.7)	9 (26.5)
7. How likely will the community-based hepatitis C treatment clinic facilitate your ability to care for your patients?	33	22 (64.7)	9 (26.5)	0 (0.0%)	2 (5.9)

Data was further analyzed to better understand the specific screening practices and referral issues for the local primary care providers who completed the Outcome Survey. The majority of primary care providers (70%) had seen 0-5 hepatitis C patients in the previous year, 30% had seen more than 6 patients. Again, there was a wide range of responses when asked about performing a risk-based HCV assessment (question 2). Of the primary care providers who responded, seven (35%) reported they would be *very likely* to perform risk-based screening; six (30%) would be *likely*; six (30%) would be *somewhat likely*; and one (5%) would be *unlikely*. A hepatitis profile would be *very likely* or *likely* ordered by 90% of the primary care providers if a patient disclosed risk for acquiring a hepatitis virus and 90% of the providers surveyed would adopt the age-based screening recommendations for HCV screening (question 4). Of the primary care providers, 85% refer patients for HCV treatment, 75% of those surveyed encountered barriers to getting patients referred. Lastly, 100% of the primary care providers reported the community-based hepatitis C treatment clinic would facilitate the care for their patients.

Health Perception Survey

A total of 47 referrals were received at the community-based hepatitis C treatment clinic between October 1, 2011 and March 15, 2012. Of those, 17 patient referrals were processed and seen for at least one appointment. Many of the remaining 30 referrals were recent and were not yet fully processed or scheduled for appointments at the time of project completion. Of the 17 initial referrals, 12 patients were willing to participate in the early program evaluation. Of the five who did not participate, two lived out of the county, two had moderately severe mental illness, and one was deemed ineligible for

treatment because of active alcohol addiction. The two patients living out of the county were not contacted to participate because of the driving distance and the other three were not contacted because they were deemed ineligible for treatment for various medical reasons. Lastly, one of the 12 patients who participated in the early evaluation initially declined but returned to the clinic one week later willing to sign the consent.

Among participants, seven (58.3%) were female while five (41.7%) were males. Ages ranged from 50 to 69 years old ($M=57.75$; $SD 5.03$). Genotype 1 was reported in 11 patients (91.7%), only one patient was reported as having genotype 3. Of those participating in the program evaluation, ten (83%) were naïve to HCV treatment (never having had treatment previously), one (8.3%) was a non-responder, and one (8.3%) was a partial-responder. Nine (75%) patients lived in the community of interest, two (16.7%) lived in a county to the south, and one (8.3%) lived in a rural county to the north. Among the 12 patients, only two required indirect referrals for further evaluation prior to initiating treatment; one patient was sent to nephrology and one to gastroenterology.

The baseline health perceptions of patients referred for hepatitis C treatment are summarized in ranked order in Table 3. In order to determine patients' perceptions of barriers to care, patients were asked to rank their perceptions on a scale of 0-200mm using the qualifiers *very little*, *somewhat*, and *very much* to guide their answers. Every two millimeters equated to 1%. Using the scale, all patients who participated in the program evaluation had perceptions of having *little* overall control over the management of their hepatitis C at baseline. Of those, 75% perceived they did not understand what was expected of them in managing their hepatitis C while the other 25% felt only *somewhat* sure of what was expected of them. Over 90% of patients reported having

inadequate resources to manage their hepatitis C. Only one patient felt they had adequate resources to manage their hepatitis C. Lack of adequate psychological/emotion support was perceived by 58.3% of patients, 33.2% perceived they had at least some support, and one patient felt adequately supported. When asked about support with decision making (question 4), less than half (41.7%) felt supported in making decisions about their hepatitis C care, 33.2% felt *somewhat* supported in making decisions about the HCV care, and 24.9% felt supported in making decisions about their HCV care. Lastly, over 70% of patients at baseline perceived confidence in their ability to follow a prescribed hepatitis C treatment plan.

Table 3

Rank Ordering of Perceived Health Perceptions at Baseline

Survey Question	Mean	Standard Deviation
1. Felt in control over the management of your hepatitis C	3.05	5.8
5. Understood what was expected of you in managing your hepatitis C	13.6	21.3
2. Had adequate resources to manage your hepatitis C	23.5	31.3
3. Had adequate psychological or emotional support	24.9	31.9
4. Felt supported in making decisions regarding your hepatitis C	43.1	38.4
6. Had confidence in yourself to follow a hepatitis C treatment regimen.	74.7	37.2

The limited number of patients in this early evaluation project prohibited a more sophisticated statistical analysis. However, a number of trends were noted from these preliminary results. Of the 12 patients who completed the first health perception survey, nine patients progressed to a physician consultation and were able to complete survey two. Table 4 summarizes the change in mean scores and standard deviations of time one surveys compared to time two surveys. Overall, perceived barriers to hepatitis C treatment improved among all patients from time one to time two. Patients' perceptions of having confidence in following a treatment plan remained at high levels in both surveys. Improvements in mean scores occurred in all patients in perceptions of *control of the management of their hepatitis C* (question one), showing an increased mean of 3.05 to 22.7. *How well they understood what was expected of them in managing their hepatitis C* (question five), had an increased mean of 13.6 to a mean of 49.6. Patient's perceptions of *having control over the management of their hepatitis C* ranked the lowest in both survey one and two.

Table 4

Rank Ordering of Health Perception from Survey 1 to Survey 2

Survey Question	M (Survey 1; n=12)	SD (Survey 1; n=12)	M (Survey 2; n=9)	SD (Survey 2; n=9)
1. Felt in control over the management of your hepatitis C	3.05	5.8	22.7	27.9
2. Had adequate resources to manage your hepatitis C	23.5	31.3	41.3	36.3
5. Understood what was expected of you in managing your hepatitis C	13.6	21.3	49.6	40.1
4. Felt supported in making decisions regarding your hepatitis C	43.1	38.4	57.7	38.3
3. Had adequate psychological or emotional support	24.9	31.9	59.0	44.6
6. Had confidence in yourself to follow a hepatitis C treatment regimen	74.7	37.2	77.6	29.0

Summary

The results of the Community Needs Assessment provided preliminary information on the local physicians' perceptions of the need for improved healthcare services for individuals with hepatitis C in the area of interest. Of those who responded, 79.1% would refer patients to the community hepatitis C clinic. The Hepatitis C Initiative Outcome Survey showed that over 90% of providers surveyed felt the community hepatitis C clinic would facilitate their ability to better care for their patients with hepatitis C. Additionally, the Health Perception Survey showed improved scores of

patients' health perceptions from the time one surveys as compared to those from time two surveys.

CHAPTER 6

DISCUSSION

This chapter will further discuss the findings of this project and highlight the successes and challenges during development and implementation. The purpose of this project was to provide improved access and care for individuals with hepatitis C in an underserved area. The project was developed in phases including evaluation of community need; development and implementation of a community-based hepatitis C clinic; enactment of an evaluation plan; and provider perceptions of early program outcomes. The efforts put forth in developing and implementing this project has resulted in increased access for individuals with hepatitis C in this community of interest and improved health perceptions of patients regarding barriers to treatment.

The project required enormous support from the Hepatitis C Initiative steering committee and institutional leadership. Their support successfully motivated other healthcare providers to complete the Community HCV Needs Assessment and the Hepatitis C Initiative Outcome Survey. The results of the surveys provided the necessary validation from local healthcare providers that improved care was needed for individuals with hepatitis C and supported the establishment of a community-based hepatitis C clinic to facilitate the provider's ability to care for their hepatitis C patients.

The use of the chronic care model for this project provided a critical framework for the exploration of barriers and facilitators of hepatitis C care defined in literature. The CCM guided the literature review, provided a focus for program developments, and served as the necessary structure for evaluation. While all of the components of the CCM were utilized for this project, the components of self-management support and healthcare delivery support were the underpinnings that promoted successful outcomes. The CCM provided the necessary link between the community, the healthcare system, and the hepatitis C clinic that developed productive interactions between a proactive team and an informed patient.

Provider Surveys

A relatively small number of responses were received from the Community Needs Assessment and the limited number was attributed to the fact that surveys were emailed to all providers in the health network regardless of their potential to refer patients for hepatitis C treatment. In retrospect, directing the hepatitis C community needs assessment to providers most likely to refer may have helped to ensure a stronger response. This may have been further augmented by mailing reminder postcards to those who had not yet responded or sending a follow up email. In addition, the shortened response time between the survey launch and deadline for replies may have affected responses rates. Yet, the Hepatitis C Community Needs Assessment validated concerns from providers regarding the lack of healthcare services for their patients with hepatitis C. The additional comments by the providers at the end of the survey were insightful and helped to catapult the project forward.

The surveys attempted to identify the number of HCV patients who were seen by providers in the community. The response remained similar between the surveys; the majority of providers responded having seen 0-5 hepatitis C patients in their practice within the last year. In retrospect, a zero value should have been added to the survey allowing providers the opportunity to respond that they had not seen a hepatitis C patient in their practice in the last year. The survey results reported lack a true understanding of how many patients are seen by the providers in the community of interest.

In regards to screening procedures for hepatitis C, the surveys showed varying practices among providers. To date, risk-based assessment remains the guideline for screening for HCV (US Preventative Services Task Force, 2004). It is widely reported that only 25% of those infected with HCV are aware of their diagnosis. The current risk-based assessment is inadequately identifying afflicted individuals. Age-based screening has been presented as a viable alternative to risk-based screening and is reported to increase the numbers of people aware of their HCV diagnosis. The Grand Round Lecture Series was an opportunity to present information on risk-based and age-based HCV screening. The majority of providers surveyed indicated they would likely adopt the age-based screening recommendations. If this holds true for these community providers, greater numbers of individuals referred to the hepatitis C clinic can be expected.

Generally, the surveys effectively gathered needed information. A more targeted provider survey for the Community Needs Assessment would have yielded more optimal results. In regards to HCV screening, the surveys validated inconsistencies in using risk-based assessments. To improve the care for individuals with hepatitis C, better screening procedures need to be adopted.

Project Development and Implementation

From the initiation of the hepatitis C project, evidence-based practice guided program development. However, defining program protocols and establishing adequate paper documentation consumed significant time in the early stages of program development. While initially this was a time concern, this early detail proved to be exceedingly valuable. Establishing the medical record for completeness and organizational flow was necessary prior to patients being scheduled at the clinic. Additionally, unanticipated challenges presented included designing coordinated clinic schedules; establishing efficient processing for patients during the work up phase of treatment; and reducing fragmentation of services.

The unanticipated challenges ultimately affected the number of patients who were seen at the clinic during the project time period. Time constraints and the community announcement letter about the hepatitis clinic lead to several patient referrals not being processed by the project completion. Those individuals who were not seen for an appointment received a letter and were informed they would be contacted when permanent HCV clinic staff was secured.

Program Evaluation

Early program evaluation provided preliminary insights on patients' perceptions in navigating barriers to treatment. Although the sample size was limited, early data trends showed improvement of all health perception questions between survey one and survey two. Patients generally felt confident to follow a treatment regimen which may prove to be beneficial as they move through the stages of pretreatment work up and treatment initiation. Of the surveys collected from time one to time two, one previously

treated patient scored high on nearly all health perception questions. Because the sample size was limited, this may have skewed the perception scores related to patients naïve to treatment.

Limitations and Challenges

Many limitations exist for this project. Some of the challenges faced when developing and implementing this project may be unique to the West Michigan area and not appropriate for other locales. For example, the location of this project was in a small cohesive community where most providers know each other. This may have allowed the project to move forward more steadily than in larger communities. The DNP student was also known in the community and may have allowed collaborations that may not exist in other communities.

Barriers for this project focus on the challenges in developing a new healthcare program without a dedicated staff and sufficient technological support. In collaborative effort with the physician, coordination of patient work-up and treatment management was hindered by a lack of autonomy for the DNP student in ordering laboratory and imaging studies; signing forms and letters; and responding to testing results. The HCV clinic was operated by the DNP student two half days per week in addition to the physician scheduling consultations two half days per month. Fortunately, the collaborating physician practiced in the clinic area weekdays managing infectious disease and HIV caseloads where he was available to view the laboratory results of HCV patients as they were periodically faxed to the clinic.

Coordinated communication efforts improved steadily over the course of the project. This included referral notification, incoming telephone messages, scheduling

patient appointments, and faxed pharmaceutical responses. The DNP student was available by cell phone and responded to emails on days she was not in the clinic. The ambulatory clinic staff nurse helped to coordinate HCV clinic activities in the absence of the DNP student. In retrospect, this type of staff assistance should have been encouraged throughout the project to ensure a smooth transition of care to the ambulatory staff should permanent staffing not be secured by the time of project completion.

Implications

The magnitude of the hepatitis C dilemma will be at its greatest this decade. The initiation of this project has increased the preparedness of a West Michigan community for the presumed increase in HCV volume if the new HCV screening recommendations are enacted. The model of care and processes used for this project can be applied to other communities. Using the model in other communities will require motivated, passionate individuals who can dedicate the time and energy to HCV program development. In sum, the time period for this project exceeded two years and included a thorough literature review on models of care for HCV treatment; completion of a Community Needs Assessment to assess provider HCV concerns; development and implementation of a community-based HCV treatment clinic; and early HCV treatment program evaluation.

Practice

Involvement of a Doctor of Nursing Practice Student

The process of establishing a community-based, multidisciplinary approach to HCV treatment involved the coordination of several members of a healthcare team. During the first phase of project initiation, the DNP student thoroughly reviewed current literature on HCV models of care and guidelines to treatment. An analysis of this

information was guided by incorporating components of the Chronic Care Model in establishing a comprehensive approach to HCV care with the greatest likelihood for improved outcomes.

The DNP student was the liaison between administrative leaders, steering committee members, stakeholders and multidisciplinary partners, patients and their families, and the clinic support staff. In collaboration with the infectious disease physician, the HCV treatment programming was developed and implemented. The DNP student provided HCV educational services to patients referred to the clinic and provided clinical expertise to the physician in HCV treatment regimens. The DNP student provided information to the clinic manager on the estimated community HCV prevalence; clinic referral statistics; HCV treatment regimens; and anticipated responsibilities of a nurse practitioner to coordinate HCV treatment services. This information was used to secure a temporary NP position at the time of project completion (Appendix R).

Community Involvement

This project allowed healthcare professionals from a variety of health services to collaborate and improve care for patients with a chronic health condition in West Michigan. This multidisciplinary approach to improving care for individuals with hepatitis C focused on the addressing common barriers to successful treatment. Stakeholders for the project included healthcare professionals from medicine, nursing, administration, pharmacy, mental health and addiction services, community agencies, public health, and finance. The efforts in this community may offer insights to other communities attempting to establish similar health improvement initiatives.

Education

In successfully navigating all the components of this project, the DNP student enacted the core competencies of the DNP degree as outlined by the American Association of Colleges of Nurses (AACN) in the Essentials of Doctoral Education for Advanced Nursing Practice (AACN, 2006). The core competencies focused on primarily for this project were leadership, scholarship, education, innovation, clinician, and advocacy. Innovating new strategies to effectively treat individuals with hepatitis C in this community required leadership skills to bring stakeholders together and present the magnitude of the problem as it existed. Translating current research into practice was accomplished by synthesizing literature and adapting guidelines in the development of protocols for treatment. Advocating for appropriate clinic staffing and strong educational components to HCV clinic programming was imperative. The potential impact of this project may generate additional DNP practice innovations from this clinical site or foster work in other communities.

Policy

The initiation of this project occurred during a time when the impact of hepatitis C started to be recognized across the nation. In 2010, the State of Michigan Hepatitis C Taskforce had already completed its 3-year investigation reviewing the dilemma of HCV and submitted 21 recommendations for greater screening, prevention, and treatment policies. As the impact of hepatitis C continues to expand, individual healthcare providers and agencies will need to decide how personnel and financial resources are allocated to manage this chronic illness.

Microsystem to Macrosystem

This community healthcare project addressed improving care for individuals with hepatitis C on a microsystem level. The efforts put forth during the project resulted in preliminary discussions on collaborations with the Federally Qualified Health Centers for HCV treatment. This type of collaborative partnership broadens the scope of HCV treatment opportunities for other community practices and, therefore, expands the project to a potential macrosystem level.

On April 31, 2012 yet another meeting was held in this community to specifically bring local hepatitis C treating providers together to discuss the challenges of managing the increasing number of referrals for HCV treatment and the workload required in offering HCV treatment. The meeting was attended by the DNP student, a family nurse practitioner, two infectious disease physicians, the medical director of the FQHC who practices primary care medicine, a gastroenterologist, and two physician assistants. Conversations focused on strategies to manage the increasing number of referrals for HCV evaluation and treatment and how the age-based screening might impact current volumes of individuals being diagnosed with the virus. The time intensity involved in educating, evaluating, and treating individuals with the HCV prohibits large numbers of patients from being treated at one time. Treatment monitoring strategies and case management were discussed as viable options to increase case loads. Additionally, the efforts in improving care in this community may be augmented by incorporating other strategies such as the use of *Doximity*, an on-line network established to allow providers the opportunity to collaborate. A specific hepatitis C treatment group has been

established for the providers in this community to discuss challenges in HCV management; eventually, case study review is planned.

Affordable Care Act

At the time of project completion, the clinic had not yet received a single referral for a patient who lacked healthcare insurance. Because hepatitis C is prevalent in vulnerable populations, it is likely that many individuals with mental illness, drug and/or alcohol addictions have not yet been screened or diagnosed with the HCV. Should the US Supreme Court uphold the decision to mandate healthcare coverage, in accordance with the Patient Protection and Affordable Care Act of 2010 (US Department of Health & Human Services, 2010) for all US citizens, millions of people will flood the healthcare system with the potential to diagnose higher numbers of people with hepatitis C. The improved preparedness of this community to care for current and increasing numbers of individuals with hepatitis C shows dedication to the welfare of the community in situations where serious healthcare system implications exist.

At the present time the outcomes of the Affordable Care Act are unknown. Profound changes in healthcare relative to hepatitis C will occur regardless of whether the Affordable Care Act passes or fails. Impacts of the new hepatitis C screening guidelines are pending and will require substantial ongoing evaluation of optimal methods of service delivery. How we advocate for those in need or increase access to the vulnerable remains a critical question for healthcare providers and the healthcare industry as a whole.

Sustainability

From the initiation of the project, institutional leaders had a clear understanding of the community need to address the inadequate care for individuals with hepatitis C. Healthcare institutions have responsibilities to the welfare of the community and therefore initiated this project as a community outreach initiative. Financial considerations for the hepatitis C clinic included billable services for provider visits, laboratory and radiology services, and hospital pharmaceuticals services. Prescription drug plans have generally covered the cost of medications with submission of prior authorization documentation. The pharmaceutical companies offer generous copay opportunities for those with high deductibles and patient assistance program are available for those with limited resources. Available grant opportunities will be sought using the preliminary data of patient volume, anticipated personnel required to manage case loads, and projected finances to manage the community-based hepatitis C clinic.

Future Research

The implementation of this community-based HCV treatment clinic generated the possibilities for future studies and practice innovation projects. For example, a study reviewing the benefits of individuals with hepatitis C participating in a support group and the rates of successful treatment may lead to increased numbers of local support groups. Another project in this community might include the evaluation the HCV treatment outcomes of collaborative efforts between a DNP prepared advanced practice nurse and leaders of a FQHC. Lastly, one of the biggest challenges in treating hepatitis C is the time intensity in monitoring laboratory testing. Improvements in the efficiencies of monitoring may be augmented with the use of electronic registries for the management of

HCV. This would be an exceptional challenge in this particular setting where paper documentation still exists (Appendix S).

Future of Nursing

Adopting structural changes in education and supporting terminal degrees for nursing practice is in line with the recommendation and key messages put forth by the Institute of Medicine (IOM, 2011) on the *Future of Nursing, Leading Change, Advancing Health*. Nurses are poised to have a greater impact on the direct and indirect delivery of national healthcare. By educating clinical and administrative nurses with the highest level of education and ensuring their knowledge of implementation science through rigorous academic requirements, improved healthcare outcomes at lower costs are assured. Additionally, collaborative efforts between nurses, physicians, and other healthcare professionals should be encouraged and will hopefully lead to changes in healthcare policies and improved health outcomes.

Summary

Hepatitis C is a major international healthcare dilemma and occurs frequently in populations who suffer from other healthcare disparities. This hepatitis C initiative included an assessment of community need; development and implementation of an evidence-based hepatitis C treatment program; evaluation of programming by analyzing individual health perceptions pertaining to barriers to treatment; and provided early outcome evaluation. The community-based hepatitis C treatment clinic was developed with collaborative efforts by healthcare providers, institutional leaders, and community professionals generating a multidisciplinary approach to hepatitis C care. The conceptual

framework of the Chronic Care Model helped to focus clinic programming on patient education, support, and collaborations between healthcare professionals.

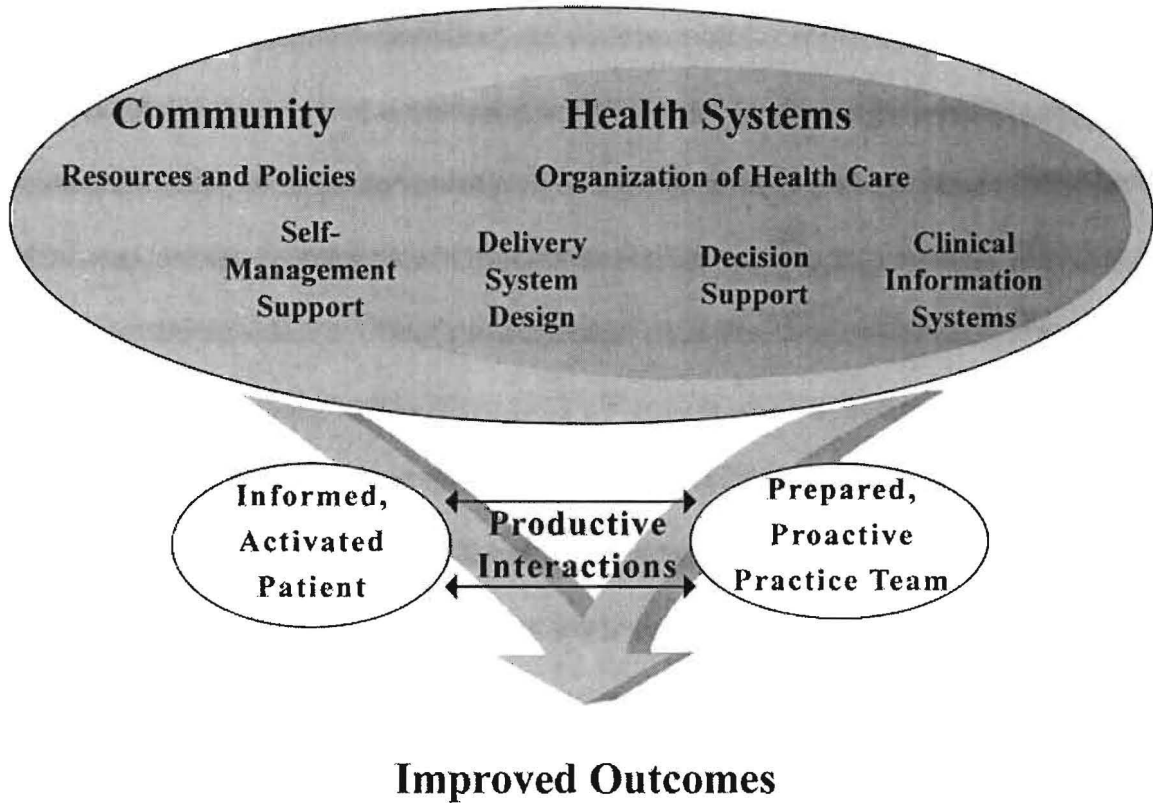
The long term outcomes of this project will be evaluated by the preparedness in this Western Michigan community for the impending impact of hepatitis C this decade. The implementation of the hepatitis C clinic allowed community providers access to adequate care for their patients and early program evaluation showed improved health perceptions of individuals with hepatitis C.

Appendices

Appendix A

Chronic Care Model

The Chronic Care Model

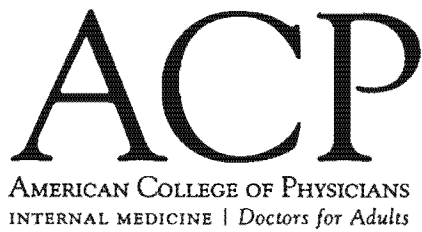


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From "Chronic Disease Management: What Will It Take to Improve Care for Chronic Illness?" Wagner, E. H. 1998, *Effective Clinical Practice*, 1. Reprinted with permission (Appendix B)

Appendix B

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WAACP1217568

June 22, 2012

Grand Valley State University
1 Campus Dr.
Allendale, MI 49401-9403

Dear Ms. Leigh;

Thank you for your request to print (dissertation) the following from *Effective Clinical Practice*:

Figure 1, *Effective Clinical Practice*, 1998, Vol1, Chronic Disease Management: What Will It Take to Improve Care for Chronic Illness? Wagner EH

Permission is granted to print the preceding material with the understanding that you will give appropriate credit to *Effective Clinical Practice* as the original source of the material. Any translated version must carry a disclaimer stating that the American College of Physicians is not responsible for the accuracy of the translation. This permission grants non-exclusive, worldwide rights for this edition in print (dissertation) for not for profit only. ACP does not grant permission to reproduce entire articles or chapters on the Internet unless explicit permission is given. This letter represents the agreement between ACP and Elaine Leigh, MSN, FNP-BC for request WAACP1217568 and supersedes all prior terms from the requestor.

Thank you for your interest in *Annals of Internal Medicine*. If you have any further questions or would like to discuss the matter further, please contact me at 856-489-8555 or fax 856-489-4449.

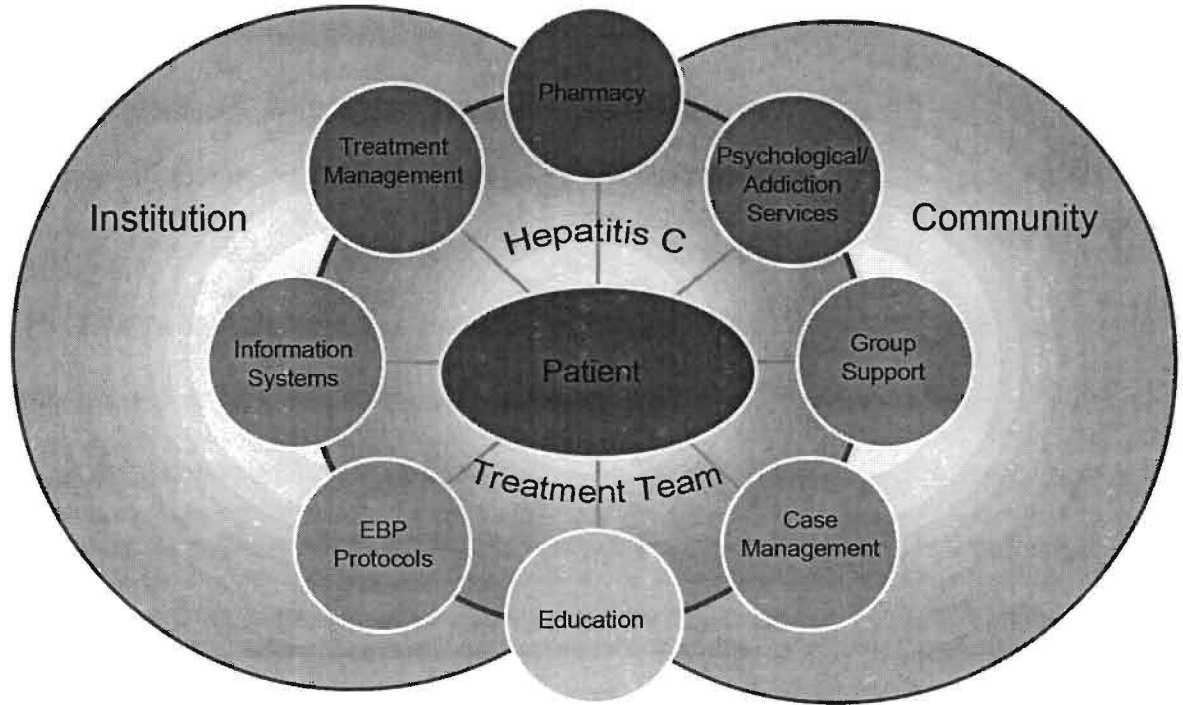
Sincerely,

Gina Brown
Permissions Coordinator

Appendix C

Multidisciplinary Model of Care for Hepatitis C

Multidisciplinary Model of Care for Hepatitis C



Appendix D

Hepatitis C Initiative Introductory Letter

Hepatitis C Initiative Introductory Letter

February 23, 2011

Colleague(s), did you know:

Hepatitis C (HCV) is the most common blood-borne infection in the United States and is the leading cause of liver disease according to the National Institutes of Health.

The Centers of Disease Control and prevention estimates that 3.2 million people are affected with HCV within the US. The number of new cases is declining, but the total number of deaths is expected to rise in the next 20 years due to prevalent cases with long-standing infection.

Chronic hepatitis C accounts for 8,000-10,000 deaths per year.

Over 700 Chronic Hepatitis C cases have been reported to the Muskegon County Health Department since 2006.

We are pleased to announce a new community healthcare initiative. A grass roots effort is taking place with support of community leaders to improve the care for individuals with hepatitis C. This initiative is moving forward through collaborative efforts with doctoral student Elaine A. Leigh on the development of a multidisciplinary hepatitis C treatment program. Ms Leigh is currently completing her Doctoral of Nursing Practice (DNP) at Grand Valley State University and brings years of experience in gastroenterology and hepatitis treatment. Her dedication to this project will assist in the development of a sustainable program and increase access to treatment for those with hepatitis C.

Barriers to treatment will be modified by securing partners in practice. Psychological services, case management, pharmaceutical support, patient education and support programs will be included in the program design.

We need your help. Assessing your opinion of the magnitude of this issue will assist in early project development. ***You are encouraged to complete the survey by clicking on the link or copy and paste the address into your web browser to Survey Monkey by March 11, 2011.***

<https://www.surveymk.com/s/GMCHepatitisCNeedsAssessment>

All information will remain confidential. At the bottom of the survey we are collecting names of providers and practices only to ensure we collect an appropriate representative sample from your area.

Thank you in advance for your support of this community healthcare initiative.

Appendix E

Community Hepatitis C Needs Assessment

Community Hepatitis C Needs Assessment

Thank you for your willingness to complete this brief survey. It is important that each provider in the practice fill out a separate survey.

Please answer the questions in numerical order

Please identify specific barriers you have encountered in getting your patients referred for

<p>1. How many hepatitis C patients have you assessed/diagnosed in the last year?</p> <p><input type="checkbox"/> 0-5</p> <p><input type="checkbox"/> 6-10</p> <p><input type="checkbox"/> 11-20</p> <p><input type="checkbox"/> 21-30</p> <p><input type="checkbox"/> >30</p>	<p>5. How likely are you to order a hepatitis profile should they disclose history of blood transfusion?</p> <p><input type="checkbox"/> Very likely</p> <p><input type="checkbox"/> Likely</p> <p><input type="checkbox"/> Somewhat likely</p> <p><input type="checkbox"/> Unlikely</p>
<p>2. How likely are you to ask a routine patient about a history of intravenous (IV) drug use?</p> <p><input type="checkbox"/> Very likely</p> <p><input type="checkbox"/> Likely</p> <p><input type="checkbox"/> Somewhat likely</p> <p><input type="checkbox"/> Never</p>	<p>6. How likely are you to refer a patient for hepatitis C treatment?</p> <p><input type="checkbox"/> Very Likely</p> <p><input type="checkbox"/> Likely</p> <p><input type="checkbox"/> Somewhat unlikely</p> <p><input type="checkbox"/> Unlikely</p>
<p>3. How likely are you to order a hepatitis profile should they disclose their use of IV drugs?</p> <p><input type="checkbox"/> Very likely</p> <p><input type="checkbox"/> Likely</p> <p><input type="checkbox"/> Somewhat likely</p> <p><input type="checkbox"/> Unlikely</p>	<p>7. How likely are you to encounter barriers in getting your patients referred for hepatitis C treatment?</p> <p><input type="checkbox"/> Very likely</p> <p><input type="checkbox"/> Likely</p> <p><input type="checkbox"/> Somewhat likely</p> <p><input type="checkbox"/> Unlikely</p>
<p>4. How likely are you to ask a routine patient about a history of blood transfusion?</p> <p><input type="checkbox"/> Very likely</p> <p><input type="checkbox"/> Likely</p> <p><input type="checkbox"/> Somewhat likely</p> <p><input type="checkbox"/> Unlikely</p>	<p>8. How likely is it for you to refer patients to a dedicated, multidisciplinary hepatitis C treatment clinic in Muskegon?</p> <p><input type="checkbox"/> Very likely</p> <p><input type="checkbox"/> Likely</p> <p><input type="checkbox"/> Somewhat likely</p> <p><input type="checkbox"/> Unlikely</p>

hepatitis C treatment: _____

Name of person who completed the questionnaire: _____

Name of practice: _____ phone: _____

Appendix F

Hepatitis C Initiative Stakeholder Meeting Invitation

Hepatitis C Initiative Stakeholder Meeting Invitation

April 1, 2011

Colleague(s)

I am writing to ask you to participate in a collaborative community healthcare initiative to improve outcomes and efficiency of care for patients with Hepatitis C. We are developing a multidisciplinary treatment program to better serve patients in our area and we are seeking your opinion. As you know, there are numerous biopsychosocial challenges in successfully caring for people with hepatitis C, and treatment programs can be labor intense for the patient and healthcare providers. Our program has two specific goals. First, to increase access to treatment and also to improve therapy outcomes by instituting a collaborative evidenced-based program.

We are developing a taskforce of professionals to further discuss the magnitude of the health dilemma posed by hepatitis C in our community by reviewing results of a recent Hepatitis C Needs Assessment from primary care providers in our area. Ultimately we are looking for individuals who are interested in assisting with the coordination of services to better serve patients with hepatitis C. If you interested in being part of this program development or have overall feedback or comments regarding this project, please join us at 7:00am on Friday April 29, 2011 (location undisclosed).

Thank you in advance for your support of this community healthcare initiative.
Respectfully Submitted,

Steering Committee Members
Hepatitis C Initiative

Appendix G

Multidisciplinary Partnerships

Multidisciplinary Partnerships

Multidisciplinary Partner	Institutional/Community Referral	Reason For Consultation	Continuation of Care
Nursing (Advanced Practice Nurse/Registered Nurse)	Institutional	Provides the initial health assessment, orders required pretreatment laboratory studies, and provides HCV education. Determines eligibility for physician consultation.	APN will provide on-going management of hepatitis C treatment once patient is deemed eligible for treatment RN will provide ongoing monitoring of medication side effects and laboratory schedules.
Infectious Disease Physician	Institutional	Provides final clearance for patient to initiate hepatitis C treatment. This will require evaluation of all pretreatment testing and referral consultations.	Collaboration with APN on treatment progress.
Primary Care Provider	Community	Provides on-going healthcare management of individual's general health and chronic illnesses.	Collaboration with HCV treatment team to manage medication side effects
Psychiatric/ Psychological	Community	Psychological evaluation for stability of mental illness	For moderate to severe mental illness, continuous monitoring treatment is required
Pharmaceutical Support	Both	Evaluation for drug-to-drug interactions, patient assistance programs, authorization requirements, and educational materials	Requires frequent authorization documentation
Social Work/Case management	Community	Evaluation for health insurance or financial barriers to receiving treatment	May require frequent updates in employment, housing, and transportation stability
Ophthalmologist/ Optometrists	Community	Evaluation of ocular and visual stability, especially for those with diabetes mellitus	Follow up care required for any visual changes during treatment
Gynecological/ Obstetrician	Community	Contraception Management (Ribavirin is a Pregnancy category 3 which requires females to adhere to sex practices using 2 forms of non-estrogen forms of birth control)	Monthly pregnancy tests for all female patient on treatment who are capable of reproduction
Radiologist/ Pathologist	Institutional	Provides and evaluates liver imaging and liver biopsies. These results partly determine the course of treatment	Repeat exams as necessary
Cardiologist/Nephrologist	Community	Evaluation for stability of history of coronary artery disease or kidney disease	May require pretreatment electrocardiogram gram and/or echocardiogram

Appendix H
Informed Consent

Informed Consent

Study Title: Evaluation of a Community-Based Hepatitis C Treatment Program

Program Evaluator: Elaine A. Leigh

Introduction

You have been asked for permission to look at your medical record. Before you decide to agree or not agree, or not to volunteer, we want you to know as much as possible about this project. The U. S. federal government expects us to provide this informed consent paper to you and you will be asked to sign it. Please read it carefully and talk to the investigator, Elaine A. Leigh, if you have any questions about the study. You may also want to talk about it with your family or friends.

There are general ideas that apply to all project involving people done at Mercy Health Partners:

1. Taking part in the project is entirely up to you. This means that you do not have to be involved in the project if you don't want to.
2. If you agree to give consent for us to review your medical record, and then change your mind, you can ask us to stop. There is no penalty for this.
3. You may not gain any benefit in taking part in the project. However, we may learn more about hepatitis C treatment programs from you, and this may help others in the future.

Has this project been approved by the hospital?

Yes. The project has been reviewed and approved by the IRB at Mercy Health Partners. The members of the IRB are physicians, other healthcare professionals and community members. They volunteer their time and expertise in reviewing all projects done at Mercy Health Partners. Because the program evaluator is a graduate student, Grand Valley State University's Human Research Review Committee (HRRC) has also approved the study.

Why was I asked to be included in this project?

You were asked to be in the project because you have been evaluated at the hepatitis C clinic. We are asking all patients who have been seen at the clinic between October 1, 2001 and March 15, 2012 for consent to look at their medical records since they have been at the clinic.

What is the purpose of the project?

The purpose of this project is to complete an initial program evaluation of the hepatitis C treatment program started at Hackley Hospital in Muskegon Michigan.

What do I have to do to be part of the project?

This project requires your permission to review your medical records. Once you have read the consent, had your questions answered, you will be asked to sign this from.

What is the duration of the project?

When the data has been collected and reported from those patients who give their consent, the project will be complete.

What are the risks and discomforts?

There are no known health risks for those who agree to be in this project. To keep your data private, it will be copied to another form without your name, address, or other personal information that could identify you.

What are the benefits of being part of this project?

There are no known benefits to you for being a part of this project, but clinic doctors and nurses will learn more about the services they give to you. It may help them find out if the hepatitis C treatment program is meeting patients' needs. This information may be shared with other nurses and doctors starting programs like this one.

What are my rights and responsibilities?

Even if you agree to give access to your medical records for this project, you may choose to have your information removed later by calling the program evaluator, Elaine A. Leigh.

Who will see my records and how will they be kept confidential?

Only those people who work on the project will see any record that could identify you. No one will give out your name or personal information. Information you give us will be added to information from other people in the project before it is reported in public. No public reports will use your name, address, or other personal data that could be linked to you. You will be asked to sign a Health Insurance Portability and Accountability Act (HIPAA) form with your informed consent to allow the program evaluator to review your information. A code will be used to further protect your data.

Also, as part of routine reviews of projects, members and staff of the Mercy Health Partners Institutional Review Board (IRB) may contact you about your experience with this study.

What are my financial responsibilities?

There is no monetary reward or cost for being part of this project.

If I take part in this project, can I also participate in other project/studies?

Agreeing to take part in this project does not keep you joining other projects.

If I don't want to be in the project any more, what should I do?

You are free to leave the project at any time. If you decide to leave the project, there is no penalty. If you decide to leave the project, all you have to do is contact the program evaluator listed at the end of this form.

Could I be taken out of the project even if I want to continue to participate?

Yes. There are some reasons why you could be taken out of the project, although unlikely, the project for some reason could be suspended or cancelled.

Who can I contact for more information about this project?

The names and contact information for the program evaluator is listed below. You may contact her if you want to:

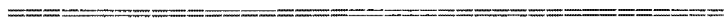
- Ask more questions
- Obtain more information about the project
- Discuss any concerns about the project you may have
- Stop participating in the project before it is finished

Elaine A. Leigh, MSN, FNP-BC
 Hepatitis C Program Evaluator
 Doctor of Nursing Practice Student
 Grand Valley State University
 301 Michigan St. NE, Grand Rapids, MI 49503
 (616) 331-5694

Who else can I contact if I have any concerns about the study?

Ruth Ann Brintnall, PhD, AOCN, CHPN, APRN-BC
 Student Advisor
 Kirkhof College of Nursing
 Grand Valley State University
 301 Michigan St. NE, Grand Rapids, MI 49503
 (616) 331-3338

If you have any questions about your rights as a participant in this project please contact: Grand Valley State University Human Research Review Committee at (616) 331-3197. Mercy Health Partners Institutional Review Board at (231) 672-3941.



I understand that by agreeing to participate in this project, I am responsible for informing the program evaluator of any concerns.

I have had a chance to ask questions about the project and was given enough time to make a decision about being part of the project. I have talked to as many people as I need to help me make my decision. I understand that my participation is **voluntary**. I have received a copy of this form and willingly agree to participate in this project.

 Participant's Signature

 Date

 Witness Signature

 Date

Appendix I
Health Perception Survey

Health Perception Survey

Directions: In order to best meet your needs, please respond to each of the following statements by marking an (X) on the line that best corresponds to your educational needs in the past two weeks. Knowing your needs will assist clinic staff in offering appropriate resources as you complete treatment for hepatitis C.

Example: How well do you understand the disease of hepatitis C? Marking an (X) near the VERY LITTLE would indicate you do not understand the disease of hepatitis C. You can mark the line anywhere along the line.

When thinking about the past two weeks, please place an (X) on the line below each statement to identify the degree to which you:

<p>1. Felt in control over the management of your hepatitis C</p> <div style="border: 1px solid black; padding: 5px; margin-top: 5px;"> <div style="display: flex; justify-content: space-between; border-bottom: 1px solid black; margin-bottom: 5px;"> </div> <div style="display: flex; justify-content: space-between; margin-bottom: 5px;"> 0 50 100% </div> <div style="display: flex; justify-content: space-between; margin-bottom: 5px;"> VERY LITTLE SOMEWHAT VERY MUCH </div> </div>
<p>2. Had appropriate resources to manage your hepatitis C</p> <div style="border: 1px solid black; padding: 5px; margin-top: 5px;"> <div style="display: flex; justify-content: space-between; border-bottom: 1px solid black; margin-bottom: 5px;"> </div> <div style="display: flex; justify-content: space-between; margin-bottom: 5px;"> 0 50% 100% </div> <div style="display: flex; justify-content: space-between; margin-bottom: 5px;"> VERY LITTLE SOMEWHAT VERY MUCH </div> </div>
<p>3. Had adequate psychological/emotional support</p> <div style="border: 1px solid black; padding: 5px; margin-top: 5px;"> <div style="display: flex; justify-content: space-between; border-bottom: 1px solid black; margin-bottom: 5px;"> </div> <div style="display: flex; justify-content: space-between; margin-bottom: 5px;"> 0 50% 100% </div> <div style="display: flex; justify-content: space-between; margin-bottom: 5px;"> VERY LITTLE SOMEWHAT VERY MUCH </div> </div>
<p>4. Felt supported in making decisions about your hepatitis C care</p> <div style="border: 1px solid black; padding: 5px; margin-top: 5px;"> <div style="display: flex; justify-content: space-between; border-bottom: 1px solid black; margin-bottom: 5px;"> </div> <div style="display: flex; justify-content: space-between; margin-bottom: 5px;"> 0 50% 100% </div> <div style="display: flex; justify-content: space-between; margin-bottom: 5px;"> VERY LITTLE SOMEWHAT VERY MUCH </div> </div>
<p>5. Understood what is expected of you in managing your hepatitis C</p> <div style="border: 1px solid black; padding: 5px; margin-top: 5px;"> <div style="display: flex; justify-content: space-between; border-bottom: 1px solid black; margin-bottom: 5px;"> </div> <div style="display: flex; justify-content: space-between; margin-bottom: 5px;"> 0 50% 100% </div> <div style="display: flex; justify-content: space-between; margin-bottom: 5px;"> VERY LITTLE SOMEWHAT VERY MUCH </div> </div>
<p>6. Had confidence in yourself to follow a HCV treatment plan</p> <div style="border: 1px solid black; padding: 5px; margin-top: 5px;"> <div style="display: flex; justify-content: space-between; border-bottom: 1px solid black; margin-bottom: 5px;"> </div> <div style="display: flex; justify-content: space-between; margin-bottom: 5px;"> 0 50% 100% </div> <div style="display: flex; justify-content: space-between; margin-bottom: 5px;"> VERY LITTLE SOMEWHAT VERY MUCH </div> </div>

Appendix J

Patient Information Handout

Patient Information Handout

To the Patient:

You are here to be evaluated for treatment for hepatitis C. We have developed a program to give you the best chance of successful treatment. Many of you may already know the treatment for hepatitis C can be challenging but we are here to support and guide you. Be aware that not everyone who is evaluated will be eligible for treatment. We carefully determine treatment eligibility on a one-to-one basis as everyone has a different healthcare background.

As part of our new program we are asking you to complete a few short surveys at the beginning of some of your visits to the clinic. Our program is focused on providing you with the best education and support to manage your illness while you are going through treatment. The survey questions allow us to determine which areas we can provide further assistance to you.

You will not be required to write anything; however, you will be asked to simply mark an "X" when answering the questions. Your surveys will remain as part of your medical record and therefore confidential.

Hepatitis C Treatment Team

Appendix K

Informed Consent Narrative

Informed Consent Narrative

Hello _____,

My name is _____ and I am a part of the office team here at the hepatitis clinic. I would like to invite you to participate in a study we are doing at the clinic to evaluate our program. We want to learn more about our patients who are enrolled at the clinic including what you think about common factors that may impact your treatment. We are inviting all patients who come to the clinic. Is it okay if I continue?

First, your participation is voluntary. You will not likely benefit directly from participating in the study but what is learned may help you or someone else. The study will not require any additional work from you. The study will use information already in your medical chart, like the surveys you may have completed already. Yet, it will require that you give us your permission to allow an investigator, who is a Doctor of Nursing Practice student at GVSU, to access your medical records. The investigator will collect information such as your age, your type of hepatitis C, and your county of residence.

Your name will not be recorded or used anywhere...as a matter of fact, your information will be coded as it is collected to fully protect you. You will have an opportunity to ask me questions and you can call the investigator if I cannot answer your questions. We want you to read your consent carefully before you decide. The consent will have addition information about the study. Do you have questions now?

Appendix L

Institutional Review Board Grand Valley State University



DATE: February 15, 2012

TO: Elaine Leigh, MSN
FROM: Grand Valley State University Human Research Review Committee
STUDY TITLE: [282940-2] Evaluation of a Community-Based Hepatitis C Treatment Program
REFERENCE #: 12-82-H
SUBMISSION TYPE: Revision

ACTION: APPROVED
EFFECTIVE DATE: February 15, 2012
REVIEW TYPE: Exempt Review

Thank you for your submission of materials for this research study. The Human Research Review Committee has reviewed your submission and approved your research plan application under Exempt review, category 1-2 and 1-4. This approval is based on no greater than minimal risk to research participants. All research must be conducted in accordance with this approved submission.

Please insert the following sentence into your information/consent documents as appropriate. All project materials produced for participants or the public must contain this information.

This EXEMPT research protocol has been approved by the Human Research Review Committee at Grand Valley State University. File No. 12-82-H.

Exempt protocols do not require formal renewal. However, we do confirm on an annual basis that the research continues to meet the criteria for exemption and that there have been no significant changes in activity or key personnel. By February 15, 2013, please complete the brief **Continuing Review Application Form**, available in your IRBNet Project Designer, or from our website, www.gvsu.edu/hrrc, and submit this form via IRBNet.

Once study enrollment and data analysis have been concluded, please complete the **Closed Protocol Reporting Form** on our website, and upload a saved copy to IRBNet.

This project remains subject to the research ethics standards of HRRC policies and procedures pertaining to exempt studies.

Please note the following in order to comply with federal regulations and HRRC policy:

1. Any revision to previously approved materials must be approved by this office prior to initiation. Please use the *Change in Protocol* forms for this procedure. This includes, but is not limited to, changes in key personnel, study location, participant selection process, etc.
2. All UNEXPECTED PROBLEMS and SERIOUS ADVERSE EVENTS to participants or other parties affected by the research must be reported to this office within two days of the event occurrence. Please use the UP/SAE Report form.

3. All instances of non-compliance or complaints regarding this study must be reported to this office in a timely manner. There are no specific forms for this report type.

If you have any questions, please contact the HRRC Office, Monday through Thursday, at (616) 331-3197 or hrrc@qvsu.edu. The office observes all university holidays, and does not process applications during exam week or between academic terms. Please include your study title and reference number in all correspondence with this office.

cc:

Appendix M

Institutional Review Board Mercy Health Partners



MERCY HEALTH PARTNERS

February 16, 2012

Elaine A. Leigh MSN, FNP-BC
15306 Forest Park Dr.
Grand Haven, MI 49417

Dear Ms. Leigh,

The MHP IRB has reviewed your project entitled, Evaluation of a Community-Based Hepatitis C Treatment Program. Specifically the following documents were reviewed:

- Written plan for the evaluation
- Hepatitis C Treatment Program Evaluation Tool.
- Informed Consent Narrative
- Informed Consent Document

This project is exempt from IRB oversight, based on a design which involves a retrospective review of existing data, and a plan for securing protected health information. Further reports to the MHP IRB are not required.

Thank you for your submission, and please contact me if you have any questions or concerns.

Sincerely,

Kathleen Thomas, RN, MSN
MHP IRB Representative

HACKLEY CAMPUS

1700 Clinton Street • P.O. Box 3302
Muskegon, MI 49443-3302
231.726.3511 • (800) 825.4677

LAKESHORE CAMPUS

72 S. State Street
Shelby, MI 49455
231.861.2156

MERCY CAMPUS

1500 E. Sherman Blvd. • P.O. Box 358
Muskegon, MI 49443-0358
231.672.2000 • (800) 368.4125

MUSKEGON GENERAL CAMPUS

1700 Oak Avenue • P.O. Box 358
Muskegon, MI 49443-0358
231.672.2000 • (800) 368.4125

www.mercyhealthpartners.org

Appendix N

Hepatitis C Treatment Program Evaluation Tool

Hepatitis C Treatment Program Evaluation Tool

_____ (Patient Code)
Demographics/History

Birth date/age	Genotype	Treatment history
	1 or 4/2 or 3	Naive/Partial Responder/Relapser
Gender	Residential County	Community Referral: Yes/No
Male/Female		Agency:

Health Perception Survey

In the previous 2 weeks have : 2mm=1%	Date (Baseline/education session)	Date (Consultation)	Date (Start of Treatment)	Date (First follow up)	Date (Second follow up)
Question 1 <i>Felt in control over the management of your hepatitis C</i>	__mm=__%	__mm=__%	__mm=__%	__mm=__%	__mm=__%
Question 2 <i>Had appropriate resources to manage your hepatitis C</i>	__mm=__%	__mm=__%	__mm=__%	__mm=__%	__mm=__%
Question 3 <i>Had adequate psychological/emotional support</i>	__mm=__%	__mm=__%	__mm=__%	__mm=__%	__mm=__%
Question 4 <i>Felt supported in making decisions about your hepatitis C care</i>	__mm=__%	__mm=__%	__mm=__%	__mm=__%	__mm=__%
Question 5 <i>Understood what is expected of you in managing your hepatitis C</i>	__mm=__%	__mm=__%	__mm=__%	__mm=__%	__mm=__%
Question 6 <i>Had confidence in yourself to follow a HCV treatment plan</i>	__mm=__%	__mm=__%	__mm=__%	__mm=__%	__mm=__%

Appendix O

Hepatitis C Clinic Documents and Correspondences

Hepatitis C Clinic Documentation and Correspondence

Hepatitis C Pretesting Requirements

Date	Test	Normal	Results
	Hepatitis C Genotype		
	VIRAL LOAD	Undetected	
	CBC w/Diff	3.8-10.8 12-16/37-47 150-450	WBC HGB/HCT PLT
	CMP	74-106 7-20/0.7-1.2 15-46/15-46	GLU BUN/CR AST/ALT
	TSH	0.47-4.68	
	Uric acid	2.5-6.6	
	Triglycerides	5-150	
	Iron studies	37-170 265-497 15-50 6.2-264	Serum Iron TIBC % Sat Ferritin
	Protime/INR	11-13sec	
	Pregnancy (when applicable)		
	Anti Nuclear Antibody (ANA)	Neg	
	Anti Smooth Muscle Antibody (ASMA)	Neg	
	Ceruloplasmin	16-45.0	
	Alphafetoprotein (AFP)	<6.0	
	Hepatitis B surface antibody (HBVsAB)	Absent	
	Hepatitis A antibodies (HAVAB)	Neg	
	HIV 1/2	Neg	
	Eye exam		
	EKG (when application)		
	Imaging (CT, Ultrasound)		
	Liver biopsy		

Hepatitis C Clinic Intake Assessment

Date: _____

Name: Birth date: Age: Address: City: State: Zip: Phone: Alt phone:	Primary Care Provider: Insurance: Pharmacy: Support person phone:
Hepatitis History	Past Medical History
Approx date of diagnosis: Genotype: HCV RNA: Liver biopsy: Previously treated: Tolerated? Imaging:	Y/N DM Y/N HTN Y/N CAD Y/N CHF Y/N COPD Y/N Other(s): Medication list reviewed: Allergies: Last Eye Exam:
Mental Health History	Substance History
Y/N Depression Y/N Bipolar Y/N Schizophrenia Y/N Currently medicated Y/N Current/former counseling Y/N Suicidal thoughts/attempts	Y/N Alcohol: Y/N Recreational drug use: Y/N Tobacco:

Risk factors	Contraception
Y/N IV drug use	Y/N Sterilization procedure: Hysterectomy/Tubal ligation/Vasectomy
Y/N Blood transfusions before 1992	Y/N Regular menstrual cycles LMP:
Y/N Tattoo, piercings	Current birth control:
Y/N Known exposure to someone w/HCV	Y/N Menopause LMP:
Y/N Healthcare personnel	
Social	Vaccinations
Y/N Married Lives with: Working hours: Sleeping hours: Source of support:	Y/N Hepatitis B Virus (HBV) Y/N Hepatitis A Virus (HAV) Y/N Seasonal flu Y/N Pneumonia
Relative Contraindication	Absolute Contraindication
Y/N Hgb < 10, ANC <1000, PLTs<50	Y/N Uncontrolled, active, major psychiatric illness-Especially depression
Y/N Hemodialysis and/or GFR <50	Y/N Hepatic Decompression (encephalopathy, coagulopathy, ascites)
Y/N Active Substance and alcohol use	Y/N Severe, uncontrolled medical disease (DM, CHF, CAD, HTN, TB, Cancer)
Y/N Anticipated Poor compliance	Y/N Untreated thyroid disease
Y/N Untreated mental health disorder	Y/N Pregnancy, nursing, child-bearing potential (anticipated pregnancy, no birth control)
Y/N Stable auto-immune disease	Y/N Active, untreated autoimmune disease
Y/N Thalassemia and sickle cell anemia	Y/N HIV co-infected Advanced uncontrolled HIV (CD4 <100) Concurrent use of didanosine (ddl)
Y/N Sarcoidosis	
Y/N For HIV co-infected: CD4< 200 or Concurrent use if Zidovudine (ZDV)	

Clinical Presentation

<p>Symptoms:</p> <p>Y/N Asymptomatic</p> <p>Y/N Fatigue</p> <p>Y/N Anorexia</p> <p>Y/N Myalgia</p> <p>Y/N Arthalgias</p> <p>Y/N Asthenia</p> <p>Y/N Weight loss (except where ascites)</p>	<p>Signs:</p> <p>Skin:</p> <p>Y/N Spider angiomas</p> <p>Y/N Porphria cutanea tarda</p> <p>Stigmata of cirrhosis:</p> <p>Y/N Mild jaundice</p> <p>Y/N Hepatomegaly</p> <p>Y/N Splenomegaly</p> <p>Y/N Peripheral edema</p> <p>Y/N Hemorrhoids</p> <p>End Stage Liver Disease (Decompensated)</p> <p>Y/N Ascites</p> <p>Y/N Encephalopathy</p> <p>Y/N Coagulopathy (PT >3sec; INR >1.3)</p> <p>Y/N Varices (bleeding or non-bleeding)</p>
---	---

Childs- Pugh

The score employs five clinical measures of liver disease. Each measure is scored 1-3, with 3 indicating most severe derangement.

Measure	1 point	2 points	3 points	Patient Value Date _____
<u>Total bilirubin</u> , µmol/l (mg/dl)	<34 (<2)	34-50 (2-3)	>50 (>3)	
<u>Serum albumin</u> , g/l	>35	28-35	<28	
<u>PT INR</u>	<1.7	1.71-2.20	> 2.20	
<u>Ascites</u>	None	Mild	Severe	
<u>Hepatic encephalopathy</u>	None	Grade I-II (or suppressed with medication)	Grade III-IV (or refractory)	

HEPATITIS C THERAPY CONSENT

Contraception

- For patients receiving pegylated interferon/ribavirin/telaprevir (Incivek) therapy

I _____ am aware that ribavirin, one of the oral components of Hepatitis C therapy, can cause birth defects. Defects can be caused if either the mother or the father is using this medication.

- I realize if I become pregnant, or impregnate someone, the resulting child could have birth defects.
- I agree to use **two forms of birth control** during my therapy and for 6 months afterwards.
- If I am female, I may be required to obtain negative pregnancy test prior to starting therapy.
- If I am female I may be required to submit to monthly pregnancy tests for the duration of my therapy and for six months after therapy is finished.
- I agree to advise the clinic if either I or my partner fail to use appropriate contraceptive or suspect a pregnancy may have occurred despite the use of contraceptives. I understand that oral contraceptive **may not** be as effective while I am on treatment.

Some examples of non-hormonal forms of birth control are: a male condom with spermicidal jelly or female condom with spermicidal jelly; a diaphragm with spermicidal jelly, a cervical cap with spermicidal jelly, or an intrauterine device (IUD).

_____ (patient initials)

- For patients receiving pegylated interferon/ribavirin therapy

I _____ am aware that ribavirin, the oral component of Hepatitis C therapy, can cause birth defects. Defects can be caused if either the mother or the father is using this medication.

- I realize if I become pregnant, or impregnate someone, the resulting child could have birth defects.
- I agree to use **two forms of birth control** during my therapy and for 6 months afterwards.
- If I am female, I may be required to obtain negative pregnancy test prior to starting therapy.
- If I am female I may be required to submit to monthly pregnancy tests for the duration of my therapy and for six months after therapy is finished.
- I agree to advise the clinic if either I or my partner fail to use appropriate contraceptive or suspect a pregnancy may have occurred despite the use of contraceptives. I understand that oral contraceptive **may not** be as effective while I am on treatment.

_____ (patient initials)

Mental Health

- I understand Hepatitis C therapy can have side effects such as depression.
- I agree to notify my physician immediately have symptoms of severe depression or suicidal thoughts or plans.
- At the presented time, I do (), do not (), have a history or current symptoms of depression or psychiatric disorders.
- If I have a history of depression or any psychiatric disorders, I may be required to have clearance by my psychologist/psychiatrist for treatment
- If I have a history of depression or any psychiatric disorders, I may be required to be monitored by my therapist throughout the entire treatment.

_____ (patient initials)

Compliance

- I understand that Hepatitis C therapy can cause a decrease in certain blood cells, and for this reason, frequent blood tests will be necessary.
- I understand the importance of:
 - Regularly scheduled appointments
 - Blood work needs to be done in a timely manner and when requested
 - Monthly pregnancy test (where applicable)
 - Taking the medication as prescribed
 - Reporting any suggested changes in my medications by any provider
- I understand that my treatment may be cancelled if I do not comply with these requirements

_____ (patient initials)

I have been informed or and understand the risks and benefits of Hepatitis C therapy. I hereby request to begin Hepatitis C therapy.

Patient signature _____ Date _____

Witness _____ Date _____

Support Person _____ Date _____

Hepatitis C Clinic Referral Letter

To Whom it May Concern,

This note is to let you know we have received a written referral from your healthcare provider for you to be seen at the hepatitis C treatment clinic. At this time, we are processing referrals and scheduling appointments but because of the complexity of treatment we have a limited number of people we can see. We will be contacting you for an appointment when we are able.

We encourage you be as educated as possible about hepatitis C before your appointment. Additional education materials will be given to you when you are seen but in the meantime a good website for gaining information is:

www.HCVadvocate.org

We appreciate your patience,

Hepatitis C Treatment Team

Medication Reconciliation

Date Reviewed	Medications	Needs Reconciliation	Date Reconciled
		Y/N	
		Y/N	
		Y/N	
		Y/N	
		Y/N	
		Y/N	
		Y/N	
		Y/N	
		Y/N	
		Y/N	
		Y/N	
		Y/N	
Date	Allergies	Reaction	
	NKMA <input type="checkbox"/>		

Date	Signature(s)	Initials

Common Medication Side Effects

Lab Work

Lab work is an important part of your chronic hepatitis C virus (HCV) therapy. Before and during treatment, your doctor will do blood tests. These tests will check for side effects, and also tell you early on how well treatment is working and how long you need to be on it. These tests may include a complete blood count (CBC), viral load test, chemistry panel, and liver function tests. You must stick to your lab schedule because it is an important part of your treatment for HCV.

Anemia

In your blood are red blood cells. Red Blood cells carry oxygen. Oxygen is needed throughout the body for your muscles and organs to work properly. If your red blood cell counts become very low, you may have a condition called anemia. Your healthcare provider (HCP) will check your red blood cell counts periodically.

Anemia is measured with a simple blood test. The blood test may show the amount of hemoglobin in a blood sample. The blood test may also report the hematocrit- the amount of red blood cells in a blood sample. Both values help to inform your HCP on the severity of anemia.

The normal levels for these blood tests are different in men and women. For women, a normal lab value for hemoglobin is > 12 g/dL and a normal hematocrit is > 36%. For men normal lab value for hemoglobin is > 13 g/dL and a normal hemocrit is > 39.

Nutrition

It is important to maintain good nutrition while on chronic hepatitis C therapy to help provide your body with the nutrients it needs. Your medical plan should include healthy food and drink choices and moderate exercise. Exercise not only helps you build muscles, it also helps your body fight off illness and it can improve your mood and your appetite.

Taste Alteration

During treatment for hepatitis C, you may notice that food tastes different. This is called dysgeusia (dis-GOOZ-ee-a), or taste alteration. Food may taste different or it can taste bad. There are things that you can do that may make this easier to live with. After you are done with treatment, you should notice that your sense of taste returns in about 2 to 12 weeks.

Flu-like Symptoms: General Information

Many people feel like they have the flu after they take their chronic hepatitis C medicine. You may have a fever, a headache, and muscle aches that start several hours or days after treatment. Some of these symptoms (fever, headache) may lessen after a few weeks as your body gets used to the medicine.

Flu-like Symptoms: Headaches

You may get headaches when you start treatment for chronic hepatitis C. They often start in the first 4 to 8 hours after treatment. Your headaches may lessen after a few weeks, once your body gets used to the treatment.

First, it is important to understand what things can lead to headaches. You may get headaches after not drinking enough water, not eating enough, stress, sleep problems, or too much or too little caffeine. There are also some medical conditions that can lead to headaches, such as history of migraines, high blood pressure, dental problems/jaw pain, allergies, sinus infection, and other problems. Talk to your healthcare provider (HCP) about what may lead to your headaches and what you can do to manage them.

Nausea

You may feel “sick to the stomach”, “queasy”, or have an “upset stomach”. This is called nausea. It can happen because you are taking chronic hepatitis C medication or because of the chronic hepatitis C itself. You may also have more saliva (spit); dizziness; light-headedness; trouble swallowing; cold, clammy skin; and a fast heart rate. You may feel the worst during the first month or so of treatment, while the body gets used to the medication.

Nausea is one of the common side effects of chronic hepatitis C therapy. Ask your HCP for a complete list of side effects.

Nausea is different for everyone. You might be a little queasy or you may feel very sick. Talk to your HCP if this feeling doesn’t allow you to do things you do every day or if it is hard to take your treatment.

Nausea can come from other things like stress, headaches, other viruses or bacteria, alcoholic beverages, or eating too little or too much. Figuring out things that bring on your nausea can help you and your HCP control it. Some easy steps can make a big difference in how you feel.

Fatigue

People being treated for chronic hepatitis C often feel tired (also known as fatigued). In fact, 65% of people said that they felt fatigued while being treated for chronic hepatitis C. If you are fatigued, you may feel tired, weak, worn out, and unable to get out of bed. Also, you may not feel like doing anything, even the things you once enjoyed, and you may feel down. You may notice these feelings getting worse throughout the day. Fatigue may also be a symptom of depression. Talk to your healthcare provider (HCP) about your fatigue and if you think you may be depressed.

It may help to know that you are not alone – many people with chronic hepatitis C also experience fatigue. Of course, it is important to talk to your HCP about how much energy you have. That way, he or she can give you ways to help.

Problem List

Date	Problem	Recommendations (see side effect management # below)	Date Resolved

	Common Side Effects	Management Suggestions
1	Itching/Rash	Hydrating lotions, apply hydrocortisone as needed, Benadryl 25mg as needed
2	Insomnia	Bedtime routines, avoid caffeine in the evenings, warm showers, low lighting,
3	Fatigue	Conserve energy, rest periods during day
4	Rectal discomfort	Keep area clean and dry, apply OTC hydrocortisone as needed
5	Poor appetite/Nausea	Small meal portions, anti-nausea medications as prescribed, ginger hard candies.
6	Taste Alteration	Eating ½ banana or chocolate may help, avoid metal utensils
7	Muscle aches	Tylenol (limit to <2000mg/day), drink plenty of fluids,
8	Depression, irritability	Report worsening symptoms, take medications as prescribed, stress reduction activities (reading, music, low impact exercise)
9	Hair thinning	Side of effect of medication, nothing can be done to slow process.

LIVER BIOPSY INSTRUCTIONS

Appointment Date: _____ Time: _____

PRE-BIOPSY INSTRUCTIONS

1. Arrive 10-15 minutes before your appointment time, provided that you have completed the necessary paperwork and signed the consent form. Please bring someone to drive you home.
2. Do **not** take any aspirin or medication containing aspirin for 48-hours or preferably one week before the biopsy.
3. Please inform us of any significant bleeding history or clotting problems you have observed. Our radiologist will review your blood tests (PT, PTT) to ensure normalcy. **This test must be performed within six (6) months of your biopsy. If you have had this test done within six months, please tell our staff where and when it was done. If not, you will need to have this test done before your biopsy.**
4. Assume a regular diet for between 2-4 hours prior to biopsy and then only a clear liquid diet for 2 hours prior to the biopsy.
5. For insulin dependent diabetics:
 - a. If eating usual diet for breakfast, take usual insulin dose.
 - b. If breakfast is only clear liquids: hold a.m. fast-acting insulin and take usual a.m. intermediate or long-acting insulin dose.

CARE AFTER LIVER BIOPSY

These instructions are recommended as the best safeguard against complications.

Please follow them closely.

1. Diet: As desired
2. If you experience nausea, stop all food for 1 hour then start with clear liquids. Progress to full liquids, then a light bland diet, then a regular diet. Any carbonated drinks should be room temperature.
3. When the local anesthesia wears off, you may feel pain and soreness. Occasionally, you may experience referred pain in your neck and/or right shoulder. If you need medication for discomfort you may take acetaminophen products such as Tylenol or ibuprofen products such as Advil, Nuprin, Motrin, etc. Do **not** take aspirin for 24 to 48 hours.
4. After your biopsy, rest the remainder of the day. The next day you may return to work or other light activities if they do not involve lifting or straining. Avoid strenuous activities for 48 hours: tennis, running, aerobics, weight lifting, skiing, etc.
5. If you experience excessive bleeding or pain at the biopsy site, light headedness or rapid heartbeat upon standing, shortness of breath, or fever above 100° contact your doctor or the hepatitis C treatment clinic at (213) 728-1887.
6. Your doctor will receive the pathology results in approximately 7 days and he or she will discuss them with you.

Eye Exam Letter

Date _____

Dear Doctor:

We would like to thank you for seeing our patient for an ophthalmologic exam. He/she is scheduled to begin treatment with pegylated interferon for chronic hepatitis C infection.

Treatment with interferon has been associated:

- Retinal artery or vein thrombosis
- Retinal hemorrhages
- Cotton-wool spots
- Optics neuritis
- Papilledema.

Because of this, this FDA has recommended that all patients receive an eye examination at baseline. Furthermore, the FDA suggests that patients with pre-existing ophthalmologic disorders (e.g. diabetic or hypersensitive retinopathy) should also receive periodic ophthalmologist exams during their interferon alpha treatment.

- If there are pre-existing ophthalmologic findings?
 - Recommend exam at three (3) month intervals until the completion of treatment (this can range from 24-48 weeks).
- If you do not find any significant pre-existing problems
 - Recommend exam if changes in vision are reported

If you have any questions or comments, please feel free to contact us at XXX-XXX-XXXX. We would appreciate a faxed ophthalmology evaluation to XXX-XXX-XXXX.

Sincerely,

Hepatitis C Care Team

Primary Care Provider Letter

PATIENT: _____

DATE: _____

RE: Hepatitis C Treatment (HCV)

Dear Healthcare Provider:

We are currently evaluating your patient for hepatitis C treatment. Based on the patients HCV genotype, the treatment course will require medications for up to 48 weeks. These medications potentially cause a wide range of side effects.

There are certain things that we request you to do to stabilize your patient prior to going on this treatment.

- _____ 1. The patient would either need a psychiatric clearance by you or by a psychiatrist.
- _____ 2. The patient would need to have a dilated eye exam to be certain that he/she has no preexisting retinopathy, as this treatment can exacerbate that.
- _____ 3. The patient would need to have a cardiac clearance to be certain that his/her would be able to handle anemia conditions and not have pre-existing coronary artery disease.
- _____ 4. The patient must be off all alcohol and illicit drugs for at least six months.

Hepatitis C infection is found in nearly 40% of patients with alcoholic liver disease (Degos, 1999) and leads to rapid development of liver fibrosis in patients admitting to >40gms per day of alcohol (Degos, 1999)

- _____ 5. We would need pre-existing co-morbid conditions stabilized, this includes things such as diabetes, hypertension, and thyroid disease.
- _____ 6. Finally, if the patient has chronic pain issues, this needs to be monitored closely by you and stabilized prior to going on hepatitis C treatment.

If the marked conditions above have been stabilized, the patient will undergo final evaluation to determine eligibility for hepatitis C treatment with pegylated interferon, ribavirin, and additionally protease inhibitor for those with known genotype 1. Once therapy is initiated, labs are checked frequently and the patient is monitored closely by scheduled visits to the clinic.

If you have any questions in this regard, please do not hesitate to call.

Sincerely, Hepatitis C Care Team

Hepatitis C Education Session

Date _____

Re: Hepatitis C Education Session

Dear Patient:

The Hepatitis C Care Team would like you to attend an educational session which may help you better understand hepatitis C and the risks for transmission of the virus. The class will also include discussions on the medical treatment for hepatitis C, potential side effects, and monitoring requirements during HCV treatment.

The next class will be held on _____ at _____ am/pm in the clinic conference room on XXXX campus.

We encourage you to bring a family member or a friend along with you.

If you have any questions, please feel free to call the XXX-XXX-XXX.

Sincerely,

Hepatitis C Care Team

Psychological Referral Letter

Date: _____

Patient: _____

DOB: _____

Dear Mental HealthCare Provider:

The above mentioned patient is being evaluated for treatment of Hepatitis C with pegylated interferon and ribavirin. The treatment is rigorous and difficult. One of the major side effects of the medication is an increase in depression, anxiety, irritability, and occasionally an increase in pain.

We have been successful in treating patients who have psychiatric diagnosis as long as they have active mental healthcare providers to whom they can turn for additional help as well as good social support. Our team would like you to evaluate this patient for ability to sustain the stress of treatment for up to 48 weeks. In addition, we would like you to work with your patient to formulate a plan of care that includes probable increased contact with a therapist for this period of time. Please fax the psychiatric clearance to: XXX-XXX-XXXX

We appreciate your time and assistance. If you have any questions, please feel free to contact our support staff at: XXX-XXX-XXXX

Sincerely,

Hepatitis C Care Team

HCV Clinic No Response Letter

Date _____

Re: Hepatitis C Treatment Clinic Referral

Dear Patient:

We have received a referral from your primary care physician _____ to schedule you an appointment. At your first appointment we will be gathering basic health information and providing you information on hepatitis C.

We have attempted to contact you by phone and have been unsuccessful in scheduling this appointment. If you are interested in scheduling this initial session please call XXX-XXX-XXXX

We encourage you bring a trusted family member or a friend along with you.

Hepatitis C Care Team

Appendix P

Hepatitis C Treatment Clinic Announcement Letter

Hepatitis C Treatment Clinic Announcement Letter

MEMORANDUM

Date: February 2, 2012
To: Medical Staff
From: Medical Director, Infection Prevention & Control
Chief Medical Officer
Subject: Hepatitis C Clinic

We are in the process of establishing a Hepatitis C Clinic at the Ambulatory Infusion Center. We have begun to see a few patients to get a better idea what the work load will be to better establish staffing requirements as we gear up for larger numbers of patients. To get a better of idea of those anticipated numbers, we would request that you fax any referrals.

At the time of referral, please send us a recent history and physical with an up to date medication list. Please have an ultrasound or CT scan of the liver done in the 12 months prior to the referral and also have the following lab work done within 6 months of the referral:

- Complete Blood Count w/diff (CBCD)
- Hepatitis C RNA Quant (HCVQRNA)
- Comprehensive Metabolic Profile (CMP)
- Protime (PT)/INR
- Iron Panel (IBCPRO) and Ferritin (FER)

Also, the following:

- Hepatitis C genotype (HCVG) – once only, no time frame
- HIV 1/2 Antibody Screen (HIV1/2AS) – within 12 months

After we receive these records, we will contact the patient to schedule an appointment.

Please manage the expectations of the patients you send us regarding:

- 1) ***Timeliness of appointments.*** We have a limited capacity to see and treat patients at this time, although we expect that to change when we increase staffing.
- 2) ***Likelihood of receiving treatment.*** There are significant number of contraindications and relative contraindications to treatment and thus not all patients will be candidates for it at the time of referral.

Contraindications:

- Alcohol use within past 6 months (must be abstinent)
 - Depression – major, uncontrolled
 - Kidney, heart or lung transplant
 - Autoimmune hepatitis or other conditions known to be exacerbated by interferon or ribavirin
 - Untreated thyroid disease
 - Severe concurrent disease such as severe hypertension, heart failure, significant coronary artery disease, poorly controlled diabetes, obstructive pulmonary disease
 - Known hypersensitivity to drugs used to treat HCV.
- 3) ***Treatment can be difficult,*** both because of their requirements for very high level of compliance with the medications combined with the fact that they have significant side effects.

UpToDate has a number of good review articles on this subject, including:

- 1) Overview of the management of chronic hepatitis C virus infection
- 2) Patient selection for antiviral therapy for chronic hepatitis C virus infection
- 3) Patient information, both basic and beyond the basics

Appendix Q

Hepatitis C Initiative Outcome Survey

Hepatitis C Initiative Outcome Survey

Additional Comments:

<p>1. How many hepatitis C patients have you seen in your practice in the last year?</p> <p><input type="checkbox"/> 0-5</p> <p><input type="checkbox"/> 6-10</p> <p><input type="checkbox"/> 11-20</p> <p><input type="checkbox"/> 21-30</p> <p><input type="checkbox"/> >30</p>	<p>5. How likely are you to refer a patient for hepatitis C treatment?</p> <p><input type="checkbox"/> Very Likely</p> <p><input type="checkbox"/> Likely</p> <p><input type="checkbox"/> Somewhat unlikely</p> <p><input type="checkbox"/> Unlikely</p>
<p>2. How likely are you to perform a hepatitis C Risk-Based assessment?</p> <p><input type="checkbox"/> Very likely</p> <p><input type="checkbox"/> Likely</p> <p><input type="checkbox"/> Somewhat likely</p> <p><input type="checkbox"/> Unlikely</p>	<p>6. How likely were you to encounter barriers in getting your patients referred for hepatitis C treatment?</p> <p><input type="checkbox"/> Very likely</p> <p><input type="checkbox"/> Likely</p> <p><input type="checkbox"/> Somewhat likely</p> <p><input type="checkbox"/> Unlikely</p>
<p>3. How likely are you to order hepatitis profile should they disclose risk(s) for hepatitis C?</p> <p><input type="checkbox"/> Very likely</p> <p><input type="checkbox"/> Likely</p> <p><input type="checkbox"/> Somewhat likely</p> <p><input type="checkbox"/> Unlikely</p>	<p>7. How likely will the community based hepatitis C treatment clinic facilitate your ability to care for your patients?</p> <p><input type="checkbox"/> Very likely</p> <p><input type="checkbox"/> Likely</p> <p><input type="checkbox"/> Somewhat likely</p> <p><input type="checkbox"/> Unlikely</p>
<p>4. How likely are you to adopt the Age-Based hepatitis C screening guidelines?</p> <p><input type="checkbox"/> Very likely</p> <p><input type="checkbox"/> Likely</p> <p><input type="checkbox"/> Somewhat likely</p> <p><input type="checkbox"/> Unlikely</p>	<p>8.</p> <p><input type="checkbox"/> You are currently practicing in primary care</p> <p><input type="checkbox"/> You are currently practicing in a specialty practice _____</p> <p><input type="checkbox"/> Other: _____</p>

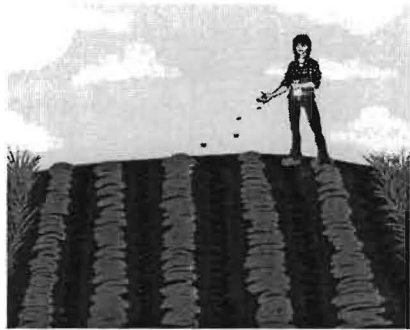
Comments:

Thank you for your participation

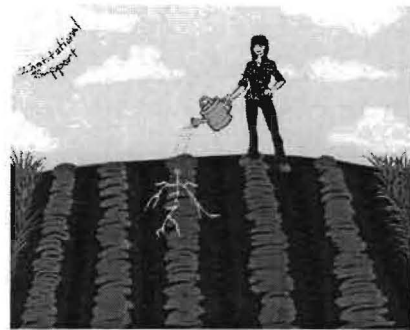
Appendix R

Pictorial of the Hepatitis C Initiative Timeline

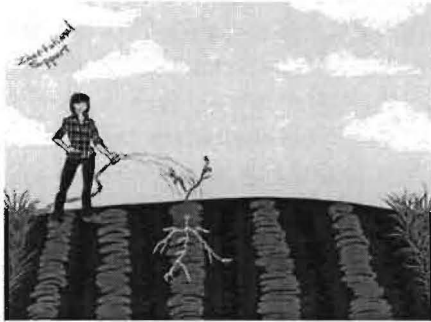
Pictorial of the Hepatitis C Initiative Timeline



2002-2008
Sow the Seeds of Innovation



February 2010 HCV Steering Committee
(DNP student as Advocate)



July 2010
Institutional Taskforce Meeting
(DNP student as Educator)



July 2010-April 2011
Community Needs Assessment and
Literature Review
(DNP student as Scholar)



April 2011
Community Taskforce Meeting
(DNP student as Leadership)



October 2011
Program Implementation
(DNP student as Clinician)

Appendix S

Pictorial of the Hepatitis C Initiative Future Research

Pictorial of the Hepatitis C Initiative Future Research



April 2012 Project Completion
(DNP opportunities for future research)

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