The Management of Hepatitis C Treatment in Massachusetts State Correctional Facilities

An Update and Analysis of the Current HCV Database

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Abstract

In 2004, a database was implemented to assess the treatment of inmates infected with hepatitis C in Massachusetts state correctional facilities. The purpose of this project was to update the database and examine the current treatment system. Inmate demographics, treatment success, and viral characteristics were assessed and analyzed for potential correlations. Recommendations to improve the database included focusing on the collection of missing data, namely the inmate's history of substance abuse and health conditions and follow up viral load measures.

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What is Hepatitis C?

By definition, hepatitis is an "inflammation of the liver" (Merriam-Webster Incorporated, 2006). It is a gastroenterological disease that results in damage to the liver cells, and depending on the severity, may even destroy them. There are a number of different types of hepatitis which can be caused by a variety of factors including other illnesses or diseases, noninfectious substances such as drugs, alcohol, or toxic chemicals, and infectious agents such as viruses or parasites (Encyclopedia Britannica, Inc., 2007). In the most common cases, hepatitis is the result of a viral infection.

Hepatitis C is one of six currently identified types of viral hepatitis (A, B, C, D, E, and G). It has become a major health concern in the United States, today, is one of the leading causes of liver disease, and a major reason for liver transplants (Jetter, 2005). True to its name, hepatitis C is a blood borne disease of the liver caused by the hepatitis C virus (HCV), a single-stranded RNA virus of the family Flaviviridae. HCV can be categorized into six major genotypes and more than 50 subtypes. Genotypes range in geographic distribution and response to treatment, but show little difference in the severity of the disease or outcome. The most common genotypes in the US are 1a and 1b, which account for over 70% of the cases (National Digestive Diseases Information Clearinghouse [NDDIC], 2006).

Characteristic of a blood borne infection, HCV is carried through the blood and transmitted primarily via contact with infected blood and blood products (NDDIC, 2006). Major risk factors associated with the transmission of HCV include blood transfusions and transplants, injection or use of illegal drugs, occupational exposure (i.e. healthcare workers), high risk sexual behavior with an infected partner, and non-sterile instrument use for tattoos or body piercing (Centers for Disease Control and Prevention [CDC], 1998). HCV may not be transmitted through casual contact with an infected person and is rarely acquired through maternal-infant transmission or household contact with infected blood or fluids. At present, injection drug use is the most common form of HCV transmission in the United States (NDDIC, 2006).

Types and Symptoms

Hepatitis C is typically categorized into one of two stages: acute hepatitis C or chronic hepatitis C. Each stage refers to the current progression of the viral infection and depends upon the length of infection time and the severity of the disease. In either case, HCV poses a potential number of dangers to the liver.

Acute hepatitis C is used to describe the first six months of infection, during which the liver is first attacked by HCV, liver inflammation initiates, and liver enzyme levels begin to rise. Persons with acute infections are usually asymptomatic and unaware of the virus they are carrying. Those who do develop symptoms exhibit mild, non-specific flu-like signs such as fatigue, sore muscles, headaches, nausea, and loss of appetite, and in some cases, may also acquire jaundice (Jetter, 2005). These symptoms usually do not develop until 6-7 weeks after infection and are often mistaken for other medical conditions or disappear before raising any serious concern. According to studies and organizations such as the National Institute of Diabetes and Digestive and Kidney Diseases, between 75% and 85% of those with acute hepatitis C will eventually progress

into a more severe, long-term chronic form of hepatitis C due to a lack of treatment or failure to respond to treatment within the first six months (CDC, 1998).

Chronic hepatitis C is defined as an HCV infection that has progressed beyond six months. It the most commonly diagnosed form of hepatitis C and is a major cause of cirrhosis, liver failure, and liver cancer (Liang, Rehermann, Seef, & Hoofnagle, 2000). Depending upon the severity of the infection, chronic hepatitis C varies greatly among patients in its course and outcome. For instance, those with mild chronic hepatitis C typically have no signs or symptoms of liver disease and exhibit rather minor damage to the liver. On the other hand, those patients with severe chronic hepatitis C demonstrate high levels of HCV virus in the blood, elevated liver enzyme levels (indicating liver disease), severe physical damage to the liver, and more specific symptoms such as muscle weakness, weight loss, itching, dark urine, fluid retention, and abdominal swelling. The majority of these patients will ultimately develop cirrhosis and end-stage liver disease. For the many patients who fall in the middle of the spectrum, chronic HCV infection is characterized by mild to moderate elevations in liver enzymes and few or no symptoms. In 1-2% of patients, chronic hepatitis C can cause complications outside the liver known as extrahepatic manifestations. These may include such conditions as cyroglobulinemia, glomerulonephritis, and porphyria cutanea tarda (NDDIC, 2006).

Despite the potential dangers of HCV infection, hepatitis C lies dormant in most patients for years. Statistics have shown that as many as 70% of those infected with HCV are unaware of the virus and more than half show no signs or symptoms of HCV infection. (Jetter, 2005; Henkel, 1999) In fact, hepatitis C is frequently not recognized until infected individuals undergo blood-donor screenings that are positive for HCV or routine physical exams that show elevated liver enzyme levels (CDC, 1998).

Testing and Diagnosis

Persons suspected to have an HCV infection must undergo a number of blood tests before they can be diagnosed with hepatitis C. Blood tests range in specificity and are designed to test for indicators of an HCV infection, HCV antibodies, and the HCV virus itself.

One of the most frequent indicators of a potential HCV infection is elevated levels of liver enzymes, or more specifically, alanine aminotransferase (ALT). Most people infected with HCV exhibit elevated levels of liver enzymes, such as ALT, on a routine blood test within 50 days of exposure (Jetter, 2005). Although not all infected patients show signs of alteration in their ALT levels, persistently abnormal levels of ALT are fair indicators that an infection may be present and that further tests should be conducted. ALT tests are not designed to confirm HCV infection, but are rather a nonspecific means of initially screening for infection (Herrine, 2002).

To determine whether or not an HCV infection is actually present, individuals are screened for the presence of HCV antibodies (anti-HCV) using a series of U.S. Food and Drug Administration (FDA) approved diagnostic tests (CDC, 1998). Anti-HCV is usually present in the blood of infected individuals within one month of exposure to the virus (NDDIC, 2006). If hepatitis C is suspected based on symptoms and/or ALT levels, an enzyme immunoassay (EIA) is first conducted and then later confirmed by a supplementary recombinant immunoblot assay (RIBA), a western blot specific for anti-HCV. Two positive results indicate an HCV infection, while two negative results

indicate no infection. Indeterminate results are usually indicative of a recently infected person, a person with chronic HCV, or poor testing. Anti-HCV test results do not characterize the type of hepatitis C or distinguish between patients with an acute, chronic, or recently treated infection (CDC, 1998).

In most patients, hepatitis C viral RNA can be detected within one to two weeks of HCV infection, long before the presence of anti-HCV or elevated ALT levels (CDC, 1998). As further confirmation of an active HCV infection, qualitative and quantitative assays can be done to detect the presence or absence of HCV RNA. Qualitative assays, such as the polymerase chain reaction (PCR) and transcription-mediated amplification (TMA) are usually done to determine whether or not HCV RNA is present in the serum. Quantitative assays, on the other hand, are conducted as indirect assessments of the amount of HCV RNA present in the blood. These viral loads determined by assays such as quantitative RT-PCR and branched DNA signal amplification do not directly correlate with the severity of hepatitis C, but are a good indication of the likelihood of a response to antiviral therapy (NDDIC, 2006).

In the majority of cases, elevated ALT levels and the presence of anti-HCV in the blood serum is enough to diagnose an individual with hepatitis C. Additional testing is typically done to either confirm the diagnosis or characterize the infection in preparation for treatment. Genotyping and liver biopsies are common examples of characterization tests performed to determine the genotype of the hepatitis C virus and the severity of the infection, respectively. Tests, like these, are good indicators of how a patient will respond to different treatments and which treatment will work best (NDDIC, 2006). Some states have also found these tests, particularly the liver biopsy, to be cost effective. In 2004, the Virginia Department of Corrections offered all inmates who tested positive for HCV RNA the opportunity to get a liver biopsy. This approach allowed physicians to avoid unnecessary treatment by treating only those inmates in the advanced state of the disease. It was estimated that liver biopsies saved almost $125,000 per 100 patients (Sterling, 2003).

Treatment

Presently, there is no cure or vaccine for hepatitis C. Like most viruses that cause chronic conditions, HCV RNA mutates very rapidly inside the human body. HCV infection elicits some response from the immune system early on, but constant mutations essentially allow the virus to evade the immune system over time and inhibit the development of preventative drugs (NDDIC, 2006). Consequently, the only options available for patients today are moderately successful treatments aimed at the elimination of detectable virus in the blood serum. Success of treatment is usually measured in terms of sustained virologic response, which can be defined as “the absence of HCV RNA in the serum during therapy and six months after completion of therapy” (Herrine, 2002).

Effective treatment for hepatitis C first began over 10 years ago, when alpha interferon was approved for treatment of non-A and non-B hepatitis in 1991 (Herrine, 2002). Treatment required that the antiviral protein be injected subcutaneously at least three times a week for approximately 12 months. Initial results indicated normalized ALT levels and a loss of detectable HCV RNA in the serum of most patients by the end of the therapy. However, long term studies of treatment with alpha interferon have

demonstrated a high relapse rate among patients and sustained viral response rates of only 15%-25% (CDC, 1998).

Current treatment therapies have replaced alpha interferon with pegylated interferon (peginterferon), a more successful recombinant form of the original protein. Chemical modification of alpha interferon by the addition of polyethylene glycol has improved the uptake, distribution, and excretion of interferon, and increased active inhibition of HCV. Like alpha interferon, peginterferon must be injected subcutaneously. Chemical improvements, however, have reduced the treatment requirements from injections three times a week to only once a week for approximately 48 weeks. Studies have shown an overall increase in sustained viral response rates with peginterferon monotherapy to approximately 35% (NDDIC, 2006).

In 1998, hepatitis C treatment was further enhanced when the FDA approved the combination of interferon and ribavirin as treatment for patients with chronic hepatitis C (Herrine, 2002). Ribavirin is an antiviral agent that is usually taken orally two times a day. It has little effect on HCV by itself, but in combination with interferon, can lower relapse rates, increase sustained viral response rates to as high as 55%, and has been shown to rapidly lower ALT levels and eliminate detectable HCV RNA in up to 70% of patients (NDDIC, 2006). Combination therapy, as it is most often referred to, has become today's standard form of hepatitis C treatment. Unless specific factors prevent the use of ribavirin, combination therapy will be applied over interferon monotherapy in all present cases (Ward and Kugelmas, 2005).

Despite the advances made over the past decade, problems continue to hinder the success of hepatitis C treatment. One of the biggest problems facing patients today is cost. On average, treatment costs approximately $20,000-$30,000 per year for the medication alone (Ward and Kugelmas, 2005). Although treatment is necessary for the management of hepatitis C in most cases, the expense of therapy often prevents individuals from pursing treatment. For those who receive treatment, medication poses the potential for side effects that can result in reduced medication dosages or an overall discontinuation of treatment. Common side effects of alpha and pegylated interferon include fatigue, muscle aches, headaches, depression, mild bone marrow suppression, and other related problems. Side effects range from mild to moderate in severity and usually diminish following the first few weeks of treatment. Common side effects of ribavirin, on the other hand, include anemia, fatigue, irritability, itching, birth defects, nasal stuffiness, sinusitis, and cough. Ribavirin is not advised for women who are pregnant or likely to become pregnant or for patients with blood related problems. Less than 2% of patients exhibit side effects uncharacteristic of interferon or ribavirin (NDDIC, 2006).

Because of the problems associated with hepatitis C therapy, treatment is not recommended for all patients. In fact, treatment is only highly recommended for chronic hepatitis C patients who have persistently elevated ALT levels, detectable HCV RNA, and a liver biopsy indicating severe inflammation or damage to the liver. These patients are considered to be at a greater risk for progression, and consequently, require treatment in order to survive. All other patients, including those with persistently normal ALT levels, advanced cirrhosis, alcohol or drug abuse problems, or contraindications such as depression, hyperthyroidism, life-threatening complications, or evidence of pregnancy, are not recommended for treatment and must receive medical clearance before beginning any such therapy (CDC, 1998).

Epidemiology

In 2000, the United States Surgeon General declared hepatitis C a "silent epidemic." With approximately 2% of the U.S. adult population infected, this appropriate declaration stems from the fact that hepatitis C is the most common chronic blood borne infection in the United States (Kim, 2002). Many of these infections will go undetected for years because victims display little to no symptoms during the early onset stages of the disease (CDC, 1998). Disease progression varies amongst individuals and depends on factors such as co-infection with other diseases, age, and alcohol/substance abuse patterns. Of those infected with the virus, up to 80% will develop chronic hepatitis and as much as 20% will progress into cirrhosis of the liver (Munoz-Plaza, et al., 2005).

Since the hepatitis C virus was only identified in the early 1990's, accurate and reliable estimates of HCV infections and mortality rates in the United States are limited. Also, many patients with acute hepatitis are asymptomatic and, therefore, are never diagnosed. Additionally, some infected individuals may not have access to medical care, a factor which also contributes to the under-reporting of hepatitis C infection. These challenges make it very difficult to assess the true incidence of infection (Munoz-Plaza, et al., 2005).

As the identification and awareness of hepatitis C has led to an expanding movement of education, means of prevention, and enhanced testing efforts among injection drug users and blood donors, it is safe to predict that the incidence of HCV infection should begin to decline. In fact, the number of people with transfusion-associated HCV infection has already decreased significantly after the 1985 guidelines for selecting safer blood donors was implemented. Similarly, an effective system for screening blood for hepatitis C via HCV antibodies began in 1989, a step forward in the prevention of this epidemic. Moreover, the occurrence of safer needle-using practices among injection drug users has increased due to HIV and HCV awareness programs (Kim, 2002).

Unfortunately, the decrease in incidence of infection is not necessarily correlated with a decrease in the frequency of individuals infected with the virus. In fact, it is predicted that the prevalence of hepatitis C will increase over the years. This is due to the fact that many people who have already been infected are asymptomatic and have not yet been reported. There is often a significant lag time between the time of infection and the symptomatic manifestation of liver disease. In fact, some people will not develop symptoms for up to 20 years or more. As a result of this duration, the Center for Disease Control and Prevention predicts a four fold increase in the number of people reported to be chronically infected between 1990 and 2015 (Kim, 2002).

Similar to the underestimations of HCV infections, the mortality projections due to HCV are undoubtedly misrepresented. Most deaths caused from hepatitis C infection are due to liver failure and chronic liver disease. However, mortality statistics are based on the "underlying cause of death". Therefore, in many cases, the U.S. system of death designation will list liver failure rather than hepatitis C as cause of death, even if the liver failure was caused by hepatitis C. In an attempt to estimate the number of deaths attributed to hepatitis C, the amount of in-hospital deaths from liver disease related to HCV was reviewed from the Healthcare Utilization Project database. In 1998, approximately 4,500 people died in hospitals in the U.S. from HCV-related liver disease (CDC, 2007).

The largest range of recorded data was used in the third National Health and Nutrition Examination Survey (NHANES) to estimate the overall prevalence of HCV in the United States. In this survey, 21,000 non-institutionalized citizens were tested for HCV antibodies as well as viral HCV RNA in serum. Percentages from of this pool of data were collected and projected onto the United States population. According to the results of the NHANES, 3.9 million U.S. civilians were infected with HCV and 2.7 million of those infected suffered from chronic infection. Demographic disparities in the results indicated that infection was more prevalent in the age range of 30 to 49 years old: men were 20% more likely to be infected than women. The disease was most common in non-Hispanic blacks and least common in non-Hispanic whites. Only 1.5% of non-Hispanic whites had HCV whereas 3.2% of non-Hispanic blacks had HCV (Kim, 2002).

Studies also suggest that individuals who suffer from severe mental illness are at a substantially higher risk for contracting blood-borne diseases such as HCV. For example, a particular study which focused on the occurrence of HCV among psychiatric patients had found that up to 19.6% of the 931 patients tested positive for HCV; this incidence rate is about 11 times higher than that of the rate of the normal adult population (Rosenberg, et al., 2001). This pattern of infection among psychiatric patients is most likely due to the high occurrence of drug use among the depressed and mentally ill populations.

Because syringe sharing and injection drug use is the major cause of HCV transmission and infection, the prevalence of HCV infection is extremely high among injection drug users. Several seroprevalence studies have shown that HCV infection occurs in up to 90% of injection drug users (Patrick, Buxton, Bigham & Mathias, 2000). When users were tested in some methadone maintenance treatment centers, as much as 96% were seropositive for HCV antibody while 62% were positive for HCV RNA (McCarthy & Flynn, 2001).

HCV in Correctional Facilities

About 85% of HCV infected inmates who were entering a Massachusetts prison reported a history of hepatitis, needle-sharing and previous drug use. Research studies have found that many inmates either begin or continue to engage in injection drug use during incarceration (Munoz-Plaza, et al., 2005). Since syringes tend to be more frequently used by many inmates in prison, the risk for sharing needles and needle syringe contamination is much higher than the outside world (Muller et al., 1995). As a result, HCV infection is relatively elevated among correctional populations.

Because injection drug users represent a dominant subpopulation in correctional facilities, a large percentage of HCV infected persons will inhabit or pass through prisons. According to surveys from the Bureau of Justice Statistics, the average length of a prison stay is approximately two-three years. One of the most recent in-depth studies was performed in 1997. It was deduced that between 29% and 43% of HCV infected people in the U.S. are released from a correctional facility in a given year (Hammett, Harmon & Rhodes, 2002). Since limited factual data is available on HCV infections, an indirect method was used to produce a rough estimate of HCV infection in prison populations. The logic of this study used the CDC's estimate of 72% to 86% of injection drug users are infected with HCV. The estimate of 24% of prison inmates with history of injection drug use was multiplied by 72% and 86% to yield an approximation that 17% to

21% of prison inmates are infected with HCV (Munoz-Plaza, et al., 2005). Furthermore, in 1997, a statistical analysis of this study produced an estimation of 1.3 to 1.9 million releases from prison had HCV; this implies that 29% to 43% of people with HCV infection have passed through a correctional facility in one year (Hammett, Harmon & Rhodes, 2002).

Despite the fact that such a large proportion of Americans with hepatitis C pass through a correctional facility, there is no national data on HCV incidence among inmates. Similarly, there is scarcely any data associating risk behaviors in prison with HCV contraction. This deficit in factual and statistical information contributes to the absence of a standardized system of health care and treatment programs in correctional settings. The collection of more data in prisons nationwide would allow for the better understanding of hepatitis C prevalence as well as the effectiveness of treatment; this would also help alleviate the controversies and challenges which have stood in the way of establishing national guidelines and recommendations for the management of this epidemic. Perhaps the establishment of a central database such as those used for cancer and HIV registries would enhance the progress of HCV intervention strategies (Allen, 2003).

Because of the growing frequency of HCV infections among incarcerated populations, the National Institute of Health (NIH) and the Center for Disease Control and Prevention have recognized the importance of improving HCV interventions in correctional facilities. Specifically, the 2002 NIH consensus statement supported a more aggressive approach to treatment compared with the 1997 statement (Hammett, 2003). It has seemed to become apparent to these organizations that the period of incarceration provides a window of opportunity to diagnose, evaluate and treat those at risk for severe health problems caused by hepatitis C. At the least, the development of a systemic screening program would identify those infected and those at risk in an attempt to reduce contraction during incarceration (Allen, 2003).

The prospect for the establishment of prevention, education and treatment programs in prisons does seem ideal considering that such a large percentage of people infected with HCV are in a confined setting. As a majority of inmates are only temporarily imprisoned and serve an average sentence of two to three years, healthcare addressing HCV would not only benefit the health of the inmates but the safety and health of the friends, families and communities to which the released prisoners return. Additionally, prison administrators and authorities are legally obligated to administer a satisfactory degree of healthcare, which treatment programs could potentially provide. A lack of interventions may leave prisons susceptible to lawsuits and criticism for neglecting the welfare of their inmates as well as the communities to which a majority of them are returned. For example, lawsuits have taken place in New Jersey when prisoners became aware of HCV programs in Pennsylvania prisons which dwarfed the comparable programs available in New Jersey facilities (Hammett, 2003).

As this issue remains a fairly new one, only a handful of prison systems have incorporated an HCV intervention program into their health management systems; among them are the Federal Bureau of Prisons, and facilities in Pennsylvania, Rhode Island, Wisconsin, Massachusetts and Indiana. (Hammett, 2003).

Management Strategies for Correctional Settings

There are many components involved in the establishment of an efficient and productive HCV treatment system in correctional facilities. The level of staff involvement, medical resources, and funding allotted for the development of an HCV management program usually varies between state correctional systems. As a result, there exists a range of protocols and tactics implemented by different correctional facilities in addressing this prevalent disease. Nevertheless, HCV management systems in correctional facilities will employ comparable strategies as well as encounter similar challenges.

Prevention and Education

A major component involving the management and containment of this disease involves methods of prevention. Because there is no vaccine for HCV, preventative tactics must rely on education and risk-reduction practices. Health education can take the form of workshops, class presentations, videos, posters and brochures. Information dispersed covers risk factors for infection, methods of prevention such as clean needle use and routes of transmission. For example, a grassroots organization in Oregon conducts educational workshops for prisoners throughout the state (Munoz-Plaza, et al., 2005). Other prisons have utilized a peer education program in which professionals train inmates on how to provide counseling and education to fellow inmates. These peer educators have several advantages including the fact that they are much more accessible for private discussions than prison authorities and staff. Also, peers provide a more trustworthy, credible and comfortable source of consultation. Prisoners have admitted that they rarely listen to staff, but they will take advice from other inmates much more seriously. Furthermore, prisoners have reported that they fear appearing like a "snitch" if they are seen while engaged in a private discussion with a staff member (Munoz-Plaza, et al., 2005).

In an Australian journal article, other more extreme measures of prevention have been suggested to combat the HCV epidemic in the Australian prison system. One approach to limit HCV incidence is to provide methadone maintenance treatments for prisoners. Methadone substitution should help opiate-dependent injectors to decrease injecting usage. Another suggestion is for prison authorities to enforce lesser punishments for the use of non-injectable drugs compared with injectable drugs. This should encourage drug-dependent prisoners to try alternative drug methods which should decrease the usage of needle use amongst inmates (Dolan, 2001). Moreover, a third major strategy would be to make sterile injection resources more available, provide disinfectants to clean needles, and/or to implement sanitary needle/exchange programs. However, this remains to be a controversial topic as authorities do not want to condone drug usage (Vlahov, Astemborski, Solomon & Nelson, 1994). It is also believed that transmission of HCV in prisons is due to unsanitary tattooing practices. An approach to limit HCV infection would be to properly train selected inmates on the sterile and proper techniques of tattooing as well as provide autoclaves and single-use ampoules of ink (Dolan, 2001).

Screening

Aside from the educational and preventative measures taken by some correctional facilities, a major initial step in an HCV management program is screening individuals for infection. Recent guidelines from the Center for Disease Control indicate that all inmates should be questioned for risk factors regarding HCV infection during their entry medical evaluation. Those inmates who affirm to any of those risk factors should be tested for HCV.

Both universal and targeted screening approaches have been practiced in different prison systems. In Indiana, mandatory testing for HCV and HIV has been enforced. The Indiana Department of Health oversees the testing procedures in which each inmate must donate blood samples. The system in Wisconsin practices a targeted screening approach in which select individuals require testing if their answers to risk-based assessments imply risk. Some of the many risks listed in the survey included a history of needle sharing, being a recipient of blood clotting factor before 1987, being on long-term hemodialysis, having been infected with hepatitis B, and having evidence of liver disease (Allen, 2003).

Although a systematic approach for antiviral treatment is available, the HCV management system in Rhode Island correctional facilities has a weakness in its screening methods. They lack any form of routine screening despite the high percentage (~26%) of inmates who are infected at any given time. As screening is not mandatory or routine, inmates in Rhode Island must individually request to be tested (Hammett, 2003).

Mental Illness and Substance Abuse

The correctional population has a high percentage of inmates with psychiatric illness and/or histories of substance abuse. These two groups used to be excluded from any type of HCV treatment. However, several findings have allowed the NIH consensus statement in 2002 to lift the standard contraindication for therapy for those with substance abuse problems. Experts believe that a correctional setting can be an ideal place for treatment since sobriety is heavily enforced. As long as substance abuse counseling is readily available and inmates are monitored closely while on treatment, substance abuse is no longer an accepted contraindication for HCV treatment. Similarly, having psychiatric illness will no longer exclude a prisoner from treatment. Because interferon will chemically lower the body's amount of tryptophan, which is a precursor of serotonin, it was originally believed that treating a mentally ill patient with interferon would dangerously exacerbate his/her psychiatric state. Currently, several studies have shown no evidence supporting the assumption that treatment will cause more severe depression in those already afflicted with mental health disorders. In addition, the close clinical monitoring which can be provided in prison may provide a safer clinical setting for treatment for mentally ill inmates. However, the eligibility criteria for receiving treatment will ultimately be decided by each correctional setting (Allen, 2003).

Challenges

Healthcare administrations for correctional facilities are concerned that the high occurrence of HCV infection among incarcerated populations combined with the steep cost of HCV treatment will overwhelm already constricted healthcare budgets. Hence, the

cost of a treatment program for HCV is most likely the largest challenge facing the establishment of diagnosis and treatment programs.

However, the development of efficient systemic approaches to testing and evaluation for treatment will drastically reduce the number of inmates eligible for treatment. As previously stated, only those with advanced infection and liver disease will receive treatment. Furthermore, inmates will be excluded from treatment if their period of incarceration is not long enough to cover the full course of treatment.

Specifically, in Rhode Island correctional systems, only a very small fraction of HCV-infected inmates received treatment. Between 1997 and 2000, 349 tested positive for HCV infection. Of this number, ninety were eligible for treatment. In order to become eligible for treatment, inmates were required to meet a list of criteria. Among the requirements, inmates had to have at least fifteen months left to serve. This would ensure that enough time was available for treatment and follow-up. In addition to this, patients had to be psychiatrically cleared on a case by case basis and those who had a history of substance abuse had to either enter a substance abuse treatment or had to have been sober for at least one year. Of the inmates eligible for treatment, forty-one of them completed the full course of treatment while the remaining forty-nine were assumed to have completed half the course. At the time, the cost of one course of antiviral treatment was about $9,500; thus, the estimated total cost was $622,250. This represented about 5% of the total health care budget of the Rhode Island Department of Corrections. Overall, this expense was not overburdening to Rhode Island's healthcare budget (Hammett, 2003). Also, an advantage of antiviral treatment for HCV is that unlike treatment for HIV which involves ongoing medical attention, it is only given for one course and then it is completed, thus

Besides cost, other factors will challenge the feasibility of the integration of HCV prevention, diagnosis and management programs in correctional facilities. Some constraints include a limited working staff as well as other healthcare priorities which may compete with HCV care. Also, a devoted cooperation and communication between correctional health and public/private health-care practices needs to be established. Moreover, incarcerated populations are relatively disliked and ostracized by the general public. The combined lack of political power and influence makes it easy for government officials to overlook their needs (Hammett, Harmon & Rhodes, 2002).

The Current Evaluation and Management Practices for the Treatment of Hepatitis C in Massachusetts Correctional Facilities

The process by which Massachusetts inmates are screened and evaluated for HCV treatment involves a methodical and thorough series of steps. To start with, instructive resources such as peer education and counseling on preventative measures are available to all inmates, regardless of their HCV status. Information offered covers the symptoms of HCV, ways the disease can be contracted, treatment options, and the side effects associated with treatment. Additionally, infected inmates are informed of behaviors which could exacerbate their condition, such as alcoholic intake which will augment liver damage.

Screening for Treatment Eligibility

During their entry medical evaluation, an individual's likelihood of HCV infection is assessed through the inmates' history of several risk factors. If the individual has a history of intravenous drug use, has received a blood transfusion before July of 1992, has had multiple sexual partners and/or has had a sexual partner with HCV, then he/she is deemed at high risk for having contracted the disease. Only one affirmation to these experiences is needed to qualify for an HCV antibody test. If the individual tests positive for HCV antibodies, then liver function tests are checked periodically. During this time, hepatitis A and hepatitis B statuses are checked and the individual is immunized for hepatitis A and hepatitis B, if possible (Brewer, Marshall, Demaria, 2007).

After one year has passed since the HCV antibodies were detected, the HCV RNA viral load is measured. If the individual tests positive for HCV RNA, then he/she undergoes a series of both medical and laboratory evaluations to determine his/her eligibility for a liver biopsy. The medical evaluation ensures that the inmate has no history of renal transplantation, decompensated cirrhosis, severe depression, major medical illnesses such as diabetes or chronic obstructive pulmonary disease (COPD), intravenous drug use or alcohol use within the past twelve months, or disciplinary reports within the past year involving substance abuse. In addition, individuals should show no evidence of any autoimmune disease and, if female, should not be pregnant. Failure to meet these criteria will most likely exclude an HCV infected individual from continuing with the treatment evaluation process.

The laboratory segment of the evaluation process consists of white blood count, serum creatine, platelet, bilirubin, albumin and prothrombin level measurements. In most cases, abnormal levels for these labs will prevent an individual from proceeding onto a liver biopsy. However, abnormal lab values are not an absolute contraindication for continuing with the treatment qualification process. An antibody test for HIV is also implemented to determine if the patient should be referred to the HIV/HCV co-infection clinic.

Upon satisfying the criteria for both the medical and laboratory assessments, the HCV infected person will undergo a liver biopsy. Liver biopsies provide the physician with evidence on whether or not moderate inflammation and/or fibrosis of the liver are occurring. Treatment is not recommended if the liver biopsy is fairly normal, but it is recommended when the health status of the liver is compromised.

Pre-treatment Protocol

Once HCV treatment is recommended, the Hepatitis C worksheet (Appendix A) must be filled out and sent to the Hepatitis C Program Manager in the UMass Correctional Health Program of UMass Medical School. The Hepatitis C Program Manager oversees the treatment waiting list for all HCV infected inmates in the seventeen Massachusetts correctional facilities. As of February 2007, there were sixty-eight inmates on therapy and twenty on the waitlist. The maximum number of inmates allowed on HCV therapy at one time is ninety-five. It is part of the manager's responsibility to update records as well as keep track of who is currently on therapy and which individuals are next on the waitlist. Inmates who have been approved to receive treatment but are on the waitlist are divided into 4 categories:

1. Treatment naïve
    a. Genotype 1, 2, 3 and 4
2. Dual Diagnosis (HCV/ HIV)
    a. Fulminant (go to top of list)
    b. Non-Fulminant
3. Relapsers, Treatment Failures and Non-Responders after Interferon/Ribavirin Combination Therapy
4. Date of biopsy and length of time since biopsy will be considered

The selection of patients to be treated occurs in increments of ten. Five individuals from category one, two to three from category two, and two to three patients from category three are chosen. Patients classified under the "Fulminant Dual Diagnosis" category are given top priority for treatment. They are the most critically sick, and as a result, are moved to the top of the list regardless of the date they were diagnosed. Additional factors which place a higher urgency to treat include the severity of the liver biopsy as well as the length of time a patient has been waiting on the treatment waitlist. Each patient in a group of ten will receive treatment before an additional group of ten inmates is to be selected (Brewer, Marshall, Demaria, 2007).

Prior to initiating HCV therapy, several parameters must be addressed. First of all, it must be verified that the patient will be incarcerated for greater than one year after treatment begins. A short sentence prevents patients from receiving a complete course of treatment as well as follow-up testing to monitor their HCV status and evaluate treatment effectiveness. Secondly, a full history and physical examination must be conducted and recorded on the Hepatitis C worksheet (Appendix A). Patients with certain other health conditions must undergo additional testing before they can be cleared for therapy. For example, patients with a history of coronary artery disease are required to have an EKG and possibly a stress test, while patients with diabetes should be tested for fasting glucose and hemoglobin levels.

The next step requires the patient to read, understand and sign the "Inmate Agreement" form (Appendix B). This sheet represents the patient's consent to begin treatment. By signing this form, the patient acknowledges his/her understanding of the disease process, its effects on their health, treatment options, side effects of treatment and the varying levels of success experienced by different HCV infected patients on treatment. The patients must acknowledge all of the health risks associated with therapy and must inform the medical staff of any symptoms. They must also pledge to avoid illegal drug and alcohol use, and tattoos. Infringing upon these rules will result in termination of treatment.

Another step before initiating therapy is the measurement of several baseline lab values, the most important being the HCV RNA viral load just prior to treatment. Others include ALT, white blood cell, hemoglobin, hematocrit, platelets, cholesterol, triglycerides, glucose, albumin and thyroid stimulating hormone (TSH) levels. Woman must take a pregnancy test to verify they are not pregnant while on treatment. Once treatment is initiated, patients are closely monitored by the medical staff to ensure they are comfortable on therapy and remain symptom free. As previously mentioned, common side effects of pegylated interferon and ribavirin are flu-like symptoms, nausea, abdominal discomfort, loss of appetite, edema, rash, reactions at injection site, muscle

aches, loss of hair and symptoms associated with depression (Brewer, Marshall, Demaria, 2007).

The Process of HCV Therapy

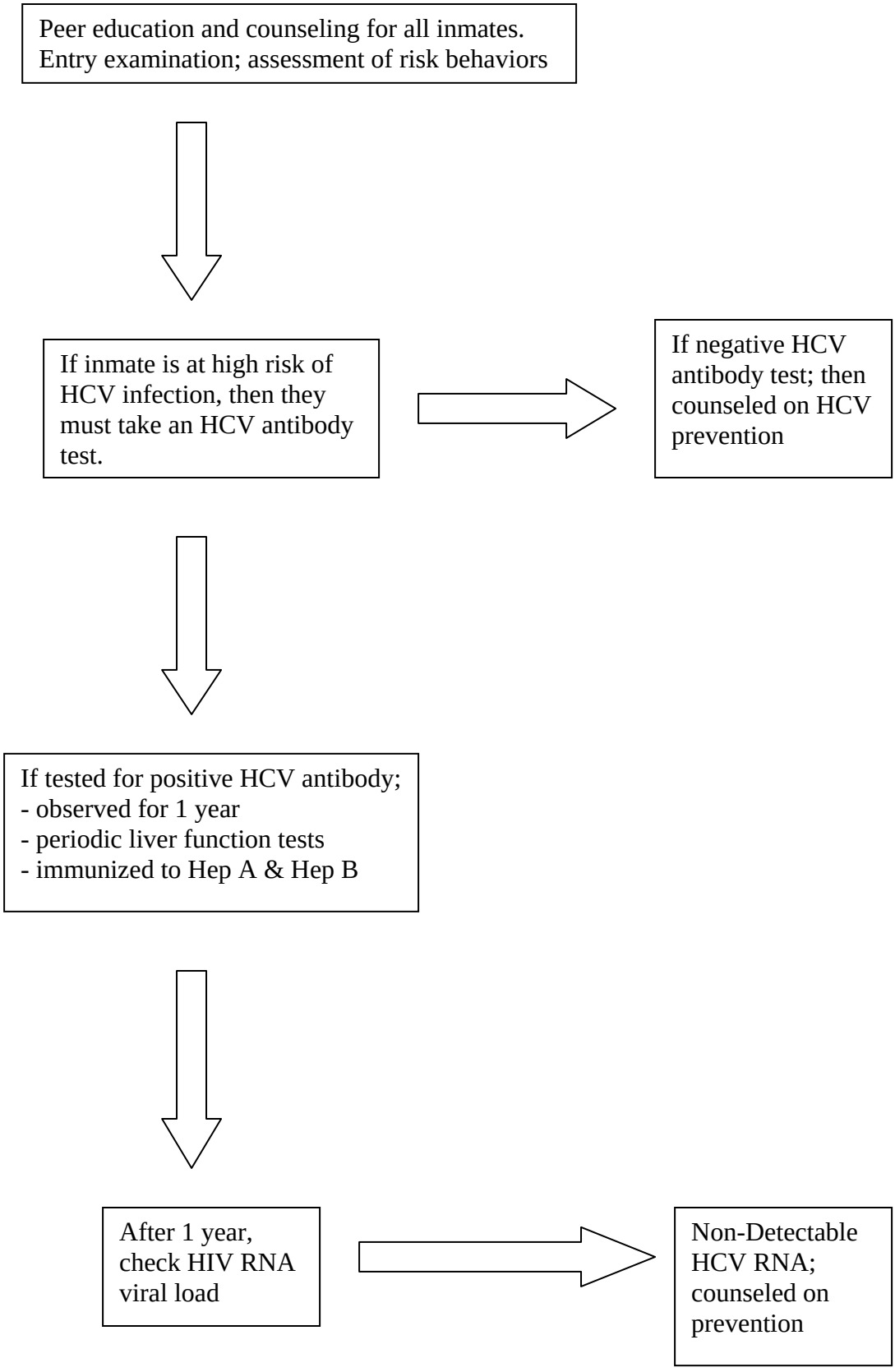
The most commonly used medications for the treatment of HCV are pegylated interferon and ribavirin. This combination therapy is recommended for all patients except for those with special circumstances, such as patients who are co-infected with HIV and HCV. After twelve weeks of HCV therapy, the HCV RNA viral load is tested. Only if there is at least a two log reduction of the HCV RNA viral load will the treatment be continued. If there is less than a two log reduction, the patient is considered unresponsive to treatment. In this case, the medication is discontinued and the patient is then closely monitored in chronic care. A full course of HCV therapy for genotypes 2 and 3 is twenty-four weeks while for other genotypes it is forty-eight weeks. The HCV-RNA viral load is again measured at the completion of treatment as well as six months after therapy ends to assess for a sustained anti-viral response.

In addition to HCV RNA viral loads, complete blood counts are drawn throughout the course of treatment to examine the effects of the medications on hemoglobin, white blood count, neutrophils, platelets, hematocrit, ALT, TSH, and viral load levels. If hemoglobin levels drop, the dosage of ribavirin is decreased. If the white blood cell count, absolute neutrophils and platelets drop, then pegylated interferon is decreased. Besides blood tests, females must also take a pregnancy test every month during therapy (Brewer, Marshall, Demaria, 2007).

The overall evaluation process for the management and treatment of hepatitis C infected inmates in Massachusetts facilities are summarized in the flow charts found on the following pages.

Inmates Co-infected with HIV and HCV

In order to be referred to the HIV/HCV co-infection clinic, the patient must have tested positive for HIV antibodies or detectable HIV RNA as well as have a positive HCV antibody test or evidence of HCV RNA. Similar to mono-infected inmates, liver function tests along with baseline labs should be drawn including complete blood counts, CD4 counts and percentages, albumin, prothrombin, and HIV RNA levels. Evaluation by the gastroenterologist and the infectious disease specialist will determine whether or not a liver biopsy will be conducted. An additional right upper quadrant ultrasound is to be done before the biopsy. If chronic HCV infection along with HIV viremia is present, Pegasys plus/minus ribavirin will be recommended as therapy if no other contraindications exist. A closer follow-up is necessary with co-infected patients in order to monitor for the expected side effects as well as the potential for other severe symptoms to occur. For some co-infected patients on treatment, antiretroviral therapy has had to be terminated due to hepatotoxicity. Other patients must have frequent endoscopies if their cirrhosis worsens in order to verify whether or not they have esophageal varices (Brewer, Marshall, Demaria, 2007).


Peer education and counseling for all inmates.
Entry examination; assessment of risk behaviors
If inmate is at high risk of HCV infection, then they must take an HCV antibody test.
If negative HCV antibody test; then counseled on HCV prevention
If tested for positive HCV antibody;
- observed for 1 year
- periodic liver function tests
- immunized to Hep A & Hep B
After 1 year, check HIV RNA viral load
Non-Detectable HCV RNA; counseled on prevention

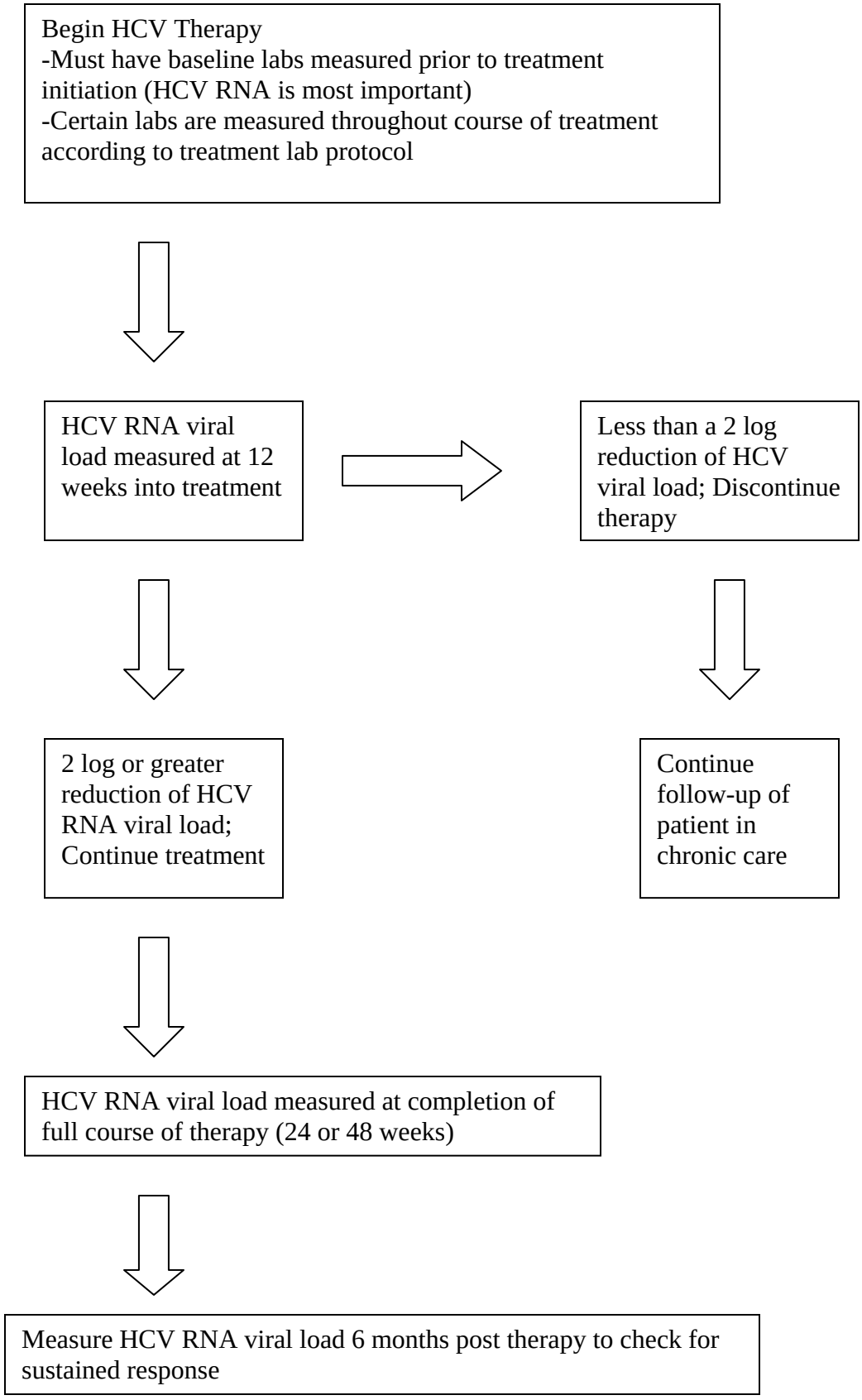
If presence of HCV RNA is detected, then patient must undergo a medical and laboratory evaluation. Only if patient meets the inclusion criteria for both the medical and laboratory evaluations can they be referred for a liver biopsy.

Medical consultation to perform liver biopsy. Physician evaluates liver biopsy for signs of inflammation/ fibrosis

HCV treatment not recommended

HCV treatment recommended
Prior to treatment
- Review/sign Inmate Agreement form
- Full History & Physical Exam; information transferred to Hep C Worksheet and sent to Hepatitis C Program Manager

Placed on waitlist
- make sure incarceration period is at least 1 year at start of treatment
- must be sober for at least 1 year before treatment begins


Begin HCV Therapy
-Must have baseline labs measured prior to treatment initiation (HCV RNA is most important)
-Certain labs are measured throughout course of treatment according to treatment lab protocol
HCV RNA viral load measured at 12 weeks into treatment
Less than a 2 log reduction of HCV viral load; Discontinue therapy
2 log or greater reduction of HCV RNA viral load; Continue treatment
Continue follow-up of patient in chronic care
HCV RNA viral load measured at completion of full course of therapy (24 or 48 weeks)
Measure HCV RNA viral load 6 months post therapy to check for sustained response

The HCV Database

The prospect of establishing hepatitis C management programs in correctional facilities does seem ideal considering that such a large percentage of people infected with HCV are in a confined setting. It has become apparent to several states that the period of incarceration provides a window of opportunity to screen, evaluate and treat those at risk for hepatitis C. Among the states which have implemented a hepatitis C treatment program in correctional facilities is Massachusetts. In 2004, a database was created to monitor and assess the treatment of hepatitis C infected individuals in Massachusetts correctional facilities. As of March 2005, 262 inmates treated were entered into this database. An analysis conducted for this data set revealed that the majority of inmates treated were Caucasian, male and infected with HCV genotype 1. The database also provided information regarding treatment response and success rates; almost half of the inmates treated had achieved a successful response, reaching an undetectable HCV viral load (Kelly, 2005).

The purpose of this project was to update the database with additional inmates who were treated up until February 2007. After the medical and treatment information from the forms of these inmates were transferred into the database, a demographic analysis was performed such that the characteristics (gender, race, age, facility) of inmates treated could be summarized. A demographic synopsis provided a review of who is treated with the benefit of minimizing any intentional or unintentional bias. Predispositions of the facilities to treat certain populations over others can be exposed through this analysis, providing the management incentive to review protocols.

Response to treatment was similarly assessed based on lab results entered in the database. HCV RNA viral loads and ALT levels proved to be important indicators of treatment success. Consequently, HCV RNA levels were used to examine any correlations between the success of treatment and viral genotype as well as HIV co-infection. Results have shown that inmates with genotype 1 have the least successful responses when compared with genotypes 2, 3 and 4. In addition, co-infection with HIV was found to drastically reduce the chance of successful treatment outcomes.

Other major components looked at in the database were reasons for treatment interruptions and causes of premature termination of treatment. Among others, these included severe and intolerable side effects, poor anti-virological response to the medications, and early release from prison. Although an inadequate amount of data was available to perform a quantitative analysis, a qualitative evaluation of the reasons for unsuccessful and incomplete courses of treatment may serve as a reference for improving upon the efficiency of the screening and treatment protocols. Several recommendations for improvements in the database included the collection of missing data and the development of a stricter follow-up system. Variables such as inmates' history of substance abuse and the presence of mental and physical health conditions were missing data for nearly half the inmates. Follow-up HCV RNA measurements were similarly missing for an even larger percentage of inmates. This information is vital in determining the success rate of treatment.

The value of the hepatitis C treatment database for HCV infected inmates in Massachusetts correctional facilities is in its contributions to the limited knowledge of this disease and its management. Despite the large proportion of HCV infected people who pass through a correctional facility, there is still a shortage of factual and statistical

information on HCV infection among inmates. Not having a database for tracking HCV incidence and treatment contributes to the absence of a standardized system of health care and treatment programs in correctional settings. The collection of more data in correctional facilities would allow for the better understanding of hepatitis C prevalence as well as the effectiveness of its treatment. Ideally, more facilities will follow in the footsteps of the Massachusetts treatment program and employ an efficient system of data collection and organization.

Materials and Methods

This project was conducted over a six month period, from November 2006 to April 2007. During this time, research was approved, data was collected, and the SPSS database was revised and updated. An analysis of the data was used to assess the effects of changes made to the original data collection process as well as examine the current state of hepatitis C treatment in Massachusetts state correctional facilities.

Research Preparation

Preparation for data collection and handling began as early as November 2006. Prior to the start of any clinical research project, an intensive review must be conducted by the Institutional Review Board (IRB). The IRB is a review committee typically composed of five members of various sexes, backgrounds, and professions. It was originally created in the 1970's to help protect the rights and welfare of human research subjects by ensuring that clinical studies are well designed, ethical, legal, and safe. IRBs have the authority to modify, approve, or disapprove any research study involving human subjects after an extensive review of the proposed course of action. Most research institutions, professional organizations, and scholarly journals have established IRBs (Epley, Erickson, and Selwitz, 2006; National Cancer Institute [NCI], n.d.).

For this particular project, data collection could not begin until an IRB training course had been completed by each individual researcher. The Collaborative IRB Training Initiative (CITI) is an online course in the protection of human research subjects that is required by the University of Massachusetts, Worcester. It is comprised of various training modules regarding the history of the IRB, the function of the IRB, and the conduction of research involving different human populations including vulnerable subjects such as prisoners. Completion of the course required a review of each module as well as a corresponding quiz. Individual certificates of completion were received at the conclusion of the course and sent for approval by the IRB at the University of Massachusetts, Worcester as well as the Massachusetts Department of Correctional Facilities. Complete IRB approval was achieved by December 2006.

Data Collection

Data was collected for this project over a two month period, from January 1, 2007 to March 1, 2007. Demographic, health, and treatment-related information was gathered on a total of 177 inmates including 109 inmates now off treatment and sixty-eight inmates currently on treatment. Data for each inmate was extracted directly from individual hepatitis C worksheets (Appendix A) completed and stored in the medical records file of each individual.

The current hepatitis C worksheet is a one-page record of inmate history and treatment. It contains basic information such as name, age, race, weight, and height; a brief medical history including current health or mental health conditions, a history of alcohol or drug abuse, and a history of co-infection; as well as treatment-related data such as treatment start and end date, lab figures, changes in treatment, and any necessary notes. Originally, the hepatitis C worksheet was a two-page treatment record updated regularly by nurses and doctors (Appendix C). However, when data collection began in 2004, information from these original worksheets was extracted and transferred to a more

organized data collection worksheet (Appendix D). Although this worksheet included all the information necessary to monitor the progress of the inmates and the types of inmates being treated, the extensive length of the paperwork resulted in an increasing amount of missing data. On September 27, 2004, a new one-page hepatitis C worksheet was created and later revised to the current worksheet in 2005 (Appendix A). This treatment record is typically filled out prior to the start of treatment by HIV/Hepatitis C case managers at each health service unit. Following the start of treatment, sheets are transferred and information is continually updated by the Hepatitis C Program Manager for UMass Medical School and the UMass Correctional Health Program.

In order to maintain the confidentiality of inmates during the data collection process, names were blacked out and inmates were coded with an arbitrary five digit number beginning with 55 or 88. A 55 number indicated inmates with data from the old hepatitis C worksheets, while an 88 number indicated inmates with data from the new hepatitis C worksheets. All data input over the course of this project was extracted from the new worksheets. This included updated information for inmates that had already completed or discontinued treatment in the past three years, old data from 2004 and 2005, and new data for inmates that had recently started treatment.

Differences were noted in the amount of information each worksheet contained. Worksheets completed within the past year were nearly, if not entirely, complete. Older, worksheets, however, were frequently missing large amounts of important information such as height, weight, incarceration date, current health conditions, history of alcohol or drug abuse, and reasons for any discontinuation of or interruptions in treatment. It was unclear as to whether or not this data was actually missing, unknown, or not applicable. In either case, all data considered missing was compiled into various "missing data logs" and sent to the program manager who had direct contact with inmates and case managers and could potentially retrieve necessary data.

Data Entry

All information collected during the course of this project was input into an SPSS database. SPSS for Windows is an analytical software program devised by SPSS Inc. for data collection, data access, data management and preparation, statistical data analysis, and reporting (SPSS Inc., 2007). Actual data entry was conducted in a large SPSS spreadsheet. Different rows indicated different inmates whereas different columns indicated different fields of data associated with the hepatitis C worksheet. Assigned row numbers and specific column headers were used to differentiate inmates and identify data requirements, respectively. Inmates were numerically ordered in the database according to their assigned five digit code beginning with 55 or 88. All data was entered into the appropriate rows and columns based on specific variables previously coded into the SPSS system. Number as well as word variables were used to define available and unknown data. Missing information was indicated in the database by blank fields.

Data Analysis

Between March 2007 and April 2007, a statistical analysis of the complete data set was conducted using the SPSS program. The analysis was focused primarily on characterizing the types of inmates being treated, summarizing the overall progress of hepatitis C treatment, and identifying potential trends or correlations between inmate

characteristics and the success of treatment. Only those fields of data which had limited amounts of missing information in the database were assessed.

To account for the changes that have taken place in hepatitis C treatment since 1999, data was analyzed based on one of two different categories: inmates who have received treatment since 1999 and inmates who have received treatment since August 2002. February 1999 marked the start of hepatitis C treatment for inmates in the database, whereas August 2002 marked the start of combination therapy as the standard form of treatment in Massachusetts state correctional facilities. Creation of the two categories allowed for a more accurate assessment of the types of inmates being treated and the current progress of treatment.

For inmates who had received treatment since 1999, data analyses were conducted to summarize the trends in inmate characteristics and treatment center operations that were unaltered by the 2002 changes in hepatitis C treatment. In particular, data was used to assess inmate demographics such as gender, age, and race, the frequency of genotypes among inmates, and the frequency of treatment at each treatment center. Assessments of additional information such as health conditions, mental health conditions, and prior history of substance or alcohol abuse were not made due to the large percentage of missing data in these fields.

Although the 2002 changes in standard treatment did not affect the types of inmates who had received treatment since 1999, they could have affected the overall outcome and progress of treatment. In order to accurately assess these effects, treatment related data was only analyzed for those inmates who had received treatment since August 2002. Data was used specifically to assess variations in ALT and HCV RNA levels prior to the start of treatment, the frequency of undetectable viral loads attained by the end of treatment, the frequency of genotypes among inmates and their potential correlation with treatment outcome, the frequency of HIV co-infection among inmates and its potential correlation with treatment outcome, the frequency of treatment interruption, and the frequency of treatment discontinuation as well as the reasons given for stopping treatment. Any additional assessments were deemed unnecessary or could not be made due to missing data constraints.

Results

To account for the division in statistical analyses, results have been classified under two different categories: inmate characteristics and response to treatment. Each category is based on a specific set of inmates whose data was used to assess a number of different fields. The results for each analyzed field have been individually summarized within their corresponding category and are based on statistical data tables originally output by SPSS. Summaries are characterized by verbal highlights, graphs, and tables similar to those generated by SPSS.

All results have been organized by SPSS in terms of valid and missing data. Valid is an expression used to define all known and legitimate data that has been input into the database. Missing, on the other hand, is an expression used to define all data that is either missing from the database, has been input into the database as unknown, or has been incorrectly input into the database as an undefined variable. Undefined variables and unknown data are specifically referred to as unknown, whereas data missing from the system is referred to by the term system.

Results from the actual SPSS analysis of valid and missing data are presented in three different forms: frequency, percent, and valid percent. "Frequency" refers to the actual number of inmates that fall within a given category. This result represents the total number of inmates analyzed within a given field, and thus includes all valid and missing data. "Percent" is the calculated percentage of inmates within a given category based on the total number of inmates analyzed. This, again, represents the total number of inmates analyzed and includes both valid and missing data. "Valid Percent" is the only result that does not include missing data. It is the calculated percentage of inmates within a given category based solely on the total number of inmates with valid data.

Due to the extent of missing data in the database, the total number of inmates with valid data was not equivalent to the number of inmates analyzed within each field. However, these figures were the most accurate representation of the data within the database. Consequently, valid frequencies and valid percents were used to summarize the results of each field.

Inmate Characteristics

The following results are based on all inmates who have received treatment since 1999. This year marked the start of hepatitis C therapy for inmates included in the database. As of March 1, 2007, data on a total of 510 treated inmates has been collected and input into the HCV database. This data was used to assess the overall characteristics of inmates receiving treatment including the facility at which they first began treatment as well as their gender, age, race, and HCV genotype.

Facility at Start of Treatment

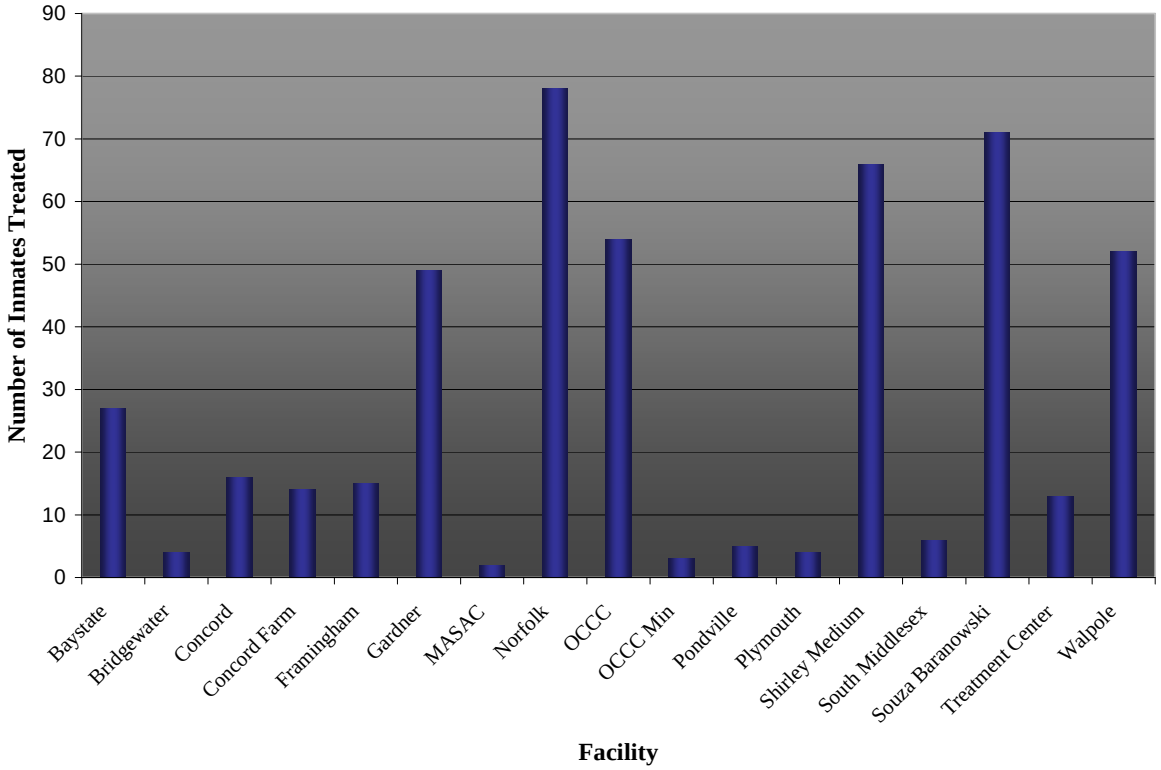
Out of 510 inmates treated, 479 (93.9%) inmates had a documented name for the correctional facility at which their treatment was initiated. A total of 17 correctional facilities were identified as having provided hepatitis C treatment since 1999. The number of inmates treated varied among the facilities, ranging from as low as 2 inmates to as high as 78 inmates. The majority were treated at Massachusetts Correctional Institution - Norfolk (78), Souza-Baranowski Correctional Center (71), and Massachusetts Correctional Institution – Shirley (66). A limited number of inmates

received treatment at the Massachusetts Alcohol and Substance Abuse Center (2), Old Colony Correctional Center Min (3), Bridgewater State Hospital (4), and Massachusetts Correctional Institution - Plymouth (4). Results for all 17 correctional facilities have been summarized in Table 1. A bar graph of the number of inmates treated at each facility at the start of treatment is shown in Figure 1.

Table 1: Frequency and Percentage of Inmates among Massachusetts State Correctional Facilities at the Start of Treatment

Facility		Number of Inmates	Percent	Valid Percent
Valid	Baystate	27	5.3	5.6
	Bridgewater	4	0.8	0.8
	Concord	16	3.1	3.3
	Concord Farm	14	2.7	2.9
	Framingham	15	2.9	3.1
	Gardner	49	9.6	10.2
	MASAC	2	0.4	0.4
	Norfolk	78	15.3	16.3
	OCCC	54	10.6	11.3
	OCCC Min	3	0.6	0.6
	Pondville	5	1	1
	Plymouth	4	0.8	0.8
	Shirley Medium	66	12.9	13.8
	South Middlesex	6	1.2	1.3
	Souza Baranowski	71	13.9	14.8
	Treatment Center	13	2.5	2.7
	Walpole	52	10.2	10.9
	Total	479	93.9	100
Missing	Unknown	6	1.2	
	System	25	4.9	
	Total	31	6.1	
Total		510	100	

Figure 1: Distribution of Inmates among Massachusetts State Correctional Facilities at the Start of Treatment



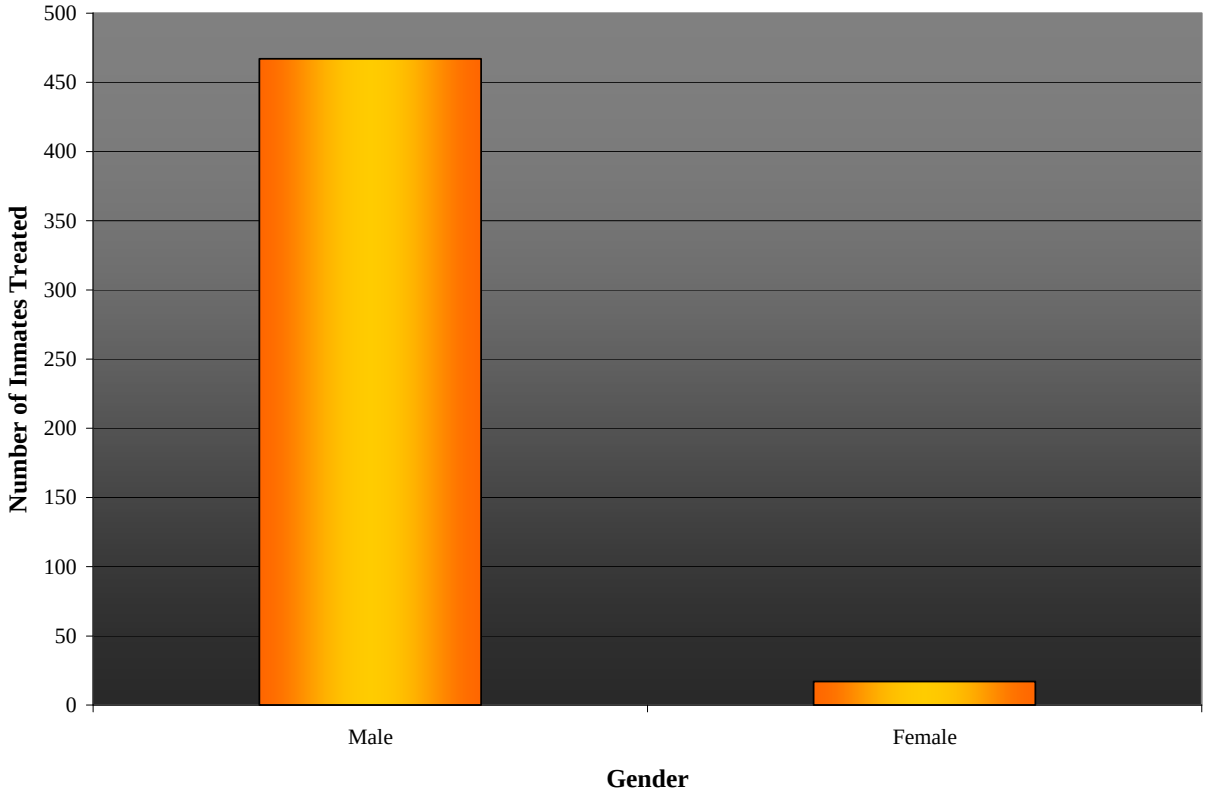
Gender

Out of 510 inmates treated, 484 (94.9%) inmates had a documented gender. 467 (96.5%) of those inmates were male, whereas only 17 (3.5%) of those inmates were female. All 17 female inmates received hepatitis C treatment at either the Massachusetts Alcohol and Substance Abuse Center (MASAC) or Massachusetts Correctional Institution – Framingham (MCI – Framingham). Statistical results for the frequency of male and female inmates treated have been summarized in Table 2 and graphed in Figure 2.

Table 2: Frequency and Percentage of Male and Female Inmates Treated

Gender		Number of Inmates	Percent	Valid Percent
Valid	Male	467	91.6	96.5
	Female	17	3.3	3.5
	Total	484	94.9	100
Missing	Unknown	1	0.2	
	System	25	4.9	
	Total	26	5.1	
Total		510	100	

Figure 2: Distribution of Male and Female Inmates Treated



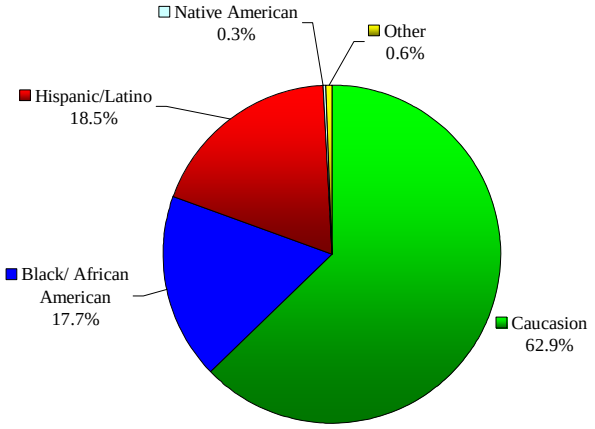
Race

The race/ethnicity of those treated for HCV in Massachusetts Correctional facilities was recorded for 356 (69.8%) of the inmates in the database. According to the known data, Caucasians were the most frequently treated race with 224 (62.9%) inmates. Hispanic/Latino and African Americans were nearly tied for the second highest race/ethnicity treated for HCV in MA facilities. There were 66 (18.5%) Hispanic/Latino inmates treated while there were 63 (17.7%) African Americans treated. One (0.3%) Native American and two (0.6%) inmates classified under "other ethnicity" were treated. Table 3 contains all of the frequencies and percentages of the inmates' ethnicities and Figure 3 displays the valid percentages of the inmates' race/ethnicities.

Table 3: Frequency and Percentage of Race/Ethnicity among Inmates Treated

Race/Ethnicity		Number of Inmates	Percent	Valid Percent
Valid	Caucasian	224	43.9	62.9
	Black/African American	63	12.4	17.7
	Hispanic/ Latino	66	12.9	18.5
	Native American	1	0.2	0.3
	Other	2	0.4	0.6
	Total	356	69.8	100
Missing	Unknown	87	17.1	
	System	67	13.1	
	Total	154	30.2	
Total		510	100	

Figure 3: Race/Ethnicity of Inmates Treated



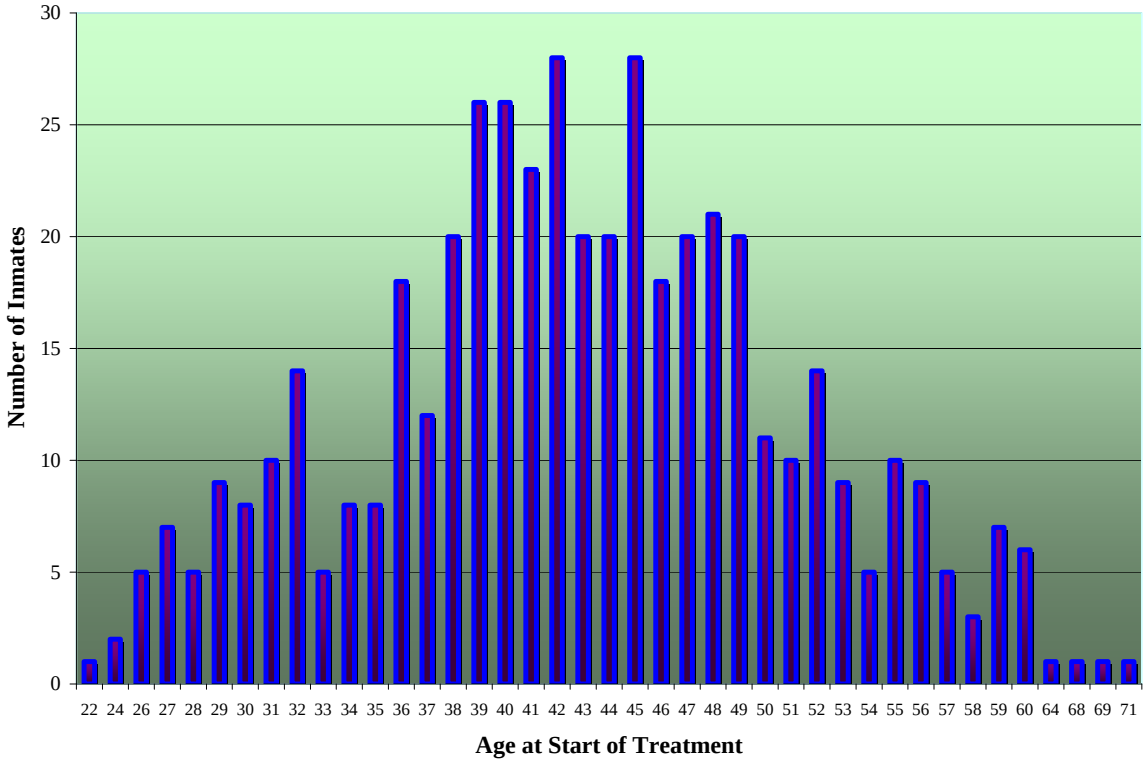
Age

A majority of the information regarding the ages of the inmates at the start of HCV therapy was entered into the database; out of the 510 inmates, 475 (93.1%) had a recorded age. The ages of those inmates who started treatment ranged from as young as 22 to as high as 71 years old. The majority of those individuals on HCV therapy began treatment when their age fell within the range of middle thirties to late forties. The two ages which had the highest number of inmates treated (28 patients), were 42 and 45 years old. The average age of inmates beginning treatment was 42.9 while the median was 43 years old. See Table 4 for the complete age data set. Figure 4 shows the number of inmates who started therapy at each specific age.

Table 4: Age of Inmates at the Start of Treatment

Age		Number of Inmates	Percent	Valid Percent
Valid	22	1	0.2	0.2
	24	2	0.4	0.4
	26	5	1	1.1
	27	7	1.4	1.5
	28	5	1	1.1
	29	9	1.8	1.9
	30	8	1.6	1.7
	31	10	2	2.1
	32	14	2.7	2.9
	33	5	1	1.1
	34	8	1.6	1.7
	35	8	1.6	1.7
	36	18	3.5	3.8
	37	12	2.4	2.5
	38	20	3.9	4.2
	39	26	5.1	5.5
	40	26	5.1	5.5
	41	23	4.5	4.8
	42	28	5.5	5.9
	43	20	3.9	4.2
	44	20	3.9	4.2
	45	28	5.5	5.9
	46	18	3.5	3.8
	47	20	3.9	4.2
	48	21	4.1	4.4
	49	20	3.9	4.2
	50	11	2.2	2.3
	51	10	2	2.1
	52	14	2.7	2.9
	53	9	1.8	1.9
	54	5	1	1.1
	55	10	2	2.1
	56	9	1.8	1.9
	57	5	1	1.1
	58	3	0.6	0.6
	59	7	1.4	1.5
	60	6	1.2	1.3
	64	1	0.2	0.2
	68	1	0.2	0.2
	69	1	0.2	0.2
	71	1	0.2	0.2
	Total	475	93.1	100
Missing	Unknown	8	1.6	
	System	27	5.3	
	Total	35	6.9	
Total		510	100	

Figure 4: Age Distribution at Start of Treatment



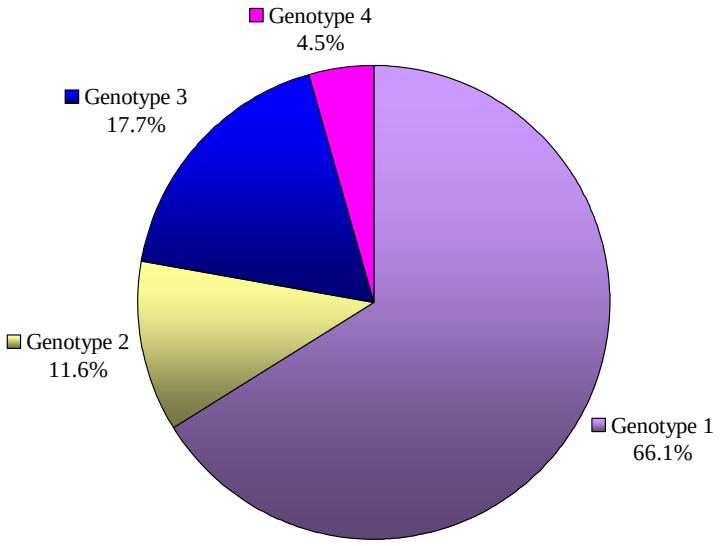
HCV Genotype

A summary of viral genotype groups was conducted from the 440 (86.3%) inmates who had a recorded HCV genotype in the database. With a frequency of 291 (66.1%), the majority of inmates were infected with HCV genotype 1. 78 (17.7%) inmates were infected with genotype 3 while 51 (11.6%) inmates were infected with genotype 2. Only 20 (4.5%) inmates had genotype 4. Table 5 lists the frequencies and percentages of the HCV genotypes. Figure 5 displays the distribution of HCV genotype groups among infected inmates who began treatment.

Table 5: Frequency and Percentage of HCV Genotypes among Inmates Treated

HCV Genotype		Number of Inmates	Percent	Valid Percent
Valid	Genotype 1	291	57.1	66.1
	Genotype 2	51	10	11.6
	Genotype 3	78	15.3	17.7
	Genotype 4	20	3.9	4.5
	Total	440	86.3	100
Missing	Unknown	39	7.7	
	System	31	6.1	
	Total	70	13.7	
Total		510	100	

Figure 5: Distribution of HCV Genotypes among Inmates Treated



Response to Treatment

The following results are based on all inmates who have received treatment since August 2002. This date marked the start of combination therapy (interferon + ribavirin) as the standard form of treatment in Massachusetts state correctional facilities. As of March 1, 2007, a total of 370 inmates have been documented in the database as having received treatment since August 2002. Data from these inmates was used to assess the overall response of inmates to treatment including variations in ALT and HCV RNA levels prior to the start of treatment, the frequency of undetectable viral loads attained by the end of treatment, the frequency of genotypes among patients and their potential correlation with treatment outcome, the frequency of HIV co-infection among patients and its potential correlation with treatment outcome, the frequency of treatment interruption, and the frequency of treatment discontinuation as well as the reasons given for stopping treatment.

Baseline ALT Levels

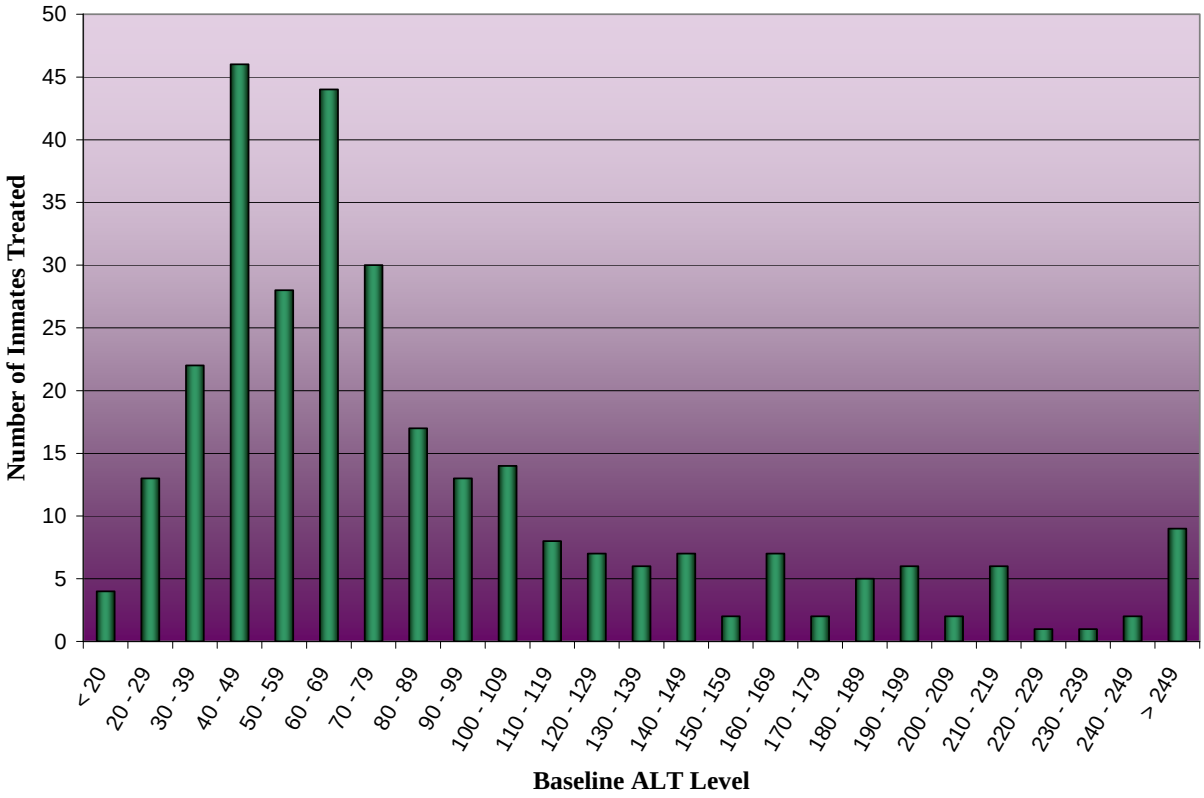
Out of 370 inmates treated, 302 (81.6%) inmates had a documented baseline value for the level of alanine aminotransferase (ALT) in the blood. These values were measured in terms of International Units per Liter (IU/L). Typically, in a normal and healthy individual, ALT levels in the blood tend to range between 0 and 40 IU/L (Franciscus and Teeter, 2006). According to the labs of inmates treated, baseline ALT levels ranged from 12 IU/L to 627 IU/L. The average ALT level was calculated around 90.26 IU/L, whereas the median ALT level was approximately 68 IU/L. The majority of inmates (60.5%) had baseline ALT levels between 30 IU/L and 79 IU/L. Due to the large

percentage of missing data, ALT levels at 12 weeks and 24 weeks into treatment could not be assessed. Refer to Table 6 for all relative data figures and percentages and Figure 6 for a bar graph of the number of inmates and their associated baseline ALT levels.

Table 6: Baseline ALT Levels among Inmates Treated

Baseline ALT Level		Number of Inmates	Percent	Valid Percent
Valid	< 20	4	1.1	1.3
	20 – 29	13	3.5	4.3
	30 - 39	22	5.9	7.3
	40 - 49	46	12.4	15.2
	50 - 59	28	7.6	9.3
	60 - 69	44	11.9	14.6
	70 - 79	30	8.1	9.9
	80 - 89	17	4.6	5.6
	90 - 99	13	3.5	4.3
	100 - 109	14	3.8	4.6
	110 - 119	8	2.2	2.6
	120 - 129	7	1.9	2.3
	130 - 139	6	1.6	2
	140 - 149	7	1.9	2.3
	150 - 159	2	0.5	0.7
	160 - 169	7	1.9	2.3
	170 - 179	2	0.5	0.7
	180 - 189	5	1.4	1.7
	190 - 199	6	1.6	2
	200 - 209	2	0.5	0.7
	210 - 219	6	1.6	2
	220 - 229	1	0.3	0.3
	230 - 239	1	0.3	0.3
	240 - 249	2	0.5	0.7
	> 249	9	2.4	3
	Total	302	81.6	100
Missing	Unknown	0	0	
	System	68	18.4	
	Total	68	18.4	
Total		370	100	

Figure 6: Distribution of ALT levels at the Start of Treatment



HCV Viral Load

Out of 370 inmates treated, 332 (89.7%) inmates had a documented baseline value for the level of HCV RNA in the blood. These values were measured in terms of International Units per milliliter (IU/mL). Baseline HCV RNA levels ranged from as low as 353 IU/mL to as high as 98,400,000 IU/mL. The average HCV RNA level was calculated around 2,363,344.53 IU/mL, whereas the median HCV RNA level was only 1,131,740 IU/mL.

Due to the large percentage of missing data, HCV RNA levels at 12 weeks, 24 weeks, and 48 weeks into treatment could not be assessed. However, results did show that inmates achieved an undetectable viral load (<615 IU/mL) as early as 12 weeks into treatment. Of the 232 inmates who had HCV RNA levels recorded beyond the baseline value, 178 (76.7%) of them achieved an undetectable viral load by the end of treatment. Not enough data was available to summarize the number of inmates who were able to attain a sustained virologic response.

Results regarding the frequency of undetectable HCV viral loads among inmates have been outlined in Table 7.

Table 7: Undetectable Viral Loads among Inmates Treated

Did Subject Have Undetectable HCV Viral Load?		Number of Inmates	Percent	Valid Percent
Valid	No	54	14.6	23.3
	Yes	178	48.1	76.7
	Total	232	62.7	100
Missing	Unknown	43	11.6	
	System	95	25.7	
	Total	138	37.3	
Total		370	100	

Correlation between HCV Genotype and Success of Treatment

Out of 370 inmates treated, 217 (58.6%) inmates had a documented HCV genotype as well as HCV RNA levels recorded beyond the baseline value. Of the 149 inmates infected with HCV genotype 1, 106 (71.1%) of them achieved an undetectable viral load (<615 IU/mL) by the end of treatment. Of the 68 inmates infected with HCV genotypes 2, 3, or 4, 62 (91.2%) of them were able to achieve a similar success in treatment with an undetectable viral load (<615 IU/mL). Statistical results regarding the correlation between HCV genotype and an inmate's ability to achieve an undetectable viral load (< 615 IU/mL) have been summarized in Table 8.

Table 8: The Effect of HCV Genotype on HCV Viral Loads

Did Subject Have Undetectable HCV Viral Load?		Genotype	
		Genotype 1	Genotype Other (2, 3, 4)
No	Number of Inmates	43	6
	Valid Percentage within Genotype	28.90%	8.80%
Yes	Number of Inmates	106	62
	Valid Percentage within Genotype	71.10%	91.20%
Total	Number of Inmates	149	68
	Valid Percentage within Genotype	100%	100%

HIV Co-infection

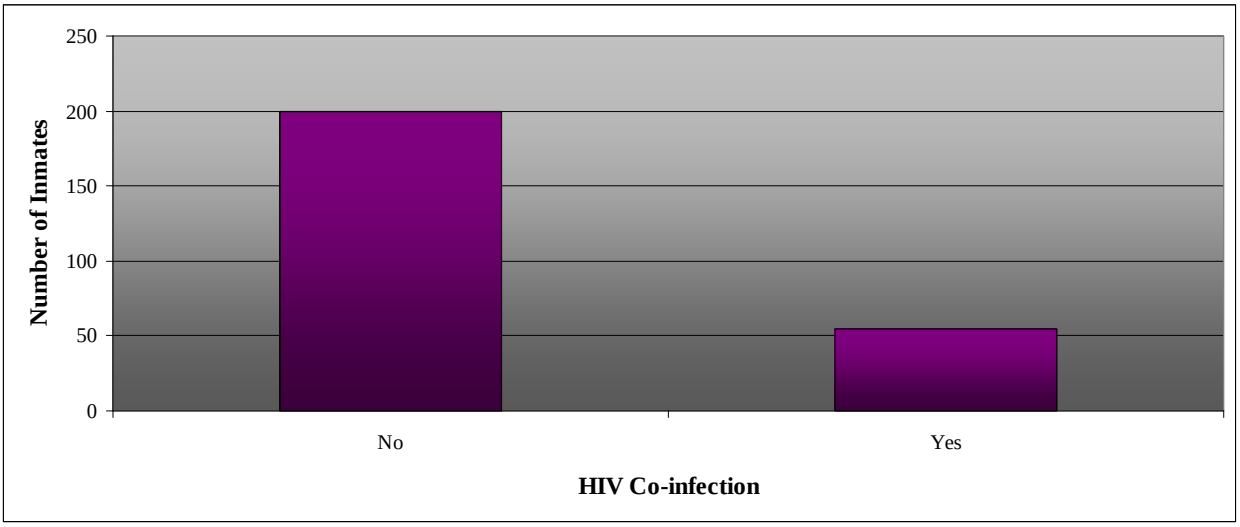
255 (68.9%) of the 370 inmates on HCV combination therapy had a documented HIV status. 200 (78.4%) were only mono-infected with HCV while 55 (21.6%) inmates

were co-infected with HIV. Table 9 lists the data involving the HIV co-infection status of inmates on HCV therapy. Figure 7 shows the frequency of patients who were either mono-infected with HCV or co-infected with HCV and HIV.

Table 9: Frequency and Percentage of Inmates Co-infected with HIV

Did Subject Have HIV Co-infection?		Number of Inmates	Percent	Valid Percent
Valid	No	200	54.1	78.4
	Yes	55	14.9	21.6
	Total	255	68.9	100
Missing	Unknown	81	21.9	
	System	34	9.2	
	Total	115	31.1	
Total		370	100	

Figure 7: Distribution of Inmates with HIV/HCV Co-infection



Correlation between HIV Co-infection and Success of Treatment

Out of the 370 inmates on combination therapy, only 165 (44.6%) inmates had a known HIV status and a recorded HCV viral load during or at the end of treatment. Despite the substantial amount of missing information, the recorded data between HIV status and treatment success was compared in an attempt to define any relationship between the two. Out of the 143 inmates who were only mono-infected with HCV, 116 (81.1%) had achieved an undetectable HCV viral load. Out of the 22 inmates who were co-infected with HIV, 12 (54.5%) had achieved an undetectable HCV viral load. Table 10 displays the cross-tabulation of data on whether or not the inmate was infected with HIV and whether or not he/she had reached undetectable HCV RNA levels.

Table 10: The Effect of HIV Co-infection on HCV Viral Loads

Did Subject Have Undetectable HCV Viral Load?		HIV Co-infection	
		No	Yes
No	Number of Inmates	27	10
	Valid Percentage within HIV Co-infection	18.90%	45.50%
Yes	Number of Inmates	116	12
	Valid Percentage within HIV Co-infection	81.10%	54.50%
Total	Number of Inmates	143	22
	Valid Percentage within HIV Co-infection	100%	100%

Treatment Interruptions

223 (60.3%) inmates had documented information on whether or not they had experienced any treatment interruptions. From this known data, 40 (17.9%) inmates did have treatment interruptions while 183 (82.1%) inmates did not. These values and percentages are organized in Table 11.

Table 11: Number of Inmates Who Experienced Treatment Interruptions

Did Subject have any Treatment Interruptions?		Number of Inmates	Percent	Valid Percent
Valid	No	183	49.5	82.1
	Yes	40	10.8	17.9
	Total	223	60.3	100
Missing	Unknown	1	0.3	
	System	146	39.5	
	Total	147	39.7	
Total		370	100	

Early Discontinuation of Treatment

From the total number of inmates on HCV combination therapy, 243 (65.7%) had recorded data on whether or not they had to stop treatment early. 137 (56.4%) inmates had prematurely terminated treatment while 106 (43.6%) inmates did not stop treatment early. Table 12 lists data regarding the amount of inmates who have discontinued treatment before they had completed a full course of therapy.

Table 12: Early Discontinuation of Treatment among Inmates

Was Treatment Stopped Early?		Number of Inmates	Percent	Valid Percent
Valid	No	106	28.6	43.6
	Yes	137	37	56.4
	Total	243	65.7	100
Missing	Unknown	6	1.6	
	System	121	32.7	
	Total	127	34.3	
Total		370	100	

Reasons for stopping treatment early was input in the database and can be classified into three main categories: poor virologic response to treatment, severe side effects and poor compliance with treatment. According to the protocol followed by MA correctional facilities, if the patient did not reach a 2 log reduction in HCV RNA viral load by the twelfth week into treatment, then that person was discontinued from therapy because he/she was not responding to the medications. Several inmates stopped treatment early for this reason.

As cautioned to the inmates before initiating therapy, HCV treatment may elicit several side effects. These side effects vary in degree and may be difficult to tolerate. Among the most common physical symptoms that were listed as reasons why treatment was stopped early are cotton wool spots, chest pain, rash, visual problems, back pain, and gastrointestinal problems including nausea, vomiting, and diarrhea. The mental health status of some inmates was also affected by the medications; other reasons for discontinuing treatment were anxiety, mood swings, agitation, and neurological symptoms including seizures and shakes. Other side effects which resulted in ending treatment early were anemia, and a decrease in hemoglobin, neutrophils and/or white blood cells. Experiencing severe side effects was the predominant category of reasons why treatment was terminated early.

Before beginning treatment, inmates were advised to avoid any high-risk behaviors as outlined in the “Inmate Treatment Agreement” form. Only a few inmates were recorded as having to end treatment early because of risky behaviors. These behaviors included getting a home-made tattoo, exhibiting maniac behavior, and having a “dirty” urine sample (testing positive for substance abuse) while on therapy. Several inmates also ended treatment early because they were released early from prison and therefore could not complete the full course of therapy.

Discussion

Over the past decade, hepatitis C has become an increasingly common occurrence in Massachusetts state correctional facilities. In a 2003 report by the Metro West Daily News, it was estimated that of the 10,000 inmates in the Massachusetts state prison system, 3,000 inmates were infected with hepatitis C, accounting for 30% of the male population and 40% of the female population (Hillman, 2003). In an effort to raise awareness of this growing epidemic and prevent the spread of hepatitis C within prisons and the society where many inmates will be released, hepatitis C treatment has become a standard in Massachusetts state correctional facilities. Since its initiation in 1999, over 500 inmates have received some form of treatment for an HCV infection.

In order to monitor the overall progress of treatment among inmates and assess the state of the treatment system in Massachusetts correctional facilities, the HCV database was created between 2004 and 2005 as a means to collect and organize information regarding the demographics, health, and treatment of inmates. In 2005, data on more than 200 inmates was collected and input into the database. By the end of this project, data on a total of 510 inmates was included in the database. This updated data was used to assess the current state of the treatment system as well as the condition of the HCV database. In terms of the treatment system, conclusions can be drawn from the results regarding the general characteristics of inmates who are receiving treatment in Massachusetts state correctional facilities and the overall response of inmates to treatment since the start of combination therapy in August 2002. Additional conclusions concerning the importance of the HCV database and ways in which it can potentially be improved can be made as well.

Characteristics

The characteristics of those inmates who were treated for hepatitis C were summarized according to five different categories. To start with, data collected on the locations of where inmates started treatment showed that a majority of HCV infected inmates were treated at Massachusetts Correctional Institution - Norfolk (78), Souza-Baranowski Correctional Center (71), and Massachusetts Correctional Institution – Shirley (66). A limited number of inmates received treatment at the Massachusetts Alcohol and Substance Abuse Center (2), Old Colony Correctional Center Min (3), Bridgewater State Hospital (4), and Massachusetts Correctional Institution - Plymouth (4). Factors which may have contributed to why certain facilities had more inmates treated than others include the populations within each facility, the percentage of inmates with long enough sentences to qualify for treatment, and the healthcare services and resources available at each facility. For example, with an average daily population of 1250 inmates, the Massachusetts Correctional Institution at Norfolk is the largest facility of its type in the Commonwealth of Massachusetts. In addition, about eighty-percent of the inmate population at the facility is serving time for violent crimes (Massachusetts Department of Correction, 2007). Based on the mere size of the facility and the percentage of inmates with long sentence times, it makes sense that Norfolk currently has the highest number of inmates who have been treated for HCV. The facility with the second highest frequency of inmates treated was Sousa Baranowski which is the state's newest correctional facility. It is a maximum security prison that offers a full range of educational, vocational, and substance abuse programming. The recent establishment of

this high security facility as well as the up-to-date healthcare program equally contributes to the high percentage of inmates receiving treatment. Massachusetts Correctional Institution-Shirley was the facility with the third highest frequency of inmates who were treated for HCV. This is likely due to the fact that MCI-Shirley Health Services Unit is fully staffed seven days a week and 24 hours a day. Healthcare includes services in the fields of medicine, dentistry, podiatry, optometry, mental health, psychiatry, psychology, and physical therapy. Inmates from all other Department of Correction facilities are transported as necessary to MCI-Shirley for these services (Massachusetts Department of Correction, 2007).

An analysis of the gender of inmates treated in Massachusetts correctional facilities showed that 96.5% of inmates treated were male while only 3.5% were female. These numbers were very consistent with the actual gender breakdown of the total inmate population in Massachusetts facilities. As of January 1, 2006, a survey from the Department of Corrections counted 8,802 males and 603 females, representing 94% and 6% of the inmate population, respectively (Massachusetts Department of Correction: Research and Planning Division, 2006). Besides the overall low percentage of female inmates in the Massachusetts facilities, it is important to note that the lower number of females receiving treatment can also be attributed to the fact that women often have shorter incarcerations, which exclude them from qualifying for the long course of HCV therapy (Carol Bova, personal communication).

According to the results regarding race/ethnicity of inmates, Caucasians were the most frequently treated race, accounting for 62.9% of all treated inmates with valid data. Hispanic/Latino and African Americans were nearly tied for the second highest race/ethnicity treated with valid percents of 18.5% and 17.7%, respectively. These values are only partially reflective of the breakdown of race amongst Massachusetts inmate populations. Between 1997 and 2006, the proportion of Caucasian inmates decreased from 48% in 1997 to 44% in 2006. The percentage of African American similarly decreased from 29% in 1997 to 27% in 2006. The percentage of Hispanic inmates was the only one to increase from 22% to 27% during this ten-year duration (Massachusetts Department of Correction: Research and Planning Division, 2006). Indeed, it is the Caucasian race that accounts for the majority of the inmate population as well as the inmates treated for HCV. However, a large disparity does exist between the high percentage of Caucasian inmates treated and the lower percentage of Caucasians within the entire inmate population. Likewise, the inmate population percentages of both Hispanics and African Americans are higher than the percentages of Hispanic and African American inmates treated for HCV. This particular data may serve as an incentive for management to reexamine treatment selection protocols. Ideally, knowing the number of inmates infected with HCV as well as the breakdown of their ethnicity would allow for a more direct display of any treatment selection bias. Unfortunately, information from the database only included information on the inmates who were selected for HCV treatment, not for all of the inmates who were infected with this virus, including those who did not apply or qualify for treatment, and the reasons for exclusion.

An analysis of the age at which inmates started treatment showed that the majority of individuals on HCV therapy began treatment in their mid thirties to late forties. The average age of inmates treated was 42.9 while the median was 43 years old. These numbers are fairly consistent with the average age of inmates among

Massachusetts correctional populations. According to the Department of Corrections survey, the median age of inmates has increased from 33 years in 1997 to 36 years in 2006. Similarly, the mean age of inmates has increased from 34 to 38 years during this ten year period. As of 2006, 39% of Massachusetts inmates are ages 40-64 while 31% are ages 30-39 (Massachusetts Department of Correction: Research and Planning Division, 2006). Because the ages of those inmates who started treatment ranged from as young as 22 to as high as 71 years old, age does not seem to influence HCV treatment eligibility.

Data collected on HCV genotype showed that the majority of inmates were infected with HCV genotype 1 (66.1%). 17.7% of Massachusetts inmates were infected with genotype 3, 11.6% of inmates was infected with genotype 2 and only 4.5% of inmates had genotype 4. At 66.1%, this high percentage of inmates infected with HCV genotype 1 directly correlates with the high prevalence of genotype 1 in the general public. It is believed that HCV genotype 1 accounts for around 70% of hepatitis C cases in the United States (NDDIC, 2006).

Treatment Outcomes

Since August 2002, combination therapy has become the standard form of treatment in Massachusetts state correctional facilities. To summarize the effects of this therapy on the outcome of treatment and to identify potential correlations between inmate characteristics and the success of treatment, various aspects of the treatment process were analyzed.

As a historical indicator of a potential HCV infection, baseline ALT levels were first analyzed to determine whether or not they accurately correlated with HCV infection among inmates. Alanine aminotransferase, or ALT, is an enzyme produced primarily by cells in the liver. In a normal, healthy individual, ALT levels in the blood tend to range between 0 and 40 IU/L; however, this range may vary depending upon the laboratory, gender, and biological make-up of an individual. When cells in the liver are damaged or die, ALT levels tend to increase in the blood. The amount of ALT does not necessarily correlate with the amount of damage to the liver, but it does signal that something may be wrong with the liver. In most individuals with hepatitis C, ALT levels are elevated at least slightly above normal. For approximately 30% of these individuals, though, ALT levels remain normal (Franciscus and Teeter, 2006).

According to the results, baseline ALT levels among inmates ranged from 12 IU/L to 627 IU/L, with the most frequent levels between 30 IU/L and 79 IU/L. The average ALT level was calculated around 90.26 IU/L; however, this value was slightly skewed as a result of the large range in ALT levels among inmates. The median value of 68 IU/L was a more accurate representation of the average baseline. Out of the 302 inmates represented in Table 6, only 43 inmates (14.2%) had baseline ALT levels in the suggested normal range of 0 IU/L to 40 IU/L. The majority of inmates (86%) had what would be considered elevated ALT levels (> 40 IU/L). Although there were a large percentage of inmates with significantly elevated ALT levels, this does not necessarily imply that ALT levels correspond with HCV infection and the potential severity of it. Many inmates may not have experienced elevated ALT levels at all, but rather, had a natural baseline ALT level outside of 40 IU/L. Studies have also shown that there is a poor correlation of ALT levels with disease progression in HCV (Carol Bova, personal

communication). The only accurate conclusion that can be drawn from these results is that ALT levels may be a fairly good indicator of an HCV infection, but they are not 100% accurate, and thus, should not be the only determinant of HCV infection. Additional tests, such as liver biopsies and HCV viral loads, should be performed to confirm whether or not liver damage is present and/or the HCV virus is present in the blood.

To evaluate the effects of treatment on baseline ALT levels, the original intent of this assessment was to look at changes in ALT levels over time. At 12 weeks and 24 weeks into treatment, reductions in ALT levels were expected to occur in direct correspondence with reductions in the level of HCV RNA in the blood. Unfortunately, there was not enough data to accurately assess ALT levels beyond the baseline measurement.

In order to determine the overall effectiveness of treatment among inmates, changes in the level of HCV RNA were assessed over time. Quantitative HCV RNA tests are used to measure the level of HCV RNA in the blood of an individual with hepatitis C. These tests do not indicate the severity of the disease or the level of damage to the liver, but they do give an exact measurement of the amount of virus in the blood. This value is most often referred to as the viral load. Prior to the start of treatment, quantitative tests are used to establish a baseline HCV RNA level (United States Department of Veterans Affairs, 2007). Values greater than 800,000 IU/mL are referred to as "high" viral loads, whereas values less than 800,000 IU/mL are referred to as "low" viral loads (Franciscus, 2006). These values are an important indication of whether or not patients will have a successful treatment as it is much more difficult to lower the level of virus in patients with "high" viral loads than patients with "low" viral loads (United States Department of Veterans Affairs, 2007).

According to the results of this study, baseline HCV RNA levels varied significantly among inmates, ranging from as low as 353 IU/mL to as high as 98,400,000 IU/mL. Because of the large range, the mean was calculated at a slightly skewed value of 2,363,344.53 IU/mL. It was more reasonable to consider the average baseline HCV RNA level around the slightly lower median value of 1,131,740 IU/mL. Of the inmates included in the aforementioned range of baseline HCV RNA levels, the majority had what would be considered "high" viral loads. Based on this data, no accurate conclusions can be drawn regarding the severity of HCV infection among inmates with higher HCV RNA levels, or whether or not there is any significance in the fact that most inmates had "high" viral loads. This data may, however, serve as an indicator for predicting which inmates have a considerably lower chance of responding well to treatment and achieving lower levels of virus within their system.

To assess the accuracy of this prediction, changes in HCV RNA levels needed to be measured over time. A patient responding well to treatment would achieve a 2-log reduction in the level of HCV RNA within 12 weeks. Unfortunately, there was not enough data to assess HCV RNA levels at 12 weeks, 24 weeks, or 48 weeks into treatment. The only factor which could accurately be assessed beyond baseline HCV RNA levels was the number of inmates who were able to successfully achieve an undetectable viral load. An undetectable viral load can be defined as the complete elimination of HCV RNA in the blood or a level of HCV RNA too low for a quantitative

assay to detect. In either case, an undetectable viral load is reported in labs as < 615 IU/mL (United States Department of Veterans Affairs, 2007).

Results showed that inmates were able to achieve undetectable viral loads (< 615 IU/mL) as early as 12 weeks into treatment. Success this early into treatment suggests that inmates either had "low" baseline viral loads or responded well to treatment as a result of health factors, viral characteristics, or overall good compliance. Of the 232 inmates with HCV RNA levels recorded beyond baseline, a total of 178 (76.7%) of them were able to achieve an undetectable viral load at least at some point during treatment. These numbers are a good indication that treatment was successful among most inmates during therapy. However, a completely successful treatment is measured in terms of a sustained virologic response. For most inmates, HCV RNA levels were not recorded beyond the end of therapy. Consequently, it could not be determined, based on the amount of available information, as to whether or not inmates who attained an undetectable viral load (< 615 IU/mL) during therapy were able to maintain the same level of virus six months later.

For those 54 (23.3%) inmates in Table 7 who were unable to achieve an undetectable viral load, a lack of success can be accounted for by a number of factors including "high" viral loads at the start of treatment, problems associated with the medication, or alternative health and viral aspects which may have hindered the inmate's response to treatment. Particular factors addressed in this project were HCV genotype, HIV co-infection, and problems associated with therapy.

An analysis was first conducted to determine whether or not HCV genotype had any effect on an inmate's ability to achieve an undetectable viral load (< 615 IU/mL). Studies have shown that variations in HCV genotype are an important indication of how a patient will respond to interferon therapy. HCV genotype 1 accounts for approximately 75% of HCV infections in the United States; however, patients infected with this genotype tend to have the most difficulty responding to interferon. Patients with genotypes 2 and 3, on the other hand, account for only 10 to 20 percent of cases in the United States and are the most likely to respond to interferon therapy (NDDIC, 2006). HCV infections caused by genotype 4 are rarely seen in the United States, but reports show that these patients have a similar difficulty in responding to interferon therapy as those infected with genotype 1 (Herrine, 2002). To account for these differences in HCV genotype and response to therapy, Massachusetts protocol requires that inmates with more problematic genotypes such as 1 and 4 receive a longer period of treatment. Whether or not this extension in treatment length actually helps inmates to achieve an undetectable viral load was the focus of the analysis.

According to the results, there were 217 inmates with a documented HCV genotype who also had recorded HCV RNA levels measured beyond the baseline value. Of the 149 inmates infected with HCV genotype 1, 106 (71.1%) were able to achieve an undetectable viral load (< 615 IU/mL) at some point during treatment. By comparison, 62 (91.2%) of the 68 inmates infected with HCV genotypes 2, 3, or 4, were able to achieve a similar HCV RNA level during treatment. Based on the shear number of inmates infected with each genotype, it is evident that the trends in HCV infection within prisons are accurately representative of the current trends in HCV infection throughout the United States. However, no definitive conclusions can be drawn as to whether or not genotype had any effect on the inmate's abilities to achieve undetectable viral loads (<

615 IU/mL). The percentages suggest that inmates with genotypes 2, 3, and 4 are more likely to achieve an undetectable viral load, but there was also a much smaller number of inmates infected with these genotypes than those infected with genotype 1. A larger set of inmates infected with genotypes 2, 3, or 4 could have caused a drastic change in the percentage that was able to achieve an undetectable viral load (< 615 IU/mL). All in all, there does not appear to be any significant correlation between HCV genotype and the success of treatment. Inmates infected with HCV genotypes 1 or 4 may not respond as well to interferon therapy, but alterations in the length of treatment seemed to help the majority of inmates achieve an undetectable viral load regardless of their genotype.

An additional factor which may account for the unsuccessful outcome of inmates in response to treatment is HIV co-infection. Like hepatitis C, HIV has been a long time problem in the prison system. In a 2003 report by the Metro West Daily News, it was estimated that of the 10,000 inmates in the Massachusetts state prison system, 300 inmates are HIV positive. Of these inmates, 70% are co-infected with HCV. This number accounts for 10% of the estimated 3,000 inmates infected with hepatitis C (Hillman, 2003). To determine whether or not this percentage was reflected in the number of inmates receiving treatment in Massachusetts state correctional facilities, the prevalence of HIV co-infection among inmates in the HCV database was assessed. Results showed that of the 255 inmates with a documented HIV status, 55 (21.6%) were HIV positive. This value represents a slightly higher percentage of inmates with an HCV/HIV co-infection than originally predicted in 2003, but this could be due to a number of factors including a lack of available data regarding HIV status, an increase in the number of inmates with an HCV/HIV co-infection in the Massachusetts prison system, or treatment preference. Under the Massachusetts protocol, inmates co-infected with HIV and HCV are moved to the top of the priority list regardless of when they were diagnosed. This preference, as well as the prevalence of HIV/HCV co-infection in Massachusetts state correctional facilities, is what is most likely reflected in the percentage of inmates who have an HIV co-infection and have received treatment since August 2002.

For most patients with an HIV co-infection, the severity of the HCV infection is amplified. Damage to the liver occurs more rapidly, HCV RNA levels in the blood are typically higher, and response to treatment is compromised. In fact, treatment for patients co-infected with HIV usually requires a much longer time period (6-12 months) and a number of extra precautions not necessarily taken in a normal therapy (CDC, 2005; CDC, 2007). For the inmates with an HIV co-infection in the HCV database, an analysis was conducted to determine whether or not HIV co-infection had any effect on an inmate's ability to achieve an undetectable viral load (< 615 IU/mL). According to the results, 165 inmates with a documented HIV status as well as HCV RNA levels recorded beyond the baseline value were taken into consideration. Of the 143 inmates infected with only HCV, 81.1% were able to achieve an undetectable viral load (< 615 IU/mL). This value is reflective of the results of the previous HCV RNA analysis and further confirms the effectiveness of combination therapy towards a successful treatment. By comparison, only 54.5% of the 22 inmates co-infected with HIV were able to achieve a similar undetectable viral load (< 615 IU/mL). These results suggest that an HIV co-infection at least slightly inhibits an inmate's ability to achieve an undetectable viral load. Out of 22 inmates, there were still a reasonable number of inmates that were able to

respond to treatment. The limited percentage is likely just a reflection of the complications caused by HIV co-infection during treatment. Further data would need to be collected in order to make any more definitive conclusions regarding the correlation between HIV co-infection and the success of treatment. However, based solely on these results, inmates with an HIV co-infection should not be excluded based on this health criterion, alone.

Besides HCV genotype and HIV co-infection, a major factor which may have contributed to the unsuccessful outcome of inmates in response to treatment is complications associated with combination therapy. In the current treatment system, complications are addressed by either a reduction in the dosage of medication or an entire discontinuation of treatment. The solution usually depends upon the nature and severity of the problem. To determine the extent to which these events have occurred since the start of combination therapy, treatment interruptions and early discontinuations in treatment were each individually assessed.

Treatment interruptions can be defined as brief periods of time in which treatment is altered in some manner. These are usually the result of side effects that require alterations in the dosage of medication or a movement between correctional facilities. Results from this study were based on the 233 inmates who had a documented indication of whether or not they had incurred an interruption during treatment. For 183 (82.1%) of these inmates, treatment was administered uninterrupted. This suggests that the majority of inmates either completed treatment successfully or discontinued treatment early as a result of a severe problem. For the remaining 40 (17.9%) inmates, at least one interruption was noted at some point during treatment. Most of these interruptions were recorded as changes in the dosage of interferon and/or ribavirin. Based on these results, it is evident that treatment interruptions were an uncommon occurrence for most inmates on combination therapy. There is no clear indication, however, as to whether or not inmates who experience interruptions in treatment still have the potential to complete treatment successfully or are more likely to cease treatment early. The only conclusion that can be drawn from this information is that for any given hepatitis C treatment, at least a few minor interruptions are to be expected. Medication dosages are not standard for every patient and may require slight variations depending upon individual responses.

Early discontinuation is normally advised for those inmates who experience more severe complications in response to therapy or have an inability to cooperate with treatment. Discontinuation of treatment is defined by a complete cessation in the administration of interferon and ribavirin. Like undetectable viral loads (< 615 IU/mL), the number of inmates who stop treatment early is a fair measure of the success of combination therapy among inmates. According to the results of this study, 243 inmates had a valid indication of whether or not their treatment was stopped early. For as many as 137 (56.4%) of these inmates, treatment was prematurely terminated. This was due primarily to complications with therapy, which appeared to be the most common reason for an inmate's inability to achieve an undetectable viral load (< 615 IU/mL). This data suggests that although combination therapy is successful among a large percentage of inmates, it is evidently just as problematic for a similar proportion of inmates. Because these results are based on a unique set of inmates with valid data, no reliable comparisons can be made between these results and those for the percentage of inmates who were able to achieve an undetectable viral load.

A qualitative assessment of the reasons for ending treatment early showed that termination for most inmates was the result of a specific, individual problem associated with therapy. Broad categories such as poor virologic response, severe side effects, and poor compliance with treatment were used to classify each specific problem and eliminate the large variation in data. The original intention of this assessment was to qualitatively as well as quantitatively analyze the frequency of each particular problem. An understanding of why most inmates are unable to achieve an undetectable viral load would not only contribute to the education of other inmates preparing for hepatitis C treatment, but it would help healthcare managers to prepare appropriately for any potential problem. Unfortunately, there was a limited amount of data from which accurate results or conclusions could be drawn.

Importance of Database

A hepatitis C treatment database is valuable tool for the collection, storage, and organization of an abundant amount of information. As a result of the data collected, demographic summaries can be periodically performed to characterize those inmates who are selected for HCV treatment. Specifically, this report has revealed a slight bias in the proportion of race/ethnicity of inmates who have been eligible for treatment. This finding was also revealed in the 2005 analysis of Massachusetts inmate demographics (Kelly, 2005). The managers of the HCV treatment program can use inmate characteristic summaries like these as a reference to minimize any intentional or unintentional bias which may be a product of the current screening/evaluation protocols and treatment qualifications.

In addition to inmate characteristics, data assessments regarding treatment response and outcomes can also provide direction for the improvement of Massachusetts correctional facility protocols for the management of hepatitis C. For example, as recently as 2005, the screening process for HCV treatment eligibility was different from the currently implemented system. At that time, elevated ALT levels (> 60 IU/L) were needed in order for an inmate to continue with the treatment evaluation process and get a liver biopsy (Kelly, 2005). However, it was later realized that many HCV infected African Americans would still have normal ALT levels (0-40 IU/L) even if they were seriously ill with HCV (Carol Bova, personal communication). As a result of this finding, alterations were made to the protocol in order to eliminate ALT eligibility requirements. Tests for HCV antibody and HCV RNA levels are now used to determine whether or not an inmate qualifies for a liver biopsy and possibly HCV therapy. This alteration will ideally minimize the exclusion of African Americans from treatment in Massachusetts correctional facilities. In this case, summaries of the demographics and outcomes of inmates revealed an issue which may have never been exposed or dealt with had their not been a system for collecting, organizing, and analyzing treatment data.

Beyond the actual process and management of the treatment system, data regarding treatment outcomes and response can serve as an important indicator of whether or not therapy is successful and whether or not this HCV treatment system is worth continuing. For instance, if only a small percentage of inmates were successfully responding to therapy, then it may be in the best interest of the Massachusetts correctional health system to invest their money and limited budget in the treatment and

care of other medical ailments. However, results from this study have shown that HCV treatment in Massachusetts correctional facilities has been very effective.

For inmates who are unable to respond successfully to treatment, data collection can only help to further improve healthcare facilities in prisons. Information regarding treatment complications such as poor response to therapy and medication side effects will keep the staff informed of common medical problems associated with HCV treatment and facilitate them in being more prepared and better equipped to help patients cope with difficult symptoms while on treatment. This information may also be used to help educate inmates on what to expect during treatment prior to the start of therapy.

Recommendations

One of the primary constraints of this project was the limited amount of available data. For all inmates, information was extracted directly from individual hepatitis C worksheets. Any areas that were left blank or had no indication of an unknown or non-applicable variable were correspondingly left blank in the database. These blank spaces were accumulatively referred to by SPSS as "missing system" data.

For most inmates, data was missing in at least one or two different fields. However, for an even larger proportion of inmates, data was missing in nearly every field. Variables such as sustained viral load measures and the inmate's history of substance abuse and health conditions were recorded for less than half the inmates included in the database. This factor not only affected the accuracy of the analyses performed for this project, but also limited the number of fields that could be assessed. In order to ensure the quality and reliability of the database as well the accuracy of statistical analyses based on information in the database, improvements must be made in the collection and recording of data.

One major problem that accounted for the majority of "missing system" data was the irregularity in data recording on the hepatitis C worksheets. Some HIV/Hepatitis C case managers indicated unknown and non-applicable fields on the worksheet with an N/A, an Ø, or a brief note. Other case managers simply left the areas blank with no indication as to whether or not information was unknown, missing, or not applicable. As a standard procedure for data collection, these blank fields were left blank in the database, but whether or not data was actually missing from these fields was unclear.

In order to avoid confusion and future issues like these, it would be ideal for all case managers to follow a standard protocol. This does not mean that data needs to be recorded in exactly the same way for every inmate, but it should be clear in every area of the hepatitis C worksheet as to whether or not data is known, unknown, missing, or not applicable. Regularity among the hepatitis C worksheets would potentially help to eliminate a large proportion of "missing system" data in the database, particularly in areas such as health conditions, mental health conditions, and history of substance abuse and alcohol abuse.

The only other major problem that accounted for "missing system" data and altered the outcome of many of the data analyses conducted for this project was the extent of missing lab results. For some inmates, lab results were extensive. Values were recorded in the hepatitis C worksheet for nearly every lab prior to the start of treatment and during treatment. For the majority of inmates, however, lab results were nearly

nonexistent. Baseline levels were recorded for the required labs, but few values were recorded beyond the start of treatment. In particular, HCV RNA levels 6 months following treatment were missing for nearly every inmate. Less than a quarter of them had any note of a sustained virologic response. The consequences of this missing data were noted primarily during this project in the inability to monitor treatment progress and success among inmates.

As a suggestion to improve the collection of lab data, specifically during and following treatment, the correctional health system may want to consider implementing a stricter data collection system. Any inmate who is receiving treatment for hepatitis C should be closely monitored both during treatment and six months following treatment. Case managers or other health care personnel within the individual facilities should help to ensure during this time that necessary labs are performed at the required times. Lab results recorded immediately following the lab will help to guarantee that data is not missing from the hepatitis C worksheet.

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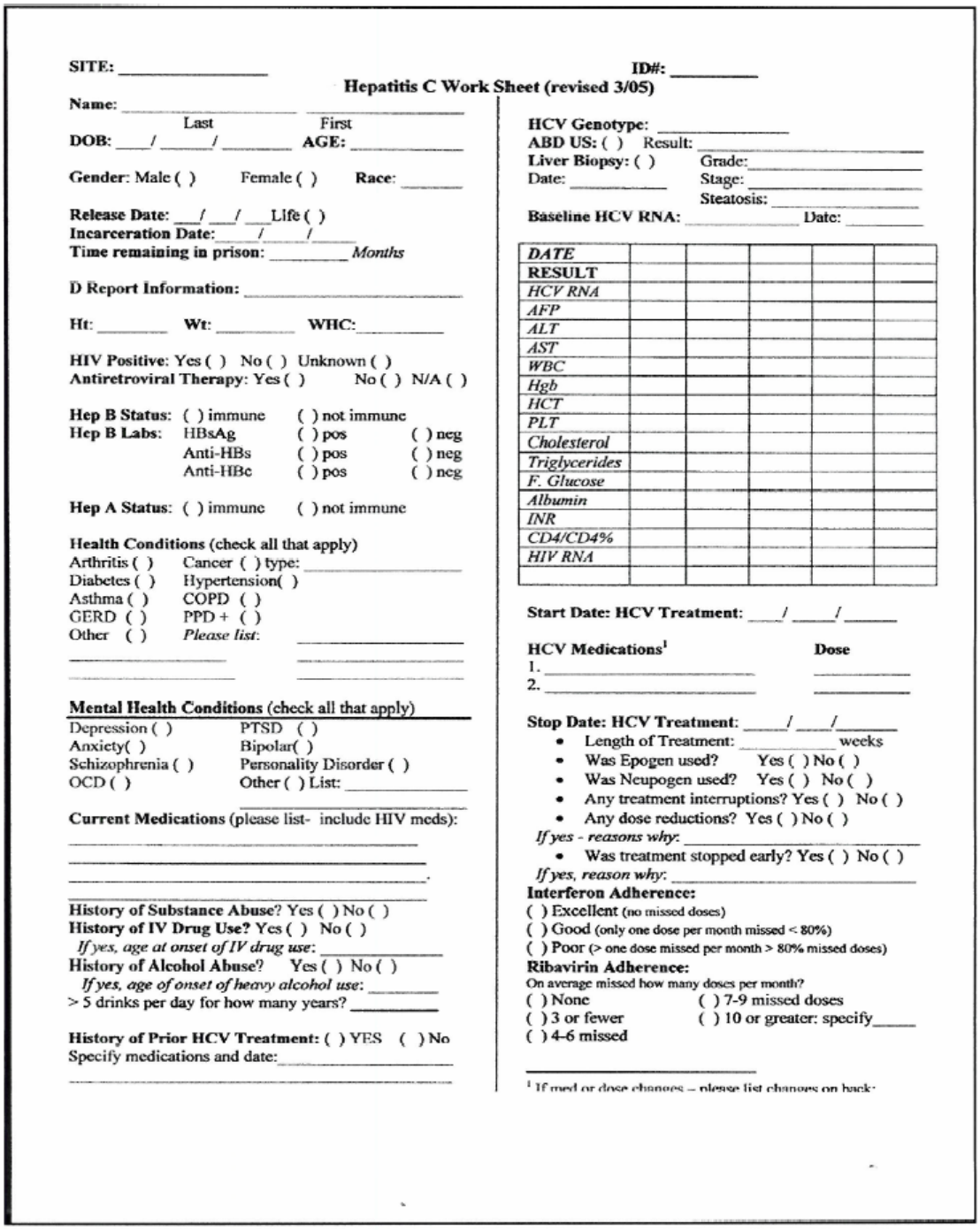
Appendix A: Hepatitis C Worksheet



SITE: _____ ID#: _____

Hepatitis C Work Sheet (revised 3/05)

Name: _____ _____
Last First
DOB: ____/_____/_____ **AGE:** _____

Gender: Male ( ) Female ( ) **Race:** _____

Release Date: ___/___/___ Life ( )
Incarceration Date: ____/____/____
Time remaining in prison: _____ *Months*

D Report Information: _____

Ht: _____ **Wt:** _____ **WHC:** _____

HIV Positive: Yes ( ) No ( ) Unknown ( )
Antiretroviral Therapy: Yes ( ) No ( ) N/A ( )

Hep B Status: ( ) immune ( ) not immune
Hep B Labs: HBsAg ( ) pos ( ) neg
Anti-HBs ( ) pos ( ) neg
Anti-HBc ( ) pos ( ) neg

Hep A Status: ( ) immune ( ) not immune

Health Conditions (check all that apply)
Arthritis ( ) Cancer ( ) type: _____
Diabetes ( ) Hypertension( )
Asthma ( ) COPD ( )
GERD ( ) PPD + ( )
Other ( ) *Please list*: _____
_____ _____
_____ _____

Mental Health Conditions (check all that apply)
Depression ( ) PTSD ( )
Anxiety( ) Bipolar( )
Schizophrenia ( ) Personality Disorder ( )
OCD ( ) Other ( ) List: _____
_____

Current Medications (please list- include HIV meds):
_____
_____
_____.
_____

History of Substance Abuse? Yes ( ) No ( )
History of IV Drug Use? Yes ( ) No ( )
If yes, age at onset of IV drug use: _____
History of Alcohol Abuse? Yes ( ) No ( )
If yes, age of onset of heavy alcohol use: _____
> 5 drinks per day for how many years? _____

History of Prior HCV Treatment: ( ) YES ( ) No
Specify medications and date: _____
_____

HCV Genotype: _____
ABD US: ( ) Result: _____
Liver Biopsy: ( ) Grade: _____
Date: _____ Stage: _____
Steatosis: _____
Baseline HCV RNA: _____ Date: _____

DATE					
RESULT					
HCV RNA					
AFP					
ALT					
AST					
WBC					
Hgb					
HCT					
PLT					
Cholesterol					
Triglycerides					
F. Glucose					
Albumin					
INR					
CD4/CD4%					
HIV RNA					

Start Date: HCV Treatment: ____/_____/_____

HCV Medications[1] **Dose**
1. _____ _____
2. _____ _____

Stop Date: HCV Treatment: _____/____/_____
- Length of Treatment: _____ weeks
- Was Epogen used? Yes ( ) No ( )
- Was Neupogen used? Yes ( ) No ( )
- Any treatment interruptions? Yes ( ) No ( )
- Any dose reductions? Yes ( ) No ( )

If yes - reasons why: _____
- Was treatment stopped early? Yes ( ) No ( )

If yes, reason why: _____

Interferon Adherence:
( ) Excellent (no missed doses)
( ) Good (only one dose per month missed < 80%)
( ) Poor (> one dose missed per month > 80% missed doses)

Ribavirin Adherence:
On average missed how many doses per month?
( ) None ( ) 7-9 missed doses
( ) 3 or fewer ( ) 10 or greater: specify_____
( ) 4-6 missed

_____

[1] If med or dose changes – please list changes on back:

Appendix B: "Inmate Agreement" Form

INMATE TREATMENT AGREEMENT

INFORMED CONSENT FOR HEPATITIS C TREATMENT WITH PEGYLATED INTERFERON AND RIBAVIRIN

General Consent and Treatment

I, _____#_____, agree to be treated for the Hepatitis C virus. I have been informed that I am diagnosed with the Hepatitis C virus. The medical staff has fully advised me regarding this disease process, the effects on my health, treatment options, side effects, and possible outcome of the treatment. I understand that this treatment, and the prescribed medication, works on some people and that it may not clear the virus for all persons receiving it. _____

Compliance

It is imperative that I avoid all illegal drug use, tattoos and alcohol. I have also received information that acquiring new tattoos, non-compliance of the medication regime, D reports for dirty urine or positive results for illegal drugs, as discussed, are grounds to terminate treatment. I understand compliance with therapy is important for a successful treatment outcome. I understand the need for and agree to have routine laboratory testing and to attend clinic visits to monitor the therapy and possible side effects._____

Risks

I have been advised of the numerous side effects which may develop during treatment, some of which are life threatening, and of the importance of notifying the medical staff of any new symptoms. Some side effects may include but are not limited to, are fatigue, hair loss, muscle soreness,"flu" like symptoms, loss of appetite, body rash, rash at injection site, mental health changes, mood swings, depression, increased anger, vision changes, gastrointestinal bleeds and upsets, heart and kidney problems, anemia and birth defects. This therapy can also cause secondary infections, which can lead to death. _____

If side effects do occur, treatment will be evaluated and altered as prescribed by medical staff. Treatment may be discontinued. I understand that after 12 weeks of therapy, my treatment plan will be evaluated for treatment response. At this time therapy may be discontinued or continued for the remaining weeks. I understand that for female patients, a pregnancy test will be done prior to treatment and every month during treatment. It is very important that men avoid fathering children and women avoid pregnancy during treatment, as well as 6 months after treatment has ended. If you are discharged to the streets it is important that you use ***two forms*** of contraceptives, again as well as 6 months after treatment has been stopped. Please ask the medical staff any questions regarding this condition. I understand, regardless of the outcome of treatment, that maintaining my overall health will be beneficial and enhance chances for successful treatment outcome. By signing this agreement, I acknowledge that I have read the above information, that the medical staff has explained the above to me, and that I have had the opportunity to ask questions regarding the disease, its treatment, possible side effects, and any other concerns I have regarding Hepatitis C.

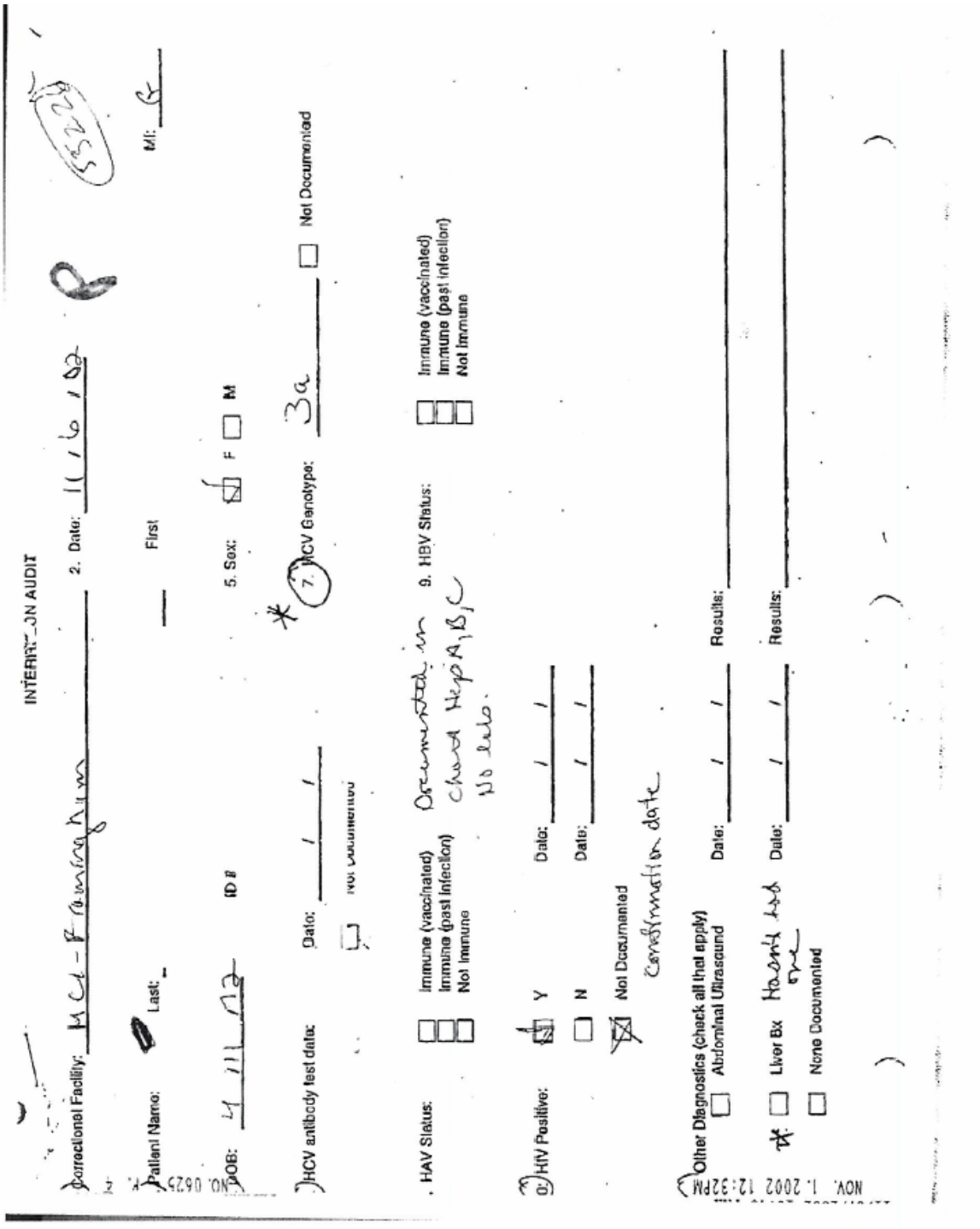
SIGNATURE of the above: _____

DATE: _____

WITNESS(staff): _____DATE:

_____

Appendix C: Example of an Original Inmate Treatment Record



INTERFERON AUDIT

For each date identified, document the results of each lab test done.

VERY IMPT.
LT/AST and V.L.

DATE			10-18-02	10-28-02	10-1-02								
			SGOT	ALT									
Results		10-31-02	187	59									
Alanine Aminotransferase	ALT												
Alpha Feto Protein	AFP												
Hepatitis C Viral Load	HCV-RNA												
HIV Viral Load	HIV VL	<50	<47										
HIV CD4 Count	CD4 ct												
HIV CD4 Percent	CD4 %												

TREATMENT

3.

Medication Regimen	Start Date	Stop Date	6mt post tx ALT	6mt post tx HCV VL
Interferon 3 MU t.i.w.	/ /	/ /		
Interferon 5 MU t.i.w.	/ /	/ /		
Ribavirin 1,200 mg/day	/ /	/ /		
Ribavirin 1,000 mg/day	/ /	/ /		
Pegylated Interferon-a2b (PEG-Intron)	12/17/02	1/30/03		
Other: _____	/ /	/ /		

. INFO WOULD BE: Clinic notes + psyche comments, etc. (wrap up time)

DITIONAL COMMENTS: will be here until August / + see top sheets.

Appendix D: Copy of First Data Collection Form

DOC/HCV Data Collection Form

ID Number _____

Facility (at start of RX)
( ) Baystate (1)
( ) Bridgewater (2)
( ) Boston Pre Rel (3)
( ) Concord (4)
( ) Concord Farm (5)
( ) Framingham (6)
( ) Gardner (7)
( ) MASAC (8)
( ) Norfolk (9)
( ) OCCC (10)
( ) OCCC Min (11)
( ) Pondville (12)
( ) Plymouth (13)
( ) Shirley Med (14)
( ) S. Middlesex (15)
( ) Souza Baran. (16)
( ) Treatment Cent (17)
( ) Walpole (18)

Time remaining in prison: _____ (months)

HCV Treatment Start Date ____ ____ ____

Age _____ (years)

Height: _____ (inches)

Weight: _____ (lbs)

BMI[1]: _____

Gender
( ) Male (1)
( ) Female (2)
( ) Transgender (3)

[1] Short cut to calculate BMI - Step 1: Multiply weight (in pounds) by 703, Step 2: Multiply height (in inches) by height (in inches), Step 3: Divide the answer for step 1 by the answer in step 2, Step 4: round off to nearest number

Race/Ethnicity
( ) Caucasian (1)
( ) Black/African American (2)
( ) Hispanic/Latino (3)
( ) Native American (4)
( ) Asian (5)
( ) Other: _____ (6)

HCV Genotype _____

HCV RNA
Baseline: _____
Week 12: _____
Week 24: _____
Week 48: _____
Other Date: Week ( ): _____

Did subject achieve an undetectable HCV VL?
No ( ) (0)
Yes ( ) (1)
Unknown ( ) (8)

Did subject achieve a sustained virologic response?
No ( ) (0)
Yes ( ) (1)
Unknown ( ) (8)

ALT
Baseline: _____
Week 12: _____
Week 24: _____
Week 48: _____
Other Date: Week ( ): _____

Liver Biopsy Findings: _____

HIV Co-Infection:
( ) No (0)
( ) Yes (1)
( ) Unknown (8)

For HIV coinfected inmates please complete the following:

HIV RNA
Baseline: _____
Week 12: _____
Week 24: _____
Week 48: _____
Other Date: Week ( ): _____

CD4 cell count
Baseline: _____
Week 12: _____
Week 24: _____
Week 48: _____
Other Date: Week ( ): _____

CD4 %
Baseline: _____
Week 12: _____
Week 24: _____
Week 48: _____
Other Date: Week ( ): _____

HIV Antiretroviral Therapy
( ) None (0)
( ) Yes on treatment (1)
( ) Unknown (8)

IF yes, specify _____
_____
_____
_____

Were HIV medications changed while on HCV treatment?
( ) No (0)
( ) Yes (1)
( ) Don't Know (8)

IF yes, reason: _____
_____

Complete the following on everyone:

Hepatitis B status
( ) immune (1)
( ) active (2)
( ) not immune (3)
( ) unknown (8)

Hepatitis A status
( ) immune (1)
( ) not immune (2)
( ) unknown (8)

AFP _____

WBC:
Baseline: _____
Week 12: _____
Week 24: _____
Week 48: _____
Other Date: Week ( ): _____

Hgb:
Baseline: _____

Week 12: _____
Week 24: _____
Week 48: _____
Other Date: Week ( ): _____

HCT Baseline: _____
Week 12: _____
Week 24: _____
Week 48: _____
Other Date: Week ( ): _____

PLT Baseline: _____
Week 12: _____
Week 24: _____
Week 48: _____
Other Date: Week ( ): _____

Other Labs: _____ Baseline: _____
Week 12: _____
Week 24: _____
Week 48: _____
Other Date: Week ( ): _____

Other Labs: _____ Baseline: _____
Week 12: _____
Week 24: _____
Week 48: _____

Other Health Conditions ( ) None (0)
( ) Yes (1)
( ) Unknown (8)

IF YES please check all that apply:

Arthritis	Yes ( ) (1)	No ( ) (0)
Cancer	Yes ( )	No ( )
Diabetes	Yes ( )	No ( )
Hypertension	Yes ( )	No ( )
Asthma/COPD	Yes ( )	No ( )
GERD	Yes ( )	No ( )
PPD +	Yes ( )	No ( )

Other (list): Yes ( ) No ( )

_____

_____

_____

_____

Medications at Baseline (list): (request med profile print- out and attach to data sheet for entry) ( ) Done

_____

_____

_____

_____

Mental Health Diagnoses ( ) No (0)
( ) Yes (1)
( ) Unknown (8)

If YES please check the following:

Depression	Yes ( ) (1)	No ( ) (0)
PTSD	Yes ( )	No ( )
Anxiety	Yes ( )	No ( )
Bipolar	Yes ( )	No ( )
Schizophrenia	Yes ( )	No ( )
Personality Dis	Yes ( )	No ( )
OCD	Yes ( )	No ( )
Other (list)	Yes ( )	No ( )

_____

_____

_____

_____

History of Substance Abuse ( ) No (0)
( ) Yes (1)
( ) Unknown (8)

History of Alcohol Abuse ( ) No (0)
( ) Yes (1)
( ) Unknown (8)

History of IV Drug Use ( ) No (0)
( ) Yes (1)
( ) Unknown (8)

If yes, onset of IV drug use: _____(year)
( ) unknown (88)

HCV Treatment Information

HCV Treatment Regimen:

Interferon alone ( ) (1)
Interferon plus Ribavirin ( ) (2)
Peg-Intron plus Ribavirin ( ) (3)
Pegasys plus Ribavirin ( ) (4)
Peg-Intron alone ( ) (5)
Pegasys alone ( ) (6)
Other ( ) (7) : _____
Unknown ( ) (8)

Length of Treatment

24 weeks ( ) (1)
48 weeks ( ) (2)
Other: ( ) (3) _____weeks
Unknown ( ) (8)

Any Treatment Interruptions? ( ) No (0)
( ) Yes (1)

If yes, specify reason: _____
_____
_____

Any does reductions? ( ) No (0)
( ) Yes (1)

IF yes, indicate med: ( ) interferon (1)
( ) Ribavirin (2)

Early Treatment Discontinuation? ( ) No (0)
( ) Yes (1)

If yes, Reason: ( ) poor virologic response (1)
( ) severe side effects (2)
Specify: _____
_____
_____
( ) poor compliance with RX (3)
( ) Other: specify below (4)
_____
_____
( ) Unknown (8)

Rate Treatment Adherence:

( ) Excellent (reported for Treatments) (1)
( ) Good – missed 1 or 2 (2)
( ) Fair – missed more than 2 But less than 5 (3)
( ) Poor – missed >5 (4)
( ) Unknown (8)

Was Epogen used
( ) No (0)
( ) Yes (1)
IF yes, specify length of time: _____
( ) Unknown (8)

Was Neupogen used?
( ) No (0)
( ) Yes (1)
IF yes, specify length of time: _____
( ) Unknown (8)

Treatment Limiting Side Effects:
Please list All side effects that resulted in a dose change or the need to interrupt or completely discontinue Hepatitis C Treatment

Side Effect	Week on Treatment	Management Strategy

Comments:

Data extracted by: _____ on _____
Initials Date