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IMPLICATIONS FOR THE STATE OF MICHIGAN OF NEW HEPATITIS C TREATMENTS

by

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INTRODUCTION

In December 2013, the United States Food and Drug Administration approved a new treatment for Hepatitis C. Sovaldi, produced by Gilead Sciences, has resulted in cure rates of up to 95% in various clinical trials. However, at $84,000 per course of treatment, the cost for Sovaldi has the potential to put a strain on the State's Medicaid and Corrections budgets. This paper provides a brief background of the biological aspect of Hepatitis C, as well as an overview of treatment options. The paper then moves into a discussion of the potential cost implications for the State of Michigan. This portion is broken down into three subsections: the population of Michigan as a whole, the Medicaid population, and the incarcerated population.

WHAT HEPATITIS C IS

Hepatitis C is a viral disease contracted mainly through blood-to-blood contact that affects the liver. For years after contracting the Hepatitis C virus (HCV), the carrier of the disease may have no symptoms. In some cases, the period with no symptoms can last between 20 and 40 years[1]. The virus can be acute or chronic in nature. In acute cases, which include 20% of the people infected, the virus will leave the person's body without medical intervention in about three to six months with no long-term impact[2].

For chronic cases of HCV, the main long-term impact of the virus is cirrhosis of the liver. Approximately 60% of people who acquire the virus will develop a long-term (chronic) infection that may not cause any problems or may go on to varying degrees of liver damage. The remaining 20% of people who contract the virus will suffer serious liver damage, although it might take around 20 to 30 years to develop serious symptoms. Within this 20% subset, 10% to 15% will remain stable and be able to survive with the chronic infection, while roughly 10% will develop liver failure and/or liver cancer. These chronic infections also may lead to severe loss of liver cells and cirrhosis[3].

Hepatitis C differs from Hepatitis A (HAV) in both the way it is transmitted and the way it is treated. Hepatitis C is mainly a blood-borne virus, while Hepatitis A is transmitted through fecal matter. Both Hepatitis C and Hepatitis B (HBV) can be transmitted through blood, as well as semen or vaginal secretions although transmission of HCV through sexual contact with an infected person is less likely than sexual transmission of HBV. Like HCV, HBV has "acute" and "chronic" variations, while Hepatitis A is strictly an "acute" illness, with symptoms lasting anywhere from a few days to a few months.

An important consideration in patients with HCV is which "genotype" of the virus they have contracted. The genotype is the classification of the virus to which they were exposed and will dictate the types of treatments they will require[4]. There are at a minimum 11 distinct HCV genotypes. In the United States, genotype 1 is the most common HCV genotype. In discerning the genotype of the HCV for the patient, the treatment response can be planned and, in many cases, a determination of the duration of treatment can be made[5].

The Hepatitis C virus is distributed in the following percentages in the United States[6]:

- 60% from injected drug use
- 15% from sexual transmission

[1] Kimmel, C. Baby boomers urged to get tested for hepatitis C, which can lay dormant for years before causing serious health problems, PennLive article.
[2] World Health Organization – Global Alert and Response (GAR) Hepatitis C.
[3] Id.
[4] United States Department of Veteran's Affairs – Hepatitis C Genotypes and Quasispecies.
[5] Centers for Disease Control – Hepatitis C Frequently Asked Questions.
[6] Centers for Disease Control – Hepatitis C Statistics.

- 10% from blood transfusion (mainly pre-1992; before the arrival of comprehensive blood screening)
- 5% from other health-related means
- 10% from unknown means

In the United States, there are about 3.2 million individuals with chronic HCV infection. Infection is most prevalent among those born between 1945 and 1965, the majority of whom were likely infected during the 1970s and 1980s when rates were highest[7].

Historically, males had accounted for twice as many cases of HCV, but in 2011 the rates for both males and females increased and overall proportions of cases were equalized at an estimated 0.4 case per 100,000 in population[8].

According to recent U.S. census data, 12% of the U.S. population is African American, while 75% is white. The HCV infection is more widespread in the African American population than in any other racial group in the United States, as African Americans represent approximately 22% of those with chronic HCV infection[9].

HOW HEPATITIS C IS TREATED

As stated in the previous section, the specific genotype for the infected patient may have a direct impact on his or her treatment decisions. The different genotypes have emerged from the tendency of the Hepatitis C virus to mutate constantly[10]. As the disease spread to diffuse parts of the globe, it began mutating along separate paths from the strain found in other areas. The major genotypes are numbered 1 through 11 and then further classified by the subtype identified as "a", "b", or "c"[11]. Table 1 summarizes genotypes by the area where the strain is highly prevalent[12].

Table 1

Genotype by Location	
1a	North America, South America, Australia
1b	Europe, Asia
2a	Japan, China
2b	United States, Northern Europe
2c	Western Europe, Southern Europe
3a	Australia, South Asia
4a	Egypt
4c	Central Africa
5a	South Africa
6a	Hong Kong, Macau, Vietnam
7a	Thailand
7b	Thailand
8a	Vietnam
8b	Vietnam
9a	Vietnam
10a	Indonesia
11a	Indonesia

[7] Centers for Disease Control – Hepatitis C Frequently Asked Questions.
[8] Centers for Disease Control – Hepatitis C 2011 Statistical Commentary.
[9] Pearlman B., *Clinical Infectious Diseases*, Hepatitis C Virus Infection in African Americans.
[10] World Health Organization – Hepatitis C. http://www.who.int/csr/disease/hepatitis/whocdscsrlyo2003/en/.
[11] The genotypes are 1a, 1b, 2a, 2b, 2c, 3a, 4a, 4c, 5a, 6a, 7a, 7b, 8a, 8b, 9a, 10a, and 11a.
[12] Hepatitis Central – Genotypes Explained. http://www.hepatitiscentral.com/hcv/genotype/explained.html.

As Table 1 shows, genotypes 1 through 3 are found globally, while type 4 is generally found in the Middle East, Egypt, and Central Africa. Type 5 is centered in South Africa, while genotypes 6 through 11 are spread across Asia.

Although the genotypes are listed separately in the table, it is possible for a person to present with multiple genotypes simultaneously. People infected with the type 1 genotypes tend to respond poorly to treatment courses that only use interferon, while genotypes 2 and 3 respond better to a single course of treatment with interferon.

For a majority of people infected with acute Hepatitis C, no symptoms present themselves, meaning that an early diagnosis of the disease is rare. One of the main risks of HCV is that the infection may remain undiagnosed until well after damage to the liver has begun. Once a Hepatitis C infection is suspected, the process to fully diagnose the disease occurs in two steps. First, the patient is screened for anti-HCV antibodies to identify infection, and then a nucleic acid test to identify HCV RNA is performed for those determined to have the antibodies mentioned above. The second step is necessary because a small percentage of the population who test positive for acute HCV do not develop chronic HCV; rather, their immune system spontaneously clears the infection[13].

Before the introduction of Sovaldi (the brand name of the drug sofosbuvir), the general course of treatment consisted of subcutaneous injections of interferon combined with the antiviral drug ribavirin[14] . Interferons are proteins produced by organisms in response to a viral infection in order to combat the virus. These proteins prevent the viral DNA from replication, thus stopping the proliferation of the virus within the body. Interferons are divided into three classes: α, β, and γ, with each class affecting the body differently. For the treatment of Hepatitis C, interferons from the α class are most effective[15]. Interferon treatments are generally accompanied by side effects that mimic flu symptoms, as well as fatigue and insomnia. In some cases, the treatment can lead to depression, weight-loss, and diabetes. In patients presenting genotypes 2 or 3, Sovaldi is combined with ribavirin, thus removing interferon therapy from the treatment plan. Additionally, patients who are ineligible to receive a treatment regimen involving interferon may be considered for a 24-week course of Sovaldi combined with ribavirin[16]. Patients are deemed ineligible if they show intolerance to interferon or have an autoimmune disorder, hypersensitivity to the drug peginterferon alfa, decompensated hepatic disease, an uncontrolled depressive illness, low baseline hemoglobin, or a history of cardiac disease[17].

The other half of the most common HCV treatment is ribavirin: a drug from the nucleoside analogue class that is taken daily in oral tablet form. Nucleoside analogues are incorporated into growing RNA strands because they mimic the make-up of RNA building blocks, but instead act as terminators in order to stop replication of the Hepatitis C virus[18]. While interferon can, in rare cases, be used as a monotherapy, ribavirin must be used in combination with another form of treatment. Like ribavirin, Sovaldi is a nucleoside analogue, meaning that treatment for HCV can now be entirely oral, with the removal of the need for interferon injections. It should be noted that treatment courses are the same regardless of which stage of the disease the individual patient is in; rather, it is the specific genotype

[13] World Health Organization: Hepatitis C Fact Sheet. http://www.who.int/mediacentre/factsheets/fs164/en/.
[14] Although the most recent treatment protocols included the use of protease inhibitors, in combination with interferon and ribavirin, many patients opted not to follow this treatment due to severe side effects.
[15] Omudhome Ogbru: Interferon, http://www.medicinenet.com/interferon/article.htm.
[16] Food and Drug Administration: Approval of Sovaldi (sofosbuvir) tablets for the treatment of chronic hepatitis C. http://www.fda.gov/forconsumers/byaudience/forpatientadvocates/ucm377920.htm.
[17] AASLD-IDSA: Commonly Used Abbreviations and Their Expansions. http://www.hcvguidelines.org/full-report/methods-table-3-commonly-used-abbreviations-and-their-expansions.
[18] Chris Barnes: The REAL Drug to Beat in Hepatitis C Treatment: Ribavirin, http://www.hepmag.com/articles/ribavirin_hepatitisc_2502_12232.shtml.

that determines duration of treatment and which medications will be used. Table 2 shows a summarization of the treatment options for HCV genotypes 1 through 4[19]:

Table 2

HCV Treatment Courses[20]		
Patient Type	**Treatment**	**Duration**
Genotype 1 or 4 CHC[a)]	Sovaldi+Peginterferon Alfa+Ribavirin[b)]	12 weeks
Genotype 2 CHC	Sovaldi+Ribavirin[b)]	12 weeks
Genotype 3 CHC	Sovaldi+Ribavirin[b)]	24 weeks
Genotype 2 or 3 CHC	Peginterferon Alfa+800mg Ribavirin	24 weeks
Genotype 1 or 4 CHC	Peginterferon Alfa+Ribavirin[b)]	48 weeks

[a)] CHC is the abbreviation of Chronic Hepatitis C.
[b)] For patients weighing less than 75 kg (approximately 165 pounds), a dosage of 1,000 mg is recommended. All others should take 1,200 mg.

Sovaldi, developed by Gilead Sciences, Inc., was approved by the Food and Drug Administration in December 2013. During clinical tests, Sovaldi was shown to increase the percentage of participants who obtained a sustained virologic response (SVR)[21]. In Study Neutrino, 327 treatment-naive patients with genotype 1 or 4 were given a combination of Sovaldi, interferon, and ribavirin over the course of 12 weeks[22]. The study resulted in an overall SVR rate of 90%, with 89% of genotype 1 participants and 96% of genotype 4 participants reaching SVR. Study Fission also studied treatment-naive patients, but those infected with genotype 2 or 3. Additionally, patients were divided into a group that received Sovaldi and ribavirin for 12 weeks, or interferon and ribavirin for 24 weeks. While the overall SVR rate was equal (67%), the patients with genotype 2 in the Sovaldi group reached SVR at a rate of 95% versus 78% in the other group. The results with Sovaldi for patients with genotype 3 were a 56% attainment of SVR versus 63% for the other group[23].

While the high percentage of patients obtaining SVR in the preceding studies is considered encouraging, it should be noted that obtaining a sustained virologic response to Hepatitis C does not prevent future infections or relapses. Since the treatment works through tricking the virus in the body not to replicate, it does not build up the body's immunity to other genotypes or future reinfection. Thus, people who were first infected through risky behavior (such as sharing needles) would place themselves at future risk by continuing such behavior.

IMPLICATIONS FOR HEPATITIS C TREATMENT IN MICHIGAN

General Population

Since it is believed that up to 50% of individuals with chronic Hepatitis C are asymptomatic, and thus unaware that they have HCV, the true number of cases in Michigan is difficult to estimate[24]. However, working from the known demographics of the disease, it is possible to estimate the potential HCV population in Michigan. Using data from the National Health and Nutrition Examination Survey

[19] Sovaldi efficacy has been established for patients with genotypes 1, 2, 3, or 4, as these are the most prevalent genotypes found in the United States.
[20] Ribavirin. http://www.drugs.com/pro/ribavirin.html.
[21] In order to reach SVR, a patient must be tested and shown to have no detectable hepatitis C virus in his or her blood six months after the end of treatment.
[22] A patient is "treatment-naive" if he or she has not undergone treatment for a particular illness.
[23] Approval of Sovaldi (sofosbuvir) tablets for the treatment of chronic hepatitis C, http://www.fda.gov/forconsumers/byaudience/forpatientadvocates/ucm377920.htm.
[24] Denniston, M. M., Klevens, R. M., McQuillan, G. M. and Jiles, R. B. (2012), Awareness of infection, knowledge of hepatitis C, and medical follow-up among individuals testing positive for hepatitis C: National Health and Nutrition Examination Survey 2001-2008. Hepatology, 55: 1652–1661. doi: 10.1002/hep.25556.

(NHANES), the prevalence of "anti-HCV positive" individuals in the United States is estimated to be about 1.6%[25]. People who are classified as anti-HCV positive include those who have an active HCV infection, those who spontaneously resolved HCV, and those who have attained an HCV-treatment-related cure. The NHANES data do not include individuals who were incarcerated or homeless, nursing home residents, undocumented immigrants, or people serving on active duty. Expanded prevalence studies that attempted to take these segments of the population into account estimated a prevalence of 2.0%. Combining this with the evidence that the number of new chronic HCV cases in Michigan during the year 2012 skewed to the higher end of the spectrum[26] means that a prevalence rate of 1.8% will be used for the purposes of this paper. The 2012 Census estimate for the population of Michigan was 9,882,519. At a prevalence of 1.8%, this would give a 2012 estimate of 177,885 cases of chronic Hepatitis C in the State. Assuming the continuing trend of approximately 80 new cases of chronic HCV per 100,000 people per year (an incidence rate of .08%) noted in the Hepatitis B and C Surveillance Report 2012 released by the Michigan Department of Community Health (DCH), this would bring the current estimate of total cases to 201,885.

The out-of-pocket costs for members of the general population will vary depending on whether they are covered by an insurance plan, and the specific details of the plan. However, a rough idea of the costs related to the treatments discussed in the previous section can be obtained by looking at the Wholesale Acquisition Cost (WAC)[27] of the drugs. Table 3 shows the WAC of the three main treatment components for HCV, while Table 4 combines the treatment cost data with the recommended courses of treatment to present an estimate of total treatment costs.

Table 3

Medication Cost by Duration[28]			
	12 weeks	**24 weeks**	**48 weeks**
Sofosbuvir	$84,000	$168,000	N/A
Ribavirin[a)]	$2,500	$5,000	$10,000
Peginterferon Alfa[a)]	$6,000	$12,000	$24,000
[a)] Due to multiple brand and generic presentations these costs are estimates.			

Table 4

Cost of Treatment			
	Treatment	**Duration**	**Estimated Total Cost**
Genotype 1 or 4 CHC[a)]	Sovaldi+Peginterferon Alfa+Ribavirin	12 weeks	$92,500
Genotype 2 CHC	Sovaldi+Ribavirin	12 weeks	$86,500
Genotype 3 CHC	Sovaldi+Ribavirin	24 weeks	$173,000
Genotype 2 or 3 CHC	Peginterferon Alfa+800 mg Ribavirin	24 weeks	$17,000
Genotype 1 or 4 CHC	Peginterferon Alfa+Ribavirin	48 weeks	$34,000
[a)] CHC stands for Chronic Hepatitis C.			

[25] The prevalence of HCV is defined as the number of people in the total population observed infected, while the incidence of HCV is the number of new infections in a specified region within a specified time period (in this case, one year).
[26] According to the Hepatitis B and C Surveillance Report 2012 published by Michigan Department of Community Health, there were 8,005 reported cases of chronic Hepatitis C. This compares to a report published by the Centers for Disease Control stating that there were 145,762 nationally reported cases with the number of reports per state ranging from a low of 521 (Wyoming) to a high of 9,747 (Pennsylvania).
[27] The WAC is defined as an estimate of the manufacturer's list price for a drug to wholesalers or other direct purchasers. This does not include discounts or rebates available for the drugs. This definition of WAC can be found in the Social Security Act, Section 1847A.
[28] University of Washington – Hepatitis C Online: Medications to Treat HCV. http://www.hepatitisc.uw.edu/page/treatment/drugs/.

According to a study performed using NHANES data, the weighted percentage of HCV patients infected with genotype 1 in the United States is approximately 75%. Additionally, genotype 2 patients make up about 16% of the infected population, while genotype 3 patients comprise 8%[29]. If it is assumed that 75% of people with HCV are aware of their diagnosis and choose to be treated, the single-year cost of replacing the current treatment with a sofosbuvir-based regimen would result in an increase of $15.0 billion statewide. If the percentage of people presenting for treatment is set at 50%, the single-year cost decreases to $10.0 billion. These figures are for the State of Michigan as a whole; thus, the entire costs would not be borne by the State.

Medicaid

To date, the Department of Community Health has not promulgated policies for the implementation and use of Sovaldi. Coupled with the fact that potential costs stemming from the use of this treatment can vary greatly depending on coverage decisions, the absence of policies makes a fiscal impact for the State difficult to pinpoint. A very rough estimate of the fiscal burden can be made by using Medicaid enrollment and parameters such as incidence rate and weighted percentages of genotype distribution. Medicaid and CHIP (Children's Health Insurance Program) enrollment for June 2014 was at 2,188,716 individuals[30] with 1,007,528 of that population being children[31]. Since it is unusual for children to have HCV and rarer for that infection to be at a level of severity requiring treatment, the child population will be removed from the estimates. This leaves an adult population of 1,181,188 individuals, and given that the prevalence rate is 1.8% with 75% of people presenting with genotype 1, 16% with genotype 2, and 9% with genotype 3, it is possible to calculate costs based on how many individuals present for treatment. If all of the approximately 21,261 people in this estimation were to receive the sofosbuvir-based treatment regimen, the single-year cost would result in an increase of approximately $2.1 billion Gross. A presentation rate of 75% would result in a cost increase of approximately $1.6 billion Gross, while a rate of 50% would result in a cost increase of approximately $1.1 billion Gross.

Several limitations of this estimation must be emphasized. The first is that the percentages used were from individual studies, which sometimes involved a small number of patients. While it is generally agreed that genotype 1 comprises the majority of cases of Hepatitis C in the United States, the specific percentage of the population varies across studies. The second limitation stems from the age distribution of Hepatitis C patients. Since the prevalence of Hepatitis C is highest among people born between 1945 and 1965, it is likely that the percentage of the Medicaid population with HCV is less than 1.8%. While the first limitation should only result in relatively incremental variance in the cost estimate, the second limitation would result in the reported estimates overstating the true cost of a sofosbuvir-based treatment regimen for the Medicaid population.

A small population of 112 individuals has been treated with Sovaldi through the DCH (10 in Fee-for-Service and 102 in the Health Plans) for a current cost of $8.9 million (approximately $79,464 per patient) prior to rebates. This can be compared to an analysis of current Medicaid spending which shows that fiscal year (FY) 2012-13 Hepatitis C-related pharmacy costs for 172 chronic Hepatitis C patients were $3.2 million Gross, or an average of $18,605 per patient[32]. Before the introduction of Sovaldi, the largest cost for chronic HCV patients occurred when cirrhosis of the liver caused

[29] Nainan, Omana V. et al: Hepatitis C Virus Genotypes and Viral Concentrations in Participants of a General Population Survey in the United States. Gastroenterology, Volume 131, Issue 2, 478-484.
[30] Department of Health and Human Services – Medicaid & CHIP: June 2014 Monthly Applications, Eligibility Determinations and Enrollment Report. http://www.medicaid.gov/AffordableCareAct/Medicaid-Moving-Forward-2014/Downloads/June-2014-Enrollment-Report.pdf.
[31] Department of Health and Human Services – Green Book Report of Key Program Statistics June 2014. http://www.michigan.gov/documents/dhs/2014_06_GreenBook_463089_7.pdf
[32] The $3.2 million reflects pharmacy costs related to Hepatitis C only, and do not reflect other general pharmacy costs for this population.

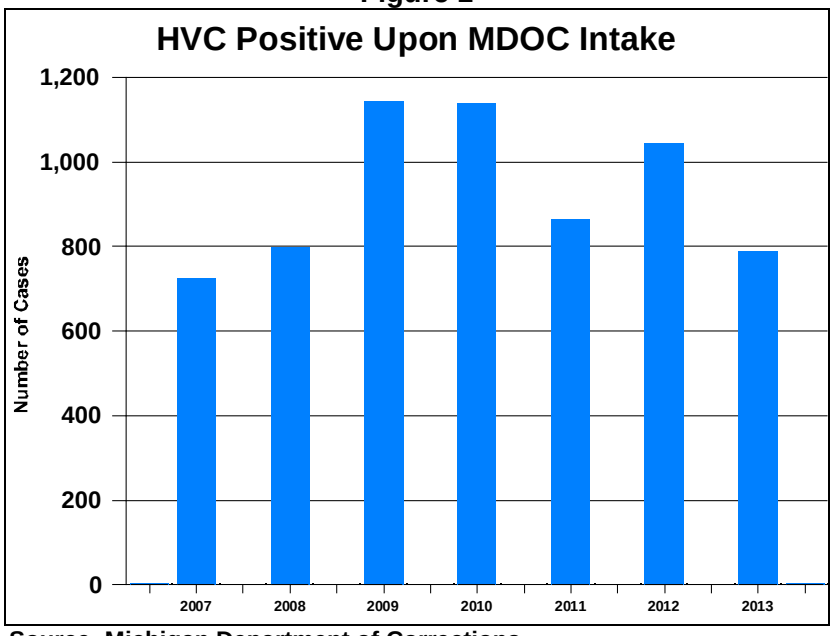
irreparable damage to the organ. In FY 2010-11, the DCH covered the costs of two liver transplants for a total of $374,206[33].

One of the main drivers of cost with chronic HCV is the presence of liver complications. The DCH has found that the cost for individuals with chronic HCV and liver complications is $39.8 million Gross higher than the cost for individuals with chronic HCV but no liver complications. Given that the population with liver complications consists of 3,378 individuals, this works out to approximately $982 in increased costs per month, per individual with liver complications[34]. While the true cost implications for the State from the implementation of Sovaldi as a main treatment for Hepatitis C are nebulous, past expenditures can provide a basis point for any future analyses.

Currently Incarcerated Individuals

Hepatitis C affects those in the prison system in greater proportion compared with the general population. This is a result of several factors, including risky behaviors such as sharing needles for drug use and engaging in unprotected sexual activity. Additionally, as the percentage of the prison population over the age of 55 increases, the impact of HVC on the medical expenses of the State also increases, as the 55-plus population generally has the highest incidence of HCV[35]. Since 2007, the Michigan Department of Corrections (MDOC) has screened for HCV in incoming and discharged prisoners. As shown in Figure 1, since 2007, the average number of incoming prisoners testing positive for HCV has been about 930 each year.

Figure 1

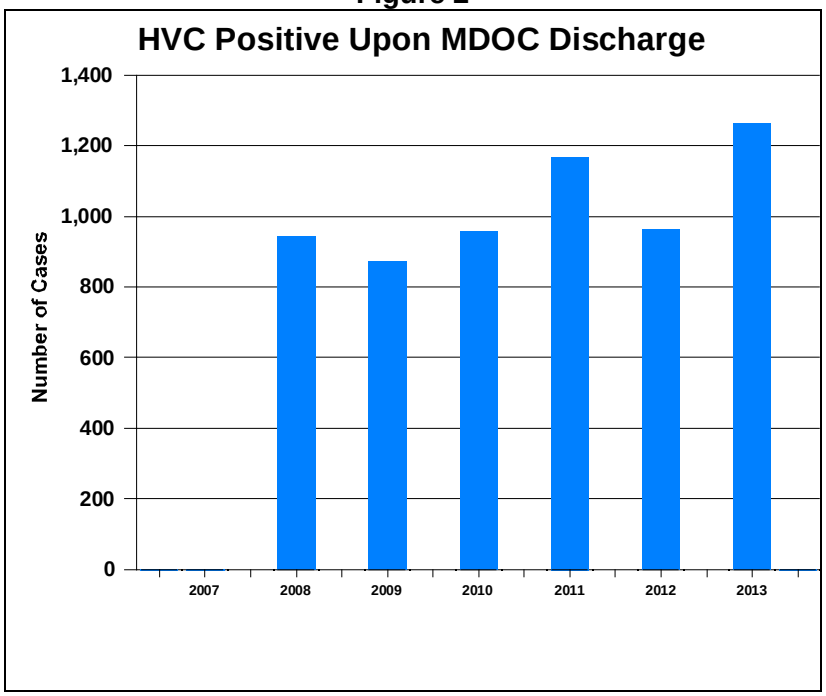


Source: Michigan Department of Corrections

[33] Statistics provided by the Department of Community Health. This figure covers the fee-for-service population only as data for the managed care population was not available.
[34] Id.
[35] Perry S., CDC: All baby boomers should get tested for hepatitis-C virus, MinnPost article.

In 2013, approximately 4,445 prisoners were HCV-positive, which was 10% of the total population. In contrast, the prevalence in the general population of the State is estimated to be about 1.8%[36]. The high number of positive tests, however, does not mean that all of the infected inmates are being treated. With the long dormant period that generally takes place with HCV, the number of critical cases in MDOC facilities is approximately 120 prisoners[37]. As shown in Figure 2, since 2008, the MDOC had averaged about 1,030 positive HCV prisoners upon discharge per year. (Data from 2007 are not available.)

Figure 2



Source: Michigan Department of Corrections

In FY 2013-14, the total expenditures on HCV drugs were around 12% (approximately $3.7 million) of the total pharmacy services line item ($31.6 million) in the MDOC budget. During FY 2013-14, approximately 37 people were treated with the second generation of Direct Acting Anti-Viral Treatment (DAA). The FY 2014-15 budget recommendation from the Governor for the HCV treatments included $4.9 million to fund 15 additional DAA treatment "slots" for critical stage HCV patients with the sofosbuvir treatment. The 15 "slots" were in addition to five of these treatment "slots" available under existing funding levels. Ultimately, the Legislature approved and the Governor signed a $4.4 million appropriation increase for new HCV treatments.

The Federal Bureau of Prisons - Department of Justice (FBOP) has set the criteria of second generation DAA treatment for prisoners with "advanced" liver fibrosis, which means stage 3 and

[36] According to MDCH estimates, there are approximately 80 HCV cases per 100,000 people in Michigan. According to several national studies, current models do not account for those individuals who are incarcerated, homeless, in nursing homes, hospitalized, or on active military duty. According to a 2011 study Hepatitis C virus infection in USA: an estimate of true prevalence, Chak et al. which includes those groups, the prevalence figure was estimated to be 5.2 million people, which equates to a 2.0% prevalence rate. In 2013, the United States as a whole had a median age of 37.5 years and the State of Michigan had a median age of 39.6 years. With this bias toward an older population, a figure of 1.8% prevalence rate was selected. The 1.8% is an attempt to include those groups of people excluded in the NHANES study.

[37] The numbers from MDOC HCV testing do not reflect the number of refusals and include discharge on the maximum sentence without parole and discharge on the maximum sentence after parole and return. Prisoners are tested for HCV within 90 days prior to parole. However, if they have a previous positive diagnosis of HCV, retesting prior to release is not required. The number of prisoners released with a positive diagnosis of HCV is those individuals counted as positive rather than the actual number of tests performed at the time of release.

stage 4, on a scale of 0-4, where 4 is cirrhosis. It also gives priority to prisoners with HIV co-infection, regardless of liver fibrosis stage. The MDOC currently treats only stage 4 HCV cases with no priority for those with HIV. The MDOC treatment guidelines are presently more restrictive than those of the FBOP.

CONCLUSION

Hepatitis C has come to the forefront of the policymaking process because its impact in the United States has grown rapidly. In 1999, the mortality rate per 100,000 people for HCV was three. For HIV, it was six per 100,000. In 2007, the mortality rate from HCV (five per 100,000) exceeded the rate from HIV (four per 100,000)[38]. Another explanation for the increasing attention on HCV is the new drugs (mentioned in previous sections) that have been introduced to combat the disease. The ultimate potential cost to the State and Federal government is unknown due to the uncertainty over pricing and who will be treated. The efficacy of the drugs is also unknown at this time. Without a long-term study on individuals with the HCV genotypes that can be treated by the new drugs, it is unknown whether the transmission of the disease may decline or if it is possible that the virus will reemerge in a person thought cured, without further exposure. It has been estimated that the peak impact of HCV will not be felt in the United States until sometime around 2030[39]. With all of the uncertainties associated with HCV, it will be important to continually examine the issue and observe how the new treatment regimens affect the outcomes of those with HCV.

[38] University of Washington – Hepatitis C Online.
[39] Id.

Appendix

Current Practices in Other States

Washington State

This State budget act provided for the development of a comprehensive Hepatitis C Strategic Plan[40]:

"Within the appropriations provided in this section, the department shall update its hepatitis C strategic plan for the state to include recommended actions pertaining to, at a minimum:

(i) Using prevalence data to determine the number of undiagnosed hepatitis C patients in the state;

(ii) How to best reach undiagnosed patients, with special consideration to people born between 1945 and 1965, and new infections;

(iii) The status of the more than sixty thousand state residents who have already been diagnosed with hepatitis C;

(iv) A framework for improving hepatitis C testing and linkage to medical care; and

(v) A framework for the prevention of hepatitis C.

The Department of Health shall present its updated strategic hepatitis C plan to the appropriate committees of the Legislature by September 15, 2014."

California

Enacted legislation provides for evidence-based Hepatitis C/HIV public demonstration projects. According to the bill's digest[41]:

"This bill would authorize the department [of Public Health] to implement up to 4 demonstration projects that may operate for a period of up to 2 years for to allow for innovative, evidence-based approaches to provide outreach, [and] HIV and Hepatitis C screenings…The bill would require, upon appropriation in an annual Budget Act, the department to award funding, on a competitive basis, to a community-based organization or local health jurisdiction to operate a demonstration project, as specified. The bill would require the department, at the conclusion of the demonstration projects, to review the effectiveness of each demonstration project and determine whether the demonstration project model can be implemented on a statewide basis."

Colorado and Connecticut[42]

Both states are instituting testing programs for Hepatitis C screenings for baby-boomer population (those born between 1945 and 1965). Colorado is recommending this screening while Connecticut is requiring primary care physicians to offer the testing to those individuals.

[40] http://apps.leg.wa.gov/documents/billdocs/2013-14/Pdf/Bills/Session%20Laws/Senate/6002-S.SL.pdf.
[41] http://www.leginfo.ca.gov/pub/13-14/bill/sen/sb_0851-0900/sb_870_bill_20140620_chaptered.htm
[42] NCSL Hepatitis C Overview: http://www.ncsl.org/research/health/hepatitis-c-overview.aspx.