Preface

Emergent increases combined with the adverse health impact of viral hepatitis remain significant and urgent public health challenges of our day. Viral hepatitis account for considerable morbidity and mortality and leave devastating fiscal and emotional costs to individuals, families, and communities in its wake.

Although estimates of chronic viral hepatitis differ, the public health community is already poised for a sharp increase in persons infected with viral hepatitis, and/or become co-infected with viral hepatitis and HIV. Labeled the silent epidemic because these infections remain asymptomatic for up to twenty years before clinical manifestations indicate treatment be sought, both chronic hepatitis B and C are the primary causes of cirrhosis and ultimately, hepatocellular carcinoma.

Although the Unites States (U.S.) has decades of investment and support under its belt, the U.S. still experiences a disproportionate burden of viral hepatitis, with substantial health disparities being observed across racial and ethnic population groups. These inequities are multifaceted, complex and are evident in access to screening; diagnosis, counseling, and treatment across these population groups. Understanding the multilevel and overlapping nature of viral hepatitis including underlying social and structural determinants, is key to effectively addressing hepatitis disparities.

To this end, this executive summary developed by the Hepatitis Foundation International, reviews highly critical findings on viral hepatitis infections B, and C and uses these findings as a foundation for augmenting and expanding the current war against viral hepatitis while decreasing stigma and addressing hepatitis disparities. This document is by no means exhaustive and seeks Stakeholder input and deliberation. HFI hopes this Stakeholder meeting and executive summary represent a starting point for Stakeholders nationwide to continue to join with us and assist in the continuing campaign against hepatitis.

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Overview

The mandate to address viral hepatitis, a national and global threat to health and longevity, is highly crucial and extends beyond the public sector. Grave disparities exist in the incidence and prevalence of viral hepatitis across different racial/ethnic groups, as well as in access to screening, diagnosis, counseling and treatment.

A multi-stakeholder approach is needed to address the scale and scope of viral hepatitis in the United States (U.S.), and to overcome challenges that disproportionately impact communities. Furthermore, it will be required in order to ensure the investment in, implementation and optimization of prevention, treatment and care initiatives across the nation.

For this reason, the Hepatitis Foundation International (HFI) has organized the National Stakeholders’ Consensus Meeting to assess unaddressed needs in the “war” against viral hepatitis which builds upon the goals of the 2011 and 2014 U.S. Department of Health and Human Services’ (HHS) Viral Hepatitis Action Plan. The HHS Viral Hepatitis Action Plan prioritizes the reduction of health disparities and calls for multi-agency, multi-stakeholder, multi-sectoral efforts in this regard.

The purpose of the HFI Stakeholders’ Meeting is to identify sound policy recommendations, key messages and initiatives that can addend, complement, and/or supplement existing strategies to reduce the disparate burden of hepatitis. The outcome of the HFI 2014 Stakeholders’ Meeting will be a well-researched white paper that can serve as a guide for education, advocacy and engagement efforts by stakeholder groups throughout the United States. In addition, HFI will use these policy findings as the basis for inclusion in its programs, services, health policy, advocacy, research and educational awareness initiatives.

To support this meeting, a preliminary version of the white paper has been prepared to serve as a executive briefing summary. After the Stakeholders’ Meeting, this briefing document will be expanded, amended, finalized, and widely disseminated so that additional stakeholders will become engaged in the fight against a virus that now leads to more deaths per year in the United States (U.S.) than HIV/AIDS. The subsections that follow provide highlights of findings from HFI’s overall preliminary hepatitis disparities white paper.
Section 1: Epidemiology and Surveillance

Where’s the Data?

In the U.S., it is estimated that liver disease affects up to 30 million people, or 1 in 10 individuals (CDC 2014). It is a common belief that most liver disease is related to alcohol. However, there are more than 100 different liver diseases and conditions. It is estimated that more than 500,000 new patients with liver damage are diagnosed each year in the U.S. as a result of rising rates of obesity, substance abuse, alcohol consumption, and viral hepatitis.

The Hepatitis B virus (HBV) and Hepatitis C virus (HCV) are the leading causes of liver-related chronic diseases in the U.S. and globally, rendering individuals at a higher risk of death from cirrhosis and liver cancer. It is estimated that 240 million people have chronic HBV infection worldwide, with 1.2 million living in the U.S (CDC 2014). More than 780,000 people die every year due to the acute or chronic consequences of hepatitis B (WHO 2014).

Currently, over 3 million Americans are infected with HCV and more than 17,000 persons per year becoming newly infected. The number of deaths in the U.S. due to chronic HCV infection now exceeds deaths due to HIV. The consequences of HCV infection are expected to grow rapidly in the coming years, with the number of advanced liver disease patients quadrupling between 2009 and 2029. Fortunately, screening for HCV coupled with newer treatment regimens now offer the opportunity to change this trajectory.

While estimates of chronic viral hepatitis differ, the public health community is already poised for a sharp increase in persons infected with viral hepatitis, and/or co-infected with viral hepatitis and HIV. Labeled the silent epidemic because these infections remain asymptomatic or pauci-symptomatic for up to twenty years before clinical manifestations indicate treatment is sought, both chronic hepatitis B and C are the primary causes of cirrhosis and, ultimately, hepatocellular carcinoma.

The National Cancer Institute estimated that in 2014 alone, another 1,665,540 Americans would join the ranks of the 13 million Americans currently living with one or more cancers. Moreover, more than 66.1% of these persons will survive for five years or more after their diagnosis. In contrast, only 16.6% of Americans with diagnosed hepatocellular carcinoma and/ or other cancers of the liver will live for five years or more. As a direct result of hepatotropic virus, hepatocellular carcinoma is considered “…the sixth most common cancer in the world, and the third most fatal cancer.”
**Image 1: Hepatitis B Virus Surface Antigen Positive (%). Source: [LabCorp.com]**

**Hepatitis B Virus Surface Antigen Positive (%)**
United States map showing percentage of positive Hepatitis B virus surface antigen samples observed in 2009. Data classified using quintiles.

![Hepatitis B Virus Surface Antigen Positive (%)](LabCorp.com)

**Image 2: Hepatitis C Virus Antibody Positive (%). Source: [LabCorp.com]**

**Hepatitis C Virus Antibody Positive (%)**
United States map showing percentage of positive Hepatitis C virus antibody samples observed in 2009. Data classified using quintiles.

![Hepatitis C Virus Antibody Positive (%)](LabCorp.com)
As is demonstrated by maps in Images 1 and 2 above, viral hepatitis is asymmetrically distributed across the United States. Accordingly, the very foundation of interventions to reduce and/or eliminate viral hepatitis infections in the United States is customized interventions guided by reliable disease surveillance. However, HBV and HCV surveillance is hampered by incomplete data submitted to the Centers for Disease Control and Prevention (CDC) by state and local health departments. For instance:

- Particulars regarding race/ethnicity were missing on 6,345 or 58.29% of the 10,902 reported cases of hepatitis B infection.
- While 185,979 chronic hepatitis C reports were submitted to the CDC in 2011, only 34 states reported.
- The data collected by several states was incomplete and only ten (10) states allowed their data to be publicly reported by CDC. This in fact led to data analysis getting skewed since 56.9% of reported cases were from the State of California.
- The National Health and Nutrition Examination Survey (NHANES) which is also used for hepatitis surveillance does have high data quality. However, it fails to collect data on institutionalized populations.

The task of obtaining improved data quality for the assessment of the prevalence and incidence of viral hepatitis has therefore been a continuing one, which requires increased prioritization and investment. As a result, the CDC explicitly cautions the public to utilize this dataset more as indicative and a tool for the identification of broad-based trends.
Section 2: Hepatitis Rates in Different Demographic, Ethnic, Veterans and Other Marginalized Groups

Despite the linkages between viral hepatitis and heptocellular cancer as well as other liver diseases, Yehia, Schranz, Umsched, and Lo Re (2014) found that significant service gaps exist in the treatment cascade for hepatitis infections and highlight the specific trends in HCV, these authors found that insufficient screening of high risk populations was a major concern. For various demographic groups, these factors present an even more dismal picture.

As per data from CDC’s National Notifiable Disease Surveillance System (NNDSS), as of 2011, the total incidence of acute HBV is 0.9 and for acute HCV is 0.4 per 100,000 suggesting a relatively higher incidence of acute HBV. However per the NNDSS data, the difference in the rate of incidence across different ethnic communities is noteworthy. A brief synopsis is presented below:

The Asian American community:
Asian Americans make up less than 5% of the total U.S. population, but they account for more than half of all Americans living with chronic hepatitis B. It is estimated that at least 1 in 12 Asian Americans are living with the virus. Not only is the prevalence of hepatitis B higher among Asian Americans, the mortality rate is also higher. According to CDC data for 2011, the highest hepatitis B mortality rates by ethnicity were observed among Asian Americans (2.7 deaths per 100,000 people). Hepatitis B-related liver cancer rates among Asian Americans are also higher than any other ethnic group. In addition, liver cancer is a leading cause of cancer-related deaths among Asian Americans. Data from the U.S. Department of Health and Human Services suggests that the risk of liver cancer is 100 times higher in people with hepatitis B infection. Despite the high rate of infections, complications, and death, many at-risk Asian Americans are not tested for hepatitis B.

The African American community:
The hepatitis C virus is a national public health crisis that is even more devastating among African Americans, who are twice as likely to be infected. According to the CDC, prevalence of the virus is 3% among African Americans, compared to 1.5% in the general population. African Americans made up about 13% of the U.S. population from 1999-2002, yet they made up nearly 23% of patients living with hepatitis C. African Americans are not only more likely to have hepatitis C; they are also more likely to die as a result of the virus. According to CDC data for the year 2011, the hepatitis C mortality rate per 100,000 people of a certain race was 4 for Caucasians and 7.72 – nearly double – for African Americans. Within the African American community, chronic liver disease, which is often hepatitis C-related, is a leading cause of death among people between the ages of 45 and 64. About 9.4% of African Americans in their 40s are, or have been, been infected with chronic hepatitis C – compared to 3.8% of Caucasians.
The Latino community:
The hepatitis C virus is a public health crisis for all Americans, yet it is particularly harmful to Latinos, which are the fastest growing minority group in the United States. Within the Latino community, prevalence of hepatitis C is 2.6% – much higher than the national average of 1.5%. Even more concerning, studies indicate that hepatitis C infections are on the rise among Latinos. The CDC reports that the prevalence of the virus rose 23.5% for Latinos from 2010-2011, compared to 21.4% between 2000 and 2010. In addition to a higher rate of hepatitis C infection, Latinos have a higher hepatitis C mortality rate. CDC data for the year 2011 shows the hepatitis C mortality rate per 100,000 people was 4 for Caucasians and 7.15 – nearly two times higher – for Latinos. A National Institute of Health (NIH) study determined Latinos with viral hepatitis have faster liver fibrosis progression rates, are infected at an earlier age, and are more likely to be HIV co-infected – all aspects which make this community especially vulnerable to the liver disease, cancer and other deadly conditions resulting from hepatitis C.

Native American Community:
Among all racial and ethnic groups, American Indians have the highest rate of hepatitis C infection, as well as the highest hepatitis C-related mortality rates. While the CDC reports that the number of Americans with hepatitis C increased within several ethnic groups from 2011-2012, American Indians experienced the highest increase (86.2%), compared to 36% among Caucasians and nearly 24% among Latinos. American Indians were also the only ethnic group with more than 0.5 cases of hepatitis C per 100,000 of the general population for the years 2002-2010, and are twice as likely to have hepatitis C as Caucasian Americans. Not only do American Indians have the highest rate of hepatitis C, they are also the most likely ethnic group to die as a result of it. According to CDC data for the year 2011, the hepatitis C mortality rate per 100,000 people was 4 for Caucasians and 10.6 for American Indians.

Baby boomers:
Another statistic to note would be the prevalence of HCV in baby boomers, (individuals born between 1946 and 1964) which ranges from 11.49 per 100,000 to 20.37 per 100,000. While progress has been made as a result of the United States Preventive Services Task Force’s (USPSTF) agreement with CDC's recommendation that one time HCV screening should be provided for all persons born between 1945 and 1965, the actual implementation of the recommended screening needs to be encouraged.

Veterans:
Research based on the National Health and Nutrition Examination Survey (NHANES) datasets reveals that prevalence rates may be higher amongst military personnel and/ or veterans. It is also important to note the overrepresentation of veterans among the homeless and among injection drug users (Vazan, Golub, and Bennett, 2013).
Other marginalized populations:
Per data collected by the CDC through the NHANES of the 5 to 7 million Americans affected by HCV, the reported prevalence range for the homeless is between 22% and 52.5%, and for the incarcerated is 23% to 41% (See Table 2).

**Table 2: Estimated Total Prevalence of Hepatitis C Virus in the USA**

<table>
<thead>
<tr>
<th>Population</th>
<th>Reported prevalence range</th>
<th>Estimated number in US population</th>
<th>Estimated range of HCV cases</th>
</tr>
</thead>
<tbody>
<tr>
<td>Homeless</td>
<td>22.2-52.5%</td>
<td>643,057 (14)</td>
<td>142,761-337,610</td>
</tr>
<tr>
<td>Incarcerated</td>
<td>23.1-41.2%</td>
<td>1,613,656 (96)</td>
<td>372,754-661,826</td>
</tr>
<tr>
<td>Veterans</td>
<td>5.4-10.7%</td>
<td>22,919,943 (97)</td>
<td>1,237,461-2,452,006</td>
</tr>
<tr>
<td>Active military duty</td>
<td>0.48%</td>
<td>1,417,747 (98)</td>
<td>6,805</td>
</tr>
<tr>
<td>Healthcare workers</td>
<td>0.9-3.6%</td>
<td>7,200,950 (99)</td>
<td>64,809-259,234</td>
</tr>
<tr>
<td>Nursing home residents</td>
<td>4.5%</td>
<td>1,413,540 (85)</td>
<td>63,609</td>
</tr>
<tr>
<td>Chronic haemodialysis</td>
<td>7.8%</td>
<td>263,820 (80)</td>
<td>20,578</td>
</tr>
<tr>
<td>Haemophiliacs with transfusions before 1992</td>
<td>76.3-100.00%</td>
<td>17,000 (92)</td>
<td>12,971-17,000</td>
</tr>
</tbody>
</table>

Section 3: Behavioral Research Based Approach

Social Determinant of Health

Viral hepatitis control cannot be solely viewed within the framework of individual change and individual prevention strategies. The CDC, through the National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP) applies the social determinants of health framework of analysis (2010) that suggests that theories of causation that focus upon health outcomes are a function of individual-level risk factors such as ethnicity, age, gender, education, marital status, etc. Specifically, this paradigm suggests that forces that are built into the very fabric of American social and economic structure are operative and instrumental in causation.

While using the data to identify trends of incidence, it is evident that if morbidity and mortality from viral hepatitis is to be reduced, strategies must be crafted that balance social determinants of viral hepatitis with patient being counseled and encouraged to assume responsibility for their actions and exercise choice. Specifically, this entails individuals taking more ownership for their health choosing to be screened for hepatitis, receiving immunizations, returning for their results, follow-up testing and adhering to their medications regimen and altering their lifestyle to support improved health.

However, it is noteworthy that an individual’s personal choices are also socially determined by variables such as: 1) differential conditions by neighborhood; 2) access to illicit markets for intravenous substance users; 3) adaptive norms that result from poverty and deprivation; 4) differential choices that reflect a poverty-based behavioral guidance system; 5) the built environment, and a range of other circumstances that systemically shape individuals’ choices. Policy change can assist in negotiating the impact of these factors. One outcome of the Stakeholders’ Meeting will be to include defining solutions to socially-determined correlates of viral hepatitis and it would therefore be important to outline two factors below at the outset:

Stigmatization

Stigma is an important social determinant and has direct relevance to health-seeking behaviors and the control and management of diseases. Stigmatization is an emotionally burdensome experience for patients living with chronic HBV and HCV. Negative stereotyping has a serious impact on one’s quality of mental health, producing increased insecurity, internalized shame, social isolation and tension in social relationships. Unfortunately, some hepatitis-infected patients believe that their physicians view their disease with prejudice and suspicion, due to in some cases their unhealthy behaviors that led to their infection. Research conducted by Zeremiski, Zebbel, Martinez et al (2013) found that providers and staff sometimes allow stigma to interfere with their patient care. This in turn can serve as a barrier to high quality care and lead to poor medication adherence by the patient (Janke et al. 2008; Sgorbini et al. 2009).
Substance Abuse

Data from the Substance Abuse and Mental Health Services Administration (SAMHSA) indicates that as of 2012, there were 124.8 million Americans who had ever used drugs and 22.4 million who had used drugs in the last month before the survey. The linkage between injection drug use and both HBV as well as HCV has been well established. Approximately 11% of persons infected with HBV are injection drug users and 64% of those who are HCV positive are injection drug users.

Therefore, a highly critical priority area listed in the updated United States Department of Health and Human Services (HHS) Viral Hepatitis Action plan involves strategies to address the needs of this very high-risk group.

As part of this Stakeholder Meeting, further strategies are to be explored for integrating behavioral health and hepatitis services by standardizing hepatitis prevention testing and treatment as a co-occurring disorder that accompanies injection drug use and identifying prevention and research opportunities to address HCV in injection drug users.
Section 4: Policy Landscape

Reducing Viral Hepatitis Incidence

The United States Preventive Services Task Force (USPSTF) has accordingly issued several recommendations regarding prioritizing HCV and HBV prevention among various categories of individuals. These recommendations by the USPSTF mark a critical step forward in the fight to significantly decrease HCV and HBV rates. These recommendations include a two pronged approach:

1. **Vaccination:** While there is currently no vaccination available for HCV, HBV vaccine is available for children as well as adults. As a result of the implementation of the vaccination program, rates of acute Hepatitis B in the United States have declined by approximately 82% since 1990. Continued implementation of HBV vaccination will further reduce HBV infection, since HBV vaccination is available under Medicare, as well as most private insurance plans.

2. **Screening:** The most challenging aspect in the fight against the incidence of liver related chronic disease is that people with HCV and HBV often do not have symptoms until they have advanced liver disease. However, HCV and HBV can be detected by screening, even when symptoms are not clinically demonstrated. According to the USPSTF, the most important risk factor for HCV infection is past or current injection drug use, blood transfusion before 1992, long-term hemodialysis, being born to an HCV-infected mother, incarceration, intranasal drug use, getting an unregulated tattoo, and other percutaneous exposures (such as in health care workers or from having surgery before the implementation of universal precautions). Projections estimate recommended screening will help identify 487,000 HCV cases over the next decade and more aggressive screening guidelines could make hepatitis C a rare disease by 2026.

HCV and HBV screening has been limited due to perceived costs and a lack of insurance coverage, until recently. USPSTF’s recommendations have helped in reducing these barriers to HCV and HBV screening. Below is a brief description on how each major healthcare payer covers such screening.

*Private Insurance:* The Patient Protection and Affordable Care Act (ACA) requires most private insurance plans in the individual and group markets cover “A” and “B” graded services without cost-sharing. Accordingly, plans are now required to cover HBV screening for pregnant women and persons at high risk of infection. Periodic HCV screening for those “at risk” also include a one-time HCV screening for “baby-boomers.”

*Medicaid:* The ACA incentivizes state Medicaid programs to cover HCV screening for those “at risk” and a one-time testing for “baby-boomers” without cost-sharing by offering the state a one
percent increase in federal matching payments for coverage of these preventive services. As of July 2014, 11 states (California, Colorado, Delaware, Hawaii, Kentucky, New Hampshire, New Jersey, Nevada, New York, Ohio and Wisconsin) have been approved to receive this increased funding for expanding preventive coverage. Furthermore, Medicaid expansion plans or “Alternative Benefits Plans” will be required to cover all “A” and “B” grade services without cost-sharing. Therefore, those “at risk” and “baby-boomer” beneficiaries enrolled in Medicaid expansion plans will also have HCV testing coverage.

Medicare: Starting June 2014, Medicare covers one-time HCV testing for “baby boomers,” and annual testing for those “at risk.” The Medicare Improvements for Patients and Providers Act of 2008 allows Medicare to cover “A” & “B” graded preventive services provided in primary care settings, after undergoing a National Coverage Determination (NCD). In June 2014, the Center for Medicare & Medicaid Services issued an NCD based on the USPSTF recommendation for HCV testing. The ACA removes beneficiary cost-sharing for these Medicare approved preventive services.

Improve Patient Care
“The Viral Hepatitis Testing Act” – legislation currently pending before the U.S. Senate (S. 2538) and House of Representatives (H.R. 3723) – would authorize $80 million over three years to create the first comprehensive national system to combat viral hepatitis. The legislation would enhance and strengthen surveillance, education, testing, and linkage to care – with the priority of reaching Americans who are most at-risk. The Patients’ Access to Treatments Act (H.R. 460) restricts the private insurance practice of specialty tiers, where patients with complex therapies are forced to pay a large percentage of the medications cost out-of-pocket. In these instances, the cost of (an often life-sustaining) therapy alone can create an insurmountable barrier to access. Knowing one’s status is the first step in being connected to care and support. To this end, the more rapidly a patient can receive an early and accurate diagnosis, the earlier they can begin therapy. Early intervention not only saves lives, it also results in costs savings for the U.S. healthcare system by mitigating the need for more serious interventions, like organ transplantation.

State Government Action
State lawmakers are taking legislative action to connect at-risk individuals with testing. Connecticut, Massachusetts, and New York recently enacted legislation requiring primary health care providers to offer one-time hepatitis C screening to all patients born between 1945 and 1965, and Colorado enacted legislation formally recommending such testing. Similar legislation requiring primary care providers offer one-time screening to baby boomers has also been introduced in California, Illinois, New Jersey, and Pennsylvania.
Section 5: Conclusion

The HFI is committed to working with the multiple stakeholders to address viral hepatitis to find innovative and effective methods to address and promote optimal health care in this nation.

The Stakeholders’ meeting serves as the starting point for strategic and ongoing collaboration to proactively address viral hepatitis disparities which remain a critical health concern for this nation.
About HFI

The Hepatitis Foundation International (HFI) is a 501 (c) 3 non-profit organization established in 1994 working to eradicate chronic hepatitis for 500 million people globally. HFI is also dedicated to increasing and promoting health and wellness, as well as, reducing the incidence of preventable liver-related chronic diseases and lifestyles that negatively impact the liver.

Some of these diseases include; obesity, diabetes, hepatitis, substance abuse, HIV/AIDS, cardiovascular disease and fatty/liver cancer. In addition to supporting overall health and wellness, HFI focuses on addressing outlying issues that negatively affect the health of the nation including: patient centered research, disparities, cultural competence, health literacy, vaccines, drug use, as well as, maternal and child health issues.

Ninety-two cents of every dollar spent by HFI is dedicated to programs and services. The Foundation provides outreach, education and interventions for people at risk and/or living with liver disease; offers continuing education for healthcare providers; and provides special education and awareness programs.

The Hepatitis Foundation International implements its mission through our touchstones to educate, prevent, serve, support and reach over 5 million patients and health care professionals annually through our public and private partnerships. Our mission has four distinct components which include:

- **Educate** the public, health care providers and hepatitis patients how to prevent, diagnose, and treat viral hepatitis and other systemic disease.
- **Prevent** viral hepatitis by promoting liver wellness and healthful lifestyles.
- **Serve** as advocates for hepatitis patients and the related medical community worldwide.
- **Support** research for the advancement of prevention efforts, innovative treatment, and cures for viral hepatitis and other diseases that negatively impact the liver.

For additional information or to contact the Hepatitis Foundation International and collaborate with us, email; info@hepatitisfoundation.org or call (800) 891-0707.
References

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