ISSUE BRIEF

HEPATITIS C IN MINORITY COMMUNITIES: AN URGENT HEALTHCARE RESPONSE IS REQUIRED!

January 2014

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EXECUTIVE SUMMARY

The challenges associated with combating the epidemic of Hepatitis C are of such magnitude that a concerted, coordinated response is required from the American healthcare research, delivery and financing system. The fact of this public health crisis must be brought to the attention of the American public in a manner that communicates the urgency of the issue, maximizes the potential for early diagnosis and treatment, reduces the risk of transmission, expedites the development of more effective and less debilitating treatments, and eliminates any stigma ascribed to the disease.

The 2011 U.S. Department of Health and Human Services action plan for the prevention and treatment of viral hepatitis in the United States[1] notes that an estimated 3.5 – 5.3 million persons are living with viral hepatitis in the United States, and millions more are undiagnosed or at risk for infection. Because viral hepatitis can persist for decades without symptoms, 65%-75% of infected Americans remain unaware of their infection, and are not receiving care and treatment needed to prevent liver cancer, cirrhosis, and other life-threatening complications.

The National Minority Quality Forum endorses the Department of Health and Human Services goals and strategies associated with identifying persons infected with viral hepatitis early in the course of their disease, improving access to and quality of care and treatment for persons infected with viral hepatitis, and advancing research to facilitate viral hepatitis prevention and enhance care and treatment for infected persons.

The National Minority Quality Forum also endorses and applauds the decision of the US Preventive Services Task Force (USPSTF) that adults born between 1945 and 1965 be offered one-time screening for HCV infection, and well as continuing the practice of screening persons at high-risk for infection. It is our belief that the new recommendations of the U.S. Preventive Services Task Force present as opportunity for all who have a voice, and a stake in the issue, to reframe the national conversation about Hepatitis C from one of victim blame — or system blame — to one of shared benefit. Failure to do so will increase the number of lives lost, and families and communities who are economically compromised.

We look forward to working with public and private sector partners to implement the following recommendations as part of the multi-sectorial response that will be required to halt this epidemic:

- The National Minority Quality Forum strongly encourages and supports efforts to use existing community-based surveillance data to prioritize the initiation of enhanced screening and treatment efforts. The Forum recognizes the weaknesses of the existing surveillance systems and supports efforts increase their comprehensiveness and reliability. The Forum believes, however, that enhanced screening and treatment initiatives cannot wait for surveillance to catch up to the epidemic.

- The U.S. Department of Health and Human Services, in partnership with the medical societies, the pharmaceutical research and manufacturing industry, and state and local public health agencies should undertake a 3-5 year national public information campaign regarding Hepatitis C must be undertaken. It can be launched during National Hepatitis Month in 2014 or 2015.

- A priority must be placed on developing first-line therapies that are effective in all populations. To do so, concerted efforts must be made to increase the participation of African Americans, black and white Hispanics, and Asian/Pacific Islanders in clinical trials that study treatments for Hepatitis C and Hepatitis B.

- The surveillance and reporting systems that monitor infectious diseases in the United States must be powered to track both acute and chronic Hepatitis C, and must all collect data regarding race and ethnicity in a consistent manner.

- Public and private insurers that cover individuals residing in the United States must cover screening for Hepatitis C in a manner that is consistent with the 2013 U.S. Preventive Services Task Force recommendation.

- Public and private insurers that cover individuals residing in the United States must cover treatment for Hepatitis C without onerous or prohibitive co-pays or co-insurance.

- The FDA, in partnership with the pharmaceutical research and manufacturing industry, are encouraged to work collaboratively to identify options for expediting the development of therapies for Hepatitis C.

The National Minority Quality Forum has prepared this report to create a common base of understanding of the complex clinical and societal factors that have resulted in this 21st century epidemic. This document would not have been possible without the extraordinary work of the National Medical Association, the Institute of Medicine, the agencies of the U.S. Department of Health and Human Services, the World Health Organization, and the national and international scholars and researchers whose efforts are referenced in the endnotes.

ISSUE BRIEF

Hepatitis C in Minority Communities:
An Urgent Healthcare Response is Required!
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INTRODUCTION

Prevention, detection and treatment of Hepatitis C may prove to be the public health challenge of the 21st century. An extraordinary effort is required in the United States to prevent the amenable morbidity and mortality that result from undiagnosed and untreated Hepatitis C. The National Minority Quality Forum has prepared this issue brief to facilitate the development of a common base of understanding of the Hepatitis C epidemic with the objective of igniting the engagement required from the public and private sectors that is necessary to avert the impending calamity.

Hepatitis C is a contagious liver disease caused by the Hepatitis C Virus (HCV).[2] Infection with HCV, and the attendant sequelae, is a national and global epidemic for which the research, financing and clinical responses lag far behind the threats to the American public. This policy brief provides an overview of the Hepatitis C epidemic in the U.S., with particular emphasis on the challenges for three priority populations — African Americans, Asian/Pacific Islanders, and Hispanic Americans. Although this document is specifically focused on the Hepatitis C epidemic as it affects these populations, we have contextualized this discourse through the lens of the global hepatitis epidemic. We do this not to de-emphasize these patient cohorts, but to strengthen the link to the broader national and international conversations.

Of the five major types of viral hepatitis, Hepatitis B (HBV) and Hepatitis C, which can lead to chronic hepatitis, are particularly prevalent. It has been estimated that 1 in 12 humans (480-520 million people) on the planet are chronically infected with HBV or HCV.[3] Approximately 240 million people worldwide are thought to be chronically infected with hepatitis B and 184 million people have antibodies to hepatitis C. [4] Globally, more than one million new cases of HCV infection are reported annually.[5]

Due to its largely asymptomatic nature, most people are unaware of their infection. Untreated chronic hepatitis B and C infection can result in liver cirrhosis and hepatocellular carcinoma (HCC). Up to twenty percent of patients with chronic HCV will develop liver cirrhosis within 20 years, and HCC may develop after 20-35 years.

According to the Global Burden of Disease estimates, Hepatitis B and Hepatitis C together caused 1.4 million deaths in 2010 worldwide, including deaths from acute infection, liver cancer and cirrhosis.[6]To put these figures in the context of other major infectious diseases, the World Health Organization report notes that malaria caused 660 000 deaths in 2010,[4] and tuberculosis and HIV 1.4 and 1.7 million deaths, respectively, in 2011.[7]

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The National Minority Quality Forum is a Washington, DC-based not-for-profit, non-partisan, independent research and education organization founded in 1998 that is dedicated to improving the quality of health care that is available for and provided to all populations. The Forum's guiding principles are designed to assure that the American health care research, financing and delivery system:

- Is inclusive of, and assigns equal value to, the healthcare and health status of all populations in the United States;
- Creates market incentives for research and innovation that are responsive to changing population demographics; and
- Places the quality and efficacy of patient care at the center of the clinical decision-making process.

Our intention in preparing this brief is to present a broad overview of issues that pertain to Hepatitis C as a point of departure for communities, clinicians, patients, policymakers, insurers and payers to seek common cause in organizing around this 21st century public health crisis. For those whose interest is piqued to explore further, we call your attention to the extraordinary work of the National Medical Association, the Institute of Medicine, the agencies of the U.S. Department of Health and Human Services, the World Health Organization, and the national and international scholars and researchers whose efforts are referenced in the endnotes.

In 2010, the 63rd World Health Assembly[8] of the World Health Organization (WHO) adopted resolution WHA 63.18 in recognition of viral hepatitis as a global public health problem. WHA 63.18 emphasized the need for governments and populations to take action to prevent, diagnose, and treat viral hepatitis, called upon the WHO to develop and implement a comprehensive global strategy to support these efforts, and designated July 28 as World Hepatitis Day. The first official World Hepatitis Day was in 2011. It is our hope that this policy brief, and the collaborations that it may kindle, will strengthen the focus on Hepatitis C in populations defined as minorities in the United States on July 28, 2014 and every day of every year thereafter.

Our rapidly changing demographics oblige us all to do so.

Gary A. Puckrein, PhD
President and Chief Executive Officer
The National Minority Quality Forum

VIRAL HEPATITIS: THE SCIENCE

A healthy liver is essential to sustain life. The liver is the largest gland in the human body and the largest internal organ. It weighs approximately 3 lbs, and is located below the diaphragm on the right in the thoracic region of the abdomen. The liver has a wide range of life sustaining functions, including detoxification (filters harmful substances from the blood, such as alcohol); storing vitamins A, D, K and B12 and minerals; synthesizing proteins (makes certain amino acids); producing biochemicals needed for digestion (such as bile); maintaining proper levels of glucose in the blood; producing 80% of the body's cholesterol (a vital lipid); storing glycogen and converting glucose to glycogen; decomposing red blood cells; synthesizing plasma protein; producing hormones; and producing urea (the main substance of urine). [9]

The word hepatitis[10] means inflammation of the liver cells. Hepatitis is not always caused by viruses, and the viruses that can trigger hepatitis are not always hepatitis viruses. Other viruses include the Epstein-Barr virus (often associated with mononucleosis), the varicella virus (which causes chickenpox), the herpes simplex virus (HSV), and the cytomegalovirus (CMV). Although viruses are the most common cause of hepatitis, other causes include autoimmune liver disease, obesity, alcohol, toxins, certain prescription and over-the-counter drugs. These forms of hepatitis can cause the same symptoms and liver inflammation that result from viral hepatitis, but are not contagious.[11]

Acute Viral Hepatitis

All viral hepatitis begins with an acute phase. Although many people with hepatitis have no symptoms during the acute phase, those who are symptomatic may experience diarrhea, fatigue, loss of appetite, mild fever, muscle or joint aches, nausea, slight abdominal pain, vomiting and weight loss. Rarely, individuals with acute infections with HAV and HBV develop severe inflammation, and the liver fails (acute fulminant hepatitis). These patients are extremely ill with the symptoms of acute hepatitis already described and the additional problems of confusion or coma (due to the liver's failure to detoxify chemicals), and bruising or bleeding (due to a lack of blood clotting factors). Up to 80% of people with acute fulminant hepatitis can die within days to weeks. Less than 0.5% of adults with acute infection with HBV will develop acute fulminant hepatitis; the rate may be slightly higher in HCV. [12]

Chronic Viral Hepatitis

Patients infected with HBV and HCV can develop chronic hepatitis. Patients with chronic viral hepatitis can transmit the infection to others. Doctors define chronic hepatitis as hepatitis that lasts longer than 6 months. In chronic hepatitis, the viruses live and multiply in the liver for years or decades. For unknown reasons, these patients' immune systems are unable to eradicate the viruses, and the viruses cause chronic inflammation of the liver. Chronic hepatitis can lead to the development over time of extensive liver scarring (cirrhosis), liver failure, and liver cancer

(hepatocellular carcinoma). Liver failure from chronic hepatitis C infection is the most common reason for liver transplantation in the U.S. [13]

In 2011, the U.S. Department of Health and Human Services published an action plan for the prevention and treatment of viral hepatitis in the United States.[14] The DHHS Action Plan notes that an estimated 3.5 – 5.3 million persons are living with viral hepatitis in the United States, and millions more are at risk for infection or undiagnosed. Because viral hepatitis can persist for decades without symptoms, 65%-75% of infected Americans remain unaware of their infection, and are not receiving care and treatment.

Viral hepatitis is the leading cause of liver transplantation in the United States. In the absence of treatment, 15%-40% of persons living with viral hepatitis will develop liver cirrhosis or other conditions that affect the liver, including liver cancer. DHHS estimates that in the decade following the publication of their action plan, more than 150,000 Americans will die from viral hepatitis-associated liver cancer or end-stage liver disease. Liver cancer incidence is highest among the Asian/Pacific Islander population cohort, and is increasing among African-Americans, persons aged 46-64, and men. Recipients of organs, blood, and tissue, along with persons working or receiving care in health settings continue to be at risk for viral hepatitis infection.

VIRAL HEPATITIS TYPES A, B, D, AND E

Five distinct hepatitis viruses have been identified: A, B, C, D and E. If a case of hepatitis cannot be attributed to any of the identified viruses, it is referenced as Hepatitis X. Researchers are continuing to explore a form of viral hepatitis that is referenced in the literature as Hepatitis G (HGV) or GBV-C.[15]

Hepatitis A

Hepatitis A (formerly called infectious hepatitis) was first differentiated epidemiologically from hepatitis B in the 1940s.. HAV infection produces a self-limited disease that does not result in chronic infection or chronic liver disease. Acute liver failure from Hepatitis A is rare. The antibody produced in response to HAV infection persists for life and confers protection against reinfection. HAV infection is primarily transmitted by the fecal-oral route, by either person-to-person contact or consumption of contaminated food or water. Blood borne transmission of HAV is uncommon. Transmission by saliva has not been demonstrated. *Hepatitis A is vaccine preventable.*

Hepatitis B

The first recorded cases of "serum hepatitis," or hepatitis B, are thought to be those that followed the administration of smallpox vaccine containing human lymph to shipyard workers in Germany

in l883. In the early and middle parts of the 20th century, serum hepatitis was repeatedly observed following the use of contaminated needles and syringes.. The incubation period for HBV from the time of exposure to onset of symptoms is 6 weeks to 6 months. HBV is found in highest concentrations in blood and in lower concentrations in other body fluids (e.g., semen, vaginal secretions, and wound exudates). HBV infection can be self-limited or chronic. In adults, only approximately half of newly acquired HBV infections are symptomatic, and approximately 1% of reported cases result in acute liver failure and death. Approximately 90% of infected infants and 30% of infected children aged <5 years become chronically infected, compared with 2%–6% of adults. Among persons with chronic HBV infection, the risk for premature death from cirrhosis or hepatocellular carcinoma is 15%–25%. *Hepatitis B is vaccine preventable.*

Hepatitis D

Hepatitis D, also known as "delta hepatitis," is a serious liver disease caused by infection with the Hepatitis D virus (HDV), which is an RNA virus structurally unrelated to the Hepatitis A, B, or C viruses. Hepatitis D, which can be acute or chronic, is uncommon in the United States. HDV is an incomplete virus that requires the helper function of HBV to replicate and only occurs among people who are infected with the Hepatitis B virus (HBV). HDV is transmitted through percutaneous or mucosal contact with infectious blood and can be acquired either as a co-infection with HBV or as super-infection in persons with HBV infection. *There is no vaccine for Hepatitis D, but it can be prevented by the Hepatitis B vaccination in individuals who have not yet been infected with Hepatitis B.*

Hepatitis E

Hepatitis E usually results in an acute infection. It does not lead to a chronic infection. HEV is transmitted via ingestion of fecal matter, even in microscopic amounts. Outbreaks are usually associated with contaminated water supply in countries with poor sanitation. E. While rare in the United States, Hepatitis E is common in many parts of the world. In the mid-1990s, a group of scientists in the NIH/NIAID Laboratory of Infectious Diseases (LID) discovered a vaccine for HEV. *There is currently no FDA-approved vaccine for Hepatitis E. There is an HEV vaccine that is produced and licensed in China.*

The focus of this policy brief is one form of viral hepatitis— Hepatitis C.

HEPATITIS C

Overview of Hepatitis C

The Hepatitis C Virus (HCV) was identified in 1989. *There is not yet a vaccine for Hepatitis C.* HCV is most efficiently transmitted through large or repeated percutaneous exposure to infected

blood. Although much less frequent, occupational, perinatal, and sexual exposures also can result in transmission of HCV.

Hepatitis C became a global epidemic in the 20th century as blood transfusions, hemodialysis, and the use of injection needles to administer licit and illicit drugs increased throughout the world. For example, the extremely high prevalence of HCV in Egypt is due to a schistosomiasis-eradication campaign that began in the 1960s, when more than 35 million injections were administered to about 6 million Egyptians.[16]

The identification of the Hepatitis C Virus in 1989 led to measures to reduce healthcare–related exposure to HCV, particularly in industrialized nations. Nevertheless, more than six billion unsafe injections are given worldwide each year. Antiviral treatments for chronic HBV and HCV infections can effectively reduce the associated morbidity and mortality from liver disease. However, access to treatment if often limited by high costs of care and by the asymptomatic nature of chronic HBV and HCV infections. Therefore, many infected people are not identified in time to benefit from antiviral treatment. [17]

The Institute of Medicine reports that an estimated 130–170 million people live with chronic HCV infection worldwide, and an estimated 350,000 die of HCV-related liver disease each year There are about 2.3–4.7 million new HCV infections each year from nosocomial[18] transmission alone. Unsafe mass immunization has led to exceedingly high HCV prevalence in some areas, such as Egypt, where 14–20% of the population has HCV antibodies.[19] [20] In most populations in Africa, North America, South America, Europe, and Southeast Asia, the prevalence of HCV in the general population is less than 3%.

Sixty to seventy percent of persons newly infected with HCV typically are usually asymptomatic or have a mild clinical illness. HCV RNA can be detected in blood within 1–3 weeks after exposure. The average time from exposure to antibody to HCV (anti-HCV) sero-conversion is 8–9 weeks, and anti-HCV can be detected in >97% of persons by 6 months after exposure. Approximately 80% of individuals infected with HCV fail to clear the virus, although this varies considerably based on sex, age at infection, immune status, route of infection, race, alcohol use, and other factors.

Chronic HCV infection develops in 70%–85% of HCV-infected persons. Approximately 60%–70% of chronically infected persons have evidence of active liver disease. The majority of infected persons might not be aware of their infection because they are not clinically ill. However, infected persons serve as a source of transmission to others and are at risk for chronic liver disease or other HCV-related chronic diseases decades after infection.

Hepatitis C Genotypes

There are at least six major HCV genotypes, and more than 90 subtypes.[21] Information available from the World Health Organization states that HCV is classified into eleven major genotypes (designated 1-11), many subtypes (designated a, b, c, etc.), and about 100 different strains (numbered 1,2, 3, etc.) based on the genomic sequence heterogeneity.[22]

The genome of HCV is highly mutable. By constant mutation, HCV may be able to escape host immunologic detection and elimination. As a consequence, most HCV-infected people develop chronic infection. HCV also knocks out the host's Innate Immunity.[23].

HCV is highly heterogeneous. These diversities have distinct consequences: although different strains have not been shown to differ dramatically in their virulence or pathogenicity, different genotypes vary in their responsiveness to interferon/ribavirin combination therapy. Moreover, such heterogeneity hinders the development of vaccines, since vaccine antigens from multiple serotypes will probably be necessary for global protection. [24]

HCV genotype identification is clinically important for prediction of response to, and in determining the duration of, antiviral therapy. Genotypes 1 and 4 are more resistant to treatment with pegylated alpha interferon and ribavirin than genotypes 2 and 3. Moreover, it has been suggested that patients with chronic HCV Genotype 1b infection show more severe liver disease than patients infected with other genotypes.[25] In additional to virus genotype, environmental, genetic, and immunological factors may contribute to the differences in disease progression, observed among HCV patients.[26]

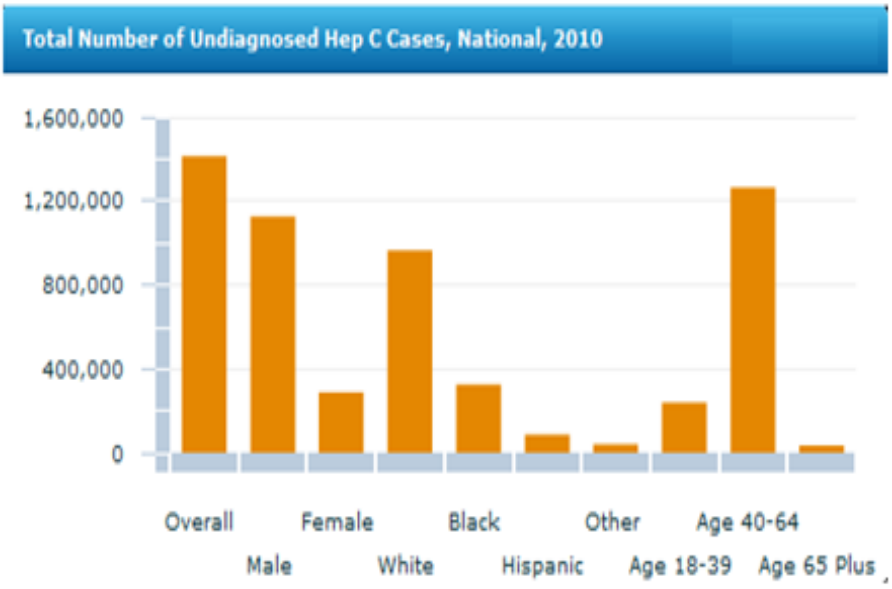
HCV genotypes have a geographic distribution, with genotype 1 being more common in the Americas and Europe, followed by genotypes 2, 3 and 4. Genotypes 1a and 1b are the most common, accounting for about 60% of global infections. They predominate in Northern Europe and North America, and in Southern and Eastern Europe and Japan, respectively. Genotype 2 is less frequently represented than Genotype 1. Genotype 3 is endemic in Southeast Asia and is variably distributed in different countries. Genotype 4 is principally found in the Middle East, Egypt, and central Africa. Genotype 5 is almost exclusively found in South Africa, and genotypes 6-11 are distributed in Asia.[27] [28]

There has been a significant rise in the incidence of HCC in many developed countries, including Japan, Spain, France, and Italy, where the proportion of HCC attributable to HCV ranges from 50% to 70%. In Japan, HCV-related HCC incidence has more than tripled over the past four decades, and accounts in the 60-70 year age group for as much as 90%.[29]

HEPATITIS C IN THE UNITED STATES

Hepatitis C virus (HCV) infection is the most common chronic blood borne infection in the United States. Approximately 3.2 million persons are chronically infected. In the United States, 70%-90% of patients and 70% of Caucasians with chronic HCV infection are genotype 1.[30] An analysis of HCV genotypes in a sample of 460 persons with HCV infection in San Francisco in discovered that, while HCV genotype 1 remains the most common among African Americans and persons born before 1970, this was not the case with the young, HCV-infected persons nor with Caucasians included in the study. Other genotypes were observable in those populations.[31]

In the United States, an estimated 49 % of all carriers of Hepatitis C are undiagnosed, representing almost 1.5 million carriers. Most undiagnosed cases (89%) are represented in the 40 to 65 age cohort.[32] This may help to explain that while the rate of new HCV infections is decreasing, the number of infected people with complications of the disease is increasing. The following chart defines the undiagnosed population by age cohort.



Source: National Health Index, 2010.

Although dramatic progress has been made towards reducing the risk for healthcare-associated HBV and HCV infections among these Americans, outbreaks continue to occur as a result of breakdowns in basic infection control and limitations in the laboratory screening of donated organs, blood, and tissues. Liver cancer and other liver diseases caused by viral hepatitis (e.g., cirrhosis) affect some U.S. populations more than others, resulting in substantial health

disparities. Persons with certain risk behaviors, including men who have sex with men (MSM) and injection-drug users (IDUs), have high rates of viral hepatitis.

The Baby Boomer Factor

Compared with other age groups, a greater proportion (about 1 in 33) of persons aged 46–64 years is infected with HCV. A recent policy change that the National Minority Quality Forum believes will prove to be the game changer in the U.S. strategy to combat the HCV epidemic is the U.S. Preventive Services Task Force recommendation regarding screening for HCV infection is adults. Specifically, the USPSTF recommends screening for HCV infection in persons at high risk for infection. The USPSTF also recommends offering 1-time screening for HCV infection to adults born between 1945 and 1965. This new recommendation carries a B Grade. The B Grade means that, based upon the data and information reviewed by USPSTF, "There is high certainty that the net benefit is moderate or there is moderate certainty that the net benefit is moderate to substantial."[33]

The USPSTF recommendation for boomer cohort-based screening, in addition to the continuation of the traditional risk-based screening, signals a reset of the basic assumptions regarding prevalence in the U.S., and of the risk factors for undiagnosed chronic infections. The USPSTF recommendation notes that, "Persons born between 1945 and 19065 are more likely to be diagnosed with HCV infection, possibly because they received blood transfusions before the introduction of screening in 1992 or have a history of other risk factors for exposure decades earlier….A risk-based approach may miss detection of a substantial proportion of HCV-infected persons in the birth cohort because of a lack of patient disclosure or knowledge about prior risk status. As a result, 1-time screening for HCV infection in the birth cohort may identify infected patients at earlier stages of disease who could benefit from treatment before developing complications from liver damage."[34]

This landmark recommendation by the USPSTF is designed to improve the quality of care and to reduce the rates of amenable morbidity and mortality from invasive HCV screening and diagnosis procedures (e.g., liver biopsy) as well as from the cirrhosis, hepatocellular carcinoma (HCC), and liver transplants that are the sequelae of untreated HCV. This constructive, proactive engagement with the baby boomer cohort is a responsible and commendable approach. It is particularly significant that the B Grade accorded the USPSTF recommendation also means that insurance plans sold through the Affordable Care Act insurance exchanges/market places must cover the screening. It is unclear whether the Grade B recommendation means that Medicaid is required to cover the screening, or whether the exchange plans or other insurance plans (including Medicare and Medicaid) are required to cover treatment for HCV in the event of a seropositive result.

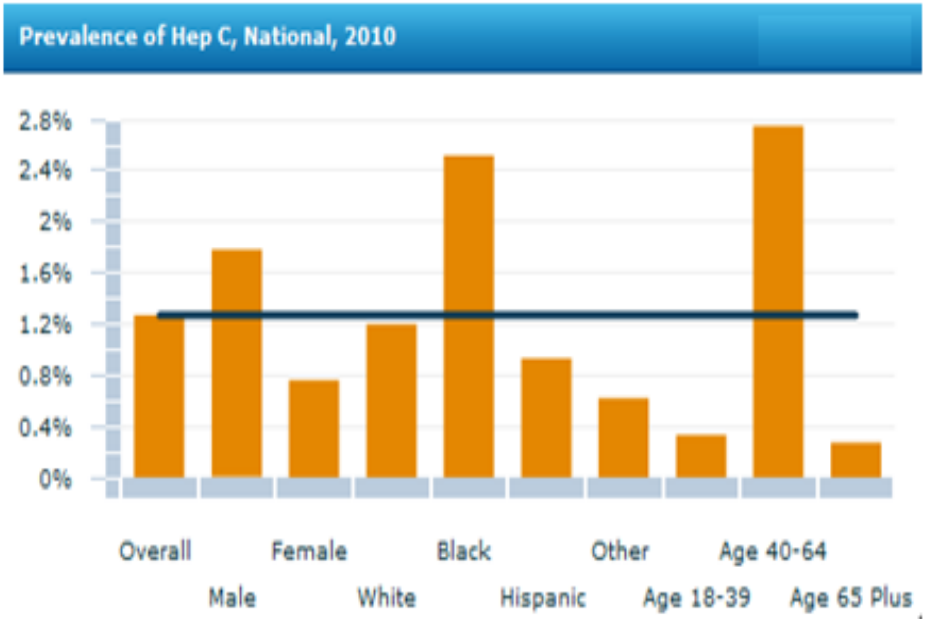
The recommendation for birth cohort screening for HCV for U.S. residents born between 1945 and 1965 creates an imperative of healthcare providers that should increase access to HCV

screening and treatment of all boomers, including those in the three priority populations of concern in this issue brief. That potential will be realized only if two conditions are met. First, that both screening and treatment are essential benefits in all health insurance policies. Second, that advanced clinical research that is designed to develop more effective HCV therapies be conducted with patient cohorts that are more inclusive of the racial and ethnic populations that experience a disproportionate share of HCV-related morbidity and mortality.

RACIAL AND ETHNIC HCV DISPARITIES IN THE U.S.

The national surveillance system for viral hepatitis in the United States is poorly funded and fragmented, resulting in incomplete coverage and inconsistent reporting of cases by jurisdictions.[35] The crisis of hepatitis C, therefore, is embedded, in part, in the absence of valid and reliable estimates of its magnitude within the United States.[36] This fact applies to all racial and ethnic populations that comprise the U.S. general population, but is particularly relevant to populations other than non-Hispanic Caucasians, in particular African-Americans, and black and white Hispanics.

Recently, the National Minority Quality Forum introduced an internet-based resource that defines Hepatitis C prevalence and total counts nationally, by state, congressional and state legislative district, as well as by zip code.[37] The following table charts HCV prevalence by age, gender, race and ethnicity.



Source: National Health Index, 2010.

The Institute of Medicine[38] reports that there are important ethnic and racial differences in the burden of chronic hepatitis C. The prevalence of HCV infection is higher in blacks than in whites. Blacks also are less likely to respond to interferon-alpha-based treatment for chronic hepatitis C; this seems to be explained to a large extent by differences in DNA sequences near the interferon lambda 3 gene. Likewise, there appears to be a greater burden of chronic hepatitis C and reduced response to treatment in Hispanic whites than in non-Hispanic whites. In both Hispanics and blacks, HCV risk is increasing, in large part because of chronic hepatitis C. However, there is less evidence than in the case of HBV infection that different HCV genotypes or higher blood HCV concentrations increase the risk of long-term disease outcomes.

African Americans

African Americans are twice as likely to be infected with HCV as Caucasian, non-Hispanics. In October 2013 the National Medical Association published the peer-reviewed consensus paper, *Hepatitis C: A Crisis in the African American Community.* The NMA researchers note that the most statistically robust study to date of HCV in the United States is the Armstrong et al study, [39] which was published in 2006 and reflect data for 1999-2002. Such reliance upon a now dated study, they note, documents the poverty of data used in establishing valid and reliable estimates of the breadth of HCV as a public health problem. The saturated use of the Armstrong study defines an urgent need for the development of accurate and current data on the prevalence on HCV incidence rates. Nevertheless, Armstrong is revealing. As documented in the NMA report, the Armstrong study found that:

- HCV rates were 100% more prevalent among African Americans (3.0%) than among Caucasians (1.5%). Of the estimated 4,060,000 persons ever infected with HCV, 2,570,000 or 64.3% were Caucasians. In contrast, 920,000 of the 4,060,000 persons, or 22.7% of those ever infected with HCV were African American.

- Approximately 13% of the US population was African American from 1999–2002, but African Americans were 22.7% of HCV cases. Thus, African Americans were 74.6% more likely to have ever been infected with HCV relative to their representation in the overall population.

- Similarly, 9.4% of African Americans 40–49 years old had ever been infected with chronic HCV compared to 3.8% of Caucasians. Thus, African Americans in this age group were 136.8% more likely to be infected with HCV.

- The prevalence of HCV antibodies was 3.2% for persons with incomes below 100% of the poverty threshold and only 1% for persons with family incomes equal to or greater than 200% of the federally defined poverty line. • Thus, the probability that an impoverished person would test positive for HCV was 220% higher than for their non-impoverished counterpart. In 2002, the last year of the NHANES survey used by

Armstrong, the poverty rate for African Americans was 24.1%. Caucasians had a poverty rate of 10.2%.

- The prevalence of HCV antibodies was 2.8% for persons with fewer than twelve years of education but only 1.3% for persons with more than 12 years of education. This represented a 115.4% difference. In 2002, 20.8% of African Americans age 25 and over had not graduated from high school compared to 11.3% of Caucasians.

Asian American/Pacific Islanders

Data regarding HBV infection in Asian/Pacific Islander populations in the United States appears to be relatively robust, but that is not the case for Hepatitis C in the American A/PI population. Approximately 1 in 12 Asian/Pacific Islanders (APIs) are living with hepatitis B, representing half of all HBV-infected persons in the United States. These health disparities are reflected in viral-hepatitis–associated morbidity and mortality; for example, liver cancer incidence is highest among APIs and is increasing among African Americans, persons aged 46–64 years, and men.[40]

Hispanic/Latino Populations

Hispanics are the fastest growing and the largest minority group in the U.S. In 2006, there were 44.3 million Hispanics lived in the continental US, 14.8% of the total population. The Hispanic population is a diverse population. In 2006, by ethnicity, the U.S. Hispanic/Latino population consisted of 64.0% Mexicans, 9.0% Puerto Ricans, 3.4% Cubans, 2.8% Dominican, 13.1% Central and South American, and 7.7% Other Hispanic origins.[41] The Armstrong study revealed that approximately 260,000 or 6.4% of those ever infected with HCV were Mexican-Americans.[42]

There is very little data regarding the natural history and treatment outcomes of chronic hepatitis C in Hispanics. A study on veterans with chronic hepatitis C found no differences between Hispanics and Caucasians in the baseline liver tests, severity of disease assessed by liver histology and, hence, fibrosis progression rate. However, Hispanics were more likely to become infected at a slightly younger age. Hispanic veterans were more likely to be genotype 1, and have a higher viral load.[43]

RECOMMENDATIONS

The preparation of this brief has, for the National Minority Quality Forum, been both enlightening and disturbing. Before we close, we would like to make a few recommendations that are the outcome of this journey. We look forward to working with public and private sector partners to refine these recommendations and to develop plans for implementation and evaluation.

- The National Minority Quality Forum strongly encourages and supports efforts to use existing community-based surveillance data to prioritize the initiation of enhanced screening and treatment efforts. The Forum recognizes the weaknesses of the existing surveillance systems and supports efforts increase their comprehensiveness and reliability. The Forum believes, however, that enhanced screening and treatment initiatives cannot wait for surveillance to catch up to the epidemic.

- The U.S. Department of Health and Human Services, in partnership with the medical societies, the pharmaceutical research and manufacturing industry, and state and local public health agencies should undertake a 3-5 year national public information campaign regarding Hepatitis C must be undertaken. It can be launched during National Hepatitis Month in 2014 or 2015.

- A priority must be placed on developing first-line therapies that are effective in all populations. To do so, concerted efforts must be made to increase the participation of African Americans, black and white Hispanics, and Asian/Pacific Islanders in clinical trials that study treatments for Hepatitis C and Hepatitis B.

- The surveillance and reporting systems that monitor infectious diseases in the United States must be powered to track both acute and chronic Hepatitis C, and must all collect data regarding race and ethnicity in a consistent manner.

- Public and private insurers that cover individuals residing in the United States must cover screening for Hepatitis C in a manner that is consistent with the 2013 U.S. Preventive Services Task Force recommendation.

- Public and private insurers that cover individuals residing in the United States must cover treatment for Hepatitis C without onerous or prohibitive co-pays or co-insurance.

- The FDA, in partnership with the pharmaceutical research and manufacturing industry, are encouraged to work collaboratively to identify options for expediting the development of therapies for Hepatitis C.

CONCLUSION

The challenges associated with combating the epidemic of Hepatitis C are of such magnitude that a concerted, coordinated response is required from the American healthcare research, delivery and financing system. The fact of this public health crisis must be brought to the attention of the American public in a manner that communicates the urgency of the issue, maximizes the potential for early diagnosis and treatment, reduces the risk of transmission, expedites the development of more effective and less debilitating treatments, and eliminates any stigma ascribed to the disease.

The National Minority Quality Forum endorses the Department of Health and Human Services goals and strategies associated with identifying persons infected with viral hepatitis early in the course of their disease, improving access to and quality of care and treatment for persons infected with viral hepatitis, and advancing research to facilitate viral hepatitis prevention and enhance care and treatment for infected persons.

The National Minority Quality Forum also endorses and applauds the decision of the US Preventive Services Task Force (USPSTF) recommendation that adults born between 1945 and 1965 be offered 1-time screening for HCV infection, and well as continuing the practice of screening persons at high-risk for infection.

Critical stakeholders must make a concerted effort to reduce the stigma that may have undermined the willingness of either individuals or healthcare providers to broach the topic. It is our belief that the new recommendations of the U.S. Preventive Services Task Force present as opportunity for all who have a voice, and a stake in the issue, to reframe the conversation from one of victim blame — or system blame — to one of shared benefit. Failure to do so will increase the number of lives lost, and families and communities economically compromised. One of the factors that significantly influenced the new recommendation from the U.S. Preventive Services Task Force is their determination that failure to constructively and proactively engage the baby boomer cohort will cost more in the short-and long-term and the costs directly associated with the engagement. This enlightened pragmatism will serve us all well when developing strategies to combat Hepatitis C as well as other chronic diseases.

ENDNOTES

[1] U.S. Department of Health and Human Services, *Combating the Silent Epidemic of Viral Hepatitis: Action Plan for the Prevention, Care & Treatment of Viral Hepatitis*, 2011.
[2] HCV is a 55-nanometer, enveloped, positive-strand RNA virus classified as a separate genus, *Hepacavirus*, in the Flaviviridae family.
[3]Institute of Medicine, *Hepatitis and Liver Cancer: A National Strategy for Prevention and Control of Hepatitis B and C*, Washington, DC; The National Academies Press, 2010.
[4] World Health Organization, 2010.
[5] Suwanna Noppornpanth. *Genetic Diversity and Molecular Evolution of Hepatitis C Virus: Thesis to obtain the degree of Doctor from the Erasmus University Rotterdam*, The Netherlands, 2008.
[6] Lozano R et al. Global and regional mortality from 235 causes of death for 20 age groups in 1990 and 2010: a systematic analysis for the Global Burden of Disease Study 2010. *Lancet*, 2012, 380(9859):2095–2128
[7]*Hepatitis C*, World Health Organization, 2002. Accessed at http://www.who.int/csr/disease/hepatitis/Hepc.pdf.
[8] The World Health Assembly is the decision-making body of WHO. It is attended by delegations from all WHO Member States and focuses on a specific health agenda prepared by the Executive Board. The main functions of the World Health Assembly are to determine the policies of the Organization, appoint the Director-General, supervise financial policies, and review and approve the proposed program budget. The Health Assembly is held annually in Geneva, Switzerland.
[9] Nordqvist, Christian. "What Is Hepatitis? Symptoms, Causes and Treatments." Medical News today. MediLexicon, Intl., 13 Apr.2009. Web. Accessed 4 Jan 2014 at <http://www.medicalnewstoday.com/articles/145869>
[10] The word hepatitis comes from the Ancient Greek word *hepar* (root word *hepat*) meaning 'liver', and the Latin *itis* meaning inflammation.
[11] WebMD, http://www.webmd.com/hepatitis/understanding-hepatitis-basics?page=3, accessed 01-05-14
[12] MedicineNet.com, http://www.medicinenet.com/viral_hepatitis/article.htm, accessed 01/07/14.
[13] MedicineNet.com, http://www.medicinenet.com/viral_hepatitis/article.htm, accessed 01/07/14.
[14] U.S. Department of Health and Human Services, 2011.
[15] Reshetnyak et al. Hepatitis G Virus, World Journal of Gastroenterology, August 14, 2008, 14(30): 4725-4734.
[16] IOM, 2010.
[17] IOM, 2010.
[18] A nosocomial, or hospital-acquired, infection is a new infection that develops in a patient during hospitalization. It is usually defined as an infection that is identified at least forty-eight to seventy-two hours following admission, so infections incubating, but not clinically apparent, at admission are excluded. With recent changes in health care delivery, the concept of "nosocomial infections" has sometimes been expanded to include other "health care–associated infections,"

including infections acquired in institutions other than acute-care facilities (e.g. nursing homes); infections acquired during hospitalization but not identified until after discharge; and infections acquired through outpatient care such as day surgery, dialysis, or home parenteral therapy.
[19] Frank, C., M. K. Mohamed, G. T. Strickland, D. Lavanchy, R. R. Arthur, L. S. Magder, T.El Khoby, Y. Abdel-Wahab, E. S. Aly Ohn, W. Anwar, and I. Sallam. 2000. The role of parenteral antischistosomal therapy in the spread of hepatitis C virus in Egypt. *Lancet* 355(9207):887-891.
[20] Lavanchy, D. 2008. Chronic viral hepatitis as a public health issue in the world. *Best Practice and Research. Clinical Gastroenterology* 22(6):991-1008.
[21] Noppornpanth, 2008.
[22] World Health Organization, 2002.
[23] World Health Organization, 2002.
[24] World Health Organization, 2002.
[25] Noppornpanth, 2008.
[26] Noppornpanth, 2008.
[27] World Health Organization, 2002.
[28] Noppornpanth, 2008.
[29] Noppornpanth, 2008.
[30] Dias, Hahn, Delwart et al. Temporal changes in HCV genotype distribution in three different high risk populations in San Francisco, California, BMC Infectious Diseases, 11:208, 2011.
[31] National Medical Association, *Hepatitis C: A Crisis in the African American Community*, October 2013.
[32] National Health Index, National Minority Quality Forum, Washington, DC, 2010.
[33] Virginia A. Moyer, MD, MPH, on behalf of the U.S. Preventive Services Task Force. *Screening for Hepatitis C Virus Infection in Adults: U.S. Preventive Services Task Force Recommendation Statement*, Annals of Internal Medicine, Vol 159, Number 5, 2013.
[34] Moyer, 2013.
[35] IOM, 2010.
[36] National Medical Association, 2013.
[37] Hepatitis C Index, National Minority Quality Forum, 2013, (http://hepcdiseaseindex.com).
[38] IOM, 2010.
[39]Nordqvist, 2009.
[40] U.S. Department of Health and Human Services, 2011.
[41] *Hispanics in the United States*, U.S. Census Bureau, www.census.gov, http://www.census.gov/population/hispanic/files/hispanic2006/Internet_Hispanic_in_US_2006.pdf, accessed 01-07-14.
[42] National Medical Association, 2013.
[43] Ramsey Cheung, MD. "Chronic Hepatitis C in the Hispanic Population", *The HCV Advocate*, March 2006.