



THE “SECRET” EPIDEMIC:

DISPARITIES IN HEPATITIS C INCIDENCE, TREATMENT, AND OUTCOMES

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On May 3, 2010, the Joint Center for Political and Economic Studies convened the Disparities in Hepatitis C Incidence, Treatment, and Outcomes Roundtable Discussion in Chicago, IL, with the goal of setting a national agenda to address the disproportionate impact of hepatitis C in communities of color. Held at the beginning of Hepatitis Awareness Month, this meeting was inspired by the need to raise awareness regarding the challenges of directing emerging resources and new treatment modalities to these communities in light of the high infection rates and harrowing consequences of chronic hepatitis C infection. Speakers from areas of academia, clinical medicine, health policy and government presented their perspectives, research, potential strategies, and solutions for addressing current and emerging issues in hepatitis C in the United States. This report summarizes the most salient points from the roundtable discussion.

HEPATITIS C: DISEASE OVERVIEW

Hepatitis C (HCV) is a viral inflammation of the liver spread primarily through percutaneous exposure with infected blood. The course of infection typically includes an incubation period of roughly six months, followed by an acute hepatitis. Of those infected, 55-85% subsequently develop a chronic HCV infection.¹ Most individuals are asymptomatic for years—or in some cases, decades—before this chronic HCV infection leads to the development of cirrhosis, liver failure, or even a form of liver cancer known as hepatocellular carcinoma (HCC).

In the United States, it is estimated that nearly 1.8% of the population may be infected with HCV. Since its discovery in 1989, the incidence of acute HCV has declined steadily from a peak of over 6,000 new reported cases per year in 1992 to just over 1,000 diagnoses of acute HCV in 2003 (actual infection rates are likely much higher).² Since 2003, the rates of acute viral hepatitis have plateaued.

Although the incidence of HCV is two decades past its peak in the United States, the prevalence of chronic HCV continued to increase into the early 2000s, peaking at 3.6

million Americans infected in 2001. Today, between 2.7 and 3.9 million Americans are infected with HCV, with 75 percent of those individuals unaware of their diagnosis. This prevalence is nearly four times the prevalence of both HIV and hepatitis B (HBV), with a significantly larger percentage of those infected with HCV yet undiagnosed. Individuals born in the 1950s have the highest rate of infection, with nearly 1.4 million individuals born in that decade infected with HCV.³

Even with infection rates continuing to decline or remain steady, the peak in HCV prevalence in 2001 is a harbinger of a new crisis to come. The unique natural history of the disease, with its long latency from infection to symptomatic presentation, coupled with its slow disease progression has led experts to predict a rise in HCV-related morbidity and mortality into the next decade. It is expected that the prevalence of HCV cirrhosis and its complications will continue to increase through the next decade, affecting 1.0 million Americans by 2020.⁴

Although the continued prevalence of HCV is problematic in communities across America, inequalities in disease prevalence, treatment, and outcomes make it a particularly important minority health issue. First, there are disparities in the prevalence of HCV infection, with African Americans being twice as likely to have ever been infected with HCV, and having a higher prevalence of chronic HCV infection compared with non-Hispanic white Americans.⁵ Additionally, there are significant disparities in access to HCV care for racial and ethnic minorities.⁶ Finally, African American and Hispanic patients with HCV infection, even once properly diagnosed, have less desirable treatment outcomes compared to white patients.⁷ These trends are indicative of a growing healthcare crisis with regards to HCV that threatens minority communities for decades to come.

3 Pyenson B, Fitch K, Iwasaki K. Consequences of hepatitis C virus (HCV): costs of a baby boomer epidemic of liver disease. Pyenson B. Milliman Inc, 2009. Available at www.milliman.com/expertise/healthcare/publications/rr/consequences-hepatitis-c-virus-RR05-15-09.php. Accessed June 2, 2010.

4 Davis GL, Alter MJ, El-Serag H, Pynard T, Jennings LW. Aging of Hepatitis C Virus (HCV)-Infected Persons in the United States: A Multiple Cohort Model of HCV Prevalence and Disease Progression. *Gastroenterology* 2010;138:513-521.

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6 Trooskin SB, Navarro VJ, Winn RJ, et al. Hepatitis C risk assessment, testing and referral for treatment in urban primary care: Role of race and ethnicity. *World J Gastro* 2007;13:1074.

7 Conjeevaram HS, Fried MW, Jeffers LJ, et al. Virahep-C study group. Peginterferon and ribavirin treatment in African American and Caucasian American patients with hepatitis C genotype 1. *Gastroenterology*. 2006 Aug; 131(2):470-7.

1 Rutherford Anna, Dienstag Jules L. "Chapter 39. Viral Hepatitis" (Chapter). Greenberger NJ, Blumberg RS, Burakoff R. *CURRENT Diagnosis & Treatment: Gastroenterology, Hepatology, & Endoscopy*: <http://www.accessmedicine.com/go.libproxy.wfubmc.edu/content.aspx?aID=6204265>. Accessed on June 4, 2010.

2 Reported cases of acute viral hepatitis, by type and year, United States, 1966-2003. National Notifiable Disease Surveillance System. Available at www.cdc.gov/hepatitis/PDFs/US-surv_table.pdf. Accessed on July 12, 2010.

HCV PREVENTION AND AFRICAN AMERICAN COMMUNITIES

A concerted and effective nationwide effort on the part of government and nongovernment entities must be made to prevent hepatitis C infection, with a particular focus on efforts in African American communities. African Americans are two to three times more likely to have been exposed to HCV than non-Hispanic whites. There is some speculation that the exposure of African Americans is greater due to potential for contact with contaminated blood through occupational exposure (an estimated 3 million African Americans are employed as health care professionals), blood transfusions (which may be required to treat sickle cell anemia, which mostly affects African Americans), or through a documented higher prevalence of injection drug use.⁸

In the general population, 55% to 85% of individuals exposed to HCV become chronically infected. This rate is much higher in African Americans (87 to 95%) than in whites (66-67%). While there is no clear scientific data that can explain this phenomenon, some experts believe that African Americans may not produce as strong an immune response against the virus as other races. Recognizing that race is a construct reflecting social stratification of groups according to phenotypic and cultural characteristics, this finding still has important implications in understanding the basis for variable outcomes in HCV infection, including differential response to antiviral therapy. Moreover, this finding warrants an even greater emphasis on preventing exposure in this population.⁹

In 2001, the CDC released the National Hepatitis C Prevention Strategy to comprehensively address the national HCV epidemic. Led by a multi agency group, the strategy was crafted to protect the public's health by preventing and controlling HCV infection. The principle components included: education of health care professionals to improve identification of risk factors; education of the public and persons at risk for infection about risk factors for HCV transmission; improving clinical and public health activities to identify, counsel, and test persons at risk for HCV infection; strengthening outreach and community-based programs to prevent practices that put people at risk for

HCV infection; and surveillance and research to better guide prevention efforts.

According to the CDC, effective implementation of the National Hepatitis C Prevention Strategy would likely reduce the number of new HCV infections, further reduce other blood borne virus infections, and prevent the projected increase in chronic liver disease due to hepatitis C. At the time of its introduction, the incidence of HCV had been steadily declining after its peak in the late 1980s. Nearly a decade later HCV rates have remained fairly consistent since the introduction of the strategy.¹⁰

In 2008, the Institute of Medicine convened a committee to assess current prevention and control activities for HCV and to determine a strategy for reducing new incidence of disease. The recommendations that arose from this committee in January 2010 focused on several strategies amounting to a multifaceted approach at reducing new infections.

First, the IOM asserts that improving knowledge and awareness about HCV, among health care providers, social service providers, and the public in general, is a key to preventing HCV infection. The committee recommends that the CDC develop educational programs for health care and social service providers to ensure that they are adept at identifying at-risk individuals and counseling them to prevent infection. Also, it was recommended that the CDC develop, coordinate, and evaluate new outreach and education programs for the general public to ensure increased knowledge of the virus and its mode of transmission. The IOM further calls for the development of comprehensive viral hepatitis services. Some key components include outreach and awareness activities, as well as strengthening services to prevent new infections.

A final HCV prevention piece of the IOM strategy is its advocacy for HCV risk factor screening as a required core component of preventive care in Medicare, Medicaid, and the Federal Employees Health Benefits Program. Incorporating these guidelines into these federally-funded health insurance programs would allow at-risk people to receive necessary blood testing for HCV, and would serve as a compelling and necessary model for private insurers as well.

8 Francis A. HCV Populations: African Americans and Hepatitis C. Hepatitis C Support Project: hcsupportFACTsheet. Available at www.hcvadvocate.org. Accessed on June 3, 2010.

9 Rosen HR, Weston SJ, Im, K, et. al. Selective Decrease in Hepatitis C Virus-Specific Immunity Among African Americans and Outcome of Antiviral Therapy. *Hepatology* 2007;46:350-357.

10 Danies D et al. Surveillance for Acute Viral Hepatitis – United States, 2007. *MMWR Morbidity and Mortality Weekly Rep.* May 22, 2009; 58(No. SS-3).

Whether it is through looking at the recommendations of the 2010 IOM report or more generally through proven strategies in public health, the development of a comprehensive strategy for HCV will prove invaluable in the years ahead. Although new infections have declined significantly over the past two decades, it remains imperative that this preventable cause of significant liver-disease and liver-related mortality be addressed swiftly and appropriately.

The Roundtable convened by the Joint Center discussed several strategies for preventing HCV in communities of color, such as:

- ***Expansion of programs to reduce the risk of HCV infection through injection-drug use.*** Programs at the federal, state, and local level that are proven to reduce the transmission of HCV, such as programs facilitating access to sterile needle syringes and drug-preparation equipment, should be expanded.
- ***Development of education programs for health care professionals and other social service providers regarding HCV.*** Sustainable and comprehensive education programs should be developed for health care and public health professionals to improve the identification of persons at risk for HCV infection and to ensure that these individuals are appropriately counseled to avoid infection.
- ***Construction of community-based outreach and education programs to inform the general public about mitigating their risk for HCV infection.*** More general support should be made available for programs aiming to inform the public and persons at risk for infection about risk factors for HCV infection and the need for testing and medical evaluation. Comprehensive community education programs should be developed to better facilitate public awareness.

IMPROVING HCV SCREENING AND DIAGNOSIS AMONG AFRICAN AMERICANS

Ensuring adequate screening for and diagnosis of HCV in minority communities is an essential element of any coordinated effort to close the gap in HCV related morbidity and mortality. While 75 percent of Americans with chronic HCV are undiagnosed, African Americans are more than twice as likely as all other populations to be chronically HCV infected. As such, it follows that a larger proportion of individuals in the African American community remain yet undiagnosed.

Many of the barriers to screening for HCV reflect the systemic problems that contribute to other existing health and healthcare disparities in minority communities. Among the barriers directly contributing to HCV disparities are issues such as access to primary care services, as well as the stigma attached to HCV risk factors, such as injection drug use.

One survey found that, even when patients do have access to primary care, only 59 percent of primary care physicians ask their patients about HCV risk factors, 70 percent test those patients at risk, and fewer 80 percent specifically test for HCV in patients who have elevated liver enzymes.¹¹ Additionally, minorities were less likely to be tested for HCV than whites in the presence of a known risk factor.¹²

In advising health care professionals, several bodies have offered guidelines for HCV screening. The CDC in 1998 recommended that routine testing be offered to persons most likely to be infected. In addition, anyone who wishes to know their HCV-infection status, as per the recommendation, should be provided the opportunity.¹³ In 2002, the NIH promoted the establishment of screening tests for all groups at high risk of HCV infection, including injection drug users and incarcerated individuals.¹⁴ Just years later, in 2004, the United States Preventive Services Task Force (USPSTF) recommended against routine screening for HCV infection in asymptomatic adults in

11 Shehab TM, Sonnad SS, Lok AS. Management of hepatitis C patients by primary care physicians in the USA: results of a national survey. *J Viral Hepat* 2001;8:377-383.

12 Trooskin SB, Navarro VJ, Winn RJ, et al. Hepatitis C risk assessment, testing and referral for treatment in urban primary care: Role of race and ethnicity. *World J Gastro* 2007;13:1074.

13 CDC: Recommendations for Prevention and Control of Infection and HCV-Related Chronic Disease. October 1998. Available at <http://www.cdc.gov/mmwr/preview/mmwrhtml/00055154.htm> Accessed on June 4, 2010.

14 National Institutes of Health Consensus Conference Statement. June 2002. Available at <http://consensus.nih.gov/2002/2002HepatitisC2002116html.htm>. Accessed on June 4, 2010.

the general population, and found insufficient evidence to recommend for or against routine screening in adults at high risk for infection.

Though the CDC is currently crafting updated screening guidelines for HCV, the current body of consensus recommendations amount to little more than inconsistent assertions for health care providers to consider. The lack of consistent guidelines for a screening approach to the general public or to individuals considered at-risk makes for a failure in establishing a concerted public health strategy for HCV.

The Roundtable convened by the Joint Center discussed several strategies for improving HCV screening and diagnosis in minority communities, including:

- ***Depart from current focus on risk factor identification as the impetus for HCV screening.*** Neutralize the impact of stigma by deemphasizing the risk factors (e.g. – injection drug use). Focus, instead, on high prevalence and the need to “know your status.”
- ***Implement alternative screening models for infection, focusing on community outreach and utilization of trusted community establishments.*** Follow the HIV model, using alternative screening models (i.e. – barbershops, salons) to inform clients. Identify trusted community agents and prepare them to pass information about HCV and educate the community.
- ***Increase funding at the state and federal levels for screening services to be implemented in communities.*** The lack of funding certainly limits efforts at the federal, state, and local level. The investment in screening and diagnosis must be commensurate to the task. With 75% of HCV-infected individuals yet unidentified, efforts must be appropriately funded to identify individuals so that they can seek treatment.

ELIMINATING DISPARITIES IN HCV TREATMENT AND OUTCOMES

With a significant burden of morbidity and mortality in minority communities, eradicating disparities in access to HCV treatment and differences in treatment outcomes for minorities are two essential elements of the emerging efforts to address this healthcare crisis. With regard to medications, it has been long established that pegylated alpha interferon (peginterferon) in combination with ribavirin given for 24 or 48 weeks is the standard therapy for chronic HCV. Even still, there is much more to successful HCV treatment than simply two medications.

In requiring weekly injections of peginterferon, as well as daily doses of ribavirin orally—both for up to 48 weeks—the demands of the therapeutic regimen for HCV are arduous for any patient, let alone individuals with barriers to access to care. The treatments, themselves, are often very expensive and produce their own level of morbidity, serving as additional barriers to patient adherence.¹⁵ In controlled clinical trials, the aforementioned combination therapy yielded sustained virologic response (SVR) rates of 54%-63% among the general population. However, the SVR rate was only 28% in blacks compared to 52% in whites.¹⁶

Of the six major genotypes of the hepatitis C virus, genotype 1 is known as both the most common HCV genotype in the United States, and also the most difficult to treat. While 70-75% of Americans with HCV are infected with genotype 1, as many as 91% of African Americans are infected with this difficult to treat genotype.¹⁷ Although this type 1 genotype typically has a poorer response to interferon treatment, the effectiveness of treatment is improved with a full year of close adherence to therapy. Unfortunately, one study indicated that only 54% of African Americans, compared to 73% of whites, met the criteria typically used in assessing compliance in combination therapy of HCV during the first 24 weeks of treatment.¹⁸ The combination of challenges in proper administration of the therapeutic regimen with the

15 Manka C, Gomes R, Reviere R, Lee C. Treatment Options for Hepatitis C and the Rationale for Low Response Rates in African Americans. *J Natl Med Assoc* 2009 Jun;101(6):604-8.

16 Conjeevaram HS, Fried MW, Jeffers LJ, et al. Virahep-C study group. Peginterferon and ribavirin treatment in African American and Caucasian American patients with hepatitis C genotype 1. *Gastroenterology*. 2006 Aug; 131(2):470-7.

17 Franciscus A. HCV Populations: African Americans and Hepatitis C. Hepatitis C Support Project: hcsupportsheet. Available at www.hcvadvocate.org. Accessed on June 3, 2010.

18 Conjeevaram HS, Fried MW, Jeffers LJ, et al. Virahep-C study group. Peginterferon and ribavirin treatment in African American and Caucasian American patients with hepatitis C genotype 1.

prevalence of a more difficult to treat viral genotype makes it all the more apparent that the current HCV treatment efforts in minority communities are inadequate.

Consistent with the differences in treatment outcomes with regard to SVR, there are corresponding disparities in both symptomatic liver disease and liver-related deaths in minorities as compared to whites. Mortality from HCV among African Americans and Hispanics increased more than in other racial or ethnic groups between 1995 and 2004.¹⁹ Additionally, the incidence of hepatocellular carcinoma (HCC) is nearly 2-fold higher among African Americans than whites.²⁰ The real implications of the poor treatment outcomes among minorities, or of the absence of treatment altogether, is in the hospitalizations, the protracted illness, and in the unnecessary lives lost.

The Roundtable discussed several strategies for eliminating disparities in HCV treatment and outcomes, such as the need to:

- ***Increase African American enrollment in clinical trials that involve HCV treatment.*** African American subjects represent only 5% to 10% of those who take part in clinical trials that involve HCV infection. In order to identify best practices in treatment to facilitate better outcomes, it is imperative that this cohort be better represented in current and future clinical trials.
- ***Support pharmaceutical innovation in developing alternative treatments for HCV that may be more conducive to better compliance.*** Novel, directly acting anti-viral agents, are currently under development. Named ‘specifically targeted anti-viral therapy for hepatitis C’ (STAT-C), these compounds, in addition to peginterferon and ribavirin can improve SVR rates at least in HCV genotype 1 patients. The continued development of these compounds may allow for augmentation of the therapeutic regimen, which could be more conducive to adherence to treatment.

CONCLUSION

It is imperative that government agencies and the legislature formulate a coordinated national response to the HCV crisis. Although risk factors for its transmission are well-established, and some communities and demographics disparately bear the burden of disease, all Americans are vulnerable to HCV. The failure to adequately prevent, screen, diagnose, and treat HCV resonates as both an unfortunate health equity issue and serious threat to our nation’s financial security.

With regards to health equity, the health care access issues that have contributed to the high prevalence of HCV infections in minority communities are both identifiable and preventable. With a prevalence as high as 13 percent of African American men between the ages of 50-59 with HCV, the label of epidemic hardly seems sufficient. Viable and robust education and prevention efforts must be initiated in the communities that are most affected. Programs facilitating successful navigation from screening to diagnosis to treatment must be supported in order to mitigate the looming crisis of chronic HCV infection and its health consequences.

Looking at the sheer cost of the HCV crisis facing the United States, particularly among minority communities, it would be far more damaging to do nothing than to invest in prevention, screening, and treatment. With the highest HCV infection prevalence rates among Americans born in the 1950s, public programs will increasingly cover this group’s health care costs over the next decade. One report noted that, over the next 20 years, total annual medical costs for patients with HCV infection would exceed \$85 billion. Medicare costs alone for HCV over the next two decades will increase fivefold, from \$5 billion to \$30 billion.²¹

The combination of moral and economic imperatives driving the push for coordinated policy intervention are glaring. Dubbed “The Secret Epidemic” in a June 17, 2010 hearing of the Committee on Oversight and Government Reform, HCV infection poses a discernable threat to the wellbeing of many in the nation’s communities as well as to the solvency of its Medicare program. With so much riding on a swift, concerted, and comprehensive effort to address the crisis, it is clear that the nation suffers if the HCV crisis is kept a secret any longer.

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21 Pyenson B, Fitch K, Iwasaki K. Consequences of Hepatitis C Virus (HCV): Costs of a Baby Boomer Epidemic of Liver Disease. Milliman, Inc. May 2009.

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