

# ***Chronic Liver Disease Foundation***

## **Endorsement Of Birth-Cohort Approach to Expand Screening for Hepatitis C**

### **Background**

Hepatitis C remains the most common blood-borne chronic viral infection in the United States. According to recent estimates<sup>1,2</sup>, as many as 5 million Americans are infected with the hepatitis C virus (HCV). Most cases will develop into chronic infection, increasing the risk for developing chronic liver diseases, such as cirrhosis and cancer. Goals for preventing chronic hepatitis C in the United States involve eliminating viral transmission and reducing morbidity and mortality among persons infected with HCV. An effective HCV screening strategy is essential for accomplishing these goals.

The CDC currently recommends HCV screening for only individuals with a previous history of certain behaviors or health indicators that are associated with HCV infection, such as injection drug use, Hemodialysis, or abnormal liver function tests<sup>3,4</sup>. Despite these recommendations, most persons living with HCV remain unaware of their infection status, and many of those who are known to be positive for HCV do not receive necessary care and treatment<sup>5,6</sup>. As a result, the burden of disease and death continues to grow despite recent advances in antiviral therapies.

This position paper represents the views and recommendations of the Chronic Liver Disease Foundation (CLDF) for a more effective strategy to identify patients with HCV infection and link such patients to expert care and treatment.

### **Current Hepatitis C Screening and Testing**

The number of patients with chronic hepatitis C that will progress to cirrhosis, liver failure, HCC, and death is expected to increase dramatically over the next decade<sup>7,8</sup>. Without changes to the HCV Diagnosis and treatment paradigms, total medical costs for patients with HCV infection are expected to more than double, from \$30 billion to over \$85 billion over the next 20 years<sup>9</sup>.

The prevalence of HCV is highest in middle-aged, non-Caucasian men and may be as high as 40% in the homeless and incarcerated<sup>5</sup>. Infection with HCV is also most prevalent among people born between 1945 and 1965<sup>10,11</sup>. Unfortunately, many of these patients are unaware of their infection and remain at risk for serious complications as time passes due to the slow, progressive nature of the disease.

Currently, the CDC recommends testing for HCV antibody only in individuals with identifiable health indicators or risk factors that suggest possible exposure to HCV<sup>4</sup>. Despite these recommendations, up to 75% of patients with chronic hepatitis C are

unaware of their HCV infection status<sup>6</sup>. Reasons for the failure to identify patients with chronic Hepatitis C include: (a) asymptomatic patients without any other medical problems may not seek medical attention, (b) many primary care physicians lack knowledge about risk factors and testing for hepatitis C, (c) patients may be reluctant to reveal risk factors, and (d) patients may be outside healthcare system (young, poor, drug addicts).

### **Birth Cohort-Based HCV Screening**

The prevalence of HCV infection among persons born between 1945 and 1965 is estimated to be 4.5 times higher than for persons born outside this birth cohort<sup>10,11</sup>. The CDC is evaluating the potential benefits of using a birth-cohort based approach to HCV screening to expand current screening recommendations and increase identification of HCV-positive patients<sup>12</sup>. This strategy avoids some of the limitations of a risk-based approach to HCV screening. A recent study by Rein et al. indicates that birth-cohort screening for HCV is cost effective and could potentially identify an additional 800,000 cases of chronic hepatitis C<sup>13</sup>.

### **Benefits of Rapid HCV testing**

Recent and future advances in the diagnosis and treatment of HCV increase opportunities to test and treat. The initial screening test for HCV detects the presence of antibodies (Ab) to HCV to evaluate exposure to the hepatitis C virus. In February 2011, the first point of care rapid HCV antibody test (OraQuick® HCV) was approved by the FDA, for use with whole blood from either fingerstick or venipuncture. The test provides accurate results in 20 minutes<sup>14</sup>. More recently, this test received CLIA-waived status from the FDA which now enables it to be administered in physician offices or public health facilities and clinics thus offering the advantage of allowing immediate discussion with HCV positive patients about follow up testing and care<sup>15</sup>.

### **CLDF Guidance on HCV Screening and Testing**

Despite the availability and increasing effectiveness of antiviral therapies, chronic hepatitis C remains a leading cause of liver related morbidity and the leading cause of liver transplantation. Screening for HCV and linking those found to be infected to expert care and treatment can improve health outcomes and reduce the human and economic costs of HCV infection. However, new educational and screening strategies, involving both public and private partners, may be required to ensure success.

Hep C Link to Care NYC (<http://www.hepclink.org/>), a program sponsored by CLDF, offered free HCV screening to at-risk patients in New York City (NYC), and established a coalition of providers to ensure follow-up care for HCV+ persons. A key aim of the study was to assess a combined birth-cohort and risk-based approach for HCV screening at primary care clinics or health fairs in at-risk communities in NYC and link patients to expert care. Over 90 HCV-treating physicians participated in an expert-led educational program and opted into a treatment coalition and on-line directory distributed to NYC primary care doctors.

## Recommendations

The following factors should be considered in order to improve the effectiveness of efforts to screen patients for HCV and to ensure adequate care and treatment for patients with chronic hepatitis C:

- Health practitioners should consider **screening for HCV among persons born between 1945 and 1965** given that the prevalence is more than 4 times higher than those individuals born outside the birth cohort.
- A newly developed **rapid point-of-care test** for HCV Ab can provide opportunities to expand testing opportunities and facilitate immediate discussions with patients about follow-up testing and care
- Educational programs aimed at primary care providers can **increase awareness of HCV risk factors (including birth cohort screening)** that will lead to more HCV testing.
- Testing for HCV in **primary care setting with establishing linkages to HCV providers** can improve the likelihood of linking patients to appropriate care.
- Creative ways are needed to increase access to HCV testing and care for injection-drug users and other marginalized and underserved populations.

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