# HEPATITIS C in NEW YORK CITY

State of the Epidemic and Action Plan



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# **EXECUTIVE SUMMARY**

"You may not remember everything that happened in the '60s and '70s, but your liver does." - Dr. Thomas Frieden, CDC Director. May 7, 2013.

As many as 3.5 million Americans and 146,500 New York City residents may have chronic hepatitis C (HCV). The disease is most prevalent in New York City neighborhoods with high poverty. Most persons living with HCV have few symptoms of illness until 10 to 30 years after initial infection, when life threatening health complications can develop, including end-stage liver disease, liver cancer and eventually death. The annual number of deaths associated with HCV has been increasing yearly and, since 2007, has exceeded deaths associated with HIV in the U.S. More effective antiviral treatments have recently been approved and more are expected in the coming years, making it possible that disease and death from HCV can be averted.

It is estimated that approximately 50% of people living with HCV are unaware that they are infected. Having ever injected drugs — even once in the remote past — is the most frequently reported risk factor. Among those diagnosed, few are offered treatment. Too few health care providers are knowledgeable enough about the disease to care for patients themselves, let alone provide treatment. The lack of physicians trained to manage and treat HCV is particularly significant in neighborhoods where most persons living with chronic HCV reside. For those who are referred to specialists, waits for appointments may take months. Moreover, the health care system is often difficult to navigate because care and treatment may require health insurance coverage and coordination among primary care providers, specialists, drug treatment programs and mental health professionals. Even when persons with HCV are insured, insurance programs may not cover all necessary HCV services.

Federal, state and local government funding for HCV surveillance, testing and treatment has been extremely limited. Modest sustained funding to detect and treat HCV could greatly alleviate the personal, social and economic burden of this disease.

This action plan identifies 7 public health objectives to address the HCV epidemic in New York City. Of them, the following 5 objectives are most critical for reducing illness and death from HCV in New York City. They will be prioritized depending on available resources.

1. Enhance health provider awareness regarding screening, diagnosis, and referral for HCV infection and clinical providers' capacity to manage and treat HCV.

To reach the large number of people infected with HCV but unaware of their infection, the New York City Department of Health and Mental Hygiene (the Health Department) will need to motivate health care providers to incorporate HCV testing into routine practice and to refer patients with current HCV infection, as needed. The Health Department will distribute educational materials, conduct training courses, and collaborate with large health care institutions to enhance provider diagnosis and management of HCV infection. Too few providers in New York City are sufficiently trained and skilled to treat HCV and manage the complicated medical and psychosocial issues that often emerge during treatment. The Health Department, through a grant from industry, has developed and implemented a model to train community-based medical providers in HCV care and treatment, using ongoing telemedicine mentoring of community health center physicians by academic medical specialists. The Department will expand these activities to include primary care physicians, infectious disease specialists, and gastroenterologists throughout the city.

2. Promote HCV testing, as per CDC guidelines.

The Health Department will encourage providers to follow new CDC guidelines to test patients born between 1945 and 1965 for HCV in addition to the traditional HCV high risk groups. Efforts also will be expended in highly affected communities to increase HCV knowledge and awareness about testing opportunities (e.g., drug treatment programs) and to identify and address structural barriers to testing.

Incarceration is an established risk factor for HCV infection. The Health Department annually provides medical services to the approximately 90,000 persons detained at Riker's Island. At least 10% of those incarcerated have a pre-existing HCV diagnosis, and an additional 10-15% are likely infected but do not know it. The Health Department will develop a program to enhance diagnosis of HCV infection at Riker's Island.

The Patient Protection and Affordable Care Act (ACA) promises to expand health insurance to most New Yorkers. However, many new immigrants with HCV may be uninsurable and will need additional assistance. Although HCV treatment cannot be guaranteed, testing alone has benefits. Patients can be counseled to minimize practices that could result in

inadvertent transmission (e.g., sharing drug using equipment) or additional liver damage (e.g., limiting alcohol intake), and they can be vaccinated against hepatitis A (HAV) and hepatitis B (HBV) viruses. The Health Department will assist community organizations in testing uninsured populations.

3. Enhance HCV surveillance activities to strengthen the Health Department's capacity to manage and utilize data for evidence-based policies and practice.

New York State law mandates reporting of positive HCV antibody and confirmatory laboratory tests (e.g., HCV RNA) to the Health Department. If the Department received results of both positive and negative tests for HCV RNA, it could estimate number of people tested, the burden of chronic HCV infection in the community and also monitor changes over time. With dedicated and sustained funding for HCV surveillance, the Department could analyze these and other data to continually update the public and providers about progress in addressing the burden of HCV and continually update policies based on the best quality evidence.

4. Enhance linkage to care of persons with current HCV infection, identify and promote successful models of care, and build clinical capacity to manage and treat HCV.

Many patients with HCV face social barriers, behavioral health issues or have co-occurring medical conditions that make it challenging for them to initiate and remain in HCV-related medical care. The Health Department proposes to work with health care facilities, care management agencies, health homes and managed care in New York City to improve care coordination. When persons living with HCV are released from custody, correctional facilities will be encouraged and assisted to link them to health care providers in their communities who can manage and treat HCV.

5. Engage and collaborate with the New York State Department of Health and other state agencies and other relevant organizations to develop, promote, and advance policies and regulations that will support the goals of this strategy.

The Health Department will partner with the State Health Department to identify and advance HCV-related legislative and regulatory opportunities. This might include expanding the HCV-related services reimbursed by Medicaid (e.g., lab and other diagnostic tests, patient navigation, drug treatment and antiviral medications), or changing lab test reporting requirements for clinical laboratories and drug treatment programs. The health care sector also will be engaged to ensure the development and implementation of quality control/assurance metrics related to HCV care and that network capacities are sufficient to manage and treat HCV.

#### **Glossary of Abbreviations**

ADAP AIDS Drug Assistance Program

AHVP Adult Hepatitis Vaccination Program (New York State)

AIDS Acquired immune deficiency syndrome
ACA Patient Protection and Affordable Care Act

ALT Alanine aminotransferase
CBO Community-based organization

CDC U.S. Centers for Disease Control and Prevention

CHS Bureau of Correctional Health Services

CME Continuing Medical Education

DHHS U.S. Department of Health and Human Service

DOHMH New York City Department of Health and Mental Hygiene

EHR Electronic health record

EIA Enzyme-linked immunoassay

EIP Emerging Infections Program (CDC)

ELC Epidemiology and Laboratory Capacity Program (CDC)
ESAP Expanded Syringe Access Program (New York State)

FDA U.S. Food and Drug Administration FPHNY Fund for Public Health in New York FQHC Federally-qualified health center

HAV Hepatitis A virus HBV Hepatitis B virus

HCC Hepatocellular carcinoma

HCV Hepatitis C virus

HepCAP Hepatitis C Assistance Program (New York State)

HIV/AIDS Bureau of HIV/AIDS

HHC Health and Hospitals Corporation (New York City)

HIV Human immunodeficiency virus

HRSA Health Resources and Services Administration

IDUHA Injecting Drug Users Health Alliance

IOM Institutes of Medicine

MMT Methadone maintenance treatment

MSM Men who have sex with men

NAT Nucleic acid test

NCHHSTP National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention

NHANES National Health and Nutrition Examination Study

NYS DOH New York State Department of Health

OASAS New York State Office of Alcoholism and Substance Abuse Services

PCIP Primary Care Information Project

PWID Persons who inject drugs

RNA Ribonucleic acid

SAMHSA Substance Abuse and Mental Health Services Administration

SEP Syringe exchange program
STD Sexually transmitted disease
SVR Sustained virologic response

TB Tuberculosis

# INTRODUCTION

#### The Significant Personal and Public Health Burden

As many as 3.5 million Americans and 146,000 New York City residents may have chronic hepatitis C (HCV).<sup>1,2</sup> Many live in neighborhoods with high levels of poverty, unemployment, and other indices of underlying health disparities.<sup>3,4</sup> Most are unaware of their infection and the life threatening health risk involved, including liver damage, end-stage liver disease, hepatocellular carcinoma, and eventual death. Many who were infected in the 1970s and 1980s are now developing end-stage liver disease and other sequelae that affect quality of life. Chronic HCV has become the most common cause of hepatic failure and accounts for approximately 40% of liver transplants in the U.S.<sup>5,6</sup> Costs of premature mortality from HCV and lost productivity alone from 2010 to 2019 are estimated to total \$75 billion.<sup>7</sup>

HCV is a leading cause of death for people with HIV.<sup>8</sup> Nationwide, deaths from HCV-related disease — hepatic and extrahepatic — now surpass those caused by HIV.<sup>9</sup> In New York City, the Health Department's Bureau of Vital Statistics has estimated that the age-adjusted rate for HCV-related deaths per 100,000 population increased by approximately 46% from 1999 to 2011. During the same period, HIV-related deaths decreased by approximately 60% (Figure 1). If current trends continue, HCV-related deaths in New York City also will surpass those from HIV within the next couple of years.

Federal funding for public health surveillance of HCV infections and for prevention activities, case management, and treatment has been extremely limited. Of the 2011 funds allocated by the Centers for Disease Control and Prevention's (CDC) National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), only 2% were for viral hepatitis. Moreover, Congress has never passed legislation that provided safety net access to HCV care and treatment for persons without health insurance, as the Ryan White Care Act did for persons living with HIV. In 2010 and 2011, respectively, the Institutes of Medicine (IOM) and Department of Health and Human Services (DHHS) published comprehensive HCV needs assessments and action plans, articulating detailed strategies for controlling the HCV epidemic (Figure 2). 11,12 Federal budgets, however, have not included the investments needed to implement them.

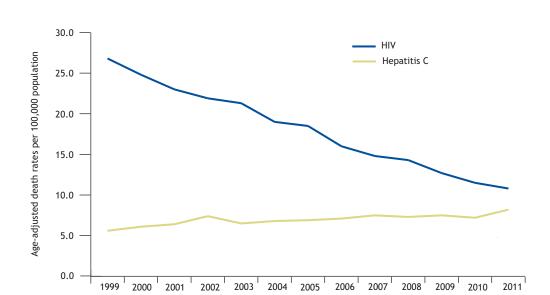


Figure 1. Trends of Age-Adjusted Death Rates per 100,000 Population of HIV and Hepatitis C: NYC 1999 to 2011 (All Events Occurring within NYC)

Source: New York City Department of Health and Mental Hygiene Notes:

- (1) based on any mention in death certificate (multiple cause of death)
- (2) deaths occurring only in NYC

#### The Health Department's HCV Action Plan: Why Now?

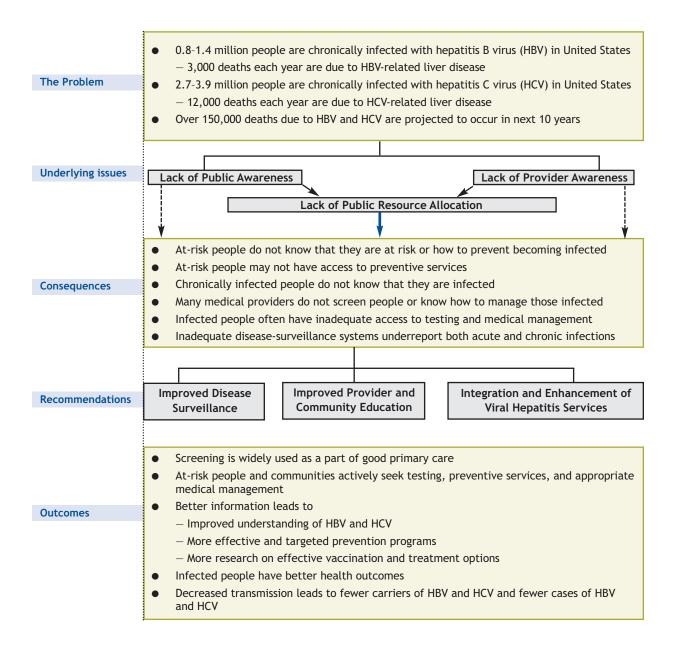
Personal, social, and economic burdens caused by HCV are substantial. If nothing is done in the coming years to intervene against it, tens of thousands of New York City residents — infected in the 1970s and 1980s — may go on to discover that they have advanced and lifethreatening liver disease. This anticipated wave of HCV-related illness, potentially leading

to billions of dollars in health care costs and lost productivity, can be blunted with a concerted public health intervention that takes advantage of new diagnostic tools and treatment options.

Instead of needing to send blood to a clinical laboratory for HCV testing — a process that can take weeks and result in persons being lost to follow-up — a new, sensitive and specific point-of-care test can now identify HCV antibodies from a finger stick in 20 minutes. This means

If nothing is done in the coming years to intervene against it, tens of thousands of New York City residents — infected in the 1970s and 1980s — may go on to discover that they have advanced and lifethreatening liver disease

Figure 2. Summary of Institute of Medicine HCV Assessment and Action Plan



Source: Colvin HM and Mitchell AE, eds. Figure 1-2, The committee's approach to its task; p. 34.

that many more at-risk individuals can be quickly identified with HCV infection and immediately linked to care. Moreover, with the advent of the Patient Protection and Affordable Care Act (ACA), many previously uninsured New Yorkers with HCV will have access to health care, enabling them to be referred to HCV experts for appropriate clinical management and treatment, as warranted.

Without more effective treatment regimens, it would be impossible to successfully face the oncoming deluge of HCV-related morbidity and mortality. Fortunately, we are about to enter a revolutionary era in HCV treatment. Highly effective and well-tolerated oral regimens are expected to be approved for use in less than two years, and many other therapeutic agents are being actively tested and will continue to become available in the years ahead. For the first time, HCV infection will be curable for the vast number of persons living with this disease.

With the advent of the Patient Protection and Affordable Care Act, many previously uninsured New Yorkers with HCV will have access to healthcare

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It is this favorable confluence of circumstances that has led the Health Department to develop this HCV action plan. Its primary goals are clear cut: 1) decrease HCV transmission and 2) cure those with infection who can be treated so that advanced liver disease can be prevented. There is more opportunity now than ever before to achieve them. However, at the same time that these epidemiologic and clinical dynamics have been taking shape, public health has been facing its most serious funding crisis in decades.

Successful implementation of the Health Department's action plan to control the HCV epidemic will require concerted efforts by various Department bureaus. It also will require engagement with and commitment from a large segment of the New York City health care community.

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1) decrease HCV transmission and 2) cure those who can be treated so that advanced liver disease can be prevented

# HCV VIRUS INFECTION AND TREATMENT

#### The Virus and Disease That It Causes

HCV is an RNA virus that infects cells in the liver. Most infections remain asymptomatic until complications from longstanding liver damage emerge — typically, 20 to 30 years after exposure. The progressive liver damage caused by HCV infection results from an ongoing, unsuccessful immune response to chronic infection. Acute HCV infection is successfully eliminated by the host's immune system in only 15-20% of cases. More typically, the virus is able to adjust to and evade immune responses, leading to chronic infection and liver damage.<sup>13</sup>

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The human and public health burden caused by HCV is considerable. Approximately 15-30% of persons with chronic HCV infection develop cirrhosis within 30 years. <sup>14</sup> Of these, roughly 30% go on to develop decompensated cirrhosis and end-stage liver disease within 10 years, and hepatocellular carcinoma (HCC) is diagnosed in another 1-3% per year <sup>14</sup> (Figure 3). Chronic HCV infection is the primary indication for liver transplant and a leading cause of death from liver disease in the U.S. <sup>5,6</sup>

Patients with HCV succumb to far more than just liver disease. According to a large, long-term cohort study, persons with chronic HCV are significantly more likely to die from a range of hepatic and extra-hepatic diseases than matched controls. Since 2007, annual mortality associated with HCV infection has exceeded annual mortality associated with HIV infection in the U.S.

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Nationally, the prevalence of HCV infection among HIV-infected patients is estimated to be 15-30%, <sup>16</sup> though it can be as high as 90% in HIV-infected patients who also inject drugs. <sup>17</sup>

HIV-HCV co-infection, especially in persons whose HIV is not well-managed, leads to higher viral loads and more rapid onset of HCV-related complications, including cirrhosis, end-stage liver failure, and hepatocellular carcinoma. 18-20

#### Person-to-Person Transmission

In the U.S., an estimated 60% of HCV infections result from drug use — even once — involving shared needles, syringes, or other drug use paraphernalia, and approximately 5% of existing chronic infections result from contaminated organs or blood component transfusions before HCV testing of the blood supply began in 1992.<sup>21</sup> Vertical transmission to

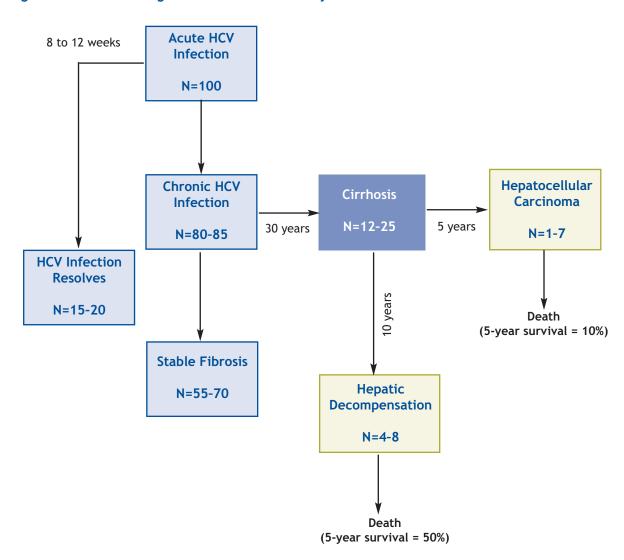


Figure 3. Schematic Diagram of the Natural History of 100 HCV Infections in the U.S. 14,22

Sources: Chen SL and Morgan TR. The natural history of hepatitis C virus (HCV) infection. International Journal of Medical Sciences. 2006; 3(2):47-52 and Harnois DM. Hepatitis c virus infection and the rising incidence of hepatocellular carcinoma. Mayo Clinic Proceedings. 2012 Jan;87(1):7-8.

infants from HCV-infected mothers, infections during hemodialysis, unsterile skin piercing activities (e.g., tattoos in prisons), and health care-associated infections account for smaller proportions of HCV cases.

The efficiency of HCV sexual transmission has been difficult to establish with confidence, primarily because most studies are unable to document past and current drug use.<sup>23</sup> The risk is thought to be low for monogamous heterosexual couples with one HCV-infected partner. Transmission risk increases in the setting of multiple partners, sexually transmitted infections, HIV and the presence of blood.<sup>23</sup> There has been growing alarm about increasing HCV incidence among HIV-infected men who have sex with men (MSM) and who take part in group sex with multiple partners, have concurrent sexually transmitted infections, use sex toys, or engage in activities that can result in anal trauma and exposure to contaminated blood or semen.<sup>24</sup> In addition to these behavioral factors, concurrent HIV infection may facilitate HCV transmission through alterations in host immune responses.<sup>25</sup>

#### **Diagnostic Testing to Assess Infection Status**

HCV infection can be diagnosed within approximately two weeks of exposure with nucleic acid tests (NATs), due to rapid replication of the virus. Unless acute infection is suspected, HCV diagnosis typically occurs with serological testing. HCV antibodies usually appear eight to 12 weeks after infection and, in the setting of long-term immune activation, remain indefinitely.

The current CDC recommendation for HCV testing is shown in Figure 4.<sup>26</sup> Serological tests, such as third-generation enzyme-linked immunoassays (EIAs) or a newly approved point-of-care lateral flow immunoassay, are commonly used to screen for HCV infection. In contrast with earlier immunoassays, these have excellent sensitivities and specificities.<sup>27</sup> False positive results are unlikely when the signal-to-cutoff ratio is above a level determined for each Food and Drug Administration (FDA)-approved test.<sup>28</sup>

HCV RNA testing with an NAT (e.g., polymerase chain reaction) is recommended for persons who test positive for antibody, to determine whether or not the patient is currently infected with HCV. Current quantitative HCV RNA assays have excellent sensitivity, obviating the need for previously-used qualitative HCV RNA test in most circumstances. RNA testing is also used following suspected false negative or indeterminate antibody testing.

HCV RNA testing is recommended for persons who test positive for antibody

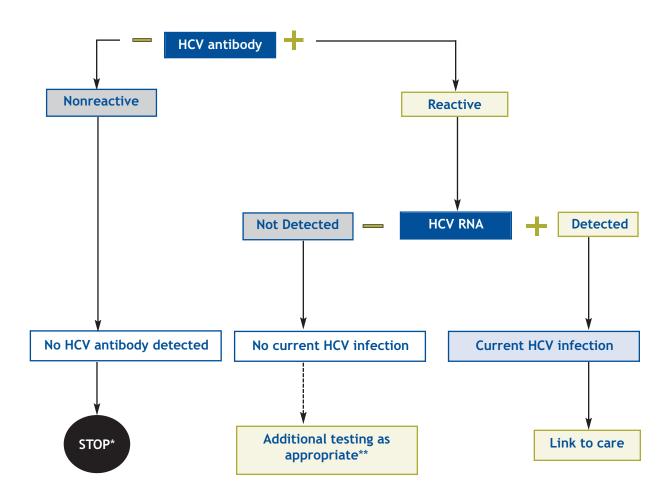


Figure 4. Recommended Testing Sequence for Identifying Current Hepatitis C Virus (HCV) Infection

Source: CDC. MMWR. 2013 May 07.

#### **Treatment**

The goal of antiviral treatment is cure, which is defined as undetectable HCV RNA six months after treatment is completed and is termed a sustained virologic response (SVR). Until 2011, only 40-50% of HCV patients chronically infected with the most common HCV genotype in the U.S. could expect to achieve an SVR following an extended and often arduous regimen of pegylated interferon and ribavirin. Side effects from interferon treatment can be severe and difficult to tolerate. With recent FDA-approval of two HCV-specific serine protease inhibitors, providers can now offer most patients infected with this genotype SVRs in the 60-88% range.<sup>29-32</sup> It is anticipated that entirely oral, non-interferon-

<sup>\*</sup> For persons who might have been exposed to HCV within the past 6 months, testing for HCV RNA or follow-up testing for HCV antibody is recommended. For persons who are immunocompromised, testing for HCV RNA can be considered.

<sup>\*\*</sup> To differentiate past, resolved HCV infection from biologic false positivity for HCV antibody, testing with another HCV antibiotic assay can be considered. Repeat HCV testing if the person tested is suspected to have had HCV exposure within the past 6 months or has clinical evidence of HCV disease, or if there is concern regarding the handling or storage of the test specimen.

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based regimens will become available within two to three years, increasing both the likelihood of cure and tolerability of treatment.<sup>33,34</sup> Modeling has estimated that if new antiviral regimens consistently resulted in an 80% response rate and if one-half of all HCV patients were treated, then within 10 years there would be 15%, 30% and 34% reductions in cases of cirrhosis, HCC, and deaths from liver disease, respectively.<sup>13</sup> In New York City, this could

amount to 2,500 to 5,000 lives saved.<sup>35</sup> It is anticipated that entirely oral, non-interferon based regimens will become available within one to two years, increasing both the likelihood of cure and tolerability of treatment (Tables 1 and 2).<sup>33,34</sup>

Current Antiviral Medications	Genotypes (GT)	Administration
Peg-interferon alpha 2a (PEG-INT)	All	Injected weekly
Peg-interferon alpha 2b (PEG-INT)	All	Injected weekly
Ribavirin (RBV)	All	Oral twice daily
Protease Inhibitors Approved		
Telaprevir (TVR)	1	Oral, with food, three times daily
Boceprivir (BOC)	1	Oral, with food, three times daily
In-Development		
Simeprevir (SMV)	1, 2 , 4, 5, 6	Oral, once daily
Faldaprevir (FDV)	1, 4, 5, 6	Oral, once daily
Nucleotide Analogue		
Sofosbuvir (SFR)	All	Oral, once daily

Table 2. Combination HCV treatment regimens: approved and some of those in-development			
Combination Regimens	Genotypes (GT)	Duration	
Approved			
PEG-INT + RBV	All	48 weeks (GT 2,3: 24 weeks)	
PEG-INT + RBV + (TVR or BOC)	1	24 or 48 weeks	
In-Development			
PEG-INT + RBV + SFR	1,4,5,6	12 weeks	
SFR + RBV	2, 3	12 or 16 weeks	
PEG-INT + RBV + SMV	1	24 or 48 weeks	
PEG-INT + RBV + FDV	1	12, 24 or 48 weeks	
DCR+SFR	1, 2, 3	24 weeks	
SFR + SMV	1	12 weeks	

# EPIDEMIOLOGY OF HCV INFECTION

#### **United States**

Local public health surveillance of HCV in the U.S. has been limited. Only a handful of jurisdictions have been awarded grants for HCV surveillance from CDC. As a result, researchers have relied on cross-sectional surveys, with or without serological testing, or sentinel surveillance to understand the epidemiology of HCV in the U.S. Both approaches have inherent limitations that may obscure the genuine distribution of HCV.

#### A. Prevalence

The most comprehensive estimate of HCV prevalence nationwide is derived from the National Health and Nutrition Examination Study (NHANES), a cross-sectional survey with laboratory testing of more than 20,000 non-incarcerated and non-homeless persons in all 50 states and the District of Columbia.<sup>36</sup> The estimated prevalence of chronic HCV infection was 1.0-1.5% of the U.S. population, or 2.7-3.9 million persons, respectively. It is likely that

An estimated
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NHANES underestimates the true chronic HCV infection burden, because homeless and incarcerated persons were not included. Of note, the highest prevalence (~2.5-4.0%) was found in persons born between 1945 and1964. Most reported a history of injecting drugs. In those who were 20-59 years of age at the time of the survey and who reported ever having injected drugs, nearly 50% were HCV seropositive. In persons with chronic HCV who were 60 or more years of age, 60% reported having had a blood transfusion before 1992.

HCV prevalence trends in persons who inject drugs (PWID) have been estimated in numerous studies. The Collaborative Injection Drug User Studies I-III found decreasing HCV prevalence in periods 1994-96, 1997-99, and 2002-04, in young injection drug using populations within four U.S. cities (65%, 35%, and 35%, respectively).<sup>37</sup> In each period,

being HCV antibody positive was associated with increased age, number of years injecting drugs, and injection frequency. A systematic review and meta-analysis of time to HCV seroconversion in PWID showed that in high-income countries mean prevalence of HCV infection was 53% after five years of injection.<sup>38</sup> Overall prevalence among U.S. injection drug users has been recently estimated at 70-77%.<sup>39</sup>

#### B. Incidence

For more than 25 years, CDC has used population-based surveillance in six sentinel U.S. counties to track estimated acute viral hepatitis incidence in the U.S. Acute HCV cases have been identified by testing for HCV antibody and/or HCV RNA in all persons with onset of hepatitis symptoms, elevated alanine aminotransferase (ALT), and no serological evidence of hepatitis A (HAV) or B (HBV) or sign of non-infectious hepatitis. However, since case ascertainment has depended on identifying and testing symptomatic patients, sentinel viral hepatitis surveillance has consistently underestimated the actual incidence of this largely asymptomatic infection. Nevertheless, these methods have been able to document what appears to be a decreasing trend in HCV incidence within these six counties from the mid-1980s to 2006 (7.4, 2.3, and 0.7/100,000 persons, respectively, in 1982-89, 1990-94 and 1994-2006).<sup>40</sup> These data must be interpreted cautiously. They reflect the documented incidence of only a small proportion of the actual new HCV infections nationwide, most of which remain asymptomatic and within difficult to reach populations that may be underrepresented in the sentinel county study.

Indeed, HCV incidence among PWID has remained persistent and brisk. Estimated rates in urban populations of PWID have ranged from approximately 10 to 40 per 100 person-years. 41-43 Of note, Massachusetts recently reported that from 2002 to 2009, when overall rates of newly reported HCV declined, the rate among persons 15 to 24 years of age increased from 65 to 113 cases per 100,000 persons. These cases were primarily in non-Hispanic white residents in urban, suburban, and rural communities. The most common self-reported risk factor was injection drug use (>70%).44

#### C. Risk Factors

Most infections have been caused by parenteral exposure to HCV. Before 1992, a substantial proportion resulted from contaminated blood products and tissue implants.<sup>45</sup> However, the primary mechanism has been exposure to HCV through injection drug use.<sup>36</sup> In addition to the risk of exposure to HCV from shared syringes and needles, approximately 40% of the infections can be attributed to sharing drug preparation equipment used to prepare or divide drugs (e.g., cookers, filtration cottons, and rinse water) or when "backloading" with

unsterile syringes.<sup>41,46</sup> Approximately 20% of PWID become infected with HCV within the first two years of drug use, suggesting that there may be a narrow preventive "window of opportunity" in this population.<sup>37</sup>

A smaller proportion of HCV infection occurs in children born to women with HCV or as a result of nosocomial exposure, including hemodialysis. HCV outbreaks also have occurred in health care facilities due to unsafe injection practices. 47-49 Since acute HCV infection typically goes undetected, it is likely that the full extent of health care-associated HCV infection is under-appreciated in the U.S. and elsewhere. Egypt's HCV prevalence of 15-20% has been epidemiologically linked to the well-documented use over decades of parenteral anti-schistosomal medications. 50 Contamination of the medication followed improper reuse of syringes and needles. Pakistan's HCV prevalence of ~5% also appears to be associated with unsafe and unnecessary therapeutic injections. 51 It is reasonable to assume that similar mechanisms have operated in many other countries.

Sexual transmission is thought to be inefficient within monogamous settings and appears to result in a small number of infections. However, there is increasing evidence that more significant transmission has been taking place among MSM with HIV. Increased risk has been linked to having multiple sexual partners, engaging in unprotected sex involving anal trauma and having a history of sexually transmitted infections. 23,25,52-54

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#### D. Demographics and Socioeconomic Factors

In NHANES, HCV seroprevalence was significantly higher in men than in women and in non-Hispanic blacks, as compared with non-Hispanic whites and Mexican Americans. Poverty and less education also were associated significantly with HCV antibody prevalence. Most persons with HCV antibody were born between 1945 and 1964. Mexican Americans, of note, were the only Hispanic population included in NHANES; Asians and other ethnic minorities also were excluded entirely.

The Racial and Ethnic Approaches to Community Health across the US Risk Factor Survey (REACH US RFS), a cross-sectional study conducted 2009-2010, addressed some of the limitations inherent to NHANES and assessed the impact of socioeconomic factors on HCV testing, infection, and linkage

Of all persons who reported a risk factor, only 40% were tested for HCV

to care among racial and ethnic minorities in 17 American states. <sup>56</sup> Of the >50,000 persons surveyed, 8.3% reported being told that they had HCV infection. Non-Hispanic blacks, Hispanics, Asians and American Indians/Alaskan Natives reported the highest HCV infection rates (9.2%, 8.3%, 6.8%, and 6.4%, respectively). Less than half of all persons reporting HCV infection were being managed for their illness, let alone treated.

Approximately 70% of Hispanics and non-Hispanic blacks who reported injection drug use were tested for HCV and roughly 80% reported HCV infection. However, of all persons who reported risk factor, only 40% were tested for HCV and 65% of the Asians who reported injection drug use were not tested for HCV. This suggests that a large number of racial and ethnic minorities with HCV risk factors are not being tested and that the actual HCV prevalence is likely to be higher than what has been reported.<sup>56</sup>

#### E. Current Trends

Reports from New York State, Wisconsin, and Massachusetts indicate that HCV infection needs to be closely monitored in adolescents and young adults who inject drugs. 44,57,58 Evidence suggests that a large proportion of young people in this population have graduated to injecting heroin after first becoming addicted to prescription oral opioids. 59

In addition to the increasing incidence among certain MSM with HIV, transgender persons who modify their bodies through the injection of hormones or silicone may also be at risk of HCV infection, perhaps particularly transgender women of color. A recent study of 517 male-to-female transgender women in the New York City area found an HCV prevalence of 4% among whites, 7% among African-Americans, and 16% among Hispanics.<sup>60</sup>

### **New York City**

Until 2012 when funding was not renewed, New York City was one of the few U.S. jurisdictions that received CDC funding to augment local efforts to conduct public health surveillance for hepatitis A, B, and C.

Since 2005, there has been a steady decrease in the number of newly reported cases of HCV in New York City (Table 3).<sup>3</sup> It is unknown whether the trend reflects an actual change in the dynamics of HCV transmission, provider practices, access to health care, or other factors. Since HCV infection often remains asymptomatic for decades, the data also do not represent the true level of current HCV infection in New York City.

Table 3. Persons newly reported with HCV, New York City, by year, from 2005-2011			
Year	Number	Rate per 100,000 people	
2005	14,297	178.5	
2006	15,504	188.7	
2007	16,691	230.2	
2008	13,932	166.6	
2009	10,846	129.7	
2010	9,992	122.2	
2011	8,716	106.6	

#### A. Prevalence

Multiple projects, summarized in Table 4, have estimated the prevalence of HCV antibody positivity and HCV infection in New York City. All studies have concluded that prevalence is somewhat higher in New York City than it is nationally. In 2004, the New York City Health and Nutrition Examination Survey (NYC-HANES), which conducted face-to-face interviews of 1,999

HCV prevalence in NYC is probably between 1.8% and 2.4%

persons of whom nearly 1,800 were tested for HCV antibody (i.e., not HCV RNA), estimated the HCV seroprevalence at 2.2% and HCV infection at 1.8%.<sup>61</sup> After adjusting for persons in

Population	Data source	Prevalence of HCV antibody positivity	Prevalence of HCV infection, No. of NYC resident	Source s
NYC residents, age 20 and older, non-institutionalized	2004 serosurvey	2.2%	1.8%, 103,000 persons	NYC-HANES survey. <sup>60</sup>
NYC residents, age 20 and older, non-institutionalized	2004 serosurvey, adjusted for institutionalized persons		2.3%, 129,000 persons	Unpublished Health Department analysis, based on published methods. <sup>61</sup>
NYC residents, age 20 and older	NYC HCV surveillance data 2000-2010		2.4% (1.5-4.9%), 146,500 persons	Health Department analysis based on published methods used to estimate hepatitis B.

correctional facilities and other institutions excluded from the survey, the study estimated that the prevalence of current HCV infection was 2.3%. Given various estimates to-date by the Health Department, it is likely that HCV infection prevalence in New York City lies somewhere in the range of 1.8 to 2.4%, though it could be as high as 3.8%.

Preliminary analysis of Health Department data from 2000-2010 indicates that 16.4% of HIV cases, or 23,900 persons, alive as of 2000, also were infected with HCV, of whom 71% were male, 42% Hispanic, and 43% black, with 60% reporting injection drug use reported as a risk factor.<sup>63</sup>

#### B. Incidence

As noted earlier, HCV incidence is difficult to estimate. Infections often go undetected because they are asymptomatic. Moreover, most new HCV infections occur among PWID who contend with unique health care access barriers, including significant stigma. Consequently, even if they become symptomatic, PWID may be less likely to seek health care than other populations.

Roughly 16% of persons living with HIV in NYC are co-infected with HCV

Incidence in cohorts of New York City injection drug users has been assessed. From 1997-1999, HCV incidence within East Harlem and Lower East Side drug injection cohorts was 9 and 34 cases per 100 person-years, respectively, 64 suggesting that there may be considerable variability in disease transmission dynamics across localized drug injection populations. In fact, analysis pointed to the following differences in the two populations. The Lower East Side population was predominantly white, had experienced homelessness in the past six months (presumably after arriving in New York City from across the U.S.), had engaged in panhandling for living expenses, and began injecting drugs at a younger age compared with those in East Harlem, where the population was mostly Hispanic, persisted on state or federal benefits, were less likely to have completed high school, and were more likely to have been incarcerated. The Health Department currently is estimating HCV incidence using a previously established prevalence model which classifies the population into two groups: those who ever injected drugs and those who did not. A mathematical model will extrapolate injection drug use trends over time and apply historical transmission rates among persons injecting drugs to obtain the number of incident cases. Estimates of HCV incidence through other routes of infection will incorporate estimates of other known transmission sources and of infected immigrant population sizes. The Health Department has not systematically assessed HCV incidence in two populations with emerging risk: MSM who are HIV-infected and engage in unprotected, high-risk sexual activities<sup>23-25</sup> and adolescents and young adults who have started to inject drugs. 57-59

#### Risk Factors

In New York City, the Health Code requires health care providers and laboratories to report HCV cases to the Health Department, including positive tests for HCV antibody and HCV RNA. However, these case reports do not contain risk factor or other information. To collect this information, the Department has surveyed a sample of newly reported cases and their providers. 65,66 Obtaining reliable risk factor data by self-report is difficult, because persons may not recall a single episode of drug use or blood transfusion decades earlier, they may be reluctant to acknowledge that they injected drugs due to associated stigma, and clinicians may not prioritize obtaining this information during a busy visit.

The most commonly reported risk factor was injecting drugs, which was reported by 43% of persons. In NYC-HANES, conducted in 2004, the risk factors that were most strongly associated with HCV seroprevalence were a lifetime history of ever injecting drugs, receiving a blood transfusion before 1992, and ever being incarcerated as an adult (64.5%, 11.9%, and 8.4%, respectively).<sup>61</sup>

#### C. Demographics and Socioeconomic Factors

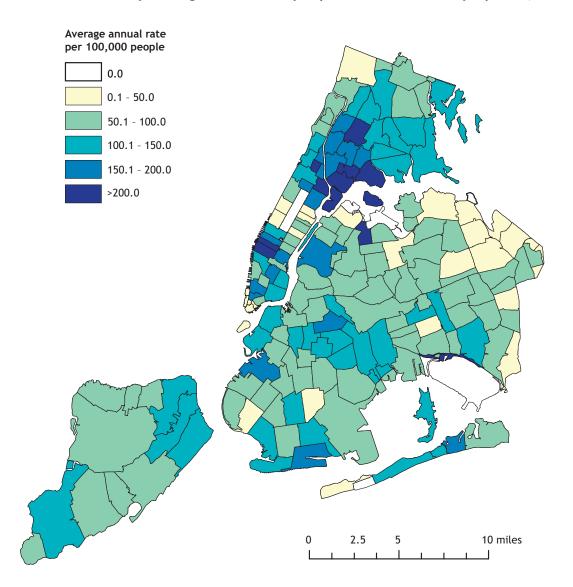
In 2010, 9,992 persons were newly reported with a positive HCV antibody or viral RNA test. Of these, 65% were male, and 56% were 40 to 59 years of age. The greatest number of newly reported HCV cases occurred in neighborhoods with high proportions of residents living in poverty. Of all boroughs, the Bronx had the highest rate with 155 newly-reported HCV cases per 100,000 persons. Among the 42 United Hospital Fund neighborhoods, those with the highest rates included Hunts Point (227 per 100,000), Highbridge-Morrisania (205 per 100,000), East Harlem (318 per 100,000), and Central Harlem (221 per 100,000) (Figure 5).<sup>3</sup>

Among 165 persons newly reported and followed up by interviews from 2009 to 2011, 65% were black or Hispanic. Most (73%) were born in the US; the next most common countries of birth were Haiti (4%), the Dominican Republic (4%), Russia (3%), and Pakistan (3%).

In NYC, the highest rate of newly reported HCV is found in the Bronx

In NYC-HANES, non-Hispanic blacks were more than twice as likely to be seropositive for HCV as non-Hispanic whites, Hispanics, or Asians (4.4%, 1.9%, 1.2%, and 1.8%, respectively). The socioeconomic factors significantly associated with HCV seroprevalence were high school education or less, public assistance, and a history of ever being incarcerated as an adult.<sup>61</sup>

Figure 5. HCV and Poverty: Average Rates of Newly Reported HCV Infection by Zip Code, 2010-11



Source: New York City Department of Health and Mental Hygiene.

# CURRENT HCV PREVENTION, TESTING, AND CARE ACTIVITIES

#### **United States**

Much of the limited CDC funding for local and state viral hepatitis activities has been for integration of prevention, testing, and other activities across agency programs. In 2000, the Division of Viral Hepatitis began funding HCV coordinator positions in states and in selected local health departments, including New York City. Coordinators were directed to focus on integrating HCV testing and prevention counseling into HIV/AIDS, STD, drug treatment, and other related services, and to create a local HCV prevention plan. With a five-year cooperative agreement in 2007, CDC extended this network of coordinators to include all states. For most of the following decade, this was the extent of dedicated federal support for HCV prevention. CDC also introduced separate funding to some health departments, including New York City, for Program Collaboration and Service Integration (PCSI) activities. PCSI is a strategic framework to strengthen collaboration across HIV/AIDS, STD, tuberculosis (TB) and viral hepatitis programs.

#### A. Primary Prevention

Since most persons with chronic HCV were infected through injection drug use, syringe exchange programs (SEPs) have contributed greatly to a dramatic reduction in HIV transmission among PWID.<sup>67-71</sup> They are essential, but relying solely on this harm reduction strategy is unlikely to have the equivalent impact with HCV, which appears to have greater infectivity than other bloodborne pathogens.<sup>72-75</sup>

Relying solely on syringe exchange is unlikely to stem HCV transmission among PWID

Harm reduction also must emphasize the potentially significant risks from sharing other drug preparation paraphernalia (e.g., cookers, filtration cottons, and rinse water) and from unsafe injection practices, such "backloading" with unsterile syringes. 41,46 The type of syringe used by persons who inject drugs and provided in SEPs also may be a factor, as HCV appears to have prolonged environmental stability in 1 ml tuberculin needles with detachable needles (high void volume syringes) compared to 1 ml insulin needles with fixed needles (low void volume syringes). 74

Multi-faceted approaches including those that bring services to PWID may have improved outcomes. Peer-delivered syringe exchange programs have the potential to expand harm reduction resources to high-risk PWID who do not use SEPs. "User-friendly" programs that operate at all hours are likely to be more effective. Moreover, outcomes are likely to be enhanced when more than one method is used, such as when combining harm reduction with public health education and drug treatment for opioid dependence. 77-80

Primary prevention activities also can be directed toward non-injection drug users for at least three reasons. First, persons share straws, pipes, and other non-injecting drug use equipment that may contain contaminated blood, thereby transmitting infection. 81-83 Second, sexual activity that may transmit HCV (e.g., HIV positive MSM who engage in high-risk activities with multiple partners) may be more prevalent among non-injecting drug users. 84 Finally, persons who use drugs orally or intra-nasally may transition to injecting drugs in the future. 85 Educating non-injection drug users about how to prevent HCV infection would address HCV risks from shared equipment, sexual activity, and the possibility of future injection use.

The federal government historically has not dedicated financial support for scientifically grounded, harm reduction efforts targeting PWID. Except for a brief period a few years ago, Congress has banned the use of federal funds for SEPs.

#### B. Screening and Testing

A large proportion of persons living with HCV are unaware of their infection status and, consequently, of the long-term risks that they face from potentially life-threatening liver disease. This may result from a number of potential barriers to HCV screening and testing, including a lack of symptoms in those who are infected, lack of knowledge of HCV exposure

risks by patients and providers, and insufficient access to health care. A sub-analysis of NHANES data determined that roughly half of those with chronic HCV may be unaware of their infection. S6,87 Similarly, a study in five U.S. cities of young adults who injected drugs found that 72% of those who were seropositive were unaware that they might be infected. Of note, participants in SEPs or drug treatment had greater knowledge of their infection status, presumably from public health education by harm reduction organizations and treating clinics.

A large proportion of persons living with HCV are unaware of their infection status and, consequently, of the long-term risks that they face from potentially life-threatening liver disease

Since 1998, CDC has recommended that health care providers query patients for the following behaviors and exposures that place them at risk and to test for HCV as warranted (see box below).45

- Persons who currently inject or ever injected drugs;
- Persons with persistently elevated alanine aminotransferase (ALT) levels;
- Recipients of clotting factor concentrates before 1987 or blood transfusions, blood components or organ transplants before 1992;
- Persons who were notified that they received blood from a donor who later tested positive for HCV infection;
- Persons ever on long-term hemodialysis;
- Children born to mothers with current HCV infection;
- Health care workers and others who have had mucosal or percutaneous exposure to HCV-infected blood: and
- Persons infected with HIV (added in 2009).

Given that such a large proportion of persons with HCV are unaware of their infection status, it is clear that the risk-based screening and testing recommendations have not yielded satisfactory results. They have been ineffective for a variety of potential reasons. As with HIV screening, it is likely that there are patient- and clinician-level and structural barriers (e.g., access to health care). 90 Patients may minimize the potential risk, selectively forget past high-risk behavior, fear that they may be infected, worry about potential stigma, or dislike interacting with the health care system.

Some clinicians also may be unfamiliar with current HCV screening and testing recommendations and that HCV RNA testing is needed if patients are seropositive for HCV antibody. Others may be inexperienced with screening techniques, have time constraints, or feel discomfort questioning patients about potential risk exposures. 90 One study of New Jersey family medicine practitioners found that of 217 respondents to a self-administered survey, 56% scored 70% or less in their knowledge of current HCV screening standards and 31% were unfamiliar with the next steps to take after

confirming that a patient was seropositive for HCV antibody. 92

To improve the effectiveness of HCV screening so that more atrisk persons are tested, CDC now recommends one-time testing of all persons in the U.S. born between 1945 and 1965, as roughly 75% of persons identified with HCV by NHANES were

CDC recommends one-time testing of all persons in the U.S. born between 1945 and 1965

born during that period.<sup>26</sup> This new strategy is meant to supplement, not replace, risk-based HCV testing.

Only limited and targeted funding, through HCV coordinators, has been provided to some health departments to facilitate and improve the efficiency of HCV testing in persons at increased risk of infection. There has been no nationwide, federally sponsored mechanism to accomplish this.

#### C. Linkage to Care, Clinical Management and Treatment

According to NHANES, ~80% of those with laboratory evidence of HCV infection had discussed the results with a health care provider or had scheduled an appointment to do so. Of those who had discussed their status with a provider, 52% were told that they had HCV and needed regular medical follow-up; however, 31% were told that they were infected with HCV and did not need to do anything or worry about it.86 This suggests that there are significant provider-level barriers to linking patients with HCV to proper clinical management (Table 5).

As with screening and testing, primary care providers may not be familiar with current HCV treatment standards and recommendations. There may not be a hepatologist or liver clinic in their vicinity where patients can be referred, or patients may have insufficient health insurance to pay for the necessary evaluation and care. Lastly, personal attitudes toward patients may come into play when providers address issues related to injection drug use

Table 5. Barriers Linking HCV Patients to Appropriate Care			
Patient-Level	Provider-Level	Structural	
Poor understanding of hepatitis C	Poor understanding of hepatitis C	Lack of readily available specialist resources in area	
Denial — especially if asymptomatic	Not familiar with current standards and recommendations	Limited to no reimbursement for patient support services	
Psychiatric disease and other co-morbidities	Personal attitudes about drug use or alcoholism	Stigma	
Internalized social and structural stigma		Lack of health care access for uninsured or under-insured patients	
Competing priorities (e.g., housing and food)		patients	
Fear of medication side effects			

that can interfere with patients being considered for HCV treatment. These strongly held opinions also can contribute to the social and structural stigma often felt, and potentially internalized, by PWID when interacting with providers, which can lead to their alienation from and avoidance of the health care system. 93-95 Strategies to counteract entrenched stigma for PWID within the health care sector are beyond the reach of this action plan. However, internists and other primary care

PWID often perceive and internalize social and structural stigma when interacting with providers

providers, infectious disease specialists, gastroenterologists and medical students and trainees can be taught that addicts can be treated successfully for HCV. Moreover, health care providers with backgrounds in addiction medicine can provide HCV management and treatment in settings that are more acceptable to PWID.

Delivering health care to PWID certainly involves potential structural and provider barriers. The patient-level issues, however, can be formidable in various ways. There may be significant psychiatric disease and other co-morbid conditions (e.g., HIV) that must be addressed before HCV treatment can be considered, let alone successfully implemented. The clinicians providing healthcare to PWID should be respectful, non-judgmental and familiar with the principles and science of addiction medicine. 98,99

Patients with newly detected HCV infection are referred typically to gastroenterologists and hepatologists for evaluation and management. There is, however, an insufficient number of hepatologists and willing gastroenterologists distributed across the U.S. to care for all patients living with HCV. This is especially so in the neighborhoods where most persons living with HCV reside. Moreover, there may be other barriers to linking many patients with current HCV infection to appropriate medical care where they can be evaluated for treatment. A large proportion may be either uninsured or under-insured. Others may not be considered good treatment candidates by specialists because of ongoing illicit drug use or a history of alcoholism. Some persons living with HCV may be disinclined to consider treatment options because of anticipated or actual past difficulties (e.g., perceived stigma) when engaging the health care system.

Non-gastroenterologists, internists and other primary care physicians, as long as they are skilled clinicians, also can manage HCV patients. For example, infectious disease specialists, already comfortable managing complicated HIV patients, have increasingly been treating persons who are co-infected with HIV and HCV.<sup>100</sup>

Persons living with HCV ideally would be treated by providers within the neighborhoods where they live. For that to occur in many urban neighborhoods and rural settings, new capacity building strategies are needed to improve the clinical skills of health care providers practicing in those locations. Academic medical researchers in New Mexico have used telemedicine technology to train rural primary care providers in HCV clinical management and treatment, linking primary care providers with hepatologists in an academic medical center to review and discuss proper management of potentially complex HCV patients. The rural providers demonstrated successful clinical outcomes that were comparable with patients treated in the liver clinic at the academic medical center. <sup>101</sup> This model also may be applicable to urban environments where primary care providers, such as those who practice in federally-qualified health centers (FQHCs) and other community health centers, are likely to play an important role in national and local HCV treatment strategies.

HCV patients are more likely to be referred for appropriate evaluation and treatment if their providers are familiar with and follow current clinical standards. In a large retrospective cohort Veterans Affairs (VA) study involving five facilities, patients with HCV were 77% less likely to receive treatment if evaluated by less experienced rather than more experienced providers. Noreover, in a large retrospective cohort study of nearly 35,000 VA patients with HCV infection, patients who received appropriate pre-treatment evaluations that were consistent with current quality of care indicators (e.g., confirming HCV viremia and determining HCV genotype) were significantly more likely to receive antiviral treatment, complete treatment and achieve SVRs than those who did not receive that pre-treatment care. These studies suggest that if HCV clinical initiatives are to be effective, they must incorporate methods to evaluate the quality of care provided by clinicians.

Two population groups appear to be ideal candidates for targeted and dedicated HCV clinical management: clients undergoing methadone maintenance treatment (MMT) and persons who are incarcerated. Injection drug use history and HCV seroprevalence are much higher in both populations than in the general public. There is now ample evidence that MMT clients, even those who currently inject drugs, can be treated successfully for HCV, as long as there is close follow-up and multi-disciplinary teams are actively managing the potential

Two population groups are ideal candidates for dedicated HCV clinical management:clients undergoing methadone maintenance treatment and persons who are incarcerated

side effects and other challenges that often occur during interferonbased antiviral treatment. 104-106 In fact, treatment outcomes in persons being treated for addiction, especially when coupled with multidisciplinary support services, have been comparable to those in the general population. 107 PWID can be treated successfully for HCV

Treating inmates living with HCV involves a number of challenges. Not all correctional facilities have the skilled medical workforce needed to manage and treat HCV. Moreover, HCV evaluations and treatments are expensive. It is unlikely that this sector would be able to embark on ambitious campaigns to cure infected inmates without major, new influxes of resources.<sup>108</sup>

Depending on the availability of resources and other circumstances, HCV treatment performance will vary in correctional facilities, where seroprevalence can be several times that of the general population. In prisons where inmates are incarcerated for years, HCV treatment can be considered a reasonable option. In Connecticut, of the 68 state prisoners who met treatment criteria, 47 (69%) completed therapy, and 32 (47%) demonstrated SVRs. <sup>109</sup> The New York State Department of Corrections and the New York State Department of Health also established HCV treatment programs for inmates living with HCV. In contrast with the Connecticut effort which was centered on long-term inmates, New York State created the Hepatitis C Continuity Program, which linked inmates who had not yet completed treatment to HCV providers in their home communities following release from prison. <sup>110</sup> Smaller proportions of persons in the New York State achieved targeted clinical outcomes than in Connecticut. <sup>111</sup>

As with screening and testing, there has been only limited federal support to provide and coordinate health care for persons living with HCV. Congress has not appropriated dedicated resources for HCV management and treatment as it has done for HIV through the Ryan White Care Act. However, the Ryan White Program, administered by HRSA's HIV/AIDS Bureau, has provided limited resources through its AIDS Drug Assistance Program (ADAP) for HCV treatment and for HBV and HAV vaccination in persons co-infected with HIV and HCV. In contrast, federal assistance has not been specifically directed to prevent HAV or HBV infection in persons mono-infected with HCV.

#### **New York City**

#### A. Primary Prevention

Most SEPs depend solely on state and local governments, which furnished 79% of the \$21.3 million budgeted nationwide for SEPs in 2008. In New York City, syringe exchange is funded by city and state tax dollars. Currently, the Health Department supports the 14 city-based licensed SEPs that served an estimated 14,000 clients in 2010.

The Health Department, the State Health Department, other government agencies and community-based organizations (CBOs) have conducted a variety of activities over the past 12 years that have likely limited transmission of HCV. Although initially intended for HIV prevention, syringe services policies and programs have helped to significantly reduce HCV infection rates.

In NYC, syringe exchange is funded entirely by city and state tax levies

The New York State Department of Health began its support of New York City SEPs in 1992, and funding has continued since then. The New York City Council first allocated funding to SEPs in the 2001-2002 city budget. This followed closely on the heels of New York State's establishment in 2001 of the Expanded Syringe Access Program (ESAP), which allowed up to 10 syringes to be sold or provided to persons over 18 years of age by pharmacies, medical providers or health care facilities. The State Health Department has reported that more than 3,200 providers have registered with this program, including numerous neighborhood-based programs in New York City. 114 Since 2003, the Injection Drug Users Health Alliance (IDUHA), a coalition of community-based syringe access providing health services to injection drug users in New York City, has successfully advocated for additional funding for syringe exchange and other harm reduction/prevention services, including HCV screening, HCV prevention education and referral for treatment, HAV and HBV vaccination, overdose prevention, methadone and buprenorphine referral, and linkage/navigation to other clinical care services. 115

City Council funding for IDUHA currently supports HCV prevention counseling, testing, and linkage to care. To supplement this funding, the Health Department since 2003 has used public and private grants to offer free HCV testing to SEP participants since 2003. Although the City Council has introduced several resolutions calling for financial support of HCV prevention since 1999, it was not until 2006 that the Council awarded two-year funding to a local CBO to prevent HCV infection and promote awareness.

In 2008, the New York State Budget included funding for HCV prevention for the first time. A total of \$1.58 million was appropriated to the State Health Department for the creation of a comprehensive HCV program, including screening, education, and social marketing, and access to care and treatment. Outcomes have included annual awareness campaigns targeting different risk groups, creation of an HCV information hotline, creation of a Statewide HCV Advisory Council, and, more recently, provision of funds for screening programs and comprehensive care programs, including four based in New York City.

From 2000 to 2004, CDC also provided funding to 15 large state and local public health agencies, including the Health Department, to demonstrate integration of viral hepatitis services into pre-existing programs. <sup>116</sup> This funding enabled the Department to offer HAV and HBV vaccination and HCV counseling, testing and referral at the Riverside STD clinic. Approximately 8,800 unique clients received hepatitis services and nearly 15,000 HAV and HBV vaccines were administered during this four-year period. Of the 279 clients who reported injection drug use, 161 (58%) indicated that they were drawn to the clinic because of the hepatitis services, and 64% of them also received STD and HIV services, suggesting that the original intent of the funding had been met. <sup>117</sup> Other local and state health departments also have demonstrated successful and effective integration of programs in drug treatment programs and STD clinics that serve clients who share risk factors, exposure to overlapping infectious diseases and social vulnerabilities. <sup>118,119</sup>

Most Health Department HCV prevention activities have focused on integrating viral hepatitis prevention, counseling, and referral into HIV, STD, TB, correctional health, drug treatment, mental health, and harm reduction programs. Additional activities have included community organizing through hepatitis task forces, creating and disseminating awareness and educational materials for consumers and providers in multiple languages, promoting HAV and HBV vaccination, training health care providers about viral hepatitis prevention and care, and providing referral resources for viral hepatitis services.

#### B. Screening and Testing

Approximately 50%, or an estimated 73,250 New Yorkers with current HCV infection, are unaware that they are infected with HCV (Figure 6).<sup>2,86</sup> If they were tested, diagnosed and linked to appropriate care, the extent of liver damage could be assessed and steps taken (e.g., HAV and HBV vaccination and liver health counseling) to prevent additional hepatic damage.

The same patient, provider, and structural barriers to screening and testing described earlier also apply to New York City. The extent to which New York City providers are

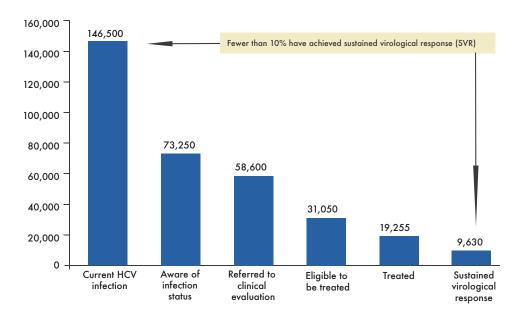


Figure 6. New York City HCV Treatment Cascade<sup>2,85</sup>

Sources: Balter et al. 2013; Denniston et al. 2012.

(1) Estimates of current HCV prevalence and awareness of infection status from Balter et al.

(2) All other estimates extrapolated from Denniston et al.

Approximately 50%, or an estimated 73,250 New Yorkers with current HCV infection, are unaware that they are infected with HCV familiar with current CDC screening and testing recommendations is unknown, though it is likely that many are not. In 2010, the Health Department published a *City Health Information* clinical guide for HCV testing and management and distributed it to thousands of New York City clinicians. <sup>120</sup> In addition, the Department in April 2013 sent a letter from the Commissioner of Health to more than 30,000 New York City health care providers, urging them to follow current CDC recommendations for HCV

testing (including HCV RNA, as warranted) and to refer all patients determined to have current HCV infection to appropriate medical care. 121

HCV screening and testing has been reliable in some at-risk populations. According to data self-reported by large HIV providers and clinics, approximately 93% of Medicaid beneficiaries living with HIV in New York State had been tested for HCV during the review period. Inmates within the New York City correctional system also are tested routinely during their medical examination.

From 2009 to 2011, the Health Department conducted a quality improvement (QI) initiative with the 22 outpatient substance use disorder treatment programs under direct contract with the Health Department to improve access to HCV testing and referral to care when warranted. This represented a small percentage of the substance use disorder treatment programs licensed in New York City. The Department provided HCV and phlebotomy training for staff and testing supplies, data support, QI methods training, learning collaboratives for participating programs, and direct brokering of partnerships with funded counseling and testing providers.

While some treatment programs have improved testing rates over the initial two-year period (as high as 50%), several key structural barriers continue to constrain improvement, including lack of clarity in state regulatory language regarding the responsibilities of state-licensed outpatient treatment programs, lack of funding for staffing at outpatient programs, and lack of resources to collect data for surveillance and program monitoring.

The Health Department
has worked with
substance use disorder
treatment programs to
facilitate HCV testing
and referral to care

From 2003 to 2012, private funders provided the Health Department with approximately \$1.7 million to coordinate free HBV and HCV testing in high-risk communities, including at SEPs. The Health Department also has published and disseminated monthly e-newsletters for service providers and produced a video public service announcement in nine languages to raise awareness about viral hepatitis and encourage testing. In addition, the Department and community partners established the New York City Hepatitis C Task Force in 2004, which has evolved into a robust, a city-wide network of service providers and advocates representing over 200 organizations that meet quarterly in each borough. The Department has maintained a resource-rich website for the taskforce that includes a community calendar, links to hepatitis-related websites and social media portals and a site locator for HCV testing and other services. Other task force initiatives have included HCV outreach worker training and a law enforcement relationship-building initiative.

The Department and community partners have established a robust and active New York City Hepatitis C

Various Health Department bureaus and divisions have participated in grant-funded HCV-related screening and testing initiatives. The Department's PCSI activities have demonstrated that integration and collaboration at the program level can be practiced and sustained effectively and that it can facilitate optimal access to and uptake of HCV screening, testing and linkage to care. To ensure that

these activities are strategically aligned with agency priorities, the Department has established inter-divisional workgroups to propose policy, establish tasks and monitor progress, including achieving core objectives.

Health Department surveillance data suggest that HCV antibody testing could be made more efficient. A recent analysis determined that from 2006 to 2010, there were more than 70,000 repeat HCV antibody tests performed on previously tested patients in New York City, at a cost of approximately \$1.4 million. Six hundred thirty-five persons were tested more than 10 times for HCV antibody, with most of this excess testing occurring

HCV RNA testing is not being conducted in approximately one-third of those who screen positive for HCV antibody

within the correctional system and in detoxification facilities.<sup>122</sup> It also found that approximately one-third of those who screened positive for HCV antibody did have follow-up HCV RNA testing, as recommended, to determine their infection status.<sup>65</sup>

Improvements in health information technology may help to mitigate this redundancy of duplicative testing. The Health Department completed implementation of a system-wide electronic health record (EHR) in New York City jails in 2011 and plans to begin to upload data to the State Health Information Network for New York (SHIN-NY) in 2013. These technology improvements have the potential to decrease the scale of repeat testing, as long as processes and procedures can be implemented that enable review of a person's medical record prior to their initial medical evaluation at intake.

## C. Linkage to Care, Clinical Management, and Treatment

Figure 6 (page 33) illustrates that of the roughly 73,000 persons in New York City living with HCV who are aware of their infections, only a small proportion, approximately 13%, have been cured. As elsewhere in the U.S., there are likely to be structural, patient-, and provider-level barriers that interfere with linking New Yorkers with current HCV infection to appropriate care, including assessment for antiviral treatment.

Only a small proportion of persons living with HCV in NYC have been cured

It is likely that disparities in health care access limit the extent to which persons living with HCV in New York City are linked to appropriate medical care. Most persons newly diagnosed with current HCV infection live in neighborhoods with high levels of poverty and where many residents lack health insurance and access to other resources (Figure 5; page 21).<sup>3,124</sup>

Clinical capacity
building will be
needed and especially
in neighborhoods
where persons with
HCV live

More than 3 million New York City residents participate in Medicaid. 125

Fewer than 50 hepatologists practice in New York City. 126 Even if all other barriers could be overcome, they would be unable to manage all of the persons living with HCV in New York City who have not been linked yet to appropriate medical care. Clinical capacity building will be needed,

and especially in New York City neighborhoods where persons infected with HCV live and within health care settings that effectively care for key at-risk populations, such as PWID and persons living with HIV.

## **At-Risk Populations**

Since persons who are co-infected with HIV and HCV progress more rapidly to advanced liver disease, including cirrhosis, than those who are mono-infected, <sup>18-20</sup> it is imperative to link co-infected individuals to appropriate medical care. In many of the largest HIV health care providers, including academic medical centers, co-infection clinics already exist, though the Health Department does not know the extent to which this already has taken place. In April 2013, the Department began to use its HIV field outreach personnel to locate and contact the most vulnerable co-infected persons - those who did not appear to be under medical care for their HIV, so that they could be linked to appropriate medical care.

Since all participants in MMT programs have a history of injecting drugs, most are likely to have been exposed to HCV at some point in their past, and many could benefit from HCV care and treatment. Of the more than 33,000 New Yorkers currently enrolled in MMT programs, 127 many receive services in clinics managed by academic medical centers, and it is likely that in some of them clients receive primary care, including management of HCV. The Health Department, however, currently does not know the extent to which this is the case.

Since persons who are coinfected with HIV and HCV progress more rapidly to advanced liver disease, it is imperative to link co-infected individuals to appropriate medical care

Treating HCV in correctional facilities is much more challenging than testing for it.

Treatment options have been limited by the high costs that would be encumbered by correctional systems, the lack of medical insurance and inconsistent health care by many inmates before and after incarceration, pre-existing psychiatric and chemical dependency

conditions, and the extended regimen durations that have been standard before the advent of newer medications. <sup>108</sup> Some incarcerated New York City residents have been treated in New York State prisons and, through its Hepatitis C Continuity Program, have been referred to Health and Hospitals Corporation (HHC) facilities if released before completion of their treatment regimen. In 2012, of the nine New York City residents who participated in the program, only three (33%) kept their initial appointments, which compared with an aggregate of 41% in previous years. <sup>128</sup> In a recent, preliminary assessment by the State Health Department, 57% of the participating patient-inmates studied in a small sample were lost to follow up, and only 15% mounted an SVR. <sup>129</sup> To improve on current performance, the Health Department, the State Health Department, and collaborating providers will need to identify strategies (e.g., patient incentives) that will promote continuity of care.

Within New York City correctional facilities, there are different challenges. The median length of stay for prisoners is only eight days, <sup>130</sup> making it unfeasible to fully evaluate many who are determined to be seropositive for HCV antibody, let alone to consider treating them. A more realistic option will be to establish robust transitional case management and referrals to health care providers in neighborhoods where prisoners will be released. Antiviral treatment would be considered only for those persons who will be incarcerated for extended periods and if funding is made available to use the newer and more expensive treatment regimens.

The Health Department's Bureau of Correctional Health Services (CHS) directs medical care for inmates detained in the New York City jail system. Inmates who test positive for HCV are evaluated in a CHS chronic care clinic and, when appropriate, are referred to an HHC facility for specialty care. HHC infectious disease physicians serve as consultants to the Health Department and its contractors in regard to HCV treatment, with a focus on patients who have a known length of stay and for whom a stable discharge plan can be formulated. Patients who arrive in jail during HCV treatment are continued on their outpatient regimen. When better HCV treatment options requiring shorter duration of treatment become available, more inmates may be treated for chronic HCV while incarcerated.

### Provider Awareness

Infrastructure is not in place that enables the Health Department to assess how common it is for health care providers to manage and treat current HCV infection, or to track the number of persons treated for HCV in New York City, or the appropriateness of and response to treatment. The Department has surveyed and interviewed a sample of providers who reported HCV cases to explore some of these issues. Management gaps were identified in

the management of patients who were found to be seropositive for HCV antibody. Fen to fourteen months after diagnosis (i.e., after sufficient time elapsed for additional laboratory testing and clinical follow up), approximately one-half of the HCV patients and 30% of HBV patients were either still susceptible to HAV or their providers did not know their HAV status. Twenty-six percent of the patients reported that they had not been counseled about avoiding alcohol. These findings suggest that a significant proportion of New York City providers

At present, the Health
Department cannot
assess the extent to
which providers manage
and treat HCV or track
clinical responses to
therapy

are not familiar with recommended management of newly diagnosed HCV patients and would benefit from additional learning opportunities.

The Health Department's Bureau of Communicable Disease (BCD) has promoted secondary prevention among those with current HCV infection. All persons newly diagnosed with HCV are mailed a booklet that explains HCV infection and the importance of taking steps to protect liver health, how to prevent HCV transmission to others and where to find support groups and treatment.<sup>131</sup> The booklet has been translated into Spanish, Arabic, Russian, and Urdu.

## **Capacity Building**

To enhance capacity to manage and treat HCV in New York City, the Health Department can turn to liver specialists, infectious disease physicians, and interested primary care providers. As noted, academic medical researchers in New Mexico have used telemedicine technology to successfully train rural primary care providers in HCV clinical management and treatment. This model also can be used in urban environments where primary care providers, such as those who practice in federally-qualified health centers (FQHCs) and other community health centers, are likely to play an important role in national and local HCV treatment strategies.

In May 2012, the Health Department launched the Check Hep C Program, a demonstration project to build capacity for HCV diagnosis and treatment in the neighborhoods disproportionately affected by HCV. Through the Fund for Public Health in New York (FPHNY), the Department received funding from multiple private funders to (1) promote HCV awareness in persons at increased risk of HCV infection who live in

The Health
Department's Check
Hep C Program may
demonstrate how to
build clinical capacity in
urban neighborhoods
with the greatest needs

neighborhoods with high prevalence of chronic HCV; (2) screen at-risk individuals for HCV with a rapid immunoassay and immediately collect blood from seropositive patients to confirm HCV infection with molecular testing; and (3) to link those with current HCV infections to comprehensive medical care and supportive services through intensive case management and patient navigation. Participating medical providers in funded community health centers take part in weekly case management videoconferences with a leading academic clinical researcher in the field of HCV care and treatment.

The goal of the Check Hep C Program has been to demonstrate that persons living with HCV in urban settings, many of whom are disproportionately poor, marginalized and lack adequate access to medical resources, can be medically managed and treated effectively and in a way that is both cost-containing and culturally competent. In its first year, the program screened and tested 4,751 persons; 880 (18.5%) were seropositive for HCV antibody. Of the 512 persons diagnosed with current HCV infection, 433 (84.5%) attended their first appointment with an HCV provider. <sup>133</sup> Initial funding for this project was only for one year. Additional grant support will be necessary to sustain the program in future years.

#### HCV-related funding issues and initiatives

The New York City eligible metropolitan area received \$121 million in Ryan White funding from HRSA in FY 2011 to provide HIV-related programming.<sup>134</sup> In view of the number of people infected with HCV and the number of preventable deaths from HCV, federal funding should similarly be provided to treat people with this infection.

In 2010, HRSA's Bureau of Primary Health Care provided funding to expand HCV treatment at Ryan White Care Centers for co-infected patients. The agency made available \$1.6 million to improve availability and expansion of HCV treatment, and four New York City clinics were each awarded \$80,000.135 The objective of funding was to aid FQHCs in implementing comprehensive interventions to increase access to and completion of HCV treatment for HIV-positive patients who were uninsured. Critical parts of this demonstration project involved evaluation of the delivery of HCV treatment among HIV-positive populations and the sharing of best practice models with Ryan White grantees and other HIV medical providers to improve access and quality of Ryan White services.

Only limited state funds have been made available to expand HCV care and treatment services in New York City. As part of the State Health Department's Comprehensive Hepatitis C Program, the AIDS Institute granted \$215,000 to each of two New York City medical centers and \$132,500 to each of two New York City FQHCs to enhance their treatment of HCV and HCV/HIV co-infection, respectively, within pre-existing HIV primary

care settings. <sup>136</sup> The State Health Department also initiated the pilot Hepatitis C Assistance Program (HepCAP) in two New York City facilities to provide HCV-related medical services to people who meet the same eligibility criteria as the NYS AIDS Drug Assistance Program (ADAP). Providers are allowed to enroll HCV mono-infected patients into the program if they are New York State residents who are uninsured and meet other established eligibility criteria. The program funds the initial HCV medical and treatment evaluation and up to 30 visits, including diagnostic evaluations and labs used to monitor treatment. Notably, HepCAP does not cover the costs of anti-HCV treatment or management of medication side effects, though persons have often been able to procure medications through pharmaceutical industry patient assistance programs.

ADAP also has provided access for co-infected New Yorkers to HCV testing and some treatment options, including pegylated interferon and ribavirin. (Note: The new HCV protease inhibitors are not yet FDA-approved for treatment of HCV in HIV co-infected patients.) Recent decreases in Ryan White funding nationwide have resulted in decreased spending for viral hepatitis services in New York State and New York City, though not to ADAP. 137 New York State has acted to fill this gap, providing both vaccines for persons with chronic HCV who have no health insurance coverage through the New York State Adult Hepatitis Vaccination Program (AHVP). 138

In 2011, New York State convened a Medicaid Redesign Team to devise a comprehensive plan to control health care costs while improving the quality of that care and ensuring that it is delivered equitably. The plan proposed increased funding to promote HCV care and treatment in primary care settings, community health centers, HIV primary care sites and substance use treatment programs. The 2012-2013 state budget included \$1.1 million for HCV screening and treatment. It is expected that the new modifications will allow for the reimbursement of crucial supportive services, including client outreach, HCV counseling and education, coordination of and adherence to HCV treatment, peer support and assistance obtaining entitlement services. The objective of this change was to create an integrated HCV care model that would ensure comprehensive and coordinated quality care for HCV mono-infected and HIV/HCV co-infected persons while reducing health care needs and accompanying costs.

# A PUBLIC HEALTH MODEL FOR REDUCING ILLNESS AND DEATH FROM HCV INFECTION IN NEW YORK CITY

Given that the current and anticipated disease burden from HCV infection in New York City will soon rival that of HIV/AIDS, the Health Department has developed an action plan to address this epidemic. Its primary goal is to reduce the morbidity and mortality from HCV with the following measures:

- 1. Prevent HCV transmission and new infections;
- 2. Diagnose persons living with HCV, link them to appropriate care, and cure current HCV infections with effective treatments;
- 3. Decrease complications and deaths from chronic HCV infections; and
- 4. Reduce disparities in prevalence and access to care and treatment among persons infected with HCV.

The Health Department HCV action plan comprises 7 objectives. To fully implement this plan, the Department needs to identify significant new funding from government (city, state, federal) or non-government entities (e.g., foundations, private industry and non-profit hospitals as part of "community benefit" activities<sup>140</sup>). Efforts will be made to identify and develop synergies among Health Department programs that derive from common missions, policy concerns, and at-risk populations that are served. Favorable pricing for new medications also will be pursued with drug manufacturers.

- 1. Enhance health provider awareness regarding screening, diagnosis, and referral for HCV infection and clinical providers' capacity to manage and treat HCV.
  - Publish and disseminate to New York City providers a *City Health Information* (CHI) issue devoted to updated HCV screening and treatment recommendations.
  - Through the NYC Hepatitis C Task Force, disseminate current HCV screening, testing and referral recommendations to CBOs engaged with harm reduction activities.
  - With academic medical experts, use telemedicine to augment the HCV-related clinical skills of primary care providers, infectious disease specialists and gastroenterologists, building HCV treatment capacity in these provider groups.

- Encourage providers to annually screen HCV patients with cirrhosis for hepatocellular carcinoma and end-stage liver disease.
- Enhance the resources available on the Health Department website for health care professionals.
- Collaborate directly with large health care institutions to enhance primary care provider, infectious disease physician and gastroenterologist diagnosis and management of HCV.
- Collaborate with academic medical centers to enhance HCV education of medical students, residents and fellows, other physicians and other health professionals.
- 2. Promote HCV testing, as per CDC guidelines.
  - Encourage providers of those at higher risk for HCV e.g., in drug treatment programs and HIV clinics — to introduce reflex PCR testing when HCV antibody is detected.
  - Send reminders to providers who do not follow positive HCV antibody tests with an assay for HCV RNA.
  - Encourage vendors to enhance capacities of EHRs, so that users are reminded when testing and other assessments are indicated.
  - Incorporate questions about HCV screening in the annual Community Health Survey to monitor the proportion of the population tested.
  - Implement effective HCV testing strategies in clinical settings where the Health Department has funded programs, such as contracted drug treatment programs, Ryan White Part A contracted programs, New York City correctional facilities, and STD and TB clinics.
  - Encourage large clinical laboratories and hospitals to implement appropriate reflex testing of specimens for HCV RNA, and encourage EHR providers to incorporate appropriate HCV RNA testing into decision support.
  - Follow up the April 2013 Commissioner's letter with outreach to primary care, infectious disease, and gastroenterology physicians in hospitals, hospital-affiliated clinics, and community health centers in New York City neighborhoods with the greatest HCV burdens.
- 3. Enhance HCV surveillance activities to strengthen the Health Department's capacity to manage and utilize data for evidence-based policies and practice.
  - Amend the New York Health Code so that negative HCV RNA tests are reportable to the Health Department, as is currently done with HIV RNA.
  - Expand capacity to manage and analyze more clinical data
    - a. Assess trends of HCV RNA testing.
    - b. Assist hospitals to improve the quality of HCV care with performance indicators.

- c. Explore the feasibility of identifying factors associated with treatment outcomes among a representative sample of HCV patients in New York City.
- 4. Enhance linkage to care for persons with current HCV infection, identify and promote successful models of care, and build clinical capacity to manage and treat HCV.
  - Encourage and assist health care facilities, care management agencies, health homes, and managed care organizations in New York City neighborhoods with the greatest HCV burdens, to strengthen linkage to care activities and networking.
  - Develop patient navigator guidance and tools, and offer training.
  - Link to care persons co-infected with HIV and HCV through the Bureau of HIV/AIDS Prevention and Control's Field Services Unit.
  - Expand capacities of Correctional Health Services to link persons with HCV infection who are released from custody to community providers capable of managing HCV infection.
  - Identify mechanisms to link clients to care for Health Department programs that currently engage with PWID.
  - Encourage organizations under contract with the Health Department (e.g., drug treatment programs and SEPs) to develop and implement processes to link clients with current HCV infection to care.
  - Encourage primary care providers and other medical professionals who manage patients with HCV to incorporate practices that promote liver health in persons with current HCV infection.
  - Assess extent to which primary care physicians, infectious disease specialists and gastroenterologists currently manage and treat persons with current HCV infection and their preferred methods for clinical education and skill development.
  - Identify best practices in HCV prevention, care, and treatment used by clinicians elsewhere, and assess for adaptation in New York City.

# 5. Promote primary prevention

- Continue to promote and support harm reduction programs that combine syringe exchange, integrated linkage to and engagement in appropriate care, as well as education and other supportive services.
  - a. Continue to work with SEPs to educate clients especially uninfected young adults who are not yet infected and active drug injectors who may have cleared an HCV infection or have been cured with antiviral treatment - about how to prevent HCV re-infection, to promote access to HCV testing and referral to care, and effective drug treatment.
- Promote HCV prevention and health education among non-injecting drug users at drug treatment programs.

- a. Through contracted drug treatment programs across New York City and through the Bureau of HIV/AIDS Prevention and Control and the Bureau of STD, address HCV risk from shared equipment, sexual activity, and potential injection use.
- b. Continue harm reduction programs by the Health Department's Bureau of Transitional Health Care Coordination at New York City's correctional facilities, including educational materials about HCV risk and prevention and a list of syringe access programs in jail discharge kits.
- c. Craft new prevention messages and provide culturally appropriate education on the risks associated with jailhouse tattooing, sharing of razors, and sharing of drug use equipment.
- d. Promote sexual practices that do not transmit HCV.
- 6. Enhance public awareness of HCV
  - Continue to engage communities through activities of the New York City Hepatitis C
     Task Force.
  - Develop public awareness materials and disseminate them through social media and other venues.
- 7. Engage and collaborate with the New York State Department of Health and other state agencies and other relevant organizations to develop, promote and advance policies and regulations that will support the goals of this strategy (e.g., obtaining favorable pricing from drug manufacturers).

#### Table 6. Core objectives within New York City HCV action plan

- 1. Enhance health provider awareness regarding screening, diagnosis, and referral for HCV infection and clinical providers' capacity to manage and treat HCV.
- 2. Promote HCV testing, as per CDC guidelines.
- 3. Enhance HCV surveillance activities to strengthen the Health Department's capacity to manage and utilize data for evidence-based policies and practice.
- 4. Enhance linkage to care for persons with current HCV infection, identify and promote successful models of care, and build clinical capacity to manage and treat HCV.
- 5. Promote primary prevention.
- 6. Enhance public awareness of HCV.
- 7. Engage and collaborate with the New York State Department of Health and other state agencies and other relevant organizations to develop, promote and advance policies and regulations that will support the goals of this strategy.

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