

# A Public Health Approach to Hepatitis C in an Urban Setting

The clinical consequences of HCV infection are increasing because the population with the highest prevalence of the infection, persons born between 1945 and 1965, is aging. As a result, health care expenditures are expected to increase.

Now that a cure for HCV infection is the norm, a public health approach is necessary to identify, link to care, and treat infected persons and prevent new infections. We believe that the success of public health interventions, such as those for tuberculosis, can be translated to HCV infection.

New York City has many HCV-infected residents and has developed a public health approach to controlling the HCV epidemic. It encompasses surveillance and monitoring, case finding, linkage to care, care coordination, increasing clinical provider capacity for screening and treatment, increasing public awareness, and primary prevention. (*Am J Public Health*. 2017;107:922–926. doi:10.2105/AJPH.2017.303718)

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In the next 20 years, hundreds of thousands of persons infected with HCV in the United States and worldwide are expected to develop cirrhosis, and thousands will develop liver cancer and die prematurely unless treated and cured of their infection.<sup>1,2</sup> Although highly effective and tolerable short-course regimens to cure HCV infection exist (<http://www.hcvguidelines.org>), public health departments have minimal resources for addressing HCV. Instead, HCV control in the United States depends almost entirely on the health care delivery system. Diagnosis is often delayed because HCV infection is often asymptomatic until late in its progression, and treatment is unavailable or inadequate because of insufficient or lack of insurance coverage, stigma, or comorbid conditions.<sup>3–5</sup> As with other infectious diseases with severe consequences and high prevalence among stigmatized populations, such as sexually transmitted infections, tuberculosis (TB), and HIV infection, a comprehensive public health approach is essential; this must include surveillance, case finding, linkage to care, disease management, medication adherence, and capacity building.<sup>6</sup>

HCV infection, which often becomes chronic, is caused by an RNA virus that mutates at a high rate, making developing an effective vaccine challenging.<sup>7</sup> In the United States, transmission of HCV primarily occurs through sharing of needles and other illicit

drug use paraphernalia, unsafe medical injections, and, until 1990, transfusion of blood and blood products.<sup>8,9</sup> Up to 80% of injection drug users are infected with HCV within 2 years of their first injection.<sup>9</sup> Despite this, success in preventing HCV transmission among injection drug users who utilize harm reduction programs such as syringe exchange services has been documented.<sup>10</sup> Such harm reduction programs are not universally accessible, and several areas of the United States are experiencing an increase in the incidence of new HCV infection among young adults who have transitioned from abuse of prescription opiates to injection drug use.<sup>11,12</sup> Screening for HCV infection using risk behaviors such as drug use is inadequate for identifying the majority of patients because of provider reluctance to ask about risky behaviors and patient lack of recall or fear of stigma.<sup>13–17</sup>

The long cryptic natural history of HCV infection and the inability to predict which patients will develop severe consequences present other challenges for the control of HCV infection.<sup>18</sup> For every 100 persons initially infected with HCV, 75 to 85 will remain

chronically infected, 60 to 70 will develop chronic liver disease, 5 to 20 will develop cirrhosis, and 1 to 5 will die of cirrhosis or liver cancer.<sup>18</sup> Since 2013, new drug regimens have made HCV treatment simpler, shorter, less toxic, and more effective than previous interferon-based regimens.<sup>19</sup>

Cure rates for all HCV genotypes with oral directly acting antiviral medications now surpass 90% in almost all cases. Successful treatment of HCV infection results in lifelong cure, decreases the risk of associated liver diseases (e.g., cirrhosis, hepatocellular carcinoma), decreases liver-related and all-cause mortality; <http://www.croiconference.org/scientific-program/electronic-materials/croi-2016>),<sup>20</sup> and reduces costs to the health care system.<sup>21,22</sup> Although global elimination of HCV infection will be challenging, elimination in defined geographic areas, such as New York City (NYC), is conceivable with the implementation of a concerted public approach and liberal access to the latest treatments.

We focus on NYC to describe the rationale for and components of a public health approach to HCV infection.

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## RATIONALE FOR PUBLIC HEALTH APPROACH

Gaps in the diagnosis and treatment of HCV infection can be visualized using a care cascade that depicts the continuum of care, similar to what is used to monitor the HIV epidemic. Figure 1 shows a care cascade derived from data available before direct-acting antivirals. Data in this figure were used to inform NYC's strategic plan (<http://www1.nyc.gov/assets/doh/downloads/pdf/cd/hepC-action-plan.pdf>). As of late 2015, we estimated that approximately 12%, or fewer than 18 000, of the estimated 146 500 HCV-infected people in NYC had been cured, an improvement from the initial care cascade. Major drop-offs occur at each level of the care continuum.

First, most people with HCV infection develop no or few symptoms until severe liver disease occurs,<sup>5</sup> most have comorbid conditions, and many experience structural barriers

(e.g., low socioeconomic status, homelessness) that make access to diagnosis and treatment of HCV infection difficult (<http://www1.nyc.gov/assets/doh/downloads/pdf/cd/hepatitis-b-and-c-annual-report.pdf>). Second, new treatment regimens, although simpler and more tolerable than previous regimens, require high levels of adherence over several months. Their high cost has resulted in severe usage restrictions by certain government (particularly Medicaid) and private insurance programs, although these restrictions have eased in recent months.<sup>3,4</sup> Third, not enough health care providers are adequately trained and incentivized to diagnose and treat HCV infection. Fourth, although treatment addresses the large pool of older adults with prevalent infection, it is unlikely to prevent incident infection among young adults in the near future.

Strengthening multiple components of the public health system can help greatly increase the proportion of

HCV-infected people who are cured. With the current NYC strategy, we are beginning to see improvements in the number of people treated and cured on the basis of surveillance data and special programs with selected hospitals.

## SURVEILLANCE AND MONITORING

NYC has a person-level HCV surveillance system that is electronically populated from laboratory reports in real time and includes patient identifiers. Because diagnosis and treatment require HCV-related laboratory tests and all tests are reportable, case ascertainment is highly complete. Data collected by the New York City Department of Health and Mental Hygiene (DOHMH) include test results (i.e., antibody, RNA, and genotype) and test date; the name of the facility where the test was ordered; laboratory and provider information; and patient name, date of birth, sex, and address.

Because race/ethnicity and risk factor and clinical information are not routinely collected, the DOHMH periodically conducts surveys and special studies to review changes in prevalence, new epidemiological trends, access to care, and patterns of care.<sup>26</sup>

Similar surveillance is needed in every state to monitor the HCV epidemic, target resources, change policy, and evaluate the effectiveness of interventions. In NYC, we have identified neighborhoods with disparate disease burden, many of which also have a high proportion of residents with incomes below the federal poverty level, and applied for grants and worked with elected officials to fund initiatives in these neighborhoods (<http://www1.nyc.gov/assets/doh/downloads/pdf/cd/hepatitis-b-and-c-annual-report.pdf>).

Bringing such data to elected officials resulted in approximately 1 million dollars in annual funding to hospitals and community health centers in high-prevalence neighborhoods and all syringe exchange programs. This funding enabled the implementation of outreach, screening, and navigation programs to increase linkage to care. After surveillance data analyses showed that more than 40% of patients did not undergo confirmatory RNA testing after a positive antibody screening test, we worked with providers to increase the proportion of patients tested and with commercial clinical laboratories to promote reflex RNA testing (<http://www1.nyc.gov/assets/doh/downloads/pdf/cd/hepatitis-b-and-c-annual-report.pdf>).

Our goal was to increase the proportion of antibody-positive persons who receive an RNA

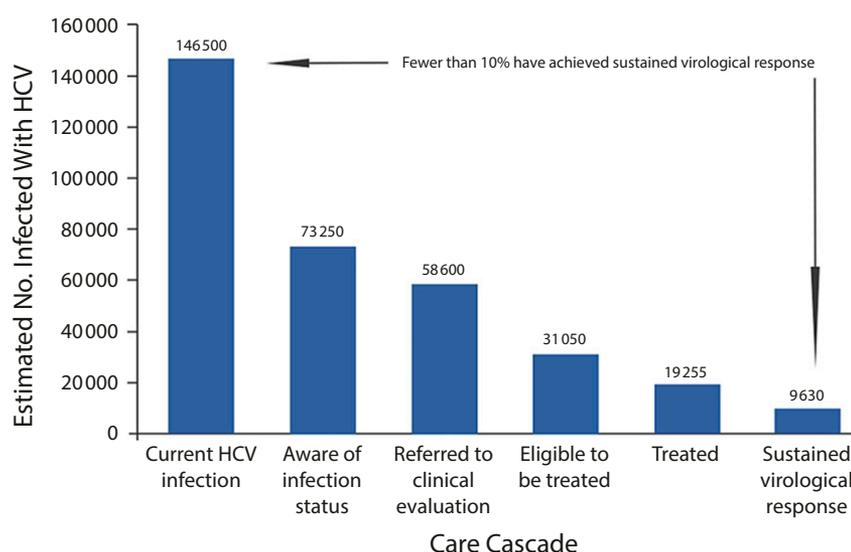


FIGURE 1—HCV Treatment Cascade: New York, NY, 2012

test within 3 months to 65%; this goal was reached in 2016, and thus the target increased to 75%. In 2014, we modified the NYC Health Code to mandate the reporting of negative HCV RNA test results. We now use these data to estimate the proportion of patients successfully treated, as we have been doing for many years with HIV. Substantial additional resources, however, are needed to support other jurisdictions to gather similar data.

## CASE FINDING AND CARE COORDINATION

Case finding is the critical first step in the care continuum. As shown in Figure 1, half of individuals with HCV infection are estimated to be unaware that they are infected and at risk for cirrhosis and premature death.<sup>1</sup> Because screening on the basis of risk factors has limited effectiveness<sup>12–15</sup> and on the basis of the high rate of HCV infection among people born between 1945 and 1965, the Centers for Disease Control and Prevention began recommending HCV screening for everyone in this age cohort.<sup>17</sup> The DOHMH sent a letter to all licensed physicians about current screening requirements, produced training materials such as a screening toolkit (<https://hepfree.nyc/hepctoolkit>), and conducted educational sessions for physicians to encourage HCV screening.

The DOHMH also began HCV screening in sexually transmitted infection clinics and is assessing the feasibility of promoting screening in emergency departments. A recent HCV serosurvey of a large NYC emergency department found

a high prevalence of anti-HCV antibodies and supports screening in emergency departments on the basis of local epidemiology (<http://www1.nyc.gov/site/doh/about/press/pr2016/pr061-16.page>).

In addition, the DOHMH began several initiatives to promote the use of reflex RNA testing, including provider education and eliciting feedback, and created an HCV Clinical Exchange Network composed of “HCV Champions” from all major health care facilities in NYC to share best practices (<https://hepcx.nyc>). The DOHMH is helping these facilities modify their electronic medical record and laboratory information systems to implement automated prompts for HCV antibody testing and reflex RNA testing for those with a positive HCV antibody test.

Many patients with a confirmed diagnosis do not receive follow-up HCV care.<sup>27,28</sup> Programs to navigate newly diagnosed patients to services increase the proportion of patients who establish care with an HCV treatment specialist in NYC.<sup>28</sup> Health departments with HCV surveillance registries can also increase linkage to care by providing lists of newly reported cases to their respective health care facilities and either mailing or texting patients to provide information about HCV and to encourage a medical visit.

Once a patient has been linked to care, maintaining that patient in care often requires additional support services. We recently adapted a care coordination program from the DOHMH HIV program<sup>29</sup> for HCV patients. The program includes patient coaching and education, navigation to specific appointments by trained

personnel, and support from a multidisciplinary team regarding HCV care, care of common comorbid conditions, and medication adherence. Such intensive care coordination is complex and expensive and not routinely covered by health insurance. Until the health care delivery system pays for programs that provide supportive services and incentivizes providers to maximize HCV infection cure rates, health departments need to provide these services in a manner that parallels the care coordination currently provided through the federal government’s Ryan White HIV/AIDS Program for people living with HIV who are underinsured or uninsured.

Probably the most relevant public health model for eliminating HCV is the TB model. In both NYC and globally, TB programs have substantially reduced illness and death by classifying patients using standardized case definitions, initiating standardized short-course chemotherapy regimens, providing active case management during treatment, including directly observed therapy, and monitoring program performance through periodic cohort reviews with standardized definitions for treatment success, failure, default, and death.<sup>30,31</sup> Although clinical trials have established the scientific basis for a similar model for HCV, no health departments in the United States, including in NYC, have the resources yet to implement it.

In smaller cities and rural areas, creating or expanding an HCV program may prove difficult, but NYC’s approach could be adapted. Three years ago, the NYC HCV program had only 6 staff members and had no statutory funding. NYC

health department staff members actively applied for and sought out federal and industry funding to develop the program and worked with community groups to advocate among elected officials for municipal funding. Health departments can also consider partnering with medical schools and academic medical centers on research to help generate local data and build hepatitis technical knowledge in the health department. Partnership with industry can help expand access to treatment through screening and linkage to care programs (e.g., <http://www.gilead.com/responsibility/corporate-contributions/2014%20corporate%20contributions%20report/how%20we%20contribute/providing%20access/focus>).

## INCREASING SCREENING AND TREATMENT CAPACITY

HCV management and treatment have traditionally been confined to specialists, primarily hepatologists, who were needed to manage the long-term complications of HCV-related liver disease as well as past HCV treatment regimens that were complex to administer and produced side effects that were difficult for patients to tolerate. With simpler treatments now recommended for all people with HCV infection, the number of physicians prepared, competent, and willing to treat HCV infection is too low to meet the demand. The state of New York has about 40 hepatologists, an insufficient number for the patients needing treatment in NYC.<sup>32</sup> Although it is unlikely that every primary care provider will have the capacity to

treat HCV infection in the near future, at minimum, all licensed health care providers should know how to screen for and confirm HCV infection. At best, in geographic areas with moderate to high HCV infection rates, specialists in gastroenterology, HIV disease, and infectious diseases, as well as general primary care providers, should be able to treat people with HCV infection who have minimal comorbid conditions and limited liver disease.

Health departments have a critical role to play in increasing the supply of trained clinicians. In NYC, the DOHMH has developed several tools and interventions to increase treatment capacity. Training materials are distributed to assist all providers with HCV screening and diagnosis, including a toolkit for screening and linkage to care and guidance for diagnosing and managing HCV infection (<https://hepfree.nyc/hepctoolkit>). The DOHMH created an HCV Clinical Exchange Network to support peer-to-peer learning among providers, provide feedback on hospital and provider performance using electronic medical records and surveillance data, and promote practice change (<https://hepcx.nyc>). Lastly, the DOHMH contracted with an association of hepatologists, the Empire Liver Foundation (<http://empireliverfoundation.org>), to mentor physicians who are new to managing HCV treatment. The New York State Department of Health AIDS Institute Clinical Education Initiative (<https://www.ceitraining.org>) also offers training and telephone consultation to physicians regarding HCV care.

Health departments can promote continuous quality improvement by using data from

electronic medical records and surveillance systems to report on the HCV care continuum for selected health care facilities.

The DOHMH has partnered with the New York State Department of Health to develop quality management data collection and analysis software to assist health care facilities in calculating HCV-related clinical indicators for quality improvement (<http://www.ehepqual.org>).

HCV treatment in NYC and across the United States currently depends exclusively on the health care delivery system. With TB, global and domestic progress toward elimination has relied primarily on direct service delivery by government public health programs. Indeed, the defunding or dissolution of government-operated TB clinics has led directly to TB epidemics, and the incidence of TB is closely related to the success of well-functioning, government-funded TB clinics and programs.<sup>33</sup> Building a system similar to TB for HCV, however, would require substantial political commitment to fund and maintain infrastructure, staffing, and access to medications.

## INCREASE PUBLIC AWARENESS

HCV infection has been called the silent killer and the hidden epidemic.<sup>34,35</sup> Even though HCV has killed more Americans than HIV since 2007, the public is largely unaware of HCV infection and its consequences. In addition, the few existing advocacy groups have had limited success in raising awareness of the disease. As demonstrated during the HIV epidemic, community advocacy

can play a major role in accelerating health-related policies, programs, and research to advance treatment.

One of the challenges of addressing HCV infection is that a large proportion of cases results from the heavily stigmatized behavior of injection drug use. Current injection drugs users may only be accessed through peers or trusted allies and have a limited voice in influencing legislature and decision-makers. Because of the importance of community engagement, in NYC we have created a community task force, the Hep C Task Force (<http://www.hepfree.nyc>), to align the interests and activities of government organizations, advocates, patients, health care providers, and community groups. Numerous new projects and interventions have arisen as a result of information obtained via needs assessments and from discussions during Hep C Task Force meetings, such as the Psychosocial Readiness Evaluation and Preparation for Hepatitis C Treatment (<https://prepc.org>).

In addition, the DOHMH developed a public service announcement to educate the public about the importance of screening for HCV infection, the availability of print materials at clinics and hospitals, resources available on its Web site, the NYC liver health mobile app, and a texting platform. Health departments need to engage community members to advance awareness, advocacy, and sustainable program development.

## PRIMARY PREVENTION

Although the most urgent challenge in the HCV epidemic involves treating people already

infected, injection drug use is increasing among young people,<sup>11,12</sup> increasing the risk of a second wave of new HCV infections. Rural areas have already seen explosive outbreaks because of increases in opioid use and a lack of harm reduction programs.<sup>11,12,36</sup> Health departments play a critical role in characterizing locations and populations of new injectors and targeting evidence-based programs, including syringe exchange and drug treatment programs.

In 2014, the DOHMH provided additional resources to syringe exchange programs, particularly in areas of NYC with high rates of overdose deaths, such as Staten Island and the Bronx, and has been supporting linkage to care and patient navigation at syringe exchange programs for persons at risk for or infected with HCV. The recent outbreak of HIV infection among injection drug users in rural Indiana highlights the importance of expanding syringe exchange programs to prevent an epidemic of HIV and HCV infections among young adults.<sup>36</sup> In addition, sexual transmission of HCV among HIV-positive men who have sex with men is an important trend to follow, especially considering that the increasing use of pre-exposure prophylaxis to prevent HIV infection could lead to a reduced use of condoms and an increase in transmission of HCV.<sup>37</sup>

Although HCV was first identified 26 years ago, deaths from this curable viral infection continue to increase, and both screening and treatment access remain limited. Insufficient political commitment and allocation of resources for health departments have left millions of people with HCV infection

reliant on the health care delivery system to diagnose, support, and treat them, and millions of people at risk for HCV infection without the education and infrastructure needed to prevent infection and provide access to a cure. In NYC, we have adapted the public health approach to HIV and other infectious diseases to HCV infection control. To reduce illness and death stemming from HCV infection on a national scale, health departments need to adopt, disseminate, and support a public health approach to HCV infection control. **AJPH**

### CONTRIBUTORS

Both authors contributed equally to the concept, planning, and implementation of the program and to the concept and writing of the article.

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### HUMAN PARTICIPANT PROTECTION

No protocol approval was necessary because no human participants were involved in this project.

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