

# Enhanced Chronic Hepatitis C Surveillance in New York City, April 2009–January 2011

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## ABSTRACT

**Objective.** We analyzed and evaluated enhanced chronic hepatitis C virus (HCV) surveillance in New York City (NYC), which involved detailed investigations on a sample of newly reported HCV patients.

**Methods.** Beginning in July 2009, we generated a simple random sample bimonthly from all patients newly reported with a positive HCV test. We administered questionnaires to clinicians and patients to collect clinical and epidemiological information on patients diagnosed from April 2009 to January 2011 and evaluated the staff resources required to conduct enhanced surveillance.

**Results.** Of 205 patients meeting inclusion criteria, 40 (19.5%) tested HCV ribonucleic acid (RNA) negative. For the remaining 165 patients, questionnaires were completed by 164 clinicians (99.4%) and 77 patients (46.7%). Many patients (54.0%) were born between 1945 and 1964, and most patients were Hispanic (32.7%) or non-Hispanic black (32.7%). Common risk factors were injection (43.0%) and intranasal (33.9%) drug use. One-third of patients were diagnosed in nontraditional medical settings including substance abuse/detoxification centers (25.0%), jail/prison (6.7%), and psychiatric facilities (1.8%). Of 98 patients with positive HCV RNA tests, 38.8% were immune to hepatitis A and 39.8% were immune to hepatitis B. Investigators required approximately 3.5 hours to complete each investigation and averaged 50 days from assignment to completion.

**Conclusions.** Although conducting enhanced HCV surveillance requires significant resources, investigating a representative sample provides detailed information about NYC's HCV population. Surveillance data have been used to plan educational initiatives for clinicians and patients, which may have led to increased awareness of HCV status, improved patient support, and better overall care.

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Hepatitis C virus (HCV) is a major public health problem, with an estimated 1.3% of Americans and 1.8%–2.4% of New York City (NYC) residents chronically infected.<sup>1–4</sup> Over time, HCV can lead to cirrhosis, liver disease, and hepatocellular carcinoma.<sup>5,6</sup> Although a recent study demonstrated that HCV mortality currently exceeds human immunodeficiency virus (HIV) mortality in the United States, resources for HIV surveillance and treatment vastly exceed those dedicated to HCV.<sup>7</sup> As newly approved, potentially more effective, and easier to tolerate HCV treatment regimens become available, it is expected that more patients will complete treatment, ultimately reducing overall HCV morbidity and mortality.<sup>8</sup>

In response to the increasing concern about HCV in the U.S., the Institute of Medicine (IOM) issued “Hepatitis and Liver Cancer: A National Strategy for Prevention and Control of Hepatitis B and C,” which calls on health departments to improve HCV surveillance. The purpose of improved surveillance is to better understand the local and national impact of HCV, increase awareness, and target resources to affected populations and risk groups. The IOM acknowledges that current funding is inadequate to support HCV surveillance needs and recommends that further funding be provided.<sup>1</sup> While NYC receives funding for hepatitis surveillance, investigation of all newly reported cases is not feasible, as the NYC Department of Health and Mental Hygiene (DOHMH) receives approximately 10,000 newly reported HCV cases a year.<sup>9</sup>

Because investigating each case is not feasible, we developed enhanced chronic HCV surveillance using a sampling protocol to collect detailed information from a representative sample of patients. We describe the results of enhanced surveillance of a sample of patients and evaluate the usefulness and resources required.

## METHODS

The NYC Health Code requires laboratories and clinicians to report positive HCV antibody tests with a high signal-to-cutoff ratio and positive recombinant immunoblot assays (RIBAs) to the health department. It is recommended that all antibody-positive patients receive ribonucleic acid (RNA) testing to determine if they are chronically infected; positive RNA tests are also reportable.<sup>10,11</sup> Required data elements include date of birth, sex, patient name, and address; type of HCV test; and clinician name and address.

Beginning in July 2009, we randomly selected 20 patients every two months from all patients newly reported with positive HCV tests in the 2–3 months before the sampling date. Analysis included patients

with diagnosis dates from April 2009 to January 2011. We excluded non-NYC residents and patients younger than 18 years of age or with no date of birth in the system. We also excluded laboratory and sampling errors discovered during investigation. Investigators identified laboratory errors through direct communication with the testing laboratory. A few sampling errors occurred because of incorrect reporting of patients’ dates of birth. Once we corrected the dates of birth, we determined that these patients matched to reports with HCV diagnosis dates earlier than specified for our sampling time frame.

Investigators, mainly graduate student interns, contacted the clinician to ensure that the patient had been notified of his/her positive HCV test. If the clinician had not informed the patient, investigators urged the clinician to do so immediately. Investigators administered questionnaires to clinicians and patients to collect demographics, risk factors, reasons for HCV testing, clinical information, and laboratory results. The DOHMH did not order or perform any laboratory tests for this study but did collect any available results. If the patient did not have an RNA test, we reminded the clinician that RNA testing is recommended.

For RNA-positive patients, questionnaires included additional questions about antiviral treatment, hepatitis A and B immunity, support groups, and counseling. Investigators faxed the questionnaire to all clinicians listed on the laboratory reports and instructed them to return it within five business days; investigators followed up with the clinician by phone to encourage completion. If clinicians mentioned that the patient had seen another clinician who may know the patient better, we contacted that clinician as well. If the clinician did not complete the questionnaire, the investigator instead reviewed the patient’s medical record. If we determined that a patient was HCV RNA-negative during the investigation process, we excluded that patient from further investigation and analysis.

One week after contacting the clinician, investigators attempted to contact the patient by phone (three attempts during one week). During the patient interview, if it was apparent that the patient was unaware of his/her positive HCV test, investigators discontinued the questionnaire and reminded the clinician to inform the patient of his/her positive test. After one month, investigators again contacted the patient. For patients who were unreachable by phone, we sent a letter and questionnaire by certified mail. If we received no response after two weeks, staff closed the investigation. At the conclusion of each investigation, investigators sent clinicians a patient education booklet called “Hepatitis C: The Facts” and a bulletin for clinicians

on HCV diagnosis and management.<sup>12,13</sup> Investigators also mailed the booklet to patients who requested it, although many patients had already received it as part of DOHMH's routine outreach.

We entered all data into Microsoft® Access and performed all analyses using SAS® software version 9.2.<sup>14</sup> We set statistical significance at  $\alpha=0.05$ . To establish representativeness of the sample, we compared sex, county of residence, and age for patients contacted as part of enhanced surveillance with all newly reported HCV patients in 2010 using Chi-square statistics. We compared demographics of patients interviewed and not interviewed using Fisher's exact test. If both clinicians and patients answered a question, we used a hierarchical algorithm with "yes" taking precedence, followed by "no," and "unknown." We examined discrepancies between clinician and patient answers for 18 selected variables (e.g., risk factor, insurance, and HIV status) to assess internal consistency. Additionally, we calculated the frequency of the response "unknown" to all 29 questions asked of clinicians, excluding sex, birth country, and race/ethnicity. DOHMH further evaluated the enhanced surveillance system by interviewing the surveillance coordinator and four investigators to ascertain the time necessary to complete investigations, challenges encountered in collecting information from patients and clinicians, and ways in which the data have been used for public health purposes. We did not assess time for training, reviewing investigations, and data entry.

We calculated response frequencies for questions asked of both clinicians and patients (165 responses), those asked only of clinicians (164 responses), and those asked only of patients (77 responses). Seven questions were only relevant for patients with positive HCV RNA tests; therefore, we calculated these frequencies out of the 98 HCV RNA-positive patients.

## RESULTS

From April 2009 to January 2011, 21,177 newly reported patients tested positive for HCV in NYC, and of these we randomly selected 220 patients. We excluded 15 patients because they did not meet inclusion criteria. According to previously reported laboratory results and any additional results received through contact with clinicians, 98 (48%) of the remaining 205 patients had a positive HCV RNA test, 40 (19.5%) had a negative HCV RNA test, and 67 (32.5%) did not receive the RNA testing necessary to determine infection status even after DOHMH staff requested such testing (Figure). Thus, we limited analyses to 165 patients after excluding the 40 HCV RNA-negative patients.

Clinicians completed 135 of 165 (81.8%) questionnaires: 131 (79.9%) by fax and four (2.4%) by mail/phone. DOHMH staff completed 29 (17.7%) additional clinician questionnaires by medical record review, which resulted in completing 164 of 165 clinician questionnaires total (99.4%). Patients completed 77 (46.7%) of 165 interviews (Figure). Reasons for incomplete interviews were: unable to contact (65.9%), refusal (9.1%), homelessness (8.0%), deceased (6.8%), out of the country (3.4%), incarcerated (2.3%), cognitive issues (2.3%), or inpatient in a substance abuse/detoxification center or psychiatric facility (2.2%) (data not shown).

We calculated the frequency of the response "unknown" to each of the 29 questions asked of clinicians. The question with the greatest percentage of unknown responses was whether the patient had contact with someone with HCV (88.5% unknown), while the question with the lowest percentage was the type of facility in which the clinician diagnosed the patient (4.2% unknown). Among the 29 specified questions, the median percentage was 50.9% unknown. Discrepancies between clinician and patient answers occurred 2.6% of the time (data not shown).

Sex, county of residence, and age were not significantly different when comparing 165 patients sampled for enhanced surveillance with all 9,992 newly reported people with a positive HCV test in 2010 (data not shown). However, when we compared enhanced surveillance patients, those interviewed were less likely to be homeless (11.1% vs. 88.9%,  $p=0.03$ ), an inpatient (21.4% vs. 78.6%,  $p=0.0001$ ), or in jail/prison (9.1% vs. 90.9%,  $p=0.01$ ) when diagnosed, and more likely to have private insurance (78.3% vs. 21.7%,  $p=0.02$ ) than those not interviewed (data not shown).

As shown in Table 1, males accounted for 61.8% and those born between 1945 and 1964 accounted for 54.0% of the sample; the median age was 53 years. Most patients were Hispanic (32.7%) or non-Hispanic black (32.7%). The most common reasons for testing were HCV risk factors (47.3%), elevated liver function tests (LFTs) (29.1%), and asymptomatic, prenatal, or donor screening (26.1%). The most common risk factors were injection (43.0%) or intranasal (33.9%) drug use and having ever been in jail/prison (32.7%). Of the 165 patients, 118 (71.5%) had insurance, most of whom had Medicaid and/or Medicare (83.1%) (Table 1). One-third of patients were diagnosed in nontraditional health-care settings, such as substance abuse/detoxification centers (25.0%), jail/prison (6.7%) (Table 2), and psychiatric facilities (1.8%) (data not shown).

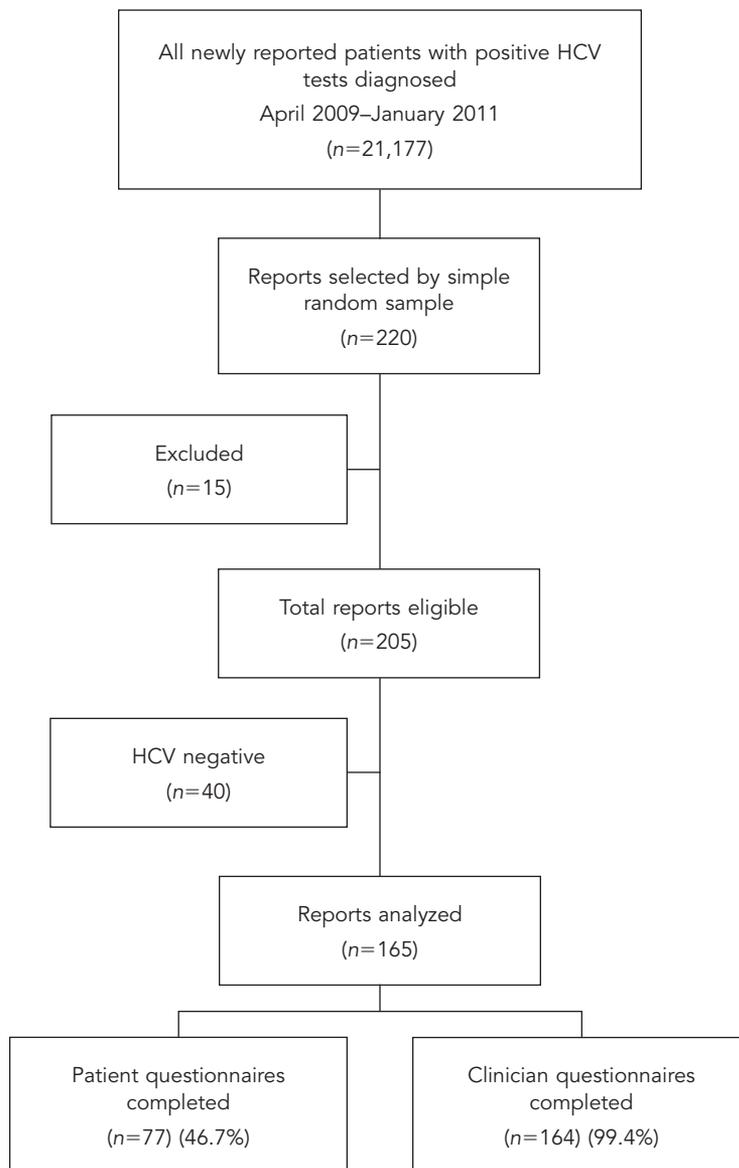
Fifty-three patients (68.8%) had a primary care clinician and 49.4% requested the educational booklet.

Of the 55 interviewed patients who were HCV RNA-positive, 17 (30.9%) who were not already attending a support group were interested in attending one (Table 3). More than half of clinicians reported that they counseled patients about alcohol use (61.2%) and HCV transmission (61.2%). Clinicians also reported that 38.8% of patients were immune to hepatitis A and 39.8% were immune to hepatitis B (Table 4).

DOHMH staff estimated that they spent a median of 3.5 hours on each investigation. The median time

from assignment to completion was 50 days. Staff indicated that the protocol was easy to follow but that patients were difficult to reach, and getting clinicians to complete the questionnaire required persistence and multiple phone calls. Investigators stated that they exhausted all opportunities to collect data from patients and clinicians; however, in many cases, patients had changed addresses since the report, had their phones disconnected, or were homeless and could not be interviewed. Staff also commented that the

**Figure. Flow diagram of enhanced chronic hepatitis C surveillance in New York City: New York City Department of Health and Mental Hygiene, 2011**



HCV = hepatitis C virus

data collected were useful for characterizing patients for educational outreach as well as identifying what tests clinicians were ordering and why. They stated that analyzing a sample of cases allows DOHMH to obtain patient characteristics that are not available from laboratory reports alone and to identify unmet needs of the population. Staff deemed the data on risk factors and the type of facility making the HCV diagnosis especially valuable in devising new strategies for prevention and patient support.

## DISCUSSION

Although resource intensive, NYC's enhanced HCV surveillance project provides a detailed look at a sample of newly reported people and suggests opportunities to increase education and improve medical care. Patients properly informed of their diagnoses can take steps to improve their own health, including obtaining appropriate vaccinations, abstaining from drinking alcohol and other hepatotoxic drugs, and possibly undergoing treatment. For health departments, having detailed surveillance data allows for planning and outreach. The sample was generally representative of the newly reported HCV population in NYC. Clinician and patient answers were relatively consistent, with questions answered differently only 2.6% of the time.

We encountered expected difficulties in reaching patients for interviews, as addresses and phone numbers were often incorrect. We do not believe the patient interview rate could have been raised even with additional staff. Difficulty in reaching clinicians with insight into patients' risk factors and medical history was compounded by the fact that 30% of interviewed patients did not have primary care clinicians and that many patients were tested in nontraditional settings, such as substance abuse/detoxification centers, jail/prison, and psychiatric facilities.

The enhanced surveillance data show that about half of the patients (47.3%) were tested for HCV due to risk factor histories, as per Centers for Disease Control and Prevention (CDC) guidelines.<sup>15</sup> However, 40% of patients were tested for elevated LFTs or health problems, which suggests that many patients are not being diagnosed early enough, potentially limiting the possibility for medical management necessary to slow or prevent disease progression or prevent them from transmitting the infection to their close contacts.<sup>1,16</sup> CDC recently proposed a one-time screening of people born between 1945 and 1964 (baby boomers) to identify undetected chronic HCV infections, which could lead to earlier diagnoses and potentially decrease the

**Table 1. Enhanced HCV surveillance information from clinician and patient questionnaires: New York City, 2009–2011 (n=165)**

Demographic characteristic	N (percent)
Sex	
Male	102 (61.8)
Female	63 (38.2)
Year of birth	
<1935	8 (4.8)
1935–1944	11 (6.7)
1945–1954	51 (30.9)
1955–1964	38 (23.1)
1965–1974	32 (19.4)
1975–1984	17 (10.3)
1985+	8 (4.8)
Race/ethnicity	
Hispanic	54 (32.7)
Non-Hispanic black	54 (32.7)
Non-Hispanic white	35 (21.2)
Non-Hispanic Asian	8 (4.9)
Other	2 (1.2)
Unknown	12 (7.3)
Country of birth	
United States	83 (50.4)
Dominican Republic	5 (3.0)
Haiti	5 (3.0)
Pakistan	3 (1.8)
Russia	3 (1.8)
Cuba	2 (1.2)
Egypt	2 (1.2)
Greece	2 (1.2)
Uzbekistan	2 (1.2)
Other <sup>a</sup>	6 (3.6)
Unknown	52 (31.5)
Possible HCV risk factors <sup>b</sup>	
Injection drug use	71 (43.0)
Intranasal drug use	56 (33.9)
Been in jail or prison	54 (32.7)
Been diagnosed with a sexually transmitted disease	33 (20.0)
Had blood sugar tested or used a glucometer	31 (18.8)
Gotten a tattoo at a location other than a professional tattoo parlor	19 (11.5)
Received a blood transfusion or organ transplant prior to 1992 or clotting factor prior to 1987	18 (10.9)
Contact with someone who has hepatitis C	15 (9.1)
Dialysis	9 (5.5)
Gotten a piercing at a location other than a professional shop	9 (5.5)
Ever been employed in the medical/dental field	9 (5.5)
Men who had sex with men	6 (3.6)
Reason for HCV testing <sup>b</sup>	
Risk factors for chronic hepatitis C	78 (47.3)
Elevated liver function tests	48 (29.1)
Asymptomatic, prenatal, or donor screening	43 (26.1)

continued on p. 515

**Table 1 (continued). Enhanced HCV surveillance information from clinician and patient questionnaires: New York City, 2009–2011 (n=165)**

Demographic characteristic	N (percent)
Follow-up to previous detected hepatitis C marker	25 (15.2)
Hepatitis symptoms/health problems	18 (10.9)
Unknown	19 (11.5)
Speaks English	
Yes	120 (72.7)
No	13 (7.9)
Unknown	32 (19.4)
HIV infection	
Yes	19 (11.5)
No	106 (64.3)
Unknown	40 (24.2)
Homeless	
Yes	9 (5.5)
No	156 (94.5)
Cirrhosis	
Yes	8 (4.9)
No	86 (52.1)
Unknown	71 (43.0)
Health insurance	
Yes	118 (71.5)
No	11 (6.7)
Unknown	36 (21.8)
Type of insurance <sup>b</sup>	
Public	98 (83.1)
Medicaid	82 (69.5)
Medicare	20 (17.0)
Private	23 (19.5)

<sup>a</sup>Albania (1), Myanmar (1), China (1), Georgia Republic (1), Guinea (1), and South Korea (1)

<sup>b</sup>Not mutually exclusive

HCV = hepatitis C virus

HIV = human immunodeficiency virus

chances of complications such as cirrhosis and liver cancer.<sup>17</sup>

Unknown race/ethnicity for routine HCV surveillance data has previously been reported as 73.6% in NYC and 51%–52% nationally.<sup>18,19</sup> With our enhanced HCV surveillance investigations, we reduced the proportion in our sample with unknown status to 7.3%. Non-Hispanic black people represented 32.7% of our sample compared with only 22.8% of the NYC population.<sup>20</sup> This disparity should be addressed by considering educational campaigns targeted specifically toward non-Hispanic black people in NYC.

Half of interviewed patients requested the “Hepatitis C: The Facts” educational booklet, and more than one-quarter of RNA-positive patients not already attending an HCV support group were interested in doing so.

This finding suggests that there are unmet educational needs in the HCV population. DOHMH developed a website that lists local HCV support groups and other patient resources and will continue distributing educational booklets to all newly reported patients.<sup>21</sup> Increased educational initiatives specifically targeting substance abuse/detoxification centers should be considered, as injection (43%) and intranasal (33.9%) drug use were the most common risk factors and 25% of patients were diagnosed in these facilities.

The data demonstrate that some newly reported patients are not receiving basic recommended medical services. One-third of patients did not receive a follow-up RNA test to determine whether they were chronically infected and, therefore, eligible for treatment. A separate article describes this population and the importance of RNA testing in detail.<sup>22</sup> The DOHMH is exploring options to increase the percentage of antibody-positive patients with known HCV infection status. Furthermore, nearly 40% of clinicians did not counsel their patients about HCV transmission or alcohol use. Alcohol is the most important modifiable risk factor to prevent progression of liver disease.<sup>23–27</sup> Additionally, even though hepatitis A and B vaccination is recommended for HCV patients, more than half of patients had unknown status or were susceptible to one or both viruses.<sup>14,28,29</sup>

**Table 2. Enhanced HCV surveillance information from clinician questionnaires: New York City, 2009–2011 (n=164)**

Surveillance information	N (percent)
Facility type where patient diagnosed	
Inpatient	42 (25.5)
Inpatient and outpatient	6 (3.7)
Outpatient	108 (65.9)
Unknown	8 (4.9)
Substance abuse/detoxification center	
Yes	41 (25.0)
No	115 (70.1)
Unknown	8 (4.9)
Jail/prison	
Yes	11 (6.7)
No	145 (88.4)
Unknown	8 (4.9)
Clinician's estimate of when patient was infected with HCV	
Past 12 months	7 (4.3)
1–5 years ago	14 (8.5)
>5 years ago	27 (16.5)
Unknown	116 (70.7)

HCV = hepatitis C virus

Although routine surveillance data on all people with HCV provide only basic information, we collected detailed demographic, clinical, and epidemiologic information by investigating a representative sample in enhanced surveillance. We used these detailed findings to develop educational materials, such as an HCV bulletin for primary care clinicians that details the need for RNA testing, counseling, and clinical management of HCV patients. Enhanced surveillance data on country of birth and primary language spoken also allowed us to prioritize translation of educational materials. DOHMH further described patients' unmet needs in terms of education, vaccination, support groups, and RNA testing to share with other stakeholders who address these needs.<sup>30,31</sup>

The 2010 IOM report's call to action proposes that health departments investigate all acute and chronic HCV and HBV cases. However, the volume of newly reported HCV cases annually in NYC would require 35,000 person-hours a year, which far exceeds available resources. Sampling, therefore, is the only feasible option. Similar sampling has been used for previous

**Table 3. Enhanced HCV surveillance information from patient questionnaires: New York City, 2009–2011 (n=77)**

Surveillance information	N (percent)
Has a primary care physician	
Yes	53 (68.8)
No	15 (19.5)
Unknown	9 (11.7)
Requested HCV educational booklet, "Hepatitis C: The Facts"	
Yes	38 (49.4)
No	18 (23.4)
Unknown	21 (27.3)
Interested in attending an HCV support group—RNA-positive only (n=55) <sup>a</sup>	
Yes	17 (30.9)
No	23 (41.8)
Already attend	1 (1.8)
Unknown	14 (25.5)
Reason for interest in attending an HCV support group—RNA-positive only (n=55) <sup>a,b</sup>	
Learn more about HCV	13 (23.6)
Emotional support	8 (14.5)
Get help with treatment/dealing with side effects	8 (14.5)
Get assistance with substance abuse	3 (5.5)

<sup>a</sup>Calculated out of 55 RNA-positive interviewed patients, as questions were only asked of patients

<sup>b</sup>Not mutually exclusive

HCV = hepatitis C virus

RNA = ribonucleic acid

**Table 4. Enhanced HCV surveillance information from clinician questionnaires for RNA-positive patients: New York City, 2009–2011 (n=98)**

Surveillance information	N (percent)
Hepatitis A status	
Immune	38 (38.3)
Susceptible	17 (17.3)
Unknown	43 (43.9)
Hepatitis B status	
Immune	39 (39.8)
Susceptible	28 (28.6)
Unknown	31 (31.6)
Clinician counseled the patient about HCV transmission	
Yes	60 (61.2)
No	6 (6.1)
Will counsel at next visit	9 (9.2)
Unknown	23 (23.5)
Clinician counseled the patient about alcohol use	
Yes	60 (61.2)
No	15 (15.3)
Will counsel at next visit	5 (5.1)
Unknown	18 (18.4)
Patient is on antiviral treatment	
Yes	13 (13.3)
No	59 (60.2)
Planning to start soon	11 (11.2)
Unknown	15 (15.3)

HCV = hepatitis C virus

RNA = ribonucleic acid

HCV projects and for surveillance on other high-volume diseases such as chronic hepatitis B, influenza, Lyme disease, and gonorrhea.<sup>30,32–35</sup> We believe that the IOM's goals can be achieved through additional funding to continue and improve this type of enhanced surveillance system.

### Limitations

This study had certain limitations. Unknown answers from clinicians were common, likely because patients were tested in non-routine care settings (e.g., detoxification and correctional facilities) where their clinicians may not know them very well. It is important to balance sample size with completeness, which is why NYC elected to investigate a small sample to achieve a high clinician completion rate (99%). Interviewing patients was also difficult; 53% of patients were not interviewed. This interview rate is not surprising given the population's mobility, and the rate is comparable with interview rates from other HCV studies ranging from 40%–68%.<sup>30,36,37</sup> Because many clinicians responded "unknown" to questions and we could not

interview half of the patients, we will continue to interview both clinicians and patients to obtain the most complete information possible. We were less successful in reaching incarcerated and homeless patients; thus, our interview data may not represent those with the greatest needs in terms of medical care and education. Surveillance data only include those reported to the health department with positive HCV tests; they do not include people untested and unaware of their HCV infection.

## CONCLUSIONS

HCV surveillance involving the investigation of every case requires a large commitment of staff resources, but investigating a representative sample of new reports is a feasible alternative. Collecting key demographic and clinical information on a sample of individuals reported with HCV allows health departments and other stakeholders to develop HCV educational initiatives and target preventive services.

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All data used in this analysis were collected as part of routine public health surveillance activities. Therefore, this study was exempt from institutional review board review.

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