

Unmet Needs Among People Reported With Hepatitis C, New York City

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Objective: This project sought to describe unmet needs among patients reported with hepatitis C in New York City. **Design:** From the New York City Health Department's hepatitis C surveillance database, we randomly selected patients whose positive hepatitis C test was in April or May 2005. In 2006, we interviewed patients by telephone and collected information from their clinicians or by medical record review. **Setting:** New York City. **Participants:** We interviewed 180 of the 387 eligible patients and collected information from clinicians for 145 of the 180 patients. **Main Outcome Measures:** These included whether patients had understood their clinicians' explanation of their hepatitis C diagnosis, if they had been counseled about not drinking alcohol, information about support group attendance, vaccination against hepatitis A and B, health status, treatment, and other factors. **Results:** Of the 180 patients, 7% stated that they had not understood their clinicians' explanation of their hepatitis C diagnosis, and 26% said that they had not been counseled about avoiding alcohol. Among the 90% of patients who had not attended a hepatitis support group, 31% were interested in attending. Among the 145 patients with information from clinicians, at least 28% were susceptible to hepatitis A and 18% to hepatitis B. **Conclusions:** This hepatitis C surveillance project, with information from patients and clinicians, illustrates a valuable use of a chronic hepatitis C surveillance system. The patients described here had several unmet needs, including hepatitis A and B vaccination, basic information about the virus, support groups, and counseling about preventing further liver damage and preventing transmission to others. Relatively simple and affordable health department activities can address these needs, improving quality of life and decreasing the likelihood of liver disease progression.

KEY WORDS: education, hepatitis C, New York City, secondary prevention, support group, surveillance, unmet needs

Hepatitis C virus is the most common chronic blood-borne infection in the United States and is a leading cause of chronic liver disease.^{1,2} The estimated incidence of new hepatitis C infection in the United States has decreased significantly since the late 1980s, while the prevalence remains high.³ Most chronic infections are among people born between 1945 and 1964,^{1,4,5} and in some cases, liver disease will progress as the virus continues to damage the liver over time.^{3,6} Improving quality of life and limiting disease progression among people with chronic hepatitis C is a major clinical and public health priority.⁷

In up to 20% of patients, cirrhosis, liver cancer, or liver failure can develop, often decades after the initial infection; in other patients, no clinically significant liver damage occurs.^{6,8,9} The current standard of care for hepatitis C treatment is pegylated interferon plus ribavirin for 24 to 48 weeks; treatment is expensive, causes serious side effects, and is successful in only 40% to 80% of patients.⁸ Therefore, treatment may not be available, affordable, indicated, or effective for many patients. However, several simple and relatively inexpensive measures may improve quality of life, decrease the likelihood of liver disease progression, and decrease the likelihood of transmitting the virus to

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This work was supported in part by an Emerging Infections Program grant from the Centers for Disease Control and Prevention.

The authors thank the many New Yorkers who spoke to them about their experience with hepatitis C, their clinicians who provided information, and staff who assisted with data collection: Firas Ahmed, Erin Bassett-Novoa, Carrie Mahowald, Catherine Richards, David Labowitz, and Elizabeth Livingstone.

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DOI: 10.1097/PHH.0b013e3182053f1b

others. National guidelines recommend hepatitis A and B vaccination, alcohol avoidance, and counseling about preventing further transmission.⁸⁻¹⁰ Access to support groups may also be useful.^{11,12} Few published studies have examined what proportion of patients with hepatitis C receive the recommended prevention and supportive care measures, and little is known about unmet needs from the patients' perspective.¹³

We used New York City (NYC) Department of Health and Mental Hygiene chronic hepatitis C surveillance data and investigated a sample of hepatitis C patients in NYC to determine whether patients had received services recommended in the national guidelines and to identify unmet needs from the patients' perspective.

● Methods

The NYC Health Code requires health care providers and laboratories to report hepatitis C among NYC residents. Reportable positive test results include recombinant immunoblot assay, enzyme-linked immunosorbent assay with signal-to-cutoff ratio above the high threshold,¹⁴ or any hepatitis C nucleic acid test. Positive antibody tests with a low signal-to-cutoff ratio, or without any signal-to-cutoff ratio, are not reportable. The health department often receives multiple positive reports for a given patient. We use an automated algorithm to link multiple reports together for each patient in the hepatitis C surveillance database.

We generated a sample of all patients in the hepatitis C surveillance database who were reported to the Health Department with a diagnosis date in April or May 2005; we excluded patients younger than 18 years (less than 0.5%). From the resulting 7730 patients, we selected a simple random sample of 440 patients. We chose this sample size on the basis of the estimated time and staff resources available to complete the project. As the investigation proceeded, we excluded patients and discontinued data collection if the clinician stated that the patient was not infected with hepatitis C or if the patient was unaware of the hepatitis C diagnosis, was deceased, spoke neither English nor Spanish, or did not reside in NYC. We did not interview patients in other languages because of limited resources.

The NYC Department of Health and Mental Hygiene's institutional review board reviewed the project protocol and determined that it is not human subject research as defined by federal regulation; as such, institutional review board approval was not required. We interviewed patients by telephone, waiting 10 to 14 months after the positive hepatitis C test to allow time for the clinician to notify the patient about the positive test result, confirm the diagnosis, complete the

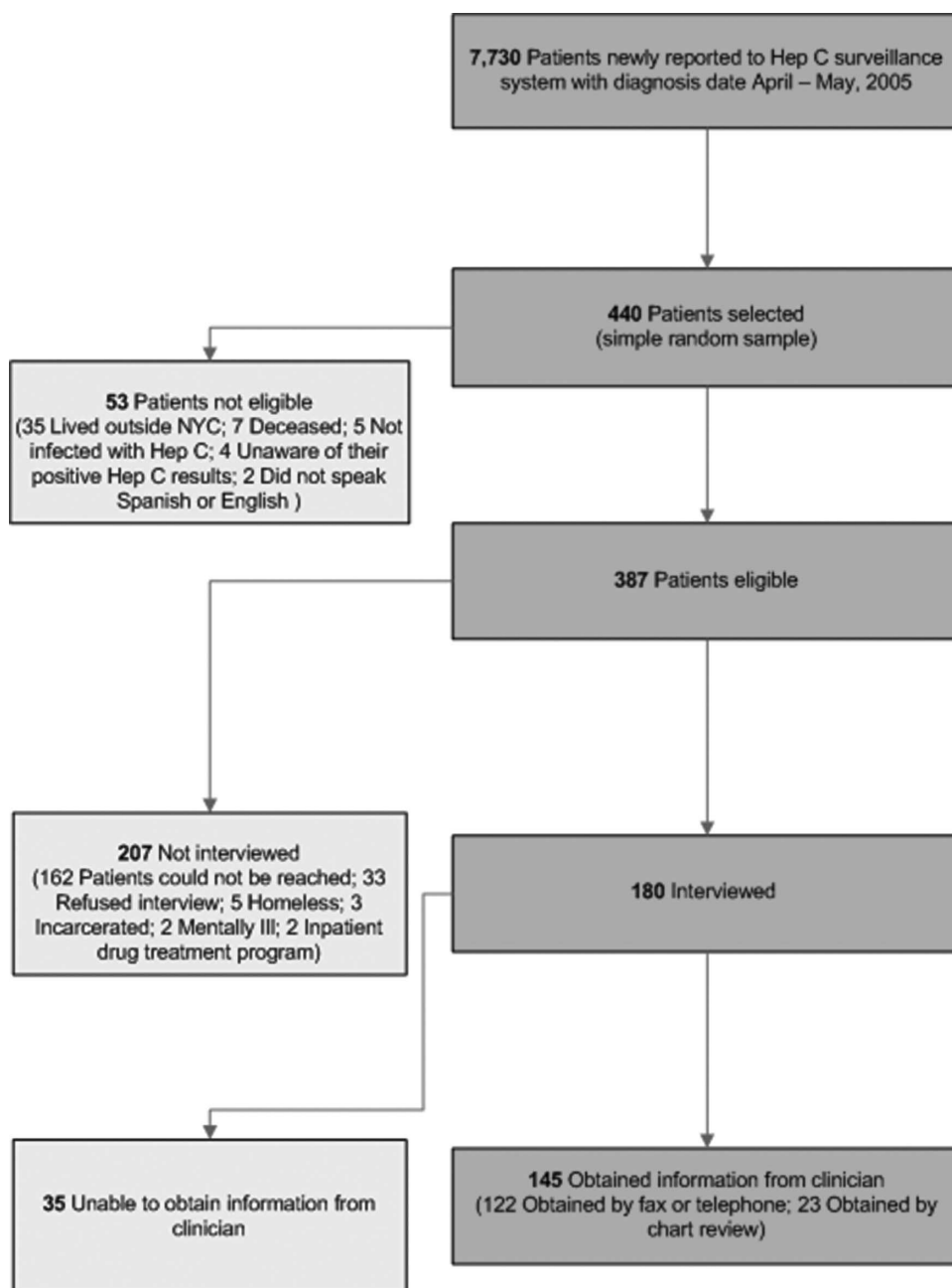
medical workup, evaluate for treatment, and provide indicated services, including counseling on preventing liver disease progression and transmission of the virus to others.

We telephoned patients a maximum of 7 times during both daytime and evenings. If we did not reach the patient, we then mailed a letter requesting that the patient telephone the Health Department for an interview. We mailed letters to patients whose telephone number was unavailable. During the interview, we first asked whether interviewees were already aware of their positive hepatitis C test, and if not, we explained their test results and advised them to follow up with their clinician; we did not interview these patients further and we excluded them from the analysis.

We asked patients whether their clinician had explained their hepatitis C diagnosis to them, and whether they had been counseled about not drinking alcohol and how to avoid transmitting the virus to other people. The Health Department routinely mails a hepatitis C education packet to newly reported patients, which includes basic information about the virus and advice on preventing liver disease progression. We asked whether patients had received this packet, and if so, whether they found it helpful. We also asked about hepatitis C risk factors, treatment and hepatitis A and B vaccination.

For the patients whom we interviewed, we then sought data from their primary care clinicians where possible, and otherwise from their specialists. We initially telephoned clinicians and asked them to complete a faxed data collection form or provide information over the phone. When clinicians did not provide information, we reviewed medical records. We collected information on hepatitis A, B and C laboratory tests, hepatitis A and B vaccination history, hepatitis C treatment, and counseling about alcohol use and preventing transmission to other people.

To assess immunity to hepatitis A and B, we examined serology results as well as vaccination history from the patient, the clinician, or the medical record. We classified patients as *immune* if they or their clinicians reported vaccination, or if their serology tests indicated immunity. We classified patients as *susceptible* to hepatitis B if hepatitis B surface antibody was negative. We classified patients as *susceptible* to hepatitis A if the hepatitis A antibody test was negative and neither the patient nor the clinician reported vaccination. We also classified patients as susceptible to hepatitis A or B if the reason given for not vaccinating was patient refusal or no access to affordable/available vaccine. We did not classify patients as susceptible if the only evidence was a statement from the patient or the clinician that the patient had not been vaccinated, since patients may have been immune because of prior infection. We

FIGURE ● Flow sheet: Sample selection and data collection.

classified patients as chronically infected with hepatitis B if there was a positive test for hepatitis B surface antigen or DNA. Discrepancies were examined further and classified on a case-by-case basis. Patients who were not classified as immune, susceptible, or chronically infected were classified as having unknown immunity to hepatitis A or B.

We used SAS v9.1 (SAS Institute, Cary, North Carolina) to summarize and analyze the data. We applied chi-square tests to compare patients interviewed with patients not interviewed and to compare patients for

whom we obtained information from clinicians or medical records with patients for whom we did not obtain such information.

● Results

Of 440 patients in the sample, 387 were eligible for investigation; 53 were excluded for reasons detailed in the Figure. We interviewed 180 patients and obtained information from clinicians for 145 of these 180 patients.

TABLE 1 • Comparison of Patients for Whom Data Were or Were Not Obtained, New York City, 2006 (n = 387)

	Patients Interviewed		Patients Not Interviewed		χ^2 P	Patients for Whom Data Was Obtained From Clinician or Chart		Patients for Whom Data Was Not Obtained From Clinician or Chart		χ^2 P
	n	row, %	n	row, %		n	row, %	n	row, %	
Total	180		207			145		242		
Sex										
Male	98	43	132	57	0.03 ^a	79	34	153	66	.03 ^a
Female	82	54	70	46		66	44	84	56%	
Unknown	0		5			0		5		
Age group, y										
15-39	11	32	23	68	0.22 ^b	8	24	26	76	.83 ^b
40-49	59	45	71	55		49	38	81	62	
50-59	77	52	72	48		59	40	90	60	
60+	33	49	35	51		29	43	39	57	
Unknown	0	0	6	100		0	0	6	100	

^aP value excludes those with unknown sex.

^bP value excludes those with unknown age.

We compared the 180 interviewed patients with the 207 patients who were eligible but not interviewed, on sex and age group (Table 1, left side). We interviewed a larger proportion of eligible women than eligible men (54% vs 43%, $P = 0.03$). Similarly, we obtained information from clinicians or chart review for a larger proportion of women than men (44% vs 34%, $P = 0.03$) (Table 1, right side). By age group, there were no statistically significant differences in the proportion we interviewed or for whom we obtained information from clinicians.

Among 180 patients interviewed (Table 2), 56% were male and 77% were born between 1945 and 1964 (ages 42-61 years at the time of interview). Patients were roughly evenly split between Hispanic (29%), white non-Hispanic (27%), and black non-Hispanic (31%); 66% were born in the United States (excluding US territories). Although we sampled patients reported to the NYC Health Department with a positive hepatitis C test in April or May 2005, most patients reported that they had tested positive earlier (51% first tested positive in 2004 or 2005, 19% in 2000-2003, and 28% before 2000).

Most patients (89%) were insured, 67% rated their overall health status as excellent or good, and 9% reported that they had been hospitalized for liver problems. When asked "how do you think you got hepatitis C?" 34% of patients reported injection drug use, 16% reported transfusion, 8% reported sexual transmission, 33% said they did not know, and the remaining 8% refused to answer the question or gave another reason. Of 180 interviewed patients, 51 (28%) said that they had not been counseled about how to prevent spreading hepatitis C to others, and 47 (26%) said that they

had not been counseled about avoiding alcohol. Overall, 31 of the 180 (17%) patients reported that they drank alcohol.

Among these 180 patients, all of whom had been informed by their clinicians about their positive hepatitis C test results, 13 (7%) stated that they had not fully understood what their clinician had told them about their hepatitis C diagnosis. Forty-four patients (24%) reported receiving the hepatitis C information packet from the Health Department; of these, 82% rated the packet as helpful or very helpful, and 48% said they learned new information from it.

Of 180 patients, 15 (8%) stated that they had attended a support group for hepatitis. Among the 162 patients who had not attended a support group, 31% said that they were interested in attending such a group.

Information for 145 patients for whom we collected information from the clinician or the medical record is presented in Table 3. Of the 145 patients, 68 (47%) had evidence of immunity to hepatitis A, 40 (28%) were susceptible to hepatitis A, and 37 (26%) had unknown immunity status. For hepatitis B, of the 145 patients, 5 (3%) had chronic infection, 97 (67%) were immune, 26 (18%) were susceptible to hepatitis B, and 17 (12%) had unknown hepatitis B immunity status.

● Discussion

In this enhanced surveillance project, we collected information from both patients and clinicians to assess the proportion of patients who received recommended hepatitis C services and prevention measures. Patients

TABLE 2 • Information From Hepatitis C Patient Interviews, New York City, 2006 (n = 180)

	n	%			
Sex			How is your health?		
Male	100	55.6	Excellent	54	30.0
Female	80	44.4	Good	66	36.7
Year of birth			Fair	36	20.0
1925-1934	9	5.0	Poor	24	13.3
1935-1944	16	8.9	Have you ever been hospitalized for liver problems?		
1945-1954	70	38.9	Yes	17	9.4
1955-1964	68	37.8	No	161	89.4
1965-1974	17	9.4	Unknown	2	1.1
Age group, y			Did you ever have liver function or liver enzyme tests?		
15-39	11	6.0	Yes	157	87.2
40-49	59	33.0	No	16	8.9
50-59	77	43.0	Unknown	7	3.9
60-69	23	12.8	Did you ever have a liver biopsy?		
70+	10	5.6	Yes	80	44.4
Race ethnicity			No	98	54.4
White Non-Hispanic	49	27.2	Unknown	2	1.1
Asian/Pacific Islander Non-Hispanic	13	7.2	Have you taken interferon or ribavirin?		
Black Non-Hispanic	56	31.1	Yes	74	41.1
Hispanic, any race	52	28.9	Planning to start soon	16	8.9
Other/unknown	10	5.5	No	89	49.4
Where were you born?			Unknown	1	0.6
USA (50 states and DC)	119	66.1	Do you work? (among 147 patients under 60)		
Caribbean/Central and South America	13	7.2	Yes, full- or part-time	64	43.5
Europe	10	5.6	No	79	53.7
US Territory	16	8.9	Other/unknown	4	2.7
Other	19	10.6	How do you think you got hepatitis C?		
Unknown	3	1.7	Injection drug use	62	34.0
When was your first positive hepatitis C test?			Transfusion	28	15.6
2004-2005	92	51.1	Sex	15	8.3
2000-2003	35	19.4	Other	13	7.2
<2000	51	28.3	Unknown	60	33.3
Unknown	2	1.1	Refused	2	1.1
Do you have health insurance?			Were you counseled about preventing spreading hepatitis C to others?		
Yes, private	74	41.1	Yes	121	67.2
Yes, public	87	48.3	No	51	28.3
No	15	8.3	Unknown	8	4.4
Unknown	4	2.2	Were you counseled about avoiding alcohol?		
What kind of clinician do you see for your hepatitis?			Yes	127	70.6
Internist or general practitioner	51	28.3	No	47	26.1
Gastroenterologist	81	45.0	Unknown	6	3.3
Hepatologist	12	6.7	Do you drink alcohol?		
Infectious disease	13	7.2	Yes	31	17.2
Unknown	23	12.8	≤1 drink per day	19	
Why were you first tested for hepatitis C?			>1 drink on some days	12	
Risk factor	60	33.3	No	146	81.1
Elevated liver function tests	48	26.7	Unknown	3	1.7
Symptoms	26	14.4	Did your clinician explain your test results to you?		
Unknown	46	25.6	Yes	167	92.8
			Yes, but I didn't understand	13	7.2
			Did you receive the information packet from the Health Dept?		
			Yes	44	24.4
			No	136	75.6

(continues)

(continues)

TABLE 2 ● Information From Hepatitis C Patient Interviews, New York City, 2006 (n = 180) (Continued)

	n	%
If received, did you find the packet helpful?		
Very helpful	11	25.0
Helpful	25	56.8
Not helpful	7	15.9
Unknown	1	2.3
If received, did you learn anything new from the packet?		
Yes, most info new	14	31.8
Yes, a few things were new	7	15.9
No	21	47.7
Unknown	2	4.5
Did you ever attend a hepatitis C support group?		
Yes	15	8.3
No	162	90.0
Unknown	3	1.7
If no, are you interested in attending one?		
Yes	50	30.9
No	105	64.8
Unknown	7	4.3

in this study had similar demographic characteristics and risk factors to previously described hepatitis C populations in the United States and in NYC.^{1,4,15} Few had extensive liver disease and two-thirds rated their health as good or excellent; most have health insurance.

However, unmet needs were identified: over one-quarter were still susceptible to hepatitis A or B, and about one-quarter said that they had not been counseled about avoiding alcohol or preventing transmission to other people. Many said that they wanted to attend a support group and a few said that they had not understood their doctors' explanation of their hepatitis C test results. Most of those who received the Health Department's hepatitis C information packet found it helpful, suggesting a need for basic information in this group.

Alcohol use is the most important modifiable cofactor for progression of hepatitis C-induced liver disease.^{6,16-19} National guidelines advise clinicians to give people with hepatitis C several important counseling messages, including avoiding alcohol.^{8,9} In our sample, 63% of patients said that they had been counseled to avoid alcohol. This is somewhat higher than the 47% who reported such counseling in a 2003 survey of patients with hepatitis C reported to King County Health Department.¹³ Clearly though, there are many patients whose clinicians do not counsel them, or who do not receive, understand or remember the message. In our sample, 17% of patients reported continuing alcohol use, increasing their risk for liver damage. The

TABLE 3 ● Information From Clinician or Medical Record for Hepatitis C Patients, New York City, 2006 (n = 145)

	n	%
Was patient counseled on preventing spread of hepatitis C to others?		
Yes	111	76.6%
No	34	23.5%
Was patient counseled about avoiding alcohol? (among the 23 patients who drink according to the clinician)		
Yes	15	65.2%
No	3	13.0%
Unknown	5	21.7%
Did this patient have any signs of hepatitis on physical exam?		
Yes	18	12.4%
No	127	87.6%
Was hepatitis C RNA testing done?		
Yes	121	83.4%
No	3	2.1%
Unknown	21	14.5%
Hepatitis A status*		
Immune	68	46.9%
Susceptible	40	27.6%
Unknown	37	25.5%
Hepatitis B status*		
Immune	97	66.9%
Susceptible	26	17.9%
Chronic	5	3.5%
Unknown	17	11.7%

*To classify hepatitis A and B immunity status, we used information from patient interviews in addition to laboratory information and information from clinicians; see the "Methods" section for details.

reasons for incomplete counseling, for patients not recalling counseling, or for patients continuing to drink, are unclear. A recent report of patient and provider interviews and focus groups found that providers give, and patients receive, mixed messages about the importance of avoiding alcohol.²⁰ More work is needed to identify reasons for continued alcohol use among some people with hepatitis C and effective approaches to assist patients with this important behavior change; support groups or clinical information about hepatitis C may help.

Counseling about transmission to others is important to ensure that patients do not donate blood or share needles or drug injection equipment. Conversely, patients need to know that routine household interactions do not pose a risk for transmission, and that changes in sexual practices with long-term monogamous partners are not recommended.²¹ Nearly a quarter of patients said that they had not been counseled about how to avoid transmission to other people; providing this information more than once, or both verbally and in writing, may help.

National guidelines recommend hepatitis A and B vaccine for people with chronic hepatitis C if they are susceptible.⁸ Although we had incomplete information, this project identified that at least 28% of patients were susceptible to hepatitis A, and 18% to hepatitis B. This finding is troubling because hepatitis A and B can be very severe in patients with preexisting liver disease.^{8,9}

Overall, these results illustrate possible gaps in providing recommended services; published surveys also have demonstrated gaps in primary care clinicians' knowledge around hepatitis C.²² In response, the NYC Department of Health and Mental Hygiene developed educational materials for primary care clinicians to increase their hepatitis C knowledge and expertise, for example, encouraging vaccination against hepatitis A and B, and counseling about avoiding alcohol and preventing transmission to other people.²³ For patients who cannot afford the vaccines and who do not have insurance to cover vaccination, our Health Department also provides free hepatitis A and B vaccination at sexually transmitted disease clinics.

A few patients stated that their clinicians had not fully explained their positive hepatitis C tests results. Also, most patients who received the Health Department's information packet found it helpful and half said that it provided new information. These findings show ongoing needs for information in this population, which can be addressed by clinicians, community groups, or health departments. In light of these findings, our Health Department updated and reformatted the hepatitis C materials we routinely mail to newly reported hepatitis C patients.²⁴ The booklets highlight the importance of alcohol avoidance and hepatitis A and B vaccination, getting support, and information about how the virus can and cannot be transmitted. Also, we worked with laboratories to increase the completeness of patient addresses in the surveillance reports, allowing us to mail the booklet to more patients. We translated the booklets into the languages most common among New Yorkers with hepatitis C. In addition to routinely mailing the booklets to newly reported patients, we also began distributing them through community groups and clinicians.

While only 8% of the patients in this study had attended support groups, 31% were interested in doing so. Research shows that support groups can be helpful for people with hepatitis C and may help patients complete antiviral treatment and reduce alcohol use.^{11,12, 25-28} In one study, the most common reason patients gave for attending a hepatitis C support group, and the most common benefit they obtained, was to get accurate and reliable hepatitis C information.¹¹ Because of stigma about this virus, many patients do not disclose their infection to family and friends, so obtaining emotional and social support is another common benefit of sup-

port groups.^{11,26} For the patients in this study, it is unclear whether the interest in support groups reflects a desire for medical information about hepatitis C, emotional and social support, support during treatment, or other factors, and this question deserves further study. Our results illustrate the need for more support groups, more accessible information about their availability, or both. In response to this, our Health Department developed and continues to expand a referral directory of support groups.²⁹

There were a few limitations with this study. Most of the patients described here are insured and in care, and therefore our findings are not generalizable to all people with hepatitis C in NYC. The response rate for patient interviews was 47%. A larger sample or a higher response rate would have allowed more confidence in our findings. It should be noted that all efforts to interview patients were exhausted, and that limited staff time was not a factor in our ability to interview patients but rather, reflect NYC's hepatitis C population: many patients were unreachable, had moved or changed phone numbers, had changed clinicians, or were lost to follow-up by their clinicians. Response rates were higher for women than for men. Patients with less stable lives (including those using illicit drugs) are generally hard to reach and therefore may be less likely to be represented here. Only 25% of patients reported receiving the Health Department's information packet. Often, surveillance reports lack patients' address and therefore we do not mail the packet (since 2007, the completeness of patient address information has improved substantially). Patients who especially liked or disliked the packet may have been more likely to recall it and report their reaction during the interview, which may bias our findings.

In interpreting these results, it should be kept in mind that the population described here includes only hepatitis C patients reported to the NYC Department of Health. The study population excludes people with undiagnosed hepatitis C. It also excludes people who had only a positive antibody test without a high signal-to-cutoff ratio, because they were never reported to the surveillance system. Such excluded patients may have less access to care and have different needs from those described here.

● Conclusion

This enhanced hepatitis C surveillance project from the NYC Department of Health and Mental Hygiene, with information from both patients and their clinicians, illustrates one of the valuable uses of a chronic hepatitis C surveillance system. While surveillance is labor-intensive, especially when the prevalence is high, it can

provide essential information for understanding the needs of the local population with hepatitis C and developing strategies to improve their health and access to prevention and counseling services. Since 2005, the Centers for Disease Control and Prevention has funded the NYC Department of Health and Mental Hygiene to conduct enhanced surveillance for acute and chronic viral hepatitis. The level of funding, the limited staffing and the large volume of hepatitis C reports (more than 15 000 patients are newly reported each year)¹⁵ precludes investigation of every patient. However, investigation of a sample, as done for this project, can greatly enhance surveillance data, provide valuable information about the population with hepatitis C, and allow the rapid development of health department initiatives to address unmet needs. Additional funding is needed for hepatitis C surveillance, screening, and primary and secondary prevention services. The patients with hepatitis C described here have several unmet needs, including basic information about the virus, hepatitis A and B vaccination, support groups, and counseling. Relatively simple and affordable health department activities can address these needs.

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