Hepatitis C Point-of-Care Screening in Retail Pharmacies in the United States

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Abstract: *Background and Aims:* Approximately half of adults with hepatitis C in the United States do not know their infection status, and the majority of persons who know they are positive for hepatitis C virus (HCV) antibodies fail to receive care. We conducted a screening program in retail pharmacies and calculated the percentages of anti-HCV–positive individuals and how many subsequently entered a pathway to care. *Methods:* At 45 Walgreens retail pharmacies in 9 US cities, direct store advertising was used to recruit individuals for HCV antibody testing. Participants were at least 18 years old with at least 1 HCV risk factor, such as being born between 1945 and 1965. One day per week at each site, a phlebotomist obtained consent from interested participants and performed the testing. Within 3 business days, an HCV management specialist contacted anti-HCV–positive individuals and provided test results and a pathway for obtaining HCV RNA testing. During the following 21 to 28 days, the same HCV management specialist telephoned individuals to determine whether they underwent an HCV RNA test. *Results:* Between September 2015 and February 2016, 1298 individuals consented. Two patients withdrew consent after testing. In all, 8% (103/1296) were HCV antibody–positive; of them, 91 (88%) were contacted by an HCV management specialist. During the 21- to 28-day follow-up, 56 individuals (62%; 56/91) were reached by an HCV management specialist, and 29 (52%; 29/56) confirmed that an HCV RNA test was ordered. *Conclusions:* These results provide evidence in support of point-of-care HCV screening in retail pharmacies for at-risk individuals in the United States.

In the United States, an estimated 1.3% of adults are positive for hepatitis C virus (HCV) antibody.[1] The prevalence is higher in certain populations, such as African Americans (3%)[2] and persons born between 1945 and 1965 (3.25%; the Baby Boomer Generation).[3] The Baby Boomer Generation accounts for an estimated three-fourths of persons with chronic hepatitis C in the United States,[3] and as the age of this cohort increases, so does the risk for progression of liver disease. Prior to 2012, the Centers for Disease

Control and Prevention (CDC) recommended that HCV screening be based on risk factors such as injected drug use, long-term hemodialysis, or receipt of a blood transfusion prior to July 1992.[4] In 2012, the CDC expanded its screening guidelines to recommend one-time HCV screening for all persons born between 1945 and 1965.[3]

The CDC's recommendation for expanded screening was made amid a changing HCV treatment landscape. Prior to 2013, all HCV regimens contained interferon, which is administered by subcutaneous injection and has poor tolerability. In addition to poor tolerability, treatment was only successful in approximately 40% of patients.[5] Currently, nearly all patients chronically infected with HCV can be cured with oral combinations of HCV direct-acting antivirals with high efficacy and generally minor adverse effects.[6] Successful treatment of HCV in patients with advanced liver disease substantially decreases the risks for hepatic decompensation events, hepatocellular carcinoma, liver transplantation, and both all-cause and liver-related mortality.[7-11] Unfortunately, although improved HCV treatment regimens are available, approximately half of Americans who are anti-HCV–positive are unaware of their infection status.[12]

The CDC has recommended that HCV screening be done using HCV antibody tests that have been approved by the US Food and Drug Administration.[13] Such tests are either laboratory-based assays ordered by health care providers or assays performed at the site of patient care. Increased accessibility of point-of-care tests means that they have the potential to increase the number of individuals who know their infection status. However, even among those who know they are anti-HCV–positive, barriers to confirming the diagnosis and receiving treatment are considerable, and the majority fail to receive care.[14,15]

Using point-of-care testing, we conducted an HCV screening program at retail Walgreens pharmacies within 9 major cities in the United States. In addition to determining the prevalence of anti-HCV positivity among individuals with HCV risk factors, we determined how many anti-HCV–positive individuals subsequently obtained an order for a confirmatory HCV RNA test.

Methods

Study Site Locations

In this screening study, participating sites were Walgreens pharmacies located in 9 major metropolitan areas in the United States (Chicago, Dallas, Houston, Miami, New York, Oakland, Philadelphia, Phoenix, and San Antonio). Each market had 5 stores and 1 assigned phlebotomist. Testing was performed at each store 1 day per week. Phlebotomists were contract employees from Maxim Staffing Solutions and were trained on the protocol and on administering informed consent. A private room for testing was utilized at each store. Participants were recruited by direct advertising in the stores. The protocol and informed consent process were approved by a central institutional review board.

Inclusion Criteria and Process for Study Entry

Participants were male or female within the birth cohort (born between 1945-1965, inclusive) or, if outside the birth cohort window, at least 18 years of age with CDC-defined high-risk factors for chronic hepatitis C. Participants had to be able to read and understand English and be willing to give written informed consent. Participants also had to provide an e-mail address and a telephone number in order to receive test results.

Interested individuals were given an informed consent form and literature on CDC-defined risk factors for hepatitis C. After consenting to participate, individuals completed a screening form.

Antibody Testing

The presence of HCV antibody was assayed using the OraQuick HCV Rapid Antibody Test (OraSure Technologies) from whole blood obtained through a finger stick. Each phlebotomist received personal training on administration of the antibody test and interpretation of the results. Each participant's information, including the OraQuick result, was entered into an electronic database (Part 11–compliant) by the phlebotomist on the same day of testing.

Communication of Results and Linkage to Follow-Up

After undergoing the blood draw, participants were provided with written instructions to wait for either an e-mail from the Chronic Liver Disease Foundation or a call from an HCV management specialist from the Help-4-Hep organization.

HCV Antibody–Negative Results Individuals who had a negative test result were notified via e-mail within 3 business days. If the e-mail message was unable to be delivered, individuals were contacted by an HCV management specialist via telephone.

HCV Antibody–Positive Results Individuals who had a positive test result were contacted by an HCV management specialist by telephone within 3 business days. The HCV management specialist communicated the positive test result, explained the test result, and provided information for a pathway to care for follow-up testing and education. Twenty-one to 28 days after the initial contact, the HCV management specialist followed up with the individual by telephone. The HCV management

Table 1. Patient Demographics

Demographics	Total (N=1296)	HCV Antibody	
		Positive (n=103)	Negative (n=1193)
Sex, n (%)			
Female	732 (56)	34 (33)	698 (59)
Male	564 (44)	69 (67)	495 (41)
Race, n (%)			
White	525 (41)	42 (41)	483 (40)
Black or African American	433 (33)	38 (37)	395 (33)
Asian	68 (5)	1 (1)	67 (6)
American Indian, Alaska Native, Native Hawaiian, or other Pacific Islander	32 (2)	3 (3)	29 (2)
Mixed race	237 (18)	19 (18)	218 (18)
Unknown	1 (1)	0	1 (1)
HCV Risk Factors, n (%)			
Birth year 1945-1965	531 (41)	57 (55)	474 (40)
Injection drug use (past or current)	90 (7)	40 (39)	50 (4)
Blood transfusion before 1992	88 (7)	15 (15)	73 (6)
Long-term hemodialysis	7 (0.5)	2 (2)	5 (0.4)
Born to an HCV-infected mother	5 (0.4)	1 (1)	4 (0.3)
Incarceration	132 (10)	41 (40)	91 (8)
Intranasal drug use	115 (9)	32 (31)	83 (7)
Tattoo	770 (59)	52 (50)	718 (60)
Other	303 (2)	5 (5)	298 (25)
Age Distribution, yrs, n (%)			
18-29	233 (18)	7 (7)	226 (19)
30-39	213 (16)	10 (10)	203 (17)
40-49	204 (16)	20 (19)	184 (15)
50-59	283 (22)	32 (31)	251 (21)
60-69	238 (18)	26 (25)	212 (18)
≥70	125 (10)	8 (8)	117 (10)

HCV, hepatitis C virus.

specialist asked if an HCV RNA test was ordered. At least 3 attempts were made to contact each individual.

Statistical Analyses

The analysis population was all individuals who properly consented, maintained consent, and had an interpretable result from a hepatitis C antibody test. The primary endpoint was the percentage of individuals with a positive hepatitis C antibody test result who subsequently underwent HCV RNA testing. The secondary endpoint was the percentage of individuals with a positive hepatitis C antibody test result.

Results

Individuals and Site Locations

Among the 9 metropolitan areas, a total of 1298 participants (Table 1) underwent screening. Two persons signed

Table 2. Numbers of Individuals Screened and Testing Positive for HCV Antibody Per City

City	First Site Opened	Last Site Closed	Number of Days Open[a]	Number of Individuals Screened	Number of Individuals Antibody-Positive
Chicago, Illinois	Oct 20, 2015	Feb 5, 2016	75	166	12
Dallas, Texas	Oct 15, 2015	Dec 11, 2015	41	33	3
Houston, Texas	Sept 22, 2015	Jan 22, 2016	85	63	9
Miami, Florida	Oct 1, 2015	Feb 5, 2016	88	101	8
New York, New York	Sept 16, 2015	Feb 5, 2016	100	183	9
Oakland, California	Sept 28, 2015	Feb 5, 2016	91	232	13
Philadelphia, Pennsylvania	Sept 15, 2015	Feb 5, 2016	100	255	17
Phoenix, Arizona	Sept 22, 2015	Dec 11, 2015	58	26	3
San Antonio, Texas	Oct 13, 2015	Feb 5, 2016	81	237	29
			Total	1296	103

[a]Excluding weekends and holidays.

Dec, December; Feb, February; HCV, hepatitis C virus; Jan, January; Oct, October; Sept, September.

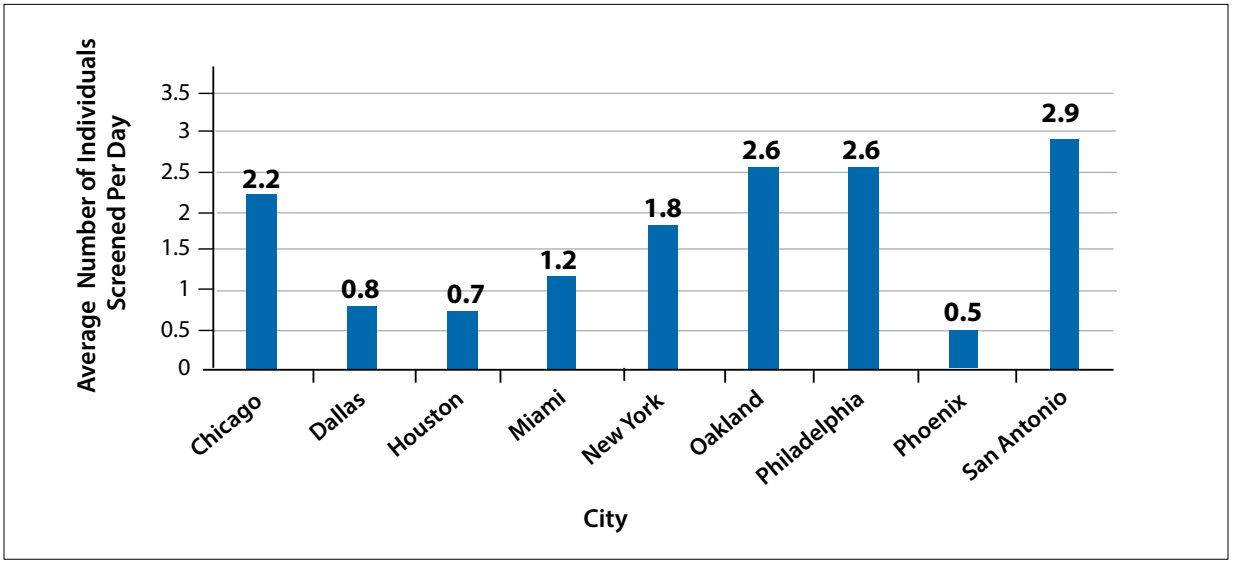

Figure 1. Average number of individuals screened per day by city.

informed consent, were tested for HCV antibody, and subsequently withdrew consent; these 2 patients were removed from analyses. Fifty-six percent (732/1296) of individuals screened were female. Forty-one percent were white, and 33% were black or African American. The HCV risk factor most commonly identified was getting a tattoo (59%), followed by birth year from 1945 to 1965 (41%). Half of the individuals screened were 50 years or older.

The first sites were opened in September 2015, and the last sites were closed in February 2016 (Table 2). Within 6 of the metropolitan areas, more than 100 persons were screened. The metropolitan area with the highest number of individuals screened overall was Philadelphia (n=255). San Antonio had the highest number of individuals screened per day, 2.9 (Figure 1).

Prevalence of Anti-HCV Positivity and Linkage to Care

A total of 8% of individuals (103/1296) were HCV antibody–positive. Fifty-five percent (57/103) of those who tested positive for HCV antibody were in the Baby

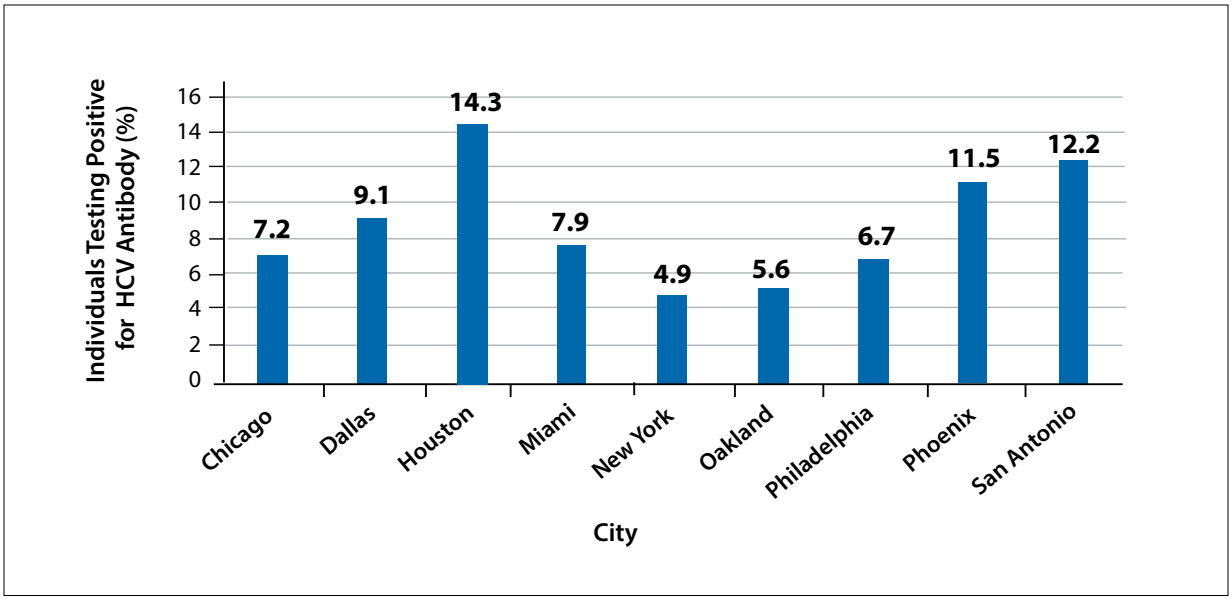

Figure 2. Percentage of individuals testing positive for HCV antibody per city.

HCV, hepatitis C virus.

Boomer Generation, and 11% (57/531) of Baby Boomers were anti-HCV–positive. The city of Houston had the highest prevalence of individuals being HCV antibody–positive, 14% (Figure 2). New York had the lowest prevalence, 5%.

Of persons who tested anti-HCV–positive, 91 (88%) were successfully contacted by an HCV management specialist (Figure 3). Twelve patients (12%) were unable to be reached. During the 21- to 28-day follow-up period, 56 patients (62%; 56/91) were reached by an HCV management specialist, and 29 (52%; 29/56) confirmed that HCV RNA testing was done.

Discussion

Our results indicate that targeted screening using point-of-care technology in urban retail pharmacies is a successful approach for identifying persons with HCV infection. During the 6 months of our screening program, a total of 1298 at-risk individuals underwent testing for HCV antibody at 45 pharmacies in metropolitan areas in the United States. Among the population screened, the most commonly identified HCV risk factor was getting a tattoo (59%), followed by being in the 1945-to-1965 birth cohort (41%). Fewer than 10% of individuals reported a history of incarceration, intranasal drug use, injection drug use, or blood transfusion before 1992. The percentage reporting these risk factors may be low because all recorded responses were self-reported. Because only 1 risk factor was required in order to be screened, some

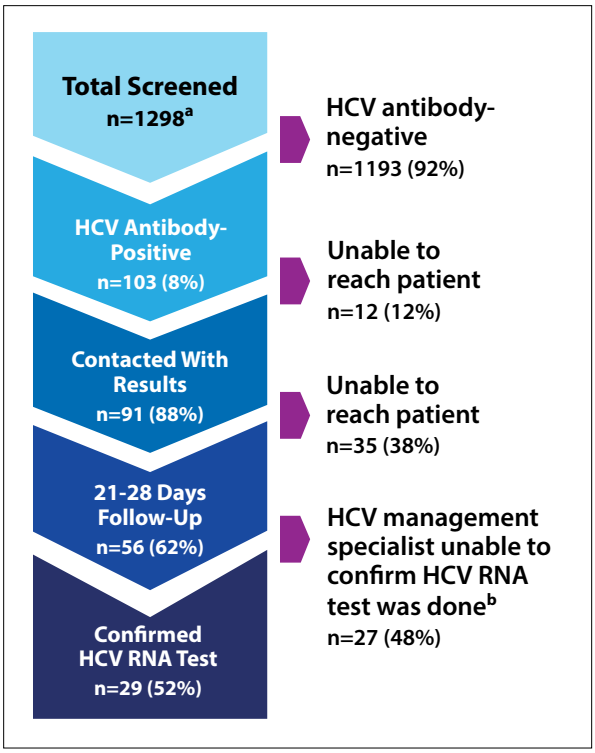

Figure 3. Hepatitis C screening and pathway to diagnosis.

HCV, hepatitis C virus.

[a]Two individuals signed an informed consent form, were tested, and subsequently withdrew consent. [b]The individual was unreachable after 3 attempts, did not want to get a confirmatory test, or was planning on having HCV RNA done but had not done so yet.

individuals may not have felt comfortable revealing all risk factors.

Among participants, 8% were HCV antibody–positive. All participants had at least 1 HCV risk factor, likely accounting for why the prevalence was higher than the 1.3% estimated for the general US population.[1] In the CDC's Hepatitis Testing and Linkage to Care (HepTLC) initiative, anti-HCV–positive tests were administered to 57,750 persons born between 1945 and 1965, and 13% were HCV antibody–positive.[16] This is comparable to the percentage of Baby Boomers being anti-HCV–positive in our analysis (11%) but higher than prior estimates in the birth cohort.[3]

The results from our program reflect existing barriers for diagnosis and treatment among anti-HCV–positive persons. Slightly more than half (52%) of the participants who received an anti-HCV–positive result and who responded to the HCV management specialist during the 21- to 28-day follow-up period reported obtaining an order for an HCV RNA analysis within 4 weeks of receiving their result. Twelve persons who were anti-HCV–positive were unable to be reached to be informed of their results, and 35 of those who were notified were unable to be reached regarding whether they underwent HCV RNA testing. For the persons who were not contacted, it is impossible to know whether they received follow-up care and, if they did not, the reasons why. It is possible that a longer follow-up time would have allowed a greater percentage to undergo an HCV RNA test since it can typically take weeks to months to obtain an appointment with an HCV specialist. Results from the HepTLC initiative indicate that HCV RNA testing is more likely to happen if it is administered the same day as anti-HCV antibody testing.[15] Additionally, having a health care professional actively schedule a date for a follow-up appointment with a specialist or primary care physician is associated with increased likelihood of receiving care.[15]

In the interferon era, poor tolerability and relatively low likelihood of success were substantial barriers to initiating treatment for chronic HCV, especially for patients with HCV genotype 1 infection. All-oral direct-acting antiviral regimens first became available for subgroups of patients in December 2013. Since then, several additional all-oral, interferon-free regimens have entered the marketplace, including regimens that offer greater-than-95% cure for all genotypes.[6] Because we are in the early stages of these newer regimens being available, it is not yet clear whether the spread of information about them to patients and providers will reduce or eliminate some of the historical barriers to HCV treatment. Even if so, several barriers, such as cost of treatment,[17] are likely to remain an issue for the foreseeable future.

Our analysis was limited by a relatively small sample size, although patients were screened at 45 different pharmacies. We did not try to ascertain whether individuals who were HCV RNA–positive attended subsequent appointments for treatment. In our program, several patients were not able to be notified of their anti-HCV–positive status. Presumably, notifying them of their results the same day as testing would have diminished this issue.

Conclusion

Our results provide evidence in support of point-of-care HCV screening in retail pharmacies in the United States for at-risk individuals. We understand many individuals are not under the care of a health care provider and use the retail pharmacy and pharmacist as their source of health education and screening. Pharmacists have continued to be more involved as a key stakeholder in patient care and are active in patient health screenings and inoculations. With HCV cure rates reaching 100%, it is critical that all health care providers screen at-risk patients for HCV. Linking anti-HCV–positive individuals to care needs further exploration and creative solutions.

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