Results from a Geographically Focused, Community-Based HCV Screening, Linkage-to-Care and Patient Navigation Program

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BACKGROUND: Many of the five million Americans chronically infected with hepatitis C (HCV) are unaware of their infection and are not in care.

OBJECTIVE: We implemented and evaluated HCV screening and linkage-to-care interventions in a community setting.

DESIGN: We developed a comprehensive, community-based HCV screening and linkage-to-care program in a medically underserved neighborhood with high rates of HCV infection in Philadelphia, Pennsylvania. We provided patient navigation services to enroll uninsured patients in insurance programs, facilitate referrals from primary care physicians and link patients to an HCV infectious disease specialist with intention to treat and cure.

PATIENTS: Philadelphia residents were recruited through street outreach.

MAIN MEASURES: We measured anti-HCV seroprevalence and diagnosis, linkage and retention in care outcomes for chronically infected patients.

KEY RESULTS: We screened 1,301 participants for HCV; anti-HCV seroprevalence was 3.9 % and 2.8 % of all patients were chronically infected. Half of chronically infected patients were newly diagnosed; the remaining patients were aware of infection but not in care. We provided confirmatory RNA testing and results, assisted patients with attaining insurance and linked most chronically infected patients to a primary care provider. The biggest barrier to retaining patients in care was obtaining referrals for subspecialty providers; however, we obtained referrals for 64 % of chronically infected participants and have retained most in subspecialty HCV care. Several have commenced treatment.

CONCLUSIONS: Non-clinical screening programs with patient navigator services are an effective means to diagnose, link, retain and re-engage patients in HCV care. Eliminating referral requirements for subspecialty care might further enhance retention in care for patients chronically infected with HCV.

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INTRODUCTION

Hepatitis C virus (HCV) is the most common blood-borne infection in the United States; an estimated five million Americans are chronically infected.[1–3] Chronic HCV infection increases the risk for hepatic fibrosis, cirrhosis and hepatocellular carcinoma (HCC), and is the leading cause of liver transplantation.[4]

Early diagnosis and treatment can prevent HCV transmission and reduce HCV-related morbidity and mortality.[5,6] However, 50–75 % of chronically infected individuals are unaware of their infections and will not benefit from these interventions[7–9]; many are diagnosed when presenting with advanced liver disease. Advances in HCV treatments can now cure more than 90 % of chronically infected individuals using interferon-free, short-term, well-tolerated regimens.[10–14] New treatment regimens present important public health opportunities to reduce HCV-related morbidity and mortality.

In 2013, the Centers for Disease Control and Prevention (CDC) expanded its recommendation for HCV screening to include one-time screening for all individuals born between 1945 and 1965 and ongoing screening for other high-risk populations.[8] Expanding HCV screening could help diagnose the chronically infected baby-boomers who are unaware of their infection.[15] Only half of individuals who test positive for antibody to HCV (anti-HCV) undergo confirmatory RNA testing.[16] Infrequent confirmatory testing culminates in lower than optimal diagnosis, linkage and retention in HCV care; only 12 to 18 % of the total HCV-infected population has undergone disease staging with liver biopsy, and only 7 to 11 % has been treated.[17]

Most patients who undergo HCV screening are tested in clinical settings.[18] However, clinical screening may not reach

individuals at highest risk, such as people who inject drugs, the homeless and the incarcerated.[19] OraQuick's© HCV Rapid Antibody Test presents an opportunity to expand rapid HCV testing in community settings. Some, although few, studies have explored HCV screening and linkage-to-care programs in community and non-clinical settings.[20–27]

Several recent efforts describe and quantify the HCV care continuum.[17,28–32] Most demonstrate that chronically infected individuals fail to progress through the continuum of care and have low rates of confirmatory testing, as well as barriers to accessing health insurance.[30,33,34]

Many HCV infections cluster geographically[35]; distance from health care resources as well as socioeconomic predictors for access to care may influence HCV screening and care.[36–40] Geographically focused interventions have been effective for addressing geographic disparities in human immunodeficiency virus (HIV) infection,[41,42] and may offer important lessons for community-based HCV programs. Urban communities often have the highest rates of HCV infection,[35] and racial and ethnic minorities have disproportionately higher HCV-related morbidity and mortality.[3,43] The city of Philadelphia, PA has a 2.9 % HCV seroprevalence; select zip codes have higher prevalence.[44]

We developed a community-based HIV and HCV screening and linkage-to-care program in a medically underserved Philadelphia neighborhood with high rates of HIV and HCV infection. The program included a social marketing campaign to promote HIV and HCV screening, door-to-door outreach, rapid HIV and HCV screening on a mobile medical unit, immediate phlebotomy for confirmatory testing for individuals with reactive antibody tests, and patient navigation to foster linkage and retention in care for all patients with HIV and chronic HCV infection.

We present an evaluation of the community HCV testing program, including patient navigation for linkage to care. We created an HCV care continuum that highlights HCV seropositivity and important steps in the linkage and retention in care process. We describe how we overcame barriers to diagnosing, linking and retaining HCV patients in care.

METHODS

Program Overview and Study Site

Do One Thing is a geographically focused, neighborhood-based HIV and HCV screening and linkage-to-care program in a medically underserved neighborhood with high rates of infection. The program provides rapid HCV testing in community-based settings, immediate phlebotomy for confirmatory testing for all reactive antibody tests, and comprehensive patient navigation services to engage all chronically infected patients in subspecialty HCV care, with intention to cure. We developed an HCV testing and linkage-to-care algorithm (Fig. 1). The Miriam Hospital and Drexel University College of Medicine Institutional Review Boards approved this research.

Testing Procedures and Data Collection

Rapid HCV testing was performed on a mobile medical unit. Participants were recruited for testing through door-to-door and street outreach and at community events. Participants were 18 years or older and provided written informed consent.

Trained HCV test counselors explained the testing procedure to participants, and administered Oraquick© HCV Rapid Antibody tests (OraSure Technologies Inc., Bethlehem, PA) using blood specimens obtained by fingerstick. While waiting for results, participants completed a web-based survey on iPads. Information on demographics, insurance status, risk behaviors and clinical history was collected.

All participants underwent risk reduction counseling and were educated about HCV prevention. HCV antibody test results were delivered to participants on site. Participants with non-reactive tests who reported high-risk behaviors, such as injection drug use, cocaine use or unprotected anal intercourse, were advised to test again in 3 to 6 months. Among patients with reactive tests, trained phlebotomists immediately drew blood for confirmatory testing. Blood was transported to a local hospital-based laboratory for serum separation within 6 hours of blood draw. Chronic infection was confirmed by quantitative HCV RNA real-time PCR (Ampliprep/Taqman Technology©).

All participants with reactive rapid tests received counseling and education. Participants with reactive rapid tests met with a patient navigator and were contacted within 72 hours with confirmatory test results.

Linkage to Care and Case Management

Participants with detectable HCV RNA were notified by phone of their chronic HCV infection. Patient navigators made home visits to deliver confirmatory results for patients unreachable by phone. The process for linkage to an HCV specialist depended on the participant's insurance status and whether the participant had a primary care provider (PCP) upon diagnosis (Fig. 1). If a chronically infected participant had health insurance and a PCP, the patient navigator provided support in requesting a referral from the PCP to a subspecialist. This included reminding the patient to call the PCP offices, or requesting the referral in person at the PCP office on the patient's behalf. If the participant had health insurance but no PCP, the patient navigator made an appointment on the participant's behalf; those participants were then referred to subspecialists.

Uninsured participants were immediately linked to clinical social workers who guided participants through the insurance application process. When participants obtained medical coverage, patient navigators assisted them in obtaining PCPs and requesting subspecialty referrals. Patient navigators provided

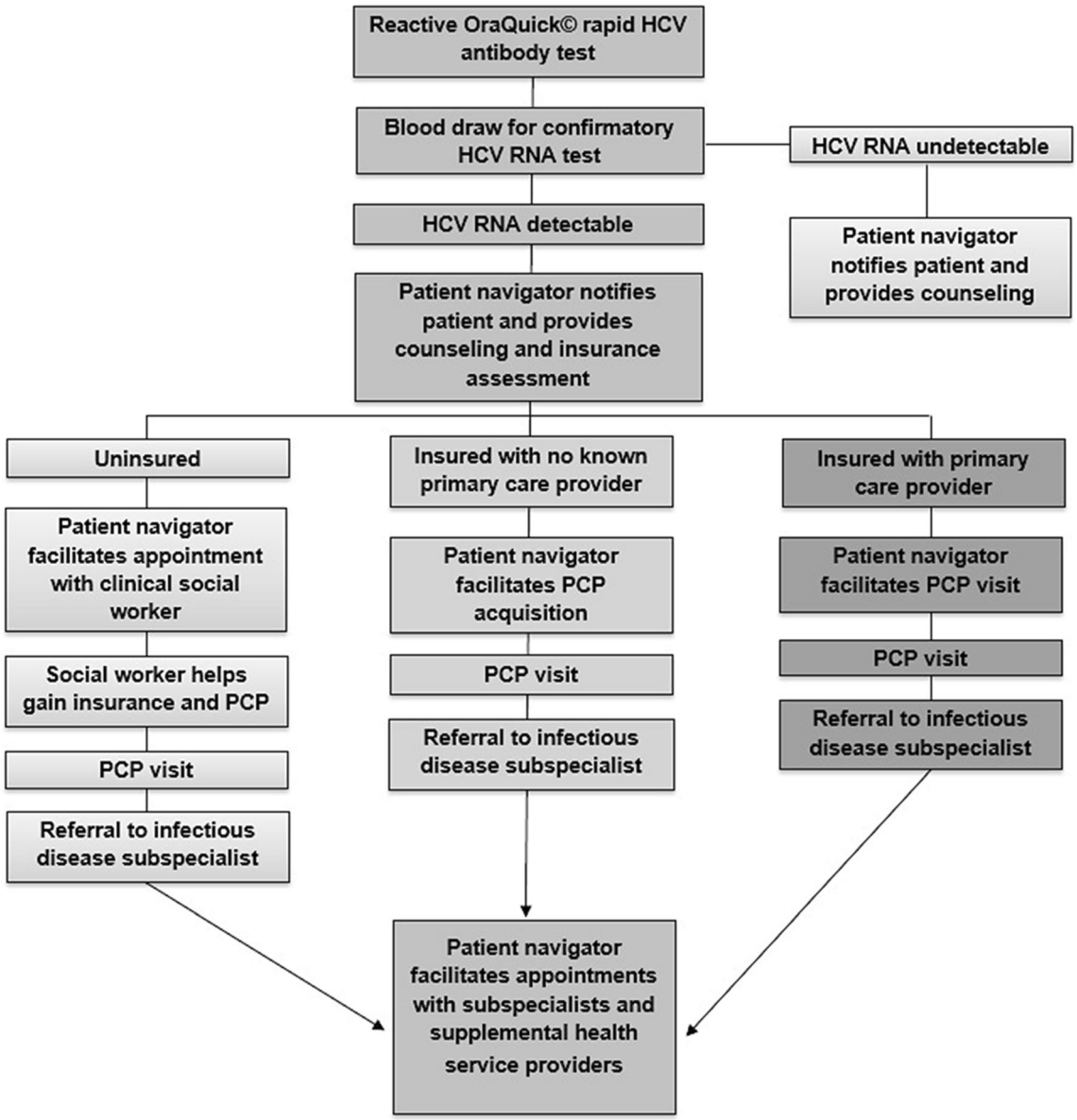

Figure 1. HCV screening and linkage-to-care protocol.

appointment reminder phone calls and text messages, made home visits, provided transit vouchers and accompanied participants to all associated medical appointments.

Subspecialty Treatment

Once insured and referred by a PCP, chronically infected participants were cared for by infectious disease (ID) specialists with HCV expertise. All participants received liver wellness counseling related to alcohol use, weight management and managing medications for comorbid conditions. Serologic testing for immunity to hepatitis A and B viruses was provided; vaccinations were given to non-immune participants. Abdominal ultrasound was conducted and a non-invasive assessment of liver fibrosis (FibroSure, HepaScore) was obtained. Additional lab work often included assessment of synthetic liver function (INR), complete blood count, comprehensive metabolic panel and HCV genotype. Patient navigators assisted participants in obtaining important health services that supplemented their HCV treatment plan, including mental health care and addiction services.

Cascade Development

Our HCV care continuum highlights results from our testing and linkage-to-care program. Our continuum focuses on points from diagnosis to linkage to subspecialty care and treatment; intervention endpoints highlight specific critical junctures at which patients could advance or be stymied in their HCV diagnosis and care (Fig. 2).[31,32] The first step is defined as the number of individuals with reactive HCV antibody tests, followed by the number of individuals who

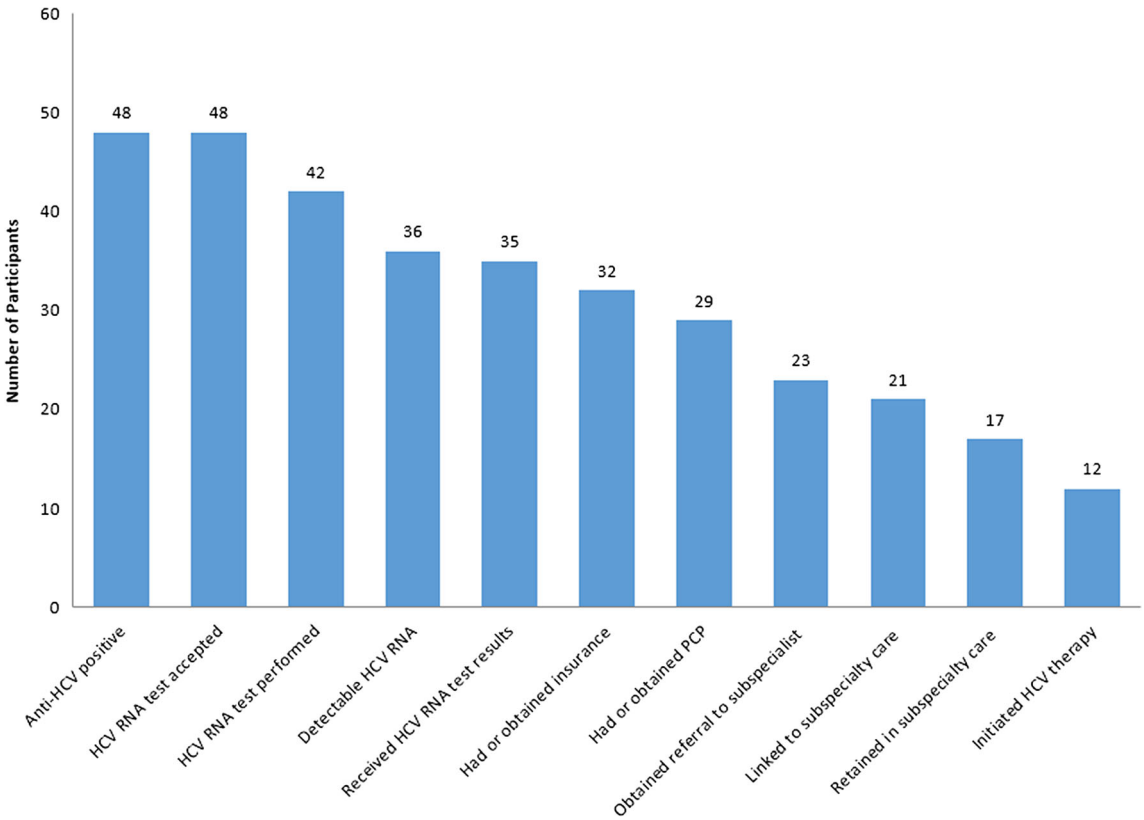

Figure 2. HCV testing and linkage-to-care cascade.

accept screening and successfully undergo phlebotomy for a confirmatory HCV RNA test. The continuum then presents individuals with detectable HCV RNA indicating chronic infection and those receiving confirmatory test results, followed by patients who have insurance at diagnosis or who obtain insurance. Because many health maintenance organizations (HMOs) require a PCP referral before seeing an HCV specialist, we included PCP referrals. The last three endpoints highlight whether patients were linked and retained in subspecialty care, and whether they initiated treatment. In Table 1, odds ratios and 95 % confidence intervals based on the logit method were estimated using SAS 9.3.

RESULTS

Screening Results and Reported Risk Behaviors

We report HCV screening results, confirmatory testing results and linkage-to-care results for the first 16 months of our program (Fig. 2). We tested 1,301 participants for HCV on our mobile medical unit from December 2012 to February 2014 (Table 1). The majority of individuals tested were African American (91 %) and were outside the baby boomer birth cohort (71 %). Anti-HCV seroprevalence was 3.9 % (n=52).

Eight percent (n=4) of participants who tested positive for anti-HCV were already engaged in HCV care and were not offered confirmatory testing; these individuals are not included in our results (Fig. 2). We consider a patient engaged in care if they have attended at least one subspecialty appointment. All remaining anti-HCV positive participants (n=48) accepted an offer for confirmatory testing and 87 % (n=42) had successful confirmatory tests performed. Of the remaining individuals (n=6), two declined services and four await confirmatory testing appointments in clinical settings.

Among those who completed confirmatory testing (n=42), 86 % (n=36) had detectable HCV RNA indicating chronic infection; the remainder had cleared the virus (Table 1 and Fig. 2). Compared to HCV-negative participants, chronically infected participants were more likely to be male [OR 4.24 (CI 1.84, 9.76)], baby boomers [OR 10.24 (CI 4.67, 22.45)] and have an incarceration history [OR 5.35 (CI 2.55, 11.19)] (Table 1). Fifty-eight percent of these individuals (n=21) were aware of their chronic infection, but not engaged in care. Confirmatory testing was provided to all participants who had a self-reported history of HCV and were not in care. Thirty-six percent (n=13) of those with chronic infection were uninsured (Table 2). The remaining 64 % (n=23) of those chronically infected had insurance (Table 2), but two lacked a PCP.

Approximately one quarter (n=11) of participants with chronic HCV infection reported drinking heavily at least weekly and 58 % (n=21) had an Audit-C score commensurate with an alcohol use disorder. Many participants had a history of using intravenous drugs (47 %), intranasal cocaine or crack cocaine (72 %). Eighty percent of participants had serious

Table 1. Demographic and Behavioral Characteristics of Participants Screened for Hepatitis C (HCV)

Variable	Number (Percent)		OR (95 % CI) for chronically infected compared to HCV negative
	HCV negative (*N*=1,249)	Chronically infected participants (*N*=36)	
Male	617 (49.4)	29 (80.6)	**4.24 (1.84, 9.76)**
African American	1,139 (91.2)	29 (80.6)	**0.40 (0.17, 0.93)**
Single	987 (79.0)	27 (75.0)	0.80 (0.37, 1.71)
Age			
< 47	883 (71.0)	8 (22.2)	REF
47–67	338 (27.2)	28 (77.8)	**10.24 (4.67, 22.45)**
> 67	24 (1.8)	0 (0.0)	—
Education			
Less than high school	200 (16.0)	12 (33.3)	REF
High school degree/GED	638 (51.1)	18 (50.0)	0.53 (0.25, 1.10)
At least some college	411 (32.9)	6 (16.7)	**0.29 (0.11, 0.74)**
Income			
Less than $10,000	456 (42.5)	24 (72.7)	REF
$10,000–$14,999	194 (18.1)	6 (18.2)	0.69 (0.29, 1.64)
$15,000–$29,999	208 (19.4)	2 (6.1)	**0.18 (0.04, 0.79)**
> $30,000	214 (20.0)	1 (3.0)	**0.18 (0.04, 0.77)**
Self-identified sexual orientation			
Heterosexual	1,114 (89.7)	35 (97.2)	REF
Gay/Lesbian	58 (4.7)	1 (2.8)	0.51 (0.07, 3.78)
Bisexual	70 (5.6)	0 (0.0)	—
Ever incarcerated	407 (32.7)	26 (72.2)	**5.35 (2.55, 11.19)**
Heavy episodic drinking			
Never	921 (74.0)	17 (47.2)	REF
Less than monthly	190 (15.3)	5 (13.9)	1.43 (0.52, 3.91)
Monthly	59 (4.7)	3 (8.3)	2.75 (0.78, 9.67)
Weekly or more	74 (6.0)	11 (30.6)	**8.05 (3.64, 17.83)**
Audit-C alcohol use disorder	372 (29.8)	21 (58.3)	**3.30 (1.68, 6.47)**
Marijuana use ever	729 (58.4)	26 (72.2)	1.85 (0.89, 3.88)
Cocaine/crack use ever	184 (14.7)	26 (72.2)	**15.05 (7.14, 31.73)**
Heroin use ever	25 (2.0)	12 (33.3)	**24.5 (11.02, 54.38)**
Prescription drug use ever	97 (7.8)	11 (30.6)	**5.22 (2.50, 10.94)**
Other drug use ever	56 (4.5)	9 (25.0)	**7.10 (3.19, 15.81)**
Alcohol use at last sex	227 (18.4)	17 (47.2)	**3.96 (2.03, 7.75)**
Injection drug use	11 (0.9)	17 (47.2)	**100.21 (41.42, 242.43)**

Values in bold are significant at $p < 0.05$

comorbid psychiatric conditions, including bipolar disorder, anxiety, depression, schizophrenia, post-traumatic stress disorder, borderline personality disorder (data not shown) and alcohol use disorders (Table 1).

Insurance Outcomes

Of the 35 chronically infected individuals who received results, 66 % (*n*=23) had insurance at the time of diagnosis. Among the remaining 12 uninsured patients, 75 % (*n*=9) obtained health insurance after chronic infection with HCV was confirmed. Nine of 12 uninsured patients met with a clinical social worker and were Medicaid-eligible; eight became insured as a result of our program, and one awaits application feedback. An additional participant obtained private insurance through his spouse. The remaining two uninsured participants were lost to follow-up.

PCP Referrals and Linkage to Subspecialty Care

Only two of the 23 insured participants who received their test results did not have a primary care provider (PCP); both obtained PCPs with the support of our clinical social worker and patient navigators. Ninety percent (*n*=29) of participants who had or gained insurance (*n*=32) obtained a PCP.

Over three-quarters of participants with PCPs (*n*=23) were able to obtain referrals for HCV specialty care, and 91 % (*n*=21) of these patients attended an appointment with an HCV specialist. More than half of previously insured participants (*n*=13; 57 %) attended an appointment with a subspecialist; 99 % (*n*=9) saw an HCV specialist multiple times. Among the newly insured participants, nearly 90 % (*n*=8) had HCV subspecialist appointments; over half (*n*=17)were retained in subspecialty care. The remainder awaited subsequent subspecialty care appointments.

The remaining participants with insurance and a PCP (*n*=7) had not obtained a HCV subspecialist referral because their PCP's information was unknown, they had been lost to follow-up, or they were not currently interested in HCV care.

HCV Subspecialty Care Outcomes

Most participants who were successfully linked to a subspecialist (91 %; *n*=21) had multiple subspecialty appointments and were retained in care. Ninety-five percent of participants in care had undergone disease staging, including liver ultrasound and liver fibrosis panels (HepaScore or Fibrosure). Seventy-two percent were non-immune to either hepatitis A or B. The majority of non-immune participants subsequently initiated vaccine series (data not shown).

Table 2 Health Insurance Status and Hepatitis C (HCV) Knowledge Among Chronically Infected Participants Served (*N*=36)

Variable	Total (N=36)
Insurance status*	
Private	5 (21.7)
Medicaid	17 (73.9)
Medicare	6 (26.1)
VA	0 (0.0)
Other	1 (4.3)
Uninsured	13 (36.1)
Primary care physician	20 (55.6)
Last primary care physician visit	
No PCP	16 (44.4)
In the last month	9 (25.0)
1–6 months ago	7 (19.4)
7–12 months ago	1 (2.8)
1–5 years ago	3 (8.3)
More than 5 years ago	0 (0.0)
Prior HCV test	
No	7 (19.4)
Yes	25 (69.4)
Don't know	4 (11.1)
Last HCV test	
No prior HCV test	7 (21.9)
In the last month	1 (3.1)
1–6 months ago	5 (15.6)
7–12 months ago	3 (9.4)
More than 1 year ago	16 (50.0)
Prior HCV test results	
Never tested	7 (19.4)
Negative	6 (16.7)
Positive	21 (58.3)
Don't know	2 (5.8)
Have heard of HCV	34 (94.4)
Self-reported HCV risk	
High risk	15 (41.7)
Moderate risk	3 (8.3)
Low risk	12 (33.3)
Not at risk	6 (16.7)

**Participants could report more than one type of insurance*

To date, 12 patients initiated HCV therapy; many others who are treatment eligible were awaiting approval from insurance companies for payment for direct-acting antiretrovirals (DAAs).

DISCUSSION

We identified many chronic HCV infections. The overall seropositivity rate was 3.9 %, which is higher than Philadelphia's rate of 2.9 %. Many individuals who were aware of their chronic HCV infection were re-engaged in care. Immediate phlebotomy and aggressive patient navigation helped ensure linkage to subspecialty care for over half (*n*=21) of chronically infected patients; many of the patients who had not yet seen a subspecialist were still in the process of being linked to insurance, a PCP or HCV subspecialty services.

Our findings add to the body of evidence suggesting that HCV screening in non-medical settings and subsequent patient navigation can enhance progression through the HCV care continuum. We were able to overcome many of the commonly cited barriers to HCV care, including access to HCV screening, confirmatory RNA testing, disease staging and treatment.[17,25,27–30,32] Patient navigation services have been effective in managing other chronic conditions, such as HIV and cancer.[45,46]

Other HCV care continua studies present outcomes for linkage and referral to care prior to confirmatory testing in the continuum; this is because approximately half of individuals never receive confirmatory testing.[16,17,44] We overcame this commonly cited barrier by conducting immediate phlebotomy and expedited HCV RNA testing. Other studies also note that not having a PCP is a barrier to engaging chronically infected individuals in HCV care.[34,43]

Notably, lack of insurance was *not* the greatest barrier to linking HCV patients to care; we were able to insure nearly all participants. Our biggest drop-off in the care continuum occurred at the subspecialty referral stage, which has not commonly been acknowledged as a barrier to care,[21,24,31] perhaps because many patients never progress to requesting referrals. Most HCV providers are subspecialists, and Health Maintenance Organizations often mandate referrals from PCPs for every visit as requirements for reimbursements. Referrals often necessitate an extra PCP visit and create an opportunity for disengagement, particularly for vulnerable populations with low health literacy. However, we note that care continuum "drop-offs," presented in Fig. 2, do not always represent disengagement from care; many patients are in care but have not fully progressed through the care continuum. We note that progression through this continuum, and ultimately to treatment and cure, is an ongoing process. Repeated referral requirements and rigid preauthorization requirements associated with direct-acting antiviral therapy (DAAs) slow progression through the care continuum. For example, all patients who have been retained but are not yet initiated on antiviral therapy (*N*=5) now await approval for medication from insurance companies. Taken together, our results suggest that dispensing with HCV subspecialist referral requirements and relaxing preauthorization requirements for DAAs present important opportunities to reduce barriers to HCV care and cure.

Many individuals previously aware of HCV infection had never been referred to subspecialists. Referral to a subspecialist presents an opportunity to be evaluated for curative therapy and to receive secondary prevention and risk reduction counseling a PCP may not provide. However, as treatment options for HCV continue to evolve and additional interferon-free regimens become available, it is expected that medications will be well tolerated and highly effective, with shorter durations. It is likely that HCV treatment may be increasingly prescribed by PCPs. Preparing PCPs to treat HCV begins with provider education and models that integrate CDC recommendations and testing algorithms into busy practices. It will also become increasingly important to disseminate information regarding new HCV treatment regimens, and to address misconceptions regarding contraindications to therapy that may contribute to barriers to

testing and referrals to care among providers.[47–49] Video conferencing to train PCPs in HCV management may be another important vehicle for scaling HCV treatment in underserved communities.[50,51]

Our patient navigators were critical for enhancing HCV care continuum outcomes, including explaining HCV antibody and PCR testing results to all patients, making and attending appointments, and assisting with referrals. Navigators also assisted with completing paperwork, coordinating radiology appointments and laboratory results. Our HCV care continuum endpoints exceed most described elsewhere.[17,29,30] Notably, our confirmatory testing rates were more than double those reported elsewhere[16,17,52]; we attribute our success to offering on site phlebotomy and confirmatory testing. Immediate, point-of-care confirmatory testing technologies are needed to further enhance confirmatory testing and linkage to care. Similarly, we had more than double the subspecialty and disease staging rates cited elsewhere.[17,28] Our results suggest that providing culturally competent, wrap-around patient navigation services was critical for successfully caring for patients with severe mental illness and a history of addiction.

Limitations and Conclusion

Our research is subject to several limitations. We did not include questions about homelessness and receptive anal sex. Perhaps somewhat surprisingly, we encountered relatively few uninsured participants. This may be because many program participants lived below the poverty line and were already enrolled in Medicaid. Many others were Medicaid-eligible. Our relative success with linking individuals to insurance may not be generalizable to other settings where a smaller fraction of individuals are Medicaid-eligible. Nevertheless, our ability to insure many high-risk individuals currently unaware of their HCV status or not engaged in HCV care highlights the importance and feasibility of community-based screening and linkage-to-care programs. We did not present data on the costs associated with this model; cost effectiveness analyses are fertile ground for future research.

Ideally, a full HCV care continuum would include data on individuals retained in care, and treated and cured individuals. Because the most effective HCV therapies were only recently approved by the U.S. Food and Drug Administration and included in many insurance formularies, many of our participants had initiated interferon-free treatment and several others were awaiting approval for treatment from insurers. Because so few participants have completed treatment, we do not present sustained virologic response data. Nevertheless, our preliminary results suggest that comprehensive patient navigation services can dramatically enhance HCV diagnosis and retention in care. This geographically focused outreach, screening and linkage-to-care program is indeed an effective way to diagnose, link, retain and even re-engage people in care who might not otherwise access health services.

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