Hepatitis C Testing and Linkage to Care Demonstration Projects, California—2016-2018, Evaluation Report





Policy and Viral Hepatitis Prevention Section / Sexually Transmitted Disease Control Branch / Division of Communicable Disease Control / California Department of Public Health

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TABLE OF CONTENTS

Ackr	nowledgments	1
	Executive Summary	
	Background	
-	Findings	
	Lessons Learned	
	Conclusions	
-	endix A – The Hepatitis C Care Cascade	
	endix B – Site-Specific Profile: Butte County Public Health Department	
	endix C – Site-Specific Profile: San Francisco Department of Public Health	
• •	endix D - Site-Specific Profile: Access Support Network of San Luis Obispo and Monterey Counties	
	endix E – Site-Specific Profile: Family Health Centers of San Diego	
	endix F – Site-Specific Profile: HepLink Los Angeles (LA)	

I) EXECUTIVE SUMMARY

BACKGROUND

Hepatitis C virus (HCV) infection is a leading cause of liver disease, liver cancer, and liver transplantation in the United States. National estimates suggest approximately half of people living with chronic hepatitis C are unaware of their infection; only 27 percent have received diagnostic testing confirming their infection, only 16 percent have been treated, and only 9 percent have been cured of their infection (see **Appendix A – The Hepatitis C Care Cascade**). Luckily, HCV can now be cured in 8-12 weeks.

INTERVENTION

The California Department of Public Health (CDPH) awarded funds for hepatitis C testing and linkage to care demonstration projects through a grant agreement process to five total sites, working in six counties: Butte, Los Angeles, Monterey, San Luis Obispo, San Francisco, and San Diego. Projects were funded from March 1, 2016 – June 30, 2018. These were the first state-funded projects of their kind and as demonstration projects, were intended to identify opportunities to enhance HCV testing and linkages to care in local health jurisdictions, and in clinical, and non-clinical settings. Organizations were funded for testing, linkages to care, and/or treatment, but not necessarily all three services. This report describes those outcomes for which data were available and collected.

RESULTS

Improved policies

One public health
department
developed reflex
testing policies
whereby any positive
HCV antibody test is
automatically
followed by a HCV
diagnostic test.

Hepatitis C testing

people were screened for HCV antibody across funded sites.

Nearly **43,000**

Linkage to care

2,064 people had a positive HCV test showing current hepatitis C infection, of whom 63 percent were linked to medical care across funded

Hepatitis C treatment

> 818 people initiated HCV treatment, of whom 657 (80 percent) were known to have completed treatment.*

Targeted outreach

40 percent of those linked to care and treated had a history of injection drug use.

KEY FINDING

People who inject drugs had the same hepatitis C linkage to care and treatment completion rates as people with no or unknown injection drug use history.

sites.*

* Linkage to care was defined as having at least one marker for clinical management, including 1) attending their first medical appointment; 2) receiving HCV genotype testing; and/or 3) receiving testing to assess their stage of liver disease. Treatment data was not available for all clients linked to care. People who inject drugs were defined as people who were known to have ever injected drugs in their lifetime.

ADDITIONAL SUCCESSES

Referrals

Funded entities also provided more than 4,500 referrals to social services.

Partnerships

Syringe exchange programs and alcohol and drug treatment programs were key to programs success, as clients tested for hepatitis C in drug treatment and syringe exchange program settings had the highest rates of HCV positivity.

Increased capacity

Staff at funded sites increased their ability to provide comprehensive HCV services.

Improved health outcomes

People cured of hepatitis C infection reported increased quality of life and increased motivation to reconnect with their families and quit smoking and/or substance use.

CONCLUSION



A one-time investment of public health resources in HCV testing and linkages to care, including having staff dedicated to helping patients access and remain in hepatitis C care and other social services (patient navigators), resulted in improved client-level, organization-level, and systems-level outcomes.

Some of the organizational capacity built through this one-time investment was able to be sustained beyond the funding period. These findings will be instrumental in guiding state and local HCV testing, linkage to care, and treatment initiatives in the future, including by establishing benchmarks for measuring their success.

This evaluation report can help local health departments, community health centers, and community-based organizations in California serving people at risk for and living with hepatitis C.

II) BACKGROUND

A) THE PROBLEM

Hepatitis C infection is a leading cause of liver disease and liver cancer in the United States. Since 2013, HCV-related deaths have outnumbered those due to all other 60 nationally notifiable infectious diseases combined, including HIV and tuberculosis.¹ California has recently seen increasing rates of newly reported cases of chronic hepatitis C infections among young adults, with the rate of newly reported hepatitis C cases among persons ages 15-29 increasing 50 percent from 2014 to 2016.² National estimates suggest approximately two-thirds of new hepatitis C infections nationwide are injection drug use-related.³ Approximately half of people living with chronic hepatitis C are unaware of their infection; national estimates suggest only 27 percent have received diagnostic testing confirming their infection; 16 percent have been treated; and only 9 percent have ever been cured. For information on the key steps of testing, diagnosis, care, treatment, and cure (see **Appendix A – The Hepatitis C Care Cascade**).⁴

Previous hepatitis C treatment regimens involved 6-12 months of weekly injections of interferon, had serious side effects, and only worked half the time. New medications can now cure hepatitis C infection in more than 90 percent of people, lasts only 8-12 weeks, and has limited side effects. This scientific advancement presents an exciting opportunity to reduce the hepatitis C burden in California.

B) INTERVENTION AND GRANTEES

In July 2015, per authorization in Senate Bill 75 (Chapter 18, Statutes of 2015), the California Legislature allocated \$6.6 million dollars to CDPH for "innovative, evidence-based approaches to provide outreach, hepatitis C screening, and linkage to, and retention in, quality health care for the most vulnerable and underserved individuals living with, or at high risk for, hepatitis C viral infection." Funding was authorized for three fiscal years (\$2.2 million per year), from July 1, 2015 through June 30, 2018.

To increase the number of people with hepatitis C infection in California who are screened, diagnosed, linked to care, treated, and cured—to improve the hepatitis C care cascade⁵— CDPH awarded funds through a competitive grant agreement process to five HCV testing and linkage to care demonstration projects, working in six counties: Butte, San Francisco, San Luis Obispo and Monterey, Los Angeles, and San Diego Counties (**Figure 1**). Funded sites prioritized vulnerable and underserved populations



Figure 1: California Hepatitis C Testing and Linkage to Care Demonstration Project grantees: 1) Butte County Public Health Department; 2) San Francisco Department of Public Health; 3) Access Support Network of San Luis Obispo and Monterey Counties; 4) HepLink Los Angeles; 5) Family Health Centers of San Diego.

¹ U.S. Centers for Disease Control and Prevention Newsroom. Hepatitis C Kills More Americans than Any Other Infectious Disease. Accessed November 12, 2017 at https://www.cdc.gov/media/releases/2016/p0504-hepc-mortality.html.

² California Department of Public Health. Chronic Hepatitis C in California, 2016 Executive Summary. Accessed June 12, 2019 at https://www.cdph.ca.gov/Programs/CID/DCDC/CDPH%20Document%20Library/ChronicHCVSurvReport ExecSum https://www.cdph.ca.gov/Programs/CID/DCDC/CDPH%20Document%20Library/ChronicHCVSurvReport ExecSum https://www.cdph.ca.gov/Programs/CID/DCDC/CDPH%20Document%20Library/ChronicHCVSurvReport ExecSum https://www.cdph.ca.gov/Programs/CID/DCDC/CDPH%20Document%20Library/ChronicHCVSurvReport ExecSum https://www.cdph.ca.gov/Programs/CID/DCDC/CDPH%20Document%20Library/ChronicHCVSurvReport ExecSum https://www.cdph.ca.gov/ https://www.cdph.ca.gov/ https://www.cdph.ca.gov/ https://www.cdc.gov/ https://www.cdc.gov/ https://www.cdc.gov/

³ U.S. Centers for Disease Control and Prevention (CDC). Hepatitis C Questions and Answers for the Public. Accessed August 12, 2019 at https://www.cdc.gov/hepatitis/hcv/cfaq.htm.

⁴ Durham DP, Skrip LA, Bruce RD; et al. The Impact of Enhanced Screening and Treatment on Hepatitis C in the United States. *Clinical Infectious Diseases*. 2016;62(3):298–304.

⁵ See **Appendix A – The Hepatitis C Care Cascade** for more information on the hepatitis C care cascade.

most at risk for hepatitis C transmission—specifically people who inject drugs. This report describes findings from the department's evaluation of those five projects, which began in March 2016 after the competitive application process was completed and funds were awarded to successful applicants. Data reported here encompass March 1, 2016 – June 30, 2018.

Demonstration project sites pursued one or more of three overarching goals originally set by CDPH:

- Goal 1: Using Surveillance to Improve the Hepatitis C Care Cascade (Butte County)
 - o Increase the proportion of people with a reactive hepatitis C antibody test who receive follow-up HCV diagnostic testing and appropriate clinical management.
 - Partner with ordering providers to identify and address policy and systems barriers to ensure all people with a positive HCV antibody test receive follow-up HCV diagnostic testing and increase local hepatitis C treatment capacity in primary care settings.
- Goal 2: Hepatitis C Testing and Linkage to Care in Community and Non-Clinical Settings (Access Support Network of San Luis Obispo and Monterey; Family Health Centers of San Diego; and San Francisco Department of Public Health)
 - o Provide outreach and hepatitis C screening, testing, and active linkages to care for vulnerable and underserved clients at high risk for hepatitis C infection.
 - Increase organizational capacity in non-healthcare settings to deliver HCV screening, testing, and linkages to care.

Goal 3: Hepatitis C Care Coordination in Clinical Settings (Family Health Centers of San Diego; HepLink Los Angeles; and San Francisco Department of Public Health)

- Provide hepatitis C care coordination and clinical management to vulnerable and underserved clients living with chronic hepatitis C infection.
- o Increase organizational capacity in primary care settings to deliver HCV screening, testing, and linkages to care to vulnerable and underserved clients.

C) EVALUATION AIMS AND METHODS

Aims

This evaluation report aims to describe:

- The extent to which funded sites provided HCV testing and linkage to care services for people at high risk of infection and/or people living with hepatitis C, with an emphasis on people who inject drugs;
- The extent to which funded sites enacted policy or program changes in their organization, and/or among community partner organizations to better serve people at risk of HCV infection and/or people living with hepatitis C;
- Barriers to successful hepatitis C outreach, testing, linkages to care, and treatment faced by sites and/or people at risk of infection and/or people living with hepatitis C infection; and
- Lessons learned and best practices for providing outreach, testing, linkages, and care to the
 most vulnerable individuals living with or at risk for hepatitis C, with an emphasis on people who
 inject drugs.

Methods

Grantees used new or existing data collection systems to record demographics, HCV test results, attendance at first medical appointment, treatment initiation, treatment completion, sustained virologic response (SVR or cure), and client-level barriers to accessing medical care. Data sources included the California Reportable Diseases Information Exchange (CalREDIE), the Local Evaluation Online (LEO) HIV

and HCV testing data system, electronic health records, and tracking logs. Grantees provided CDPH with client-level data monthly in Microsoft Excel or Access format via secure file transfer protocol. Sites also submitted quarterly narrative reports. CDPH drafted this evaluation report summarizing project findings, challenges, and lessons learned using qualitative and quantitative data from these sources, as well as from notes from site visits, technical assistance calls, and meetings, with sites' input. CDPH staff produced aggregate statistics on HCV testing, linkage to care, and treatment outcomes using SAS 9.4.

Limitations

Standardized methods and data systems for collecting information about HCV testing and linkage to care are not available. Funded sites had varying capacities to develop and maintain data systems to track variables for HCV risk factors, testing, linkage to care, and clinical care management. Certain variables could not be aggregated across sites because they were not collected consistently across all projects. Sites' baseline HCV-related activities and capacity varied, and could not be accurately or consistently measured for pre/post grant intervention comparison. Data are presented across Goal 2 and Goal 3 sites when they could be aggregated accurately; see supplemental site-specific profiles for more information.

Results likely represent underestimates. In particular, the number/proportion of people served who injected drugs is likely underestimated due to people's reluctance to disclose injection drug use and due to providers not eliciting or recording this information consistently. Treatment completion and the number of people cured are likely underestimates due to difficulty locating people for treatment completion and test of cure appointments. Direct-acting antiviral HCV medications are more than 90 percent effective, so clients who completed treatment but did not return for a test of cure were likely still cured.⁶

Guide to this Report

This report highlights the overall findings of the projects in aggregate, starting with Goal 1. Goal 1 outcomes include systems, organization, and client-level. Goal 2 and Goal 3 HCV testing and linkage to care outcomes and Goal 3 clinical management outcomes are presented first at the client level, followed by overarching barriers identified and lessons learned at the systems, organization, and client-levels; site specific outcomes for all five sites are described in further detail in supplemental site-specific reports.

Notable themes emerged in the demonstration project sites' narrative quarterly reports when describing the experience of clinicians, who described feeling increased job satisfaction after learning to treat hepatitis C in a primary care setting; of clients, who described fears of discrimination in health care settings and relief after having been cured of hepatitis C; and of care navigators, who reported pride when their clients overcame seemingly insurmountable barriers and were successfully linked to care, treated, and cured of hepatitis C. A sampling of quotes from these narrative reports are highlighted throughout this report.

III) FINDINGS

A) USING SURVEILLANCE TO IMPROVE THE HEPATITIS C CARE CASCADE (GOAL 1)

⁶ Cunningham EB. Adherence to sofosbuvir and velpatasvir among people with chronic HCV infection and recent injection drug use: The SIMPLIFY study. Int J Drug Policy. Dec 2018;62:14-23.

Butte County Public Health Department (BCPHD) was funded to use surveillance data to improve hepatitis C outcomes, with an emphasis on identifying people with a positive HCV antibody result but no HCV ribonucleic acid (RNA) result (incomplete diagnostic testing). An HCV RNA test is used after a positive HCV antibody screening test to diagnose current hepatitis C infection, and is a necessary step in hepatitis C care and treatment. To address local gaps in diagnostic testing, BCPHD conducted a retrospective analysis examining HCV lab reports received between June 2015 and September 2016, and identified three local hospitals and two dialysis/renal care clinics that accounted for more than 70 percent of people in Butte County with incomplete diagnostic testing. Between September 2016 and March 2017, BCPHD launched a campaign to improve diagnostic testing completion rates at local health facilities. As part of the campaign, BCPHD staff leveraged the leadership and authority of the local health officer (who personally contacted local health facility officials); met with health care providers, hospital infection prevention leads, and local laboratory directors at leading facilities; and assisted local laboratory directors with modifying their HCV testing protocols. By the end of March 2017, all three local hospitals had enacted HCV reflex testing policies wherein all HCV antibody positive results are automatically followed by HCV RNA diagnostic testing. One dialysis and renal care clinic changed their HCV testing protocols; another did not. The percentage of people reported with an HCV antibody positive test with HCV RNA diagnostic testing increased in all three hospitals that enacted reflex testing policies, and in one dialysis and renal care clinic in Butte County, suggesting this intervention successfully increased timely HCV RNA diagnostic testing through systems interventions (Figure 2).

Butte County, June 1, 2015 - February 28, 2018 82% (116/141)Hospital/Facility 1 99% (85/86)64% (81/127)Hospital/Facility 2 91% (43/47)56% (15/27)Hospital/Facility 3 100% (8/8)Pre-Reflex Testing Campaign - June 1, 2015 - December 31, 2016 Post-Reflex Testing Campaign - January 1, 2017 - February 28, 2018

Figure 2: Proportion of People Who Received Confirmatory HCV RNA Testing among People with a Reported Positive HCV Antibody Result, Pre and Post Reflex Testing Campaign—

Note: Data from dialysis/renal care clinic that changed HCV testing protocols was suppressed due to small cell size numbers.

In addition to addressing systemic gaps in diagnostic testing, BCPHD created a database to facilitate enhanced HCV case follow-up. BCPHD used the database to identify and track people with a positive HCV antibody test result without a reported HCV RNA diagnostic test reported from June 2015 to February 2018. BCPHD contacted health care providers (and in some cases contacted people directly) to ensure diagnostic testing was completed. BCPHD performed additional follow-up for people with a HCV RNA positive result to ensure they were connected to medical care, improving client outcomes and establishing protocols for future local health department use. BCPHD also began offering HCV RNA testing through their public health laboratory, increasing their organizational capacity to address gaps in

care for people living with hepatitis C; partnered with larger medical facilities and local federally qualified health centers to develop and improve HCV screening and testing practices and to increase their communitywide HCV treatment capacity; and began exploring how to offer hepatitis C treatment to Medicaid (Medi-Cal) beneficiaries through BCPHD Health Clinic. They also integrated HCV testing into a syphilis testing initiative focused on testing people in drug treatment centers and venues serving people experiencing homelessness, reducing barriers at the client level to syphilis and HCV testing for persons who may be at high risk for both infections. For more information on Butte County's model, see Appendix B – Site-Specific Profile: Butte County Public Health Department.

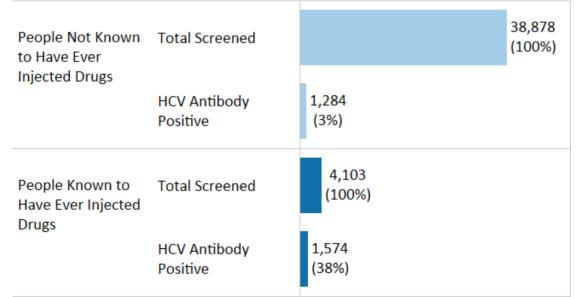
B) HEPATITIS C TESTING AND LINKAGE TO CARE IN COMMUNITY AND NON-CLINICAL SETTINGS (GOAL 2 AND GOAL 3): CLIENT OUTCOMES

From March 1, 2016 through June 30, 2018, Goal 2 and Goal 3 sites screened a combined total of 42,981 people for HCV antibody, 2,858 (7 percent) of whom had a reactive antibody result. One Goal 3 site (SJWCFC) conducted universal HCV screening, accounting for more than half (52 percent) of all those screened. Among those with a reactive HCV antibody result, 1,574 (55 percent) were known to have ever injected drugs. Testing people with a known history of injection drug use yielded higher HCV antibody positivity than testing people with no or unknown injection drug use history. Figure 3 shows the difference in the percentage of people with an HCV antibody positive result among people with a known history of injection drug use, as compared to those not known to have ever injected drugs.

"A lot of [clients] won't disclose...the first day you meet, until you start building that trust. Sometimes you just have a casual conversation with a person and gradually open up the conversation to talking about their tattoos, and where they got them. Sometimes they tell you...they got them in prison, or...on the street. Eventually you can tie it in and say, 'did you know you might have been exposed to Hep C at that time?' A lot of people are surprised, and others will disclose...they have it."

HCV Demonstration Project Patient Navigator

Figure 3: Number of People Screened for HCV Antibody and Those with a Reactive Antibody Result, by Injection Drug Use History, Goal 2 and 3 Sites—California, March 1, 2016 – June 30, 2018



Note: Percentages calculated as a proportion of those who completed the previous step in the cascade. The number of people known to have injected drugs is underestimate due to the limited ability of Goal 3 sites to collect this information in their electronic health records.

Follow-up HCV RNA diagnostic testing was offered both to those who newly tested HCV antibody positive (N=2,858) and to those who had tested antibody positive previously but fallen out of care among Goal 2 and Goal 3 sites. Among those who newly tested HCV antibody positive, 1,904 (66 percent) completed HCV RNA testing. An additional 1,499 people who had tested antibody positive previously but had fallen out of care completed HCV RNA testing. Overall, 3,403 people completed HCV RNA testing, of whom 2,064 (61 percent) tested HCV RNA positive. People with positive HCV RNA results were referred to medical care, and 1,298 (64 percent) people were known to have at least one marker for linkage to care or clinical care management, including 1) attending their first HCV medical appointment; 2) receiving HCV genotype testing; and/or 3) receiving testing to assess their stage of liver disease. These results are stratified by injection drug use history in **Figure 4**.

People Not Known to Have Ever Injected Drugs People Known to Have Ever Injected Drugs 2,161 (100%)1,242 1,117 (100%)947 (52%)721 (76%)577 (65%)(61%)Total Tested for RNA Positive Linked to Care, or Total Tested for RNA Positive Linked to Care, or RNA Receiving Clinical RNA Receiving Clinical

Figure 4: Number of People Who Received HCV RNA Testing, Test Results and Linkage to Medical Care, by Known Injection Drug Use History—Goal 2 and 3 Sites, March 1, 2016 – June 30, 2018

Note: Percentages calculated as a proportion of those who completed the previous step in the cascade. The number of people known to have injected drugs is underestimate due to the limited ability of Goal 3 sites to collect this information in their electronic health records.

Care Management

Of the 1,298 people seen by Goal 2 and Goal 3 sites known to be connected to HCV medical care, 577 (44 percent) were known to have ever injected drugs in their lifetime. Figure 4 shows the percentage of people with a positive HCV RNA result who were linked to HCV medical care among people with a known history of injection drug use, as compared to those not known to have ever injected drugs. Notably, people with known injection drug use history had comparable linkage to care rates as those with no or unknown history of injection drug use. (There was no statistically significant difference between the linkage to care rates between people with and without known injection drug use history.)

Figure 5 highlights other characteristics of people most likely to be linked to care among people who tested HCV RNA positive. Linkage to care rates varied based on key demographics, including age (39 years of age or younger vs. 40 years of age or older); housing stability (stably vs. unstably housed); and race/ethnicity. Overall, people 40 years of age and older were more likely to be linked to care than people who were younger, and people who were stably housed were more likely to be linked to care than people who were unstably housed, although linkage to care rates in each of these categories ranged from 56 to 65 percent. There were no differences in linkage rates by gender.

Among people who tested HCV RNA positive and who were linked to care, Hispanic/Latinos had the highest rates of linkages to care (69 percent) and were more likely to be linked to care than Whites.

Care Management

African Americans/Blacks also had higher rates of linkages to care (64 percent) than Whites (59 percent). Hispanic/Latinos, African Americans/Blacks, and Whites accounted for 91 percent of those who were HCV RNA positive and eligible for being linked to hepatitis C care.

Figure 5: Characteristics of People Most Likely to be Linked to Hepatitis C Care Among People Who Tested HCV RNA Positive by Age, Housing Status, and Race/Ethnicity - Goal 2 and 3 Sites, March 1, 2016 – June 30, 2018

People most likely to be linked to care among people who tested HCV RNA positive

• People 40 years of age or older

• People who were stably housed

• Hispanic/Latinos

Among the remaining racial/ethnic groups, linkage to care rates varied widely—from 71 percent among Asian American/Pacific Islanders and 50 percent among American Indians/Alaska Natives to 33 percent among people who self-identified as Multi-Racial. These percentages should be interpreted with caution, however, because the overall number in each of these latter groups was low.

For more information on the outcomes of Goal 2 sites, see Appendix C – Site-Specific Profile: San Francisco
Department of Public Health, Appendix D
- Site-Specific Profile: Access Support
Network of San Luis Obispo and
Monterey Counties, and Appendix E –
Site-Specific Profile: Family Health
Centers of San Diego.

For more information on the outcomes of Goal 3 sites, see the site specific profiles in **Appendix C – Site-Specific Profile**: San Francisco Department of Public Health, Appendix E – Site-Specific Profile: Family Health Centers of San Diego, and Appendix F – Site-Specific Profile: HepLink Los Angeles (LA).

C) HEPATITIS C CLINICAL CARE COORDINATION, TREATMENT, AND CURE IN CLINICAL SETTINGS (GOAL 3): CLIENT OUTCOMES

Among the 1,298 people known to be connected to HCV medical care by both Goal 2 and Goal 3 sites, 1,118 (86 percent) were provided with hepatitis C clinical care coordination and tracked by Goal 3 sites. An additional 421 clients who had been previously diagnosed but had fallen out of care were also provided with hepatitis C clinical care coordination and tracked by Goal 3 sites. Among 1,539 people who received clinical care coordination, 818 (53 percent) initiated hepatitis C treatment between March 1, 2016 and June 30, 2018. Of those who initiated treatment, 657 (80 percent) were known to have completed treatment, the vast majority of whom, given the

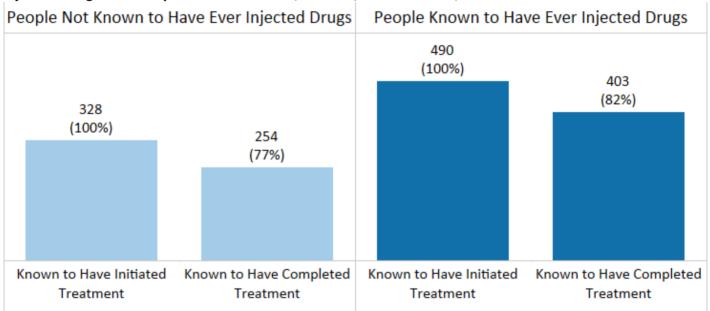
"A Caucasian transgender female [in her 40s] is living in single-room occupancy housing and using [methamphetamine]. She was diagnosed with hepatitis C [last year] and was enrolled in directly observed therapy (DOT). She began therapy [in mid-winter] and completed therapy [in early spring]. She met with our DOT coordinator every day and had no missed doses. Her last [viral load] was not detected. She is scheduled for a follow up test for [cure]."

HCV Demonstration Project Patient Navigator

high success rate of direct-acting antivirals, likely achieved virologic cure (Figure 6).

Among all people known to have completed treatment, 488 (74 percent) people were known to have received a test of cure 12 weeks after the end of treatment, of whom 464 (95 percent) were cured. Among the 464 people that were cured, 279 (60 percent) were known to have ever injected drugs. The percentage of people who completed hepatitis C treatment among those that initiated treatment among people with a known history of injection drug use, as compared to those not known to have ever injected drugs is shown in Figure 6. Notably, there was no statistically significant difference in the rate of treatment completion among people with a known history of injection drug use and those with no or unknown injection drug use history.

Figure 6: Number of People Who Were Known to Have Initiated and Completed Treatment, by Known Injection Drug Use History—Goal 2 and 3 Sites, March 1, 2016 – June 30, 2018



Note: Percentages calculated as a proportion of those who completed the previous step in the cascade. The number of people known to have injected drugs is underestimate due to the limited ability of Goal 3 sites to consistently collect this information.

"It's comforting sometimes just to hear someone acknowledge that I'm trying."

HCV Demonstration Project Client

"[The navigation staff] are my team and extended family in my fight to get my medicine and a new, healthy life."

HCV Demonstration Project Client

For more information on outcomes for Goal 3 sites, see the site specific profiles in **Appendix C – Site-Specific Profile: San Francisco Department of Public Health**, **Appendix E – Site-Specific Profile: Family Health Centers of San Diego**, and **Appendix F – Site-Specific Profile: HepLink Los Angeles (LA)**.

D) PATIENT NAVIGATION AND SOCIAL SERVICES REFERRALS (GOAL 2 AND GOAL 3) IN CLINICAL AND NON-CLINICAL SETTINGS: CLIENT OUTCOMES

Delivering HCV testing and linkage to care services entailed numerous hours of client contact, including phone calls, street outreach encounters, and visits to drug treatment programs, homeless shelters and encampments, syringe exchange programs, and other settings. Successful client navigation often entailed tracking clients over many months while clients waited for pending benefits enrollment, medical appointments, test results, HCV treatment authorizations, and during intermittent periods of homelessness, incarceration, and other crises.

While not all sites tracked their client navigation activities, sites that did so recorded conducting more than 5,000 contacts, including more than 1,500 phone calls, text messages and/or in-person visits for appointment reminders and/or scheduling assistance. Among 35 clients with complete information on patient navigation time spent from HCV testing to cure, the total amount of time patient navigators dedicated to each client ranged from as little as 20 minutes to as much as 23.25 hours, with half of clients successfully navigated with 2.5-7.5 hours of dedicated navigation work each. Similarly, not all sites recorded the average time from outreach contact to first medical appointment, or from linkage to care to treatment initiation and completion.

For those sites that did track this information, their records showed that each step in the process, from linking clients to their first medical appointment, starting treatment after being linked to care, and completing treatment, often took more than a month, and sometimes took almost two years, often due to significant barriers to care, as shown in **Figure 7.**

It is important to note here that the number of people included in each time measurement varied depending on the availability of the data to measure the time points, as sites tracked different information depending on the intervention they were implementing. Additionally, the number of people included in each time measurement depended on the services they received during the demonstration projects. Not all people included in each time measurement required all services for hepatitis C linkage to care and care coordination. People who received genotype testing may have been previously linked to care before the start of the demonstration projects, and therefore would not be included in the linkage to care time measurement. People who initiated hepatitis C treatment may not have had a genotype completed during the

Figure 7: Range of Times for Completion of Hepatitis C Linkage to Care, Treatment Initiation, and Treatment Completion for Clients with Tracked Outcomes Goal 2 and 3 Sites, March 1, 2016 – June 30, 2018

Testing, Treatment and Cure Took a Long Time for Clients with Tracked Outcomes

HCV RNA Result to
Attending First
Medical
Appointment
(N=311)

Median: 35 daysRange: 1 to 540 days

• Half of clients linked in 21-70 days, Goal 2 sites only

Genotype Testing to Initiation of Treatment (N=362) Median: 100.5 daysRange: 8 to 699 days

• Half of clients started treatment in 59-182 days, Goal 3 sites only

Initiation of Treatment to Completion of Treatment (N=486) Median: 175 daysRange: 73 to 524 days

•Half of clients completed treatment in 167-200 days, Goal

3 sites only

Barriers to Care Associated with Delays Housing Stability, Stigma,
 Discrimination, Organizational and Structural Barriers demonstration projects, and therefore would not be included in the genotype to treatment initiation time measurement.

Nevertheless, tracking the linkage process showed that it often took people a long time to get through testing, treatment and cure. Housing stability, stigma, discrimination and other structural and organizational barriers contributed to lengthy and time-consuming patient navigation and delays in moving through the hepatitis C care cascade, and resulted in people falling out of care. However, patient navigators showed tremendous persistence in repeatedly finding and re-engaging their clients in care and other support services to assure they were linked to care, treated, and ultimately cured of their hepatitis C infection. (See pages 15-17 for additional information on barriers to care.)

"We developed a system where we can go back and put a face to the name and...follow up with them.

Working with the medical provider on the mobile [health van]—a lot of patients feel more of a trust there. We then help them to the next step of getting them to the clinic. We provide transportation, bus tokens to help people to get to medical care."

HCV Demonstration Project Patient Navigator Sites provided numerous ancillary support services both to make successful HCV linkages possible and to support clients to meet other self-identified health goals, including accessing hygiene supplies, housing, behavioral health services, and syringe exchange. While not all sites consistently tracked referrals, those sites that did so recorded referrals for 4,699 clients to the following social supports:

- 2,446 referrals to syringe exchange services
- 1,891 referrals to housing services
- 1,334 referrals to substance use disorder treatment
- 730 referrals to mental health services.

Note: Totals exceed 5,000 because many clients received referrals to more than one social support.

For more information on the outcomes of Goal 2 sites, see **Appendix C – Site-Specific Profile: San Francisco Department of Public Health, Appendix D - Site-Specific Profile: Access Support Network of San Luis Obispo and Monterey Counties**, and **Appendix E – Site-Specific Profile: Family Health Centers of San Diego**.

For more information on the outcomes of Goal 3 sites, see the site specific profiles in **Appendix C – Site-Specific Profile**: San Francisco Department of Public Health, Appendix E – Site-Specific Profile: Family Health Centers of San Diego, and Appendix F – Site-Specific Profile: HepLink Los Angeles (LA).

E) ORGANIZATIONAL AND SYSTEMS CHANGE (GOAL 1, GOAL 2, AND GOAL 3)

All sites were funded to increase their organizations' capacity to provide comprehensive HCV outreach, testing and linkage to care services, and to develop partnerships to improve services provided to people at risk for and/or living with HCV in their communities. Sites enacted many kinds of organizational policy and programmatic change. Key organizational capacity and systems-level changes are highlighted below:

- 23 demonstration project site staff and volunteers became newly certified as HIV/HCV test counselors, allowing them to perform rapid HCV antibody tests under California law.⁷
- 7 non-clinical staff became newly certified in phlebotomy, enabling patient navigators to seamlessly provide rapid HCV testing and perform a blood draw for follow-up diagnostic testing

⁷ California Health and Safety Code Section 120917.

- One site tripled its phlebotomy capacity, from 1.5 full time equivalents (FTE) to 5.0 FTE.
- 14 clinicians became newly certified to prescribe buprenorphine, a medication assisted treatment for opioid use disorder known to reduce hepatitis C infection rates among young people who inject drugs by 50 percent.⁸
- One primary care clinic and two methadone clinics provided HCV treatment to patients experiencing homelessness via directly observed therapy.
- One local public health laboratory initiated HCV RNA testing, increasing access to diagnostic testing.
- One organization reopened the only syringe services program in the county, increasing access to preventive services for people who inject drugs and who are at the highest risk for hepatitis C infection.
- One public health network increased the number of primary care clinics providing HCV treatment from 3 to 12 clinics.

"[Curing my patients of hepatitis C is] something that really brings joy to my practice."

Hepatitis C
Demonstration Project
Primary Care Provider

"When the support is tailored to what the client needs, people can get through treatment."

HCV Demonstration Project Primary
Care Provider

IV) LESSONS LEARNED

A) BARRIERS TO HEPATITIS C OUTREACH, TESTING, LINKAGES, CARE, AND TREATMENT

Hepatitis C testing and linkage to care demonstration project sites, and the clients they served, faced many barriers to finding people at risk for hepatitis C and offering them testing, linking them to care, and treating and curing their infections. Some barriers were structural (due to larger social and economic forces), while others were specific to particular organizations or geographic locations, or specific to individual clients. Housing instability/homelessness and stigma/discrimination against people who inject drugs emerged as overarching themes and are described in further detail here along with other barriers.

Housing Instability/Homelessness

All sites identified homelessness and housing instability as their most challenging and frequent barrier, regardless of setting, geography, project model, or specific goals/objectives. This finding was borne by results showing that people with unstable housing were less likely to be linked to care than those stably housed.

 Relocation of homeless encampments by law enforcement or other local officials made it difficult for clients to store their possessions, including their medications, and made it difficult for patient navigators to locate and track clients for medical care.

⁸ Platt L; et al. Needle syringe programmes and opioid substitution therapy for preventing hepatitis C transmission in people who inject drugs. Cochrane Database of Systematic Reviews 2017, Issue 9. Art. No.: CD012021.

- Inability to safely secure possessions (such as behind a locked door) made clients hesitant to leave their encampments to attend medical appointments due to fear of theft and/or loss of possessions.
- Clients' shame about poor hygiene made them not want to attend medical appointments.
- Clients not having a mailing address or a consistently working cell phone/cell phone number made it difficult for patient navigators to keep track of clients during linkage, care, and treatment.
- Police presence in areas frequented by people experiencing homelessness made clients fearful of arrest and incarceration, hesitant to stay in places that could be easily located, and reluctant to carry safe injection equipment, which would identify them as people who inject drugs to police and potentially subject them to search.⁹

Stigma and Discrimination against People Who Inject Drugs and People with Hepatitis C

All sites encountered stigma and discrimination against people who inject drugs, which often extended to people with hepatitis C infection regardless of whether they had ever injected drugs. This presented barriers on many levels.

- Health care providers in multiple jurisdictions refused to treat people who inject drugs for hepatitis C, despite research and clinical guidelines supporting such treatment, including July 2015 California Department of Health Care Services guidelines prioritizing people who inject drugs for hepatitis C treatment to prevent further transmission.
- Patient navigators reported having to stop referring clients to certain health care providers because those providers treated people poorly and judgmentally due to their injection drug use.
- Finding an appropriate, experienced HCV-treating provider sometimes required assisting clients with switching to a different health plan, primary care provider, or medical home, which was time intensive and disruptive.
- Clients were often reluctant to attend medical appointments due to fear of judgment and discrimination based on previous negative experiences interacting with the health care system.
- Demonstration project sites, particularly those in rural areas, reported difficulty finding and retaining phlebotomists with the skills, experience, and nonjudgmental approach needed to successfully draw blood from people with collapsed and scarred veins, including people who inject drugs, for followup HCV RNA testing.

"[A female client] has been fearful to seek medical attention, because she thinks that medical providers will treat her like 'trash' when they see track marks on her body, especially now that she is pregnant. With the encouragement and support of our Health Counselor, she was able to get connected to prenatal care, and has attended child-birthing classes."

HCV Demonstration Project Patient
Navigator

Other Barriers

Other barriers impeding successful HCV testing and linkages to care, including structural, organization, and individual-level barriers, were also identified.

⁹ Williams CT, Metzger DS. Race and Distance Effects on Regular Syringe Exchange Program Use and Injection Risks: A Geobehavioral Analysis. *AJPH*. 2010;100(6): 1068-1074.

Structural/Environmental

- Natural disasters, including multiple wildfires and dam spillages understandably took priority for local health department staff during emergencies
- Geographically dispersed populations in both urban and rural settings
- Limited local health infrastructure, particularly in rural areas
- Lack of standard HCV metrics or statewide HCV clinical case management data systems
- Lack of dedicated federal resources for HCV testing and linkages to care, including the unanticipated ending in September 2016 of federal substance use treatment funds that had been used in a number of counties to offer HIV and HCV testing in drug treatment programs

Organizational

- Limited organizational data management capacity; data management being seen as competing with direct client services for limited resources and infrastructure
- Staff turnover/vacancies
- Time intensive nature of outreach and patient navigation exceeding staffing capacity
- Lack of transportation, both for demonstration project sites (mobile vans) and for clients

Client

- Lack of awareness about hepatitis C treatment advances, including non-interferon based treatments, among both clients and health care providers
- Young people (under 40 years of age) were less likely than those 40 and older to be linked to care; this may have been due to a lack of youth-specific services or self-perceptions of invulnerability to long-term disease consequences, but needs further exploration

B) FACILITATORS OF SUCCESSFUL HEPATITIS C OUTREACH, TESTING, LINKAGES, CARE, AND TREATMENT

Programs were most successful when they adopted the following approaches to HCV testing and linkages to care.

Hiring/Staffing/Training

- Hired patient navigation staff with demonstrated skills in critical thinking, creativity, and persistence
- Employed people with lived experience with hepatitis C infection and treatment, injection drug use, incarceration, and/or homelessness as peer educators and patient navigators
- Cross trained patient navigators to conduct street outreach, HCV rapid antibody testing, phlebotomy, patient navigation, and accompaniment to facilitate continuity of care
- Assigned staff dedicated to navigating treatment authorizations from insurance companies
- Assigned staff dedicated to data entry, data management, and data quality assurance

Engaging with People Experiencing Homelessness and/or People Who Inject Drugs

Acknowledged drug use without requiring abstinence for participation (harm reduction)¹⁰

¹⁰ According to California's Framework for Injection Drug User Health and Wellness, one of the best ways to encourage healthy behaviors among people who use drugs is to foster value for health and wellness, as well as a sense of worth and self-acceptance not contingent upon abstinence from drugs. The Framework emerges from a harm reduction philosophy, which treats people who use drugs with dignity and as full members of society, and emphasizes the assets of individuals and communities rather than their deficits. To read the Framework, visit

- Prioritized client needs and supported clients in setting their own health and survival goals
- Allocated sufficient time for rapport-building and for the process to unfold over time (low-threshold, client-centered care)
- Celebrated positive life changes people made once they were cured of hepatitis C, such as repairing relationships, quitting smoking, and addressing chronic conditions, such as diabetes

"There is hope, hope to live a long life for my grandchildren."

HCV Demonstration
Project Client

Delivering Effective Patient Navigation Services

- When conducting HCV rapid antibody testing, offered same-day
 phlebotomy for HCV RNA testing; when conducting HCV antibody testing via blood draw,
 ordered HCV antibody to HCV RNA reflex testing, such as by removing antibody-only testing
 options from the laboratory requisition form or drop-down menu
- Collected detailed contact information to assist with follow-up, including primary and secondary phone numbers, social media accounts, locations of where clients spend time during the day, where they sleep, and people to try contacting if the client cannot be reached by other means
- Provided appointment reminders, transportation to and from appointments, accompaniment to appointments, and assistance with other social service needs (e.g., food, housing, benefits)
- Offered incentives (such as gift cards for basic needs) for returning for test results and medical appointments, including the diagnostic test and the test for cure

Engaging with Clinical and Non-Traditional Partners

- Collaborated with other internal and external programs, such as homeless outreach teams, syringe exchange programs, and housing programs, who are reaching the same population
- Identified and partnered with health care providers who were known to deliver nonjudgmental health care, including primary care and hepatitis C treatment, to people who inject drugs and/or people experiencing homelessness to facilitate treatment linkages and track client progress
- Focused testing on syringe exchange and drug treatment settings for a high positivity rate (15-20 percent) and a high concentration of people most likely to be out of hepatitis C care
- To gain buy-in from new clinical partners for offering HCV treatment, community-based partners suggested that clinic staff start by evaluating which of the patients in their existing panel had a positive HCV antibody result but no HCV RNA result, or who have a positive HCV RNA diagnostic test result but no record of HCV evaluation or treatment; this led clinic leadership to identify an unmet need for increased in-house hepatitis C clinical management capacity

V) CONCLUSIONS

A one-time investment of public health resources in HCV testing and linkages to care resulted in improved client, organizational, and systems outcomes, including more people aware of and, in many instances, cured of their hepatitis C infection; organizations better equipped to screen for, diagnose, and cure hepatitis C infection among vulnerable populations, including people who inject drugs; and policy changes in place with the

"I'm looking forward to getting treatment because [hepatitis C] was like a big black cloud over me."

HCV Demonstration Project Client

potential to sustain these gains over time. Of particular note, people with a known history of injection

https://www.cdph.ca.gov/Programs/CID/DOA/CDPH%20Document%20Library/Framework%20for%20IDU%20Heal th%20and%20Wellness ADA.pdf.

drug use had the same rates of hepatitis C linkage to care and treatment completion as those with no or unknown injection drug use history, contrary to misconceptions about adherence rates among people who inject drugs. This is particularly important because modeling studies suggest eliminating hepatitis C as a public health threat will require a three-pronged approach focused on expanding access to hepatitis C treatment, sterile syringes and injection equipment, and medication assisted treatment for opioid use disorder to reduce the pool of prevalent hepatitis C infections and prevent further hepatitis C transmission.¹¹

The experiences of these demonstration projects can provide valuable insights into the barriers to, and facilitators of, successful use of surveillance data for improving hepatitis C outcomes, and successful hepatitis C outreach, testing, linkages to care, treatment, and cure, especially for people who inject drugs. They also illustrate the unique contributions of local health departments, community-based organizations, and clinical providers.

- Local health departments can use surveillance data to identify people with incomplete diagnostic testing who are out of care to promote hepatitis C best practices with health systems and health care providers, including laboratory hepatitis C antibody to RNA reflex testing policies at local hospitals and health facilities. They can also use surveillance data to conduct enhanced case follow-up, and to promote the integration of HCV prevention into other efforts, such as syphilis and outreach to people experiencing homelessness.
- Community-based organizations can train non-clinical staff, including peers with lived experience with homelessness, incarceration, and injection drug use, to reach people who inject drugs, people experiencing homelessness, and other priority populations. Facilitators of successful HCV linkage included street-based outreach, HCV rapid testing, and same-day phlebotomy in mobile vans, at syringe exchange programs, shelters, homeless encampments, drug treatment centers, and other community settings; assistance with appointment reminders and transportation; incentives; and referrals to other social services.
- Community health centers and other health systems may consider implementing routine, optout hepatitis C screening with reflex to HCV RNA as one urban primary care clinic had success in screening for hepatitis C on an opt-out basis; use electronic health records to identify existing patients at risk who have not been screened for hepatitis C or who have incomplete diagnostic testing or care; and train care coordinators to assist clinicians with supporting the hepatitis C care and treatment process. Clinician champions can train other primary care and mid-level providers to treat hepatitis C in primary care and non-traditional settings, including opioid substitution therapy and syringe exchange programs.

Areas for further exploration include implementation of broader HCV RNA reflex testing policies, standardized HCV care cascade metrics, systems for case management tracking, and interventions to reduce homelessness, stigma, discrimination, and other social barriers to prevention, testing, and care for people living with and at risk for hepatitis C infection.

This evaluation report should help local health departments, community health centers, and community-based organizations serving people living with or at risk for hepatitis C to assess how they can contribute their particular skills and resources to applying the lessons learned and best practices identified through these demonstration projects.

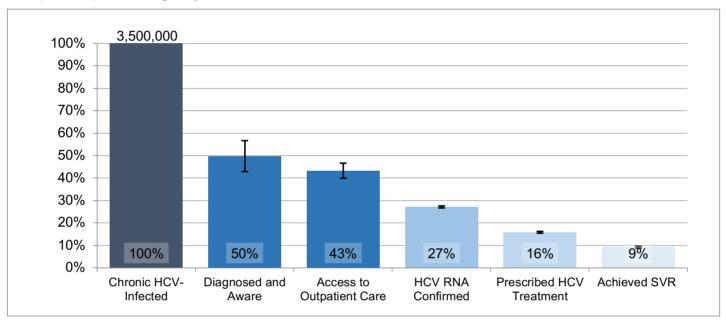
19

¹¹ Fraser H, Zibbell J, Hoerger T; et al. Scaling-up HCV prevention and treatment interventions in rural United States-model projections for tackling an increasing epidemic. Addiction. 2018 Jan;113(1):173-182

APPENDIX A - THE HEPATITIS C CARE CASCADE

The steps needed for an individual at risk for hepatitis C infection to receive appropriate screening, diagnostic testing, linkage to care, clinical management, treatment, and cure is often called the hepatitis C "care cascade," a concept adapted from HIV care. The first national estimate of the hepatitis C care cascade conducted in 2014 showed that few people with hepatitis C infection were appropriately diagnosed or treated and cured (**Figure 8**).

Figure 1: Estimated number of people with chronic hepatitis C infection and percentages who are aware of their infection, have access to outpatient healthcare, received HCV RNA testing, or achieved SVR (or cure), including 95 percent confidence intervals—United States, 2000-2010¹²



Note: Proportions are calculated as a percentage of the first bar. Proportion of people that underwent liver biopsy was calculated and displayed the original publication of this data. This bar was excluded from this graphic, as liver biopsy is no longer a routine procedure in the hepatitis C care cascade.

While the steps along the HIV care cascade are well defined, standard metrics for measuring the hepatitis C care cascade have not yet been established and standards of hepatitis C continue to evolve. Currently, the hepatitis C care cascade begins with a two-step testing process. First, people at risk are screened for HCV antibody, which shows whether they have ever been infected with HCV. Those with a positive antibody screening test should receive a follow-up test to look for hepatitis C virus in the blood, also known as HCV RNA diagnostic testing, which shows evidence of current infection. People with current infection should be linked to clinical care for various assessments (e.g., of liver damage). Once linked to care, treatment with direct-acting antiviral medications is offered. The goal of treatment is sustained virologic response (or cure), which is marked by absence of detectable virus 12 weeks after treatment. To ensure that people have been cured, a test for HCV RNA should be done 12 weeks after treatment completion. If HCV RNA is not detected, they are confirmed to be cured. Treatment cures chronic hepatitis C infection in about 95 percent of individuals, including people actively injecting drugs.¹³

¹² Yehia BR, Schranz AJ, Umscheid CA, Re VL. The Treatment Cascade for Chronic Hepatitis C Virus Infection in the United States: A Systematic Review and Meta-Analysis. Plos-One. Jul 2014; 9(7):e101554.

¹³ Grebely J, Hajarizadeh B and Dore G. Direct-acting antiviral agents for HCV infection affecting people who inject drugs. Nat Rev Gastroenterol Hepatol. 2017 Nov;14(11):641-651.

APPENDIX B - SITE-SPECIFIC PROFILE: BUTTE COUNTY PUBLIC HEALTH DEPARTMENT



GOAL 1: USING SURVEILLANCE TO IMPROVE HEPATITIS C VIRUS OUTCOMES

A) SITE BACKGROUND AND INTERVENTION

Butte County is a rural jurisdiction situated in the northern Sacramento Valley. The overall mission of the Butte County Health Department (BCPHD) is to protect and improve the public's health by promoting individual, community, and environmental health. The BCPHD Community Health and Sciences Division, which is responsible for monitoring communicable diseases, investigating disease outbreaks, and preventing and controlling disease transmission, carried out the activities for this project.

The objective of BCPHD's demonstration project was to use public health surveillance data to identify local health care facilities and providers that ordered hepatitis C virus (HCV) antibody screening without appropriate follow-up HCV ribonucleic acid (RNA) diagnostic testing; work with facilities and providers to improve HCV diagnostic testing



practices; and, if needed, increase the number of local providers offering HCV care and treatment. Butte County sought to achieve these aims through partnerships with local health care facilities and providers.

B) METHODS AND RESULTS

HCV Diagnostic Reflex Testing Policies

The California Department of Public Health (CDPH) used statistical analysis software (SAS) to generate a line-list of California Reportable Diseases Information Exchange (CalREDIE) incidents with an HCV antibody positive result but no known HCV RNA diagnostic test at the beginning of the demonstration projects. These data were analyzed by BCPHD staff to identify health facilities with the highest volume of patients with incomplete HCV diagnostic testing for follow-up. Based on this analysis, BCPHD identified three local hospitals and two dialysis/renal care clinics ("high volume facilities") accounting for more than 70 percent of people with incomplete diagnostic testing between July 2015 and September 2016.

Between July 2016 and March 2017, BCPHD ran a campaign to improve diagnostic testing completion rates at local high volume facilities. The campaign included phone calls to and meetings with clinic managers, hospital infection preventionists, and other officials in high volume facilities. During these meetings, they discussed current HCV screening and diagnosis recommendations and opportunities to

incorporate recommended practices into facility processes. The Local Health Officer contacted local hospital laboratory directors by phone and by mail to explain the problem, outline national HCV testing algorithm recommendations, and request changes in local high volume hospital HCV diagnostic testing policies. BCPHD project staff followed up to assist local facilities with changing their testing protocols.

By April 2017, all three local high volume hospitals had enacted HCV reflex testing policies wherein all HCV antibody positive results are automatically followed by HCV RNA testing, which is needed to diagnose current infection and to identify the need for linkage to hepatitis C treatment. One of two high volume dialysis/renal care clinic changed their HCV testing protocol. The percentage of people reported with an HCV antibody positive test with complete HCV RNA diagnostic testing increased in all three hospitals with HCV reflex testing policies, and in one dialysis/renal care clinic in Butte County following BCPHD's campaign (Figure 1).

Pre- and Post-Reflex Testing Campaign—Butte County, June 2015 – February 2018 82% (116/141)Hospital/Facility 1 99% (85/86)64% (81/127)Hospital/Facility 2 91% (43/47)56% (15/27)Hospital/Facility 3 100% (8/8)56% Dialysis/Renal (9/16)Care Clinic 1 77% (17/22)Pre-Reflex Testing Campaign - June 1, 2015 - December 31, 2016 Post-Reflex Testing Campaign - January 1, 2017 - February 28, 2018 Note: Dialysis/Renal Care Clinic 2 was suppressed from this figure to due cell size numbers.

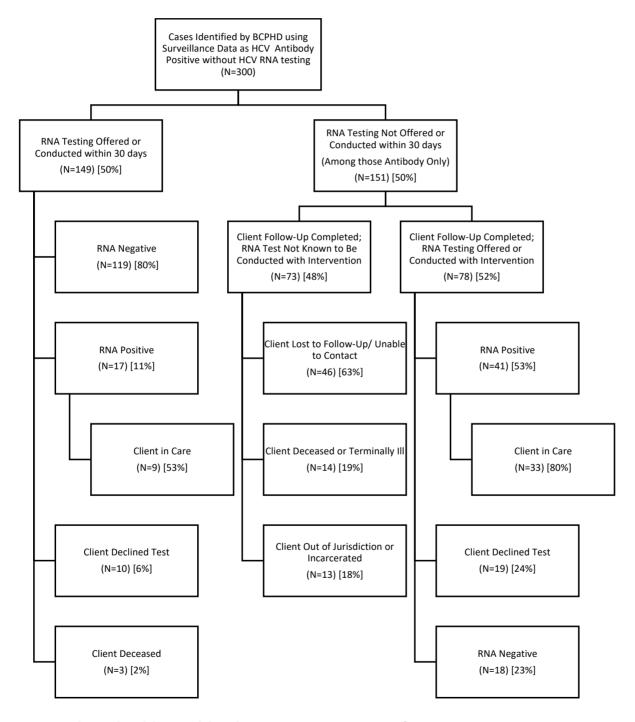
Figure 1: Proportion of People with a Reported HCV Antibody Positive Result Who Received HCV RNA Testing,

HCV Patient Tracking Database

In addition to addressing gaps in diagnostic testing, CDPH assisted BCPHD with creating a Microsoft Access database to facilitate enhanced HCV case follow-up. From June 2015 to February 2018 (when BCPHD stopped tracking new cases to allow enough time for case follow up before the project ended) BCPHD used the Access database to identify and track 300 people with a positive antibody test result without a reported HCV RNA diagnostic test reported to the health department. BCPHD contacted health care providers with a fax-back form requesting information on diagnostic testing and care in instances where more than 30 days passed after a positive HCV antibody result without a known HCV RNA result. If after obtaining medical records the person still had not received diagnostic testing, a communicable disease investigator conducted additional follow up. A public health nurse conducted enhanced case follow-up for medically complex cases and those under age 18. In some cases, BCPHD

contacted people directly to ensure that diagnostic testing was completed. BCPHD performed additional follow-up for people who received a HCV RNA positive result to ensure they were connected to medical care. BCPHD found primary care providers were responsive to follow up, whereas some urgent care and emergency department clinicians understandably reported not seeing care for chronic hepatitis C infection as their role outside of a hepatitis C-related medical emergency. **Figure 2** shows the disposition of those for whom BCPHD conducted follow up to ensure HCV diagnostic testing.

Figure 2: Disposition of Clients with a Positive HCV Antibody Result and No Known HCV RNA Result—Butte County Public Health Department, June 1, 2015 – February 28, 2018



Increased Local Public Health Laboratory HCV Testing Infrastructure

In the course of conducting case follow up for people with incomplete diagnostic HCV testing, BCPHD identified that many people lacked insurance or a regular primary care provider, including people who only accessed care in the emergency room. In March 2017, BCPHD began offering HCV RNA testing

through the county public health laboratory to increase access to HCV RNA testing for people who were uninsured or who did not have a primary care provider. From March 2017 to June 2018, 19 RNA tests were performed by BCPHD laboratory, 68 percent of which were positive.

Capacity Building Partnerships

With HCV reflex testing policies in place at all three local hospitals, BCPHD shifted gears toward the end of the project to focus on increasing local hepatitis C treatment capacity after identifying numerous barriers to complete HCV diagnostic testing, care, and treatment. These barriers included homelessness and wait times of 3-5 months to see the few local primary care providers who accepted Medi-Cal insurance. Specifically, BCPHD participated in local initiatives focused on homelessness, adding a question on a local homeless census questionnaire to assess where people experiencing homelessness accessed care. BCDPH also partnered with a local sexual health resource center to offer HCV rapid testing; promoted participation in a University of California San Francisco's HCV Project Extended Community Health Outcomes (ECHO) initiative that uses videoconferencing to train primary care providers in rural areas to treat hepatitis C; organized continuing medical education events for local clinicians on hepatitis C and sexually transmitted diseases; and began exploring how to offer hepatitis C treatment to Medi-Cal beneficiaries through the BCPHD Health Clinic.

Project staff increased local HCV prevention capacity by arranging for a certification training for local health care providers to prescribe medication-assisted treatment for opioid use disorders; inviting CDPH to present on the intersection between opioids and infectious diseases at a local opioid summit; and offering technical assistance to local health officials on syringe exchange best practices. These partnerships helped Butte County respond to multiple natural disasters during and after the demonstration project, including multiple major wildfires and the evacuations of local areas due to flooding damage at a local dam. At the same time, responding to natural disasters at time strained BCPHD resources when the staff dedicated to this project were pulled away to assist in disaster response.

Integrated HCV and Syphilis Testing for People Experiencing Homelessness

BCPHD integrated HCV testing into a county-funded syphilis outreach initiative in drug treatment centers and venues serving people experiencing homelessness. Participants were offered rapid syphilis testing, HCV rapid antibody testing, HIV testing and/or a safer sex kit. Clients with a positive HCV antibody test result were offered an immediate blood draw and HCV RNA testing through the local public health laboratory, as well as follow-up diagnostic testing if needed. Among the 523 syphilis tests administered, 16 tests (3 percent) were positive, a high positivity rate not typically seen in primary care settings. Among the 456 HCV antibody tests completed, 44 tests (10 percent) were positive, also a high positivity rate not seen in primary care settings. Among the 444 instances where both tests were administered for the same person, 2 (0.4 percent) were positive for both syphilis and HCV antibody.

C) LESSONS LEARNED

Establishing and maintaining an enhanced HCV surveillance data system is time-intensive and requires additional expertise and support, but is feasible at the local level with sufficient resources and technical assistance. Butte County Public Health Department leveraged a modest investment in local public health surveillance infrastructure to yield lasting policy change by implementing HCV RNA reflex testing policies. Butte County's relatively small size facilitated direct communication and close professional relationships between the local health officer and the leaders of local health systems.

Local data systems could generate reports tailored to individual providers and health systems, allowing for real-time evaluation and improvement of local HCV testing and care practices. However, the high portion (40 percent) of test results with an initial antibody reactive result but no known HCV RNA result that turned out to have been tested for HCV RNA suggests negative HCV RNA reporting is needed to more fully and efficiently use HCV surveillance data to monitor and improve the HCV care cascade.

The development of partnerships focused on improving hepatitis C testing, diagnosis, and care led to increased interest in hepatitis C treatment among local safety net clinic providers, increasing the demand for training, as well as partnerships on intersecting issues, including homelessness and opioids. Butte County's model of using routine public health surveillance data to identify people needing additional HCV testing and/or care could be applied in other rural local health jurisdictions and/or larger health system with relatively limited resources, and would be improved by the implementation of reporting of negative HCV test results and broader adoption of HCV RNA reflex testing policies. Reporting of negative HCV RNA results, promoting wider adoption of HCV reflex testing policies, and electronic case reporting using electronic health records, are all being explored at the state level, which may hold promise in increasing the efficiency of hepatitis C case identification and follow up.

APPENDIX C - SITE-SPECIFIC PROFILE: SAN FRANCISCO DEPARTMENT OF PUBLIC HEALTH









SAN FRANCISCO DEPARTMENT OF PUBLIC HEALTH

GOAL 2: HEPATITIS C TESTING AND LINKAGE TO CARE

GOAL 3: HEPATITIS C CARE COORDINATION

A) SITE BACKGROUND AND INTERVENTION

The San Francisco Department of Public Health (SFDPH) seeks to protect and promote the health of all San Franciscans in a geographically small but densely populated city. SFDPH achieves its mission through the work of two Divisions: San Francisco Health Network (SFHN) and Population Health and Prevention. SFHN is the City's safety net health system, with 2 hospitals and more than 15 primary care health centers. SFDPH contracted with a local syringe exchange program (Glide Harm Reduction Services) to carry out hepatitis C virus (HCV) education, outreach, screening, testing, and linkages to care for this project. SFHN provided training and support for primary care and mid-level providers to treat hepatitis C in primary care settings, and provided staffing support for hepatitis C treatment in a methadone clinic.



San Francisco's state-funded HCV testing and linkage to care demonstration project coincided with—and helped catalyze—a citywide, multi-sector hepatitis C elimination initiative (End Hep C SF), which has been described elsewhere. It also coincided with the implementation of city-funded HCV patient navigation grants at another syringe exchange program (San Francisco AIDS Foundation) and at one non-city-operated health clinic (HealthRight360), as well as with a hepatitis C-related practice improvement

¹⁴ Gaudino A; et al. Localized US Efforts to Eliminate Hepatitis C. Infect Dis Clin N Am. 2018;32:293-311.

¹⁵ Centers for Disease Control and Prevention (CDC). CDC Public Health Grand Rounds: Working Together to Eliminate the Threat of Hepatitis B and C. Slides accessed December 27, 2018 at https://www.cdc.gov/grand-rounds/pp/2018/20180417-presentation-eliminate-hepatitis-H.pdf.

¹⁶ For more information about End Hep C SF, visit http://www.endhepcsf.org/.

project led by San Francisco Health Plan, a local Medicaid (Medi-Cal) Managed Care Plan.¹⁷ This profile focuses on SFDPH's HCV testing and linkages to care and hepatitis C care coordination activities funded by the California Department of Public Health (CDPH). This profile touches only briefly on other aspects of San Francisco's broader hepatitis C related work, including those areas where other efforts contributed to the outcomes of the state-funded HCV testing and linkage to care demonstration project. A comprehensive evaluation of the relative contribution of each of these individual efforts to San Francisco's overall hepatitis testing and treatment outcomes was beyond the scope of this report.

B) METHODS AND RESULTS

Glide Harm Reduction Services

Hepatitis C Awareness Campaign Materials Developed for and by People Who Inject Drugs
Using other funding sources, Glide conducted focus groups with people who inject drugs (PWID) to
assess their knowledge, attitudes, and beliefs about hepatitis C and to identify which hepatitis C
transmission, prevention, and treatment messages would most resonate with them. Information from
these focus groups was used to develop hepatitis C awareness campaign materials (posters, t-shirts,
stickers) and slogans, with an emphasis on three key messages promoting prevention, testing, and
treatment, respectively:

- "Sharing equipment spreads hep C. Come get sterile stuff."
- 2. "We can't treat hepatitis C if we don't know we have it."
- "Living with hep C? New treatments have changed the game."

Campaign materials featured pictures of Glide outreach team staff alongside one of the above slogans, which staff wore on outreach events, helping to increase awareness and establish positive associations with new hepatitis C treatment regimens. These slogans helped combat beliefs held over from the era of interferon-based regimens that treatment was worse than the disease (see **Figure 1**). CDPH grant funds helped expand the campaign to include five other organizations serving people at high risk for hepatitis C in San Francisco, including a syringe exchange program; an HIV testing program; two methadone clinics; and a primary care clinic offering hepatitis C treatment services co-located with Glide Health Services.

Sharing equipment spreads Hep C Come get sterile stuff



There is new hope for people with Hep C Come visit us to talk about the new cure

Glide Harm Reduction Program - 5th floor 330 Ellis Street (between Taylor & Jones) San Francisco, CA 94102 (415) 674-5188 / hepc@glide.org For more info, visit www.endhepcsf.org





Figure 1: Glide Hepatitis C Awareness Campaign Flyer. Image credit: endhepcsf.org. Used with permission.

¹⁷ San Francisco Health Plan, Performance Improvement Program, 2018 All Participant Guide. Accessed January 25, 2019 at https://www.sfhp.org/files/providers/pip/FINAL_PIP_2018_Primary_Care_Program_Guide-All_Participants.pdf

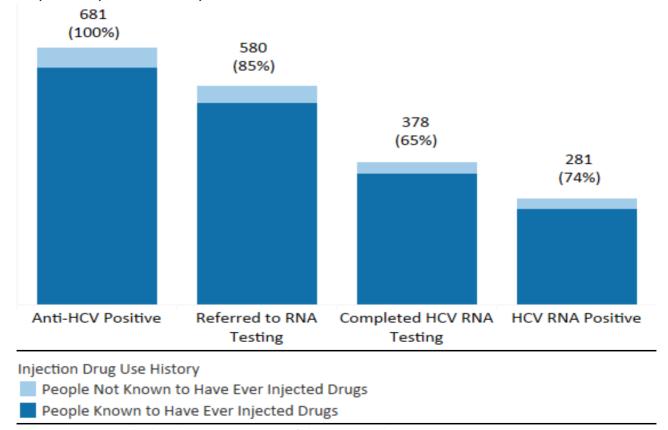
Broad-Sweeping HCV Outreach and Testing Activities

Glide focused its HCV testing on settings with high concentrations of PWID, offering drop-in HCV rapid testing at their office and partnering with organizations such as the SFDPH street medicine team to establish regular and one-time HCV testing events. Together, they offered testing in shelters, single room occupancy (SRO) hotels, other syringe exchange programs, homeless navigation centers, and a medical respite facility for people experiencing homelessness. Glide HCV patient navigators conducted street outreach, inviting people back to their office for testing during daytime, evening, and weekend hours, increasing availability of HCV testing for PWID. Clients were offered rapid HCV testing followed by a same-day blood draw for HCV diagnostic testing if the rapid test was reactive. All blood samples were spun in a centrifuge at Glide's offices and delivered daily by courier to the SFDPH public health laboratory for processing. SFDPH public health lab provided HCV RNA test processing in-kind.

Glide conducted hepatitis C antibody testing for 3,034 total clients, 68 percent of whom were known to have ever injected drugs. Among 2,067 people with a history of injection drug use, 30 percent tested hepatitis C antibody positive. Notably, five percent of those without a reported history of injection drug use also tested hepatitis C antibody positive. Many reported other HCV risk factors, including stimulant use (94 percent); having been born during 1945-1965 (79 percent); and having been incarcerated (10 percent); one-third reported unstable housing. (The U.S. Preventive Services Task Force recommends hepatitis C testing for people with a history of intranasal drug use or incarceration or who were born during 1945-1965 [also known as baby boomers].) Clients often had overlapping HCV risk factors.

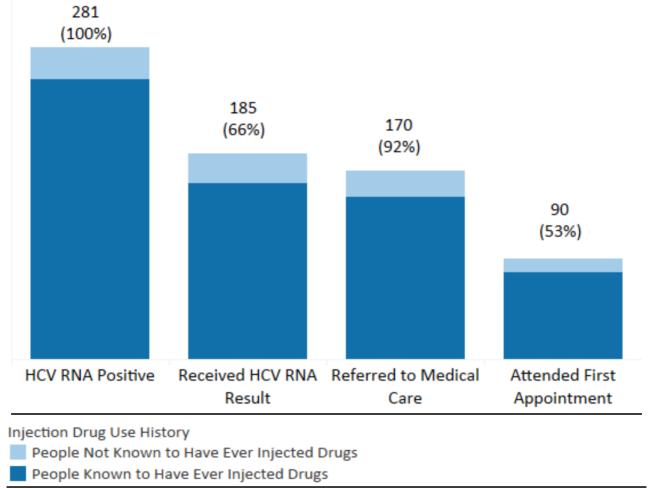
Figure 2 and **Figure 3** show the testing and linkage to care cascades for the 681 Glide clients who tested positive for hepatitis C antibody, by PWID status.

Figure 2: Number of Clients with Positive HCV Antibody Result Who Were Referred to RNA Testing, Received RNA Testing, and RNA Test Results, by Known Injection Drug Use History—Glide Harm Reduction Services, San Francisco, March 1, 2016 – June 30, 2018



Note: Proportions are calculated as a percentage of the previous bar.

Figure 3: Number of Clients with Positive HCV RNA Result Who Received Their Result, Were Referred to Medical Care and Attended their First Medical Appointment—Glide Harm Reduction Services, San Francisco, March 1, 2016 – June 30, 2018



Note: Proportions are calculated as a percentage of the previous bar. Percentages of clients who attended first medical appointment are likely underestimates, as Glide was unable to systematically collect this information from medical providers to whom Glide referred clients for hepatitis C care.

Hiring and Cross Training People with Lived Experience

Glide emphasized hiring people with lived experience with homelessness, injection drug use, hepatitis C infection (and treatment), and/or incarceration. This helped to create trust and credibility with clients. It also helped to ensure that staff cross trained in HCV rapid testing, patient navigation, and phlebotomy would be skilled at finding a vein when conducting blood draws needed for HCV diagnostic testing for clients who had vein damage following extended periods of injection drug use. This approach helped increase Glide's phlebotomy capacity from 1.5 full-time equivalent (FTE) at the beginning of the project to 3-5 FTEs during Years 2 and 3, with the exact number varying at any given time due to staff turnover.

Peer Education

One of Glide's patient navigators, Orlando Chavez took information from his personal experience being treated for hepatitis C and developed an HCV peer education training curriculum, which he used to train more than two dozen Glide clients to educate their own communities about hepatitis C. Clients who took the training received a certificate of completion and became champions for hepatitis C treatment with their peers. When Mr. Chavez died unexpectedly, End Hep C SF issued a funding announcement for an HCV peer navigation program named in his honor. Three organizations, including Glide, received \$20,000 grants from End Hep C SF to expand the HCV peer navigation model with their clients.

Testing and Treatment Colocation and Working Groups

A partnership with HealthRight360, a community health clinic located in the same building as Glide Harm Reduction Services, helped to facilitate quick linkage to hepatitis C care and treatment. Glide staff met weekly with staff from HealthRight360 to coordinate linkages to care, conduct case conferences, and identify and address barriers to hepatitis C care and treatment as they arose. Glide staff accompanied clients to medical appointments, provided appointment reminders, and offered incentives to support attendance at key medical visits (such as returning for diagnostic test results and for test of cure following treatment). Glide staff also encouraged their clients to attend bimonthly hepatitis C education groups, which enabled participants to learn from their peers about undergoing treatment with new direct-acting antiviral medications, which are easier to tolerate than previous hepatitis C regimens. Glide staff also participated in the End Hep C SF working group focused on testing and linkages to care, which included other agencies providing similar services and allowed for sharing of best practices and lesson learned.

San Francisco Health Network

SFHN both trained primary care providers to treat hepatitis C in non-specialty care settings and supported direct patient care coordination in select non-specialty clinical sites, with an emphasis on methadone clinics. Both approaches complemented the work of community-based HCV patient navigators by increasing the capacity of local safety net clinics to accept hepatitis C treatment referrals.

Provider Education

SFHN used several complementary approaches to training primary care providers to treat hepatitis C: inperson trainings, electronic clinical consultation, and technical assistance from HCV-experienced primary care physicians. An evaluation by an SFDPH-commissioned external evaluator found that all three aspects of providing training were useful because different providers responded better to some training modalities than others. The first in-person training for more than 70 primary care physicians, mid-level practitioners, and SFHN staff was offered in February 2016 (after SFDPH was notified that its application for a CDPH HCV demonstration project grant was successful but three months before the demonstration project officially began). A second in-person training for primary care providers and clinical staff was conducted in October 2016, further increasing local hepatitis C treatment capacity.

In February 2016, SFHN launched an electronic clinical consultation system, called eReferral, through which SFHN primary care providers could submit a referral to an HCV-experienced primary care provider for recommendations on the appropriate course of hepatitis C treatment based on an individual client's test results and clinical history. (Complex cases of hepatitis C, such as among people with liver cancer, were referred to specialty care.) Clinical consultation/eReferral requests were submitted through a secure, web-based electronic portal and responses were received within 72 hours. CDPH funds were used to support 0.05-0.10 FTE of a consulting clinician's time and 0.10 FTE of a consulting pharmacist's time. These staff fielded and responded to eReferral requests and developed standardized responses to questions regarding topics such as assessing readiness for hepatitis C treatment, selecting treatment regimens, staging liver disease, and obtaining treatment authorization from health insurers. There were 25 eReferral requests per quarter on average in 2016 as the service got started, after which the average number of eReferral requests per quarter leveled off at 36 per quarter in 2017 and the first half of 2018.

¹⁸ Facente S, Burk K, Eagen K, Mara E, Smith A, Lynch C. New Treatments Have Change the Game: Hepatitis C Treatment in Primary Care. Infect Dis Clin N Am. 2018; 32:313-322.

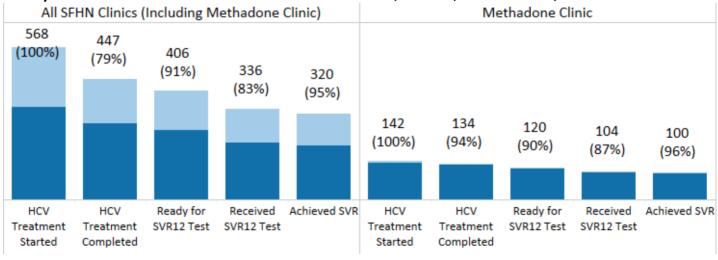
Two HCV clinician champions, one supported by the CDPH grant and another whose contributions were in-kind, assisted SFHN clinic leaders with integrating hepatitis C care and treatment into their clinic workflows. The HCV clinical champions emphasized the ways in which treating hepatitis C in primary care had greatly increased their own job satisfaction, which helped to increase interest among other primary care providers. (HCV-treating clinicians were also supported in becoming certified to prescribe buprenorphine, enabling them to address both hepatitis C and substance use disorders in their patients.) As a result of these efforts, the number of SFHN clinics treating hepatitis C increased from 5 before March 2016 to 15 in June 2018, and the number of SFHN clinicians treating hepatitis C in primary care clinics increased from 51 before March 2016 to 170 in June 2018, creating lasting care and treatment infrastructure.

Direct Patient Care

SFHN used CDPH funds to support a dedicated HCV care coordinator at the methadone clinic within its large county safety net hospital. An 0.80 FTE registered nurse coordinated care for methadone clients, including monitoring laboratory tests and assisting with obtaining treatment approvals from insurers, while the supervising physician wrote the HCV medication prescriptions. Clinic staff delivered HCV treatment medications to the county jail when clients were arrested during treatment to assure treatment completion and supported clients in using directly observed therapy if needed to support treatment adherence. When the demonstration project ended, SFDPH continued supporting the care coordinator position.

Overall, SFHN clinics reported 568 people initiated hepatitis C treatment, 447 completed treatment and 320 were known to have been cured, among whom 202 (63%) were known to have injected drugs (see **Figure 4**). SFDPH performed a retrospective analysis of their electronic health record data and identified an additional 74 people that initiated treatment for hepatitis C in primary care clinics and were cured during the demonstration projects, but that were not reported to SFDPH. This analysis showed that 642 people initiated treatment, 502 (78.2 percent) of whom had a negative HCV RNA viral load 20 weeks after completing treatment. **Figure 4** shows the care cascades for SFHN clinics and the methadone clinic.

Figure 4: Number of Clients Who Started Treatment, Completed Treatment, Received Testing for Sustained Virologic Response 12 Weeks After Treatment (SVR12), and Achieved SVR, by Known Injection Drug Use History—San Francisco Health Network and Methadone Clinic, March 1, 2016 – June 30, 2018



Injection Drug Use History

People Not Known to Have Ever Injected Drugs

People Known to Have Ever Injected Drugs

Note: Proportions calculated as a percentage of the previous bar.

Data-Sharing Between Primary Care and Substance Use Treatment Facilities

Federal regulations¹⁹ governing data sharing between substance use disorder treatment facilities and other health care providers initially presented barriers to information sharing between SFHN primary care and methadone clinic providers and SFDPH staff managing the demonstration projects. However, with the assistance of the City Attorney, the Behavioral Health Services Director, and the SFDPH Privacy Office, SFDPH developed an information-sharing agreement that protected client confidentiality while enabling sharing of client-level data necessary for grant reporting and care coordination. Data sharing between methadone clinic and primary care commenced once the agreement was in place, enabling SFDPH to report aggregate client outcomes to CDPH.

Data Management Support

SFDPH used CDPH grant funds to support a full-time data analyst to actively track HCV testing, linkage to care, and treatment outcomes for community-based HCV testing sites and SFHN clinics. The analyst worked with SFDPH information technology staff to develop a database, first in Excel and then in Microsoft Access, to track HCV outcomes at the client level across multiple SFHN clinics, and trained providers in using the registry to facilitate patient care. The development of an HCV registry allowed SFDPH to track clients treated for hepatitis C, and helped to demonstrate the burden of hepatitis C infection in SFHN clinics. All of the 12 clinics that treated more than one person for hepatitis C during the demonstration project used a template HCV care tracking sheet, which fed into the HCV registry maintained by the program assistant. The ability of clinics to enter data into the tracking sheet in a timely manner varied based on staffing resources. When data entry delays occurred, the program assistant conducted chart reviews to assess HCV treatment outcomes, which was time intensive. Moving forward, SFDPH is tracking hepatitis C treatment within SFHN using positive and negative HCV laboratory test results while moving to a passive data system that will pull from public health surveillance, community-based HCV testing, and SFHN health records to assess the local hepatitis C care cascade.

C) LESSONS LEARNED

A robust bottom-up and top-down strategy to test people in community settings and equip the health care safety net to receive HCV treatment referrals by training primary care providers resulted in large number of people at risk for hepatitis C who were tested and linked to care and who were treated and cured. These successes were made possible in part by a considerable investment of largely in-kind resources, including the vision, time, and leadership of the SFDPH Viral Hepatitis Prevention Coordinator, who coordinated efforts across all participating organizations, and two clinician champions who trained other clinicians and provided leadership throughout the HCV demonstration project.

Like other sites, providers and clients in San Francisco faced individual and structural barriers to testing, linkage, and treatment. Client-level barriers included misinformation about hepatitis C treatments, stigma, mental health and substance use disorders, homelessness, poverty, lack of transportation, competing priorities with greater urgency, and incarceration, among many others. Organizational and structural barriers included turnover and unexpected deaths among HCV navigation staff, turnover among providers, policy barriers to data-sharing, complex treatment approval processes, challenges switching clients to a different medical home to facilitate hepatitis C treatment, and limited resources. An unexpected challenge also arose toward the end of the project when the people who were highly

¹⁹ Code of Federal Regulations, Title 42, Chapter 1, Subpart D

motivated to be treated for hepatitis C had already been located, linked to care, and treated, and those who remained untreated were harder to find, harder to link to care, and more difficult to retain in care.

Despite these barriers, SFDPH identified strategies to assure successful testing, linkage, care, and treatment for priority populations. Strategies for successful testing and linkage to care included hiring people with lived experience as HCV navigators and cross training them in HCV rapid testing and phlebotomy; developing outreach materials for and by people who inject drugs; offering testing and care in settings where people already are (such as syringe exchange and drug treatment programs); case conferencing to identify and address any barriers; and offering incentives to support attendance at key medical appointments. Strategies for increasing the number of treating providers included offering a combination of learning modalities and having centralized data supports and technical assistance.

Developing local infrastructure through a one-time investment of state funds had lasting benefits in San Francisco, including through personnel and programs being supported with local funds once the state funds ended; SFDPH staff and partners publishing their findings in peer-reviewed medical journals and presenting at national conferences; and inspiring hepatitis C elimination initiatives in other jurisdictions in California, including Los Angeles and San Diego, as well as other cities nationwide. ^{20,2122,23}

²⁰ Nelson R. San Francisco's ambitious plan to eliminate hepatitis C. The Lancet. 2018;3(6):378.

²¹ Eagan K. Practical Advice for Developing an Active Hepatitis Treatment Program in Your Clinic: The Details. Oral presentation at University of California San Francisco, San Francisco, December 6, 2016.

²² Facente S; et al. Estimated hepatitis C prevalence and key population sizes in San Francisco: A foundation for elimination. PloS ONE. 2018;13(4): e0195575.

²³ Woody S, Sheriffs A, Casey A, Harkin P. SYNCing HCV Testing, Navigation and Linkage to Care with HIV Programs: Leveraging Opportunities for Service Integration. Oral presentation at SYNChronicity: The National Conference for HIV, HCV, and LGBT Health, April 22-24, 2018, Arlington.

APPENDIX D - SITE-SPECIFIC PROFILE: ACCESS SUPPORT NETWORK OF SAN LUIS OBISPO AND MONTEREY COUNTIES





GOAL 2: HEPATITIS C TESTING AND LINKAGE TO CARE

A) SITE BACKGROUND AND INTERVENTION

Access Support Network (ASN) began providing support for people living with HIV/AIDS in San Luis Obispo (SLO) County in 1984 and for people living with hepatitis C infection in 1999. In July 2015, ASN expanded their services to Monterey and San Benito Counties. ASN is the sole community based organization in San Luis Obispo, Monterey, and San Benito Counties offering supportive services to residents living with and at risk for HIV/AIDS and hepatitis C.

ASN's demonstration project focused on hepatitis C virus (HCV) education, outreach, and screening in community-based settings and on ensuring diagnostic testing and linkages to care and other services for people with hepatitis C in SLO and Monterey counties. This profile highlights the unique aspects of ASN's HCV testing and linkage to care demonstration project.



B) METHODS AND RESULTS

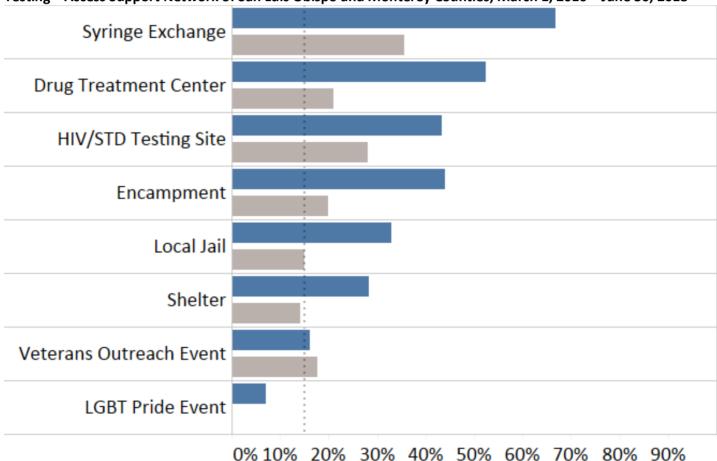
Dynamic Hepatitis C Outreach and Screening Strategies

At the beginning of their demonstration project, ASN employed broad education and outreach strategies to locate and offer hepatitis C testing to people who inject drugs (PWID) and who were at the highest risk for hepatitis C infection. ASN was hoping to reach people at high risk for hepatitis C in rural SLO County, which lacked the open air drug markets or visible homeless encampments common in many urban counties. (Outreach in Monterey County was made easier by there being a centralized Skid Row area (known as Chinatown) and by ASN opening a syringe exchange program there.) Initial outreach strategies included running local television and radio ads in English and Spanish, which helped to increase testing uptake among people born during 1945-1965 (a group for whom the U.S. Centers for Disease Control recommends one-time testing for hepatitis C, regardless of risk factors). ASN also initially offered testing at local lesbian, gay, bisexual, transgender, and queer (LGBTQ) pride events, but stopped after these events yielded no positive hepatitis C antibody test results. Additional outreach

efforts were made at a local syringe exchange program in SLO but the program lacked the physical space to conduct more than 1-2 hepatitis C tests in a limited weekly two-hour service window. In Monterey County, ASN began testing at the local jail, but stopped due to logistical challenges, clients' confidentiality concerns, and lack of linkage to care resources.

Over time, ASN narrowed its outreach efforts to focus solely on settings with consistently higher rates of hepatitis C antibody positivity (15 percent or more), including drug treatment programs, shelters, outreach events for veterans experiencing homelessness, and ASN's syringe exchange program in Monterey County, which was consistently able to test 4-7 program clients each week. Figure 2 shows HCV positivity and percent tested who reported ever injecting drugs by setting.

Figure 2: Percentage of People Who Were Known PWID Among Those Who Received HCV Antibody Testing, and Percentage of People Who Received a Positive HCV Ab Test Results Among Those Who Received HCV Antibody Testing—Access Support Network of San Luis Obispo and Monterey Counties, March 1, 2016 – June 30, 2018



People Who Were Known PWID Among Those Who Received HCV Ab Testing

People Who Received a Positive HCV Ab Test Results Among Those Who Received HCV Ab Testing Note: Dotted line represents threshold of 15 percent HCV antibody positivity.

Rapid HCV Antibody Testing Partnerships with Drug Treatment Programs and Other Providers

HCV testing in community-based settings was made possible by extensive work establishing and strengthening partnerships with governmental, community-based, and health care organizations. For example, ASN developed a memorandum of understanding (MOU) with the SLO County Drug and Alcohol Services Division to conduct rotating quarterly HCV testing events in drug treatment programs countywide. ASN developed agreements with other partners conducting outreach or services to people

who are homeless, including the Homeless Outreach Team of Transitions Mental Health Association and Mobile Assistance Services for the Homeless, to reach their shared priority populations.

Mobile Health Vans

ASN partnered with other organizations with mobile health vans (which can be prohibitively expensive for small community-based organizations to purchase, operate, and maintain) to conduct joint outreach. These partnerships helped ASN to locate people who had tested positive for HCV to help them obtain HCV diagnostic testing and care in conjunction with other services. When other programs' vans were unavailable, ASN began renting cargo vans and outfitting them with outreach supplies, attaching a large magnet of ASN's logo on the side of the van to make their presence known as they went into the field.

HCV RNA Testing Partnerships with Local Phlebotomy Providers

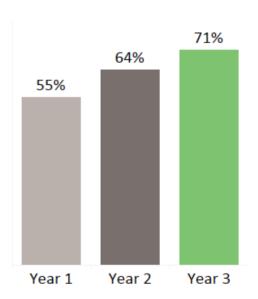
After establishing successful outreach strategies for reaching people at high risk for hepatitis C to offer HCV antibody rapid testing, ASN faced significant challenges assuring their clients who had a positive HCV screening result received follow-up HCV ribonucleic acid (RNA) testing, which is needed to diagnose current infection, and which requires a blood draw. Their initial strategy was to provide clients who had a reactive HCV rapid test result with a laboratory slip and a referral to a private laboratory for a blood draw. The phlebotomy services were billed to the client's insurance or paid for by ASN through a

contract with the laboratory, and ASN provided transportation and incentives if needed. Barriers to phlebotomy included a lack of transportation, competing priorities, and a lack of cultural competency and skill among some private laboratory staff in drawing blood among PWID.

ASN took multiple approaches to facilitate on-site HCV diagnostic testing during the project, which increased the proportion of clients who received HCV RNA testing from 55 percent in Year 1 to 71 percent in Year 3 (Figure 3). Specifically, ASN recruited skilled contract phlebotomists from private laboratories to work part-time at ASN in SLO County conducting blood draws at the main office and on the mobile van during screening events. They also enrolled phlebotomists to be trained as HIV/HCV test counselors so they could perform both HCV rapid and diagnostic testing, and began providing transportation and accompaniment for clients to get their blood drawn. Attempts to enroll ASN staff in phlebotomy certification courses were thwarted by local phlebotomy programs being at capacity for months at a time and by staff not passing the course exam.

ASN also experienced challenges with locating clients to receive their HCV RNA results due to delays in getting test results back because multiple test results (e.g., HCV RNA, genotype, liver enzymes, and drug resistance testing for selected genotypes) were still pending; this problem was resolved when ASN changed its contract with a private laboratory to focus solely on HCV RNA testing.

Figure 3: Percentage of People Who Completed RNA Testing Among Those with a Positive HCV Ab Test Result by Year*—Access Support Network of San Luis Obispo and Monterey Counties, March 1, 2016 – June 30, 2018



*Year 1 - March 1, 2016 - June 30, 2016 Year 2 - July 1, 2016 - June 30, 2016 Year 3 - July 1, 2017 - June 30, 2018

Creative Strategies for Follow-up Testing and Retention in Care

Re-Establishing a Syringe Exchange Program

In January 2017, ASN began operating a syringe exchange program in Monterey County as part of an unfunded agreement authorized by the Monterey County Board of Supervisors. In addition to providing a critical HCV prevention service, offering syringe exchange services in Monterey County provided an opportunity for repeated contact with people who inject drugs to establish rapport, build trust, answer questions, and enable clients to access other services, including HCV testing and linkages to care, if and when they were ready. Through syringe exchange services, ASN often reestablished contact with clients who had been lost to follow-up due to incarceration, hospitalization, or another emergency; the syringe exchange program enabled ASN to reengage people who inject drugs in hepatitis C care.

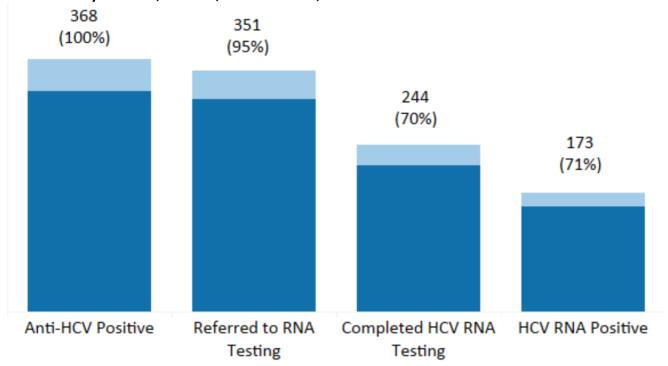
In-Depth Contact Information Form

ASN also adopted an in-depth contact information form developed by researchers at the University of California San Francisco to track young people who inject drugs, which helped to facilitate tracking, linkages to care, retention in care, and follow-up. In addition to typical questions about name, address, phone number, and email, the form includes questions about multiple alternate contacts, along with multiple hangout and sleeping locations, social media accounts, and other location information.

Weekly Outreach Trips

ASN conducted weekly trips to an area of town in which people experiencing homelessness congregate and was able to find multiple program participants this way, including people who were unable to attend appointments but who attended services when offered a drop-in spot and transportation at a moment when they were ready. **Figure 4** shows the HCV RNA testing cascade for ASN testing clients.

Figure 4: Number of Clients with Positive HCV Antibody Result Who Were Referred to RNA Testing, Received RNA Testing, and RNA Test Results, by Injection Drug Use History—Access Support Network of San Luis Obispo and Monterey Counties, March 1, 2016 – June 30, 2018



People Not Known to Have Ever Injected Drugs

People Known to Have Ever Injected Drugs

Note: Proportions are calculated as a percentage of the previous bar.

Wraparound Services

Providing a range of services, including syringe exchange, free socks, a food pantry, housing linkages, pay-as-you-go phones, and care coordination helped to both meet the multiple survival and support needs of ASN program participants, and provide opportunities to reestablish contact with clients who had been lost to follow-up. Wraparound services also included communicating weekly with treating clinicians to identify and address any issues with coverage or logistics, assisting clinics with locating and communicating with clients, and scheduling and accompanying clients to appointments.

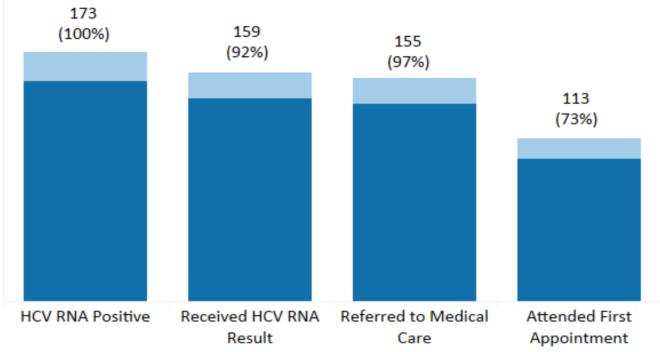
ASN provided \$10-25 gift cards to compensate people for their time when completing key appointments, such as HCV RNA testing and results and medical appointments, and to meet with ASN staff to receive feedback on the client's experience, answer questions, and prepare for the next step in the hepatitis C care cascade. These meetings helped with retention in care and with identifying care coordination issues. They also led ASN to stop referring to health care providers if clients reported negative experiences, particularly if clients reported experiencing judgmental attitudes towards their drug use. Instead, ASN referred clients to health care providers with positive reviews from clients.

Office-Based Medication Storage

While ASN does not have medical staff on-site to provide directly observed therapy for HCV treatment, several clients requested that ASN store their medications at the office for the client to self-administer. This was particularly useful for program participants with unstable housing as well as those with concerns about privacy or security.

The hepatitis C linkage cascade for ASN clients is show in Figure 5.

Figure 5: Number of Clients with Positive HCV RNA Result Who Received Their Result, Were Referred to Medical Care and Attended the First Medical Appointment, by Injection Drug Use History—Access Support Network of San Luis Obispo and Monterey Counties, March 1, 2016 – June 30, 2018



Injection Drug Use History

People Not Known to Have Ever Injected Drugs

People Known to Have Ever Injected Drugs

Note: Proportions are calculated as a percentage of the previous bar.

Leveraging Existing HIV Testing and Linkage to Care Data Systems

Among the five HCV testing and linkage to care demonstration project sites, ASN was the only one that used an existing statewide HIV data system to track HCV testing clients. The Local Evaluation Online (LEO) system, which is maintained by the California Department of Public Health Office of AIDS, only included two basic fields related to hepatitis C testing—antibody test type and antibody test result—when this project began. State staff modified LEO to include a second set of fields specific to HCV diagnostic testing and linkages, with fields to include diagnostic testing date, test results, first medical appointment date, and client-perceived barriers to accessing care, such as the need for transportation.

Using LEO enabled ASN to integrate existing HIV service flows, but also proved challenging, requiring time-consuming data entry that ASN did not always have dedicated staff available to conduct, and requiring ASN to rely on the state to run aggregate reports of the numbers of people tested, percent positive, number linked to care, etc. While running such reports was possible for HIV testing sites, those features had not yet been developed for HCV testing activities. LEO also proved challenging because it did not include names and was not designed to track client-level case management and care coordination activities and outcomes over time, leading ASN to use multiple data systems, including LEO, CareWare case management software, and secure electronic spreadsheets, for each client.

Increasing Community Capacity for Hepatitis C Treatment

ASN found they needed to conduct follow-up on clients linked to care to ensure clients actually received HCV care and treatment. This led to multiple collaborations to identify and address barriers to care.

Assessing the Hepatitis C Treatment Landscape

At the project outset, ASN found local safety net clinics required primary care providers to refer patients to a specialist for hepatitis C treatment, which presented a barrier for clients who lacked a primary care provider, or who faced delays in accessing primary and specialty care. After obtaining a client consent to release information to allow ASN to follow up with the client's primary care provider to track the clients care, ASN often had to call the primary care clinic to ensure a specialist referral was made and then call the specialist to ensure the client received an appointment for hepatitis C care. Many clients were lost to follow-up waiting for their specialty care appointment and specialists were sometimes unwilling to follow-up if clients missed appointments. One specialist charged \$50 for missed appointments, despite ASN clients often experiencing significant barriers to attending appointments, such as violence, displacement, and arrest. While ASN was able to get exemptions to this fee in certain circumstances, these barriers highlighted the need for primary care-based hepatitis C treatment.

Cultivating Primary Care-Based HCV-Treating Clinician Champions

In Year 2, ASN entered into a formal agreement with a local federally qualified health center (FQHC) wherein ASN referred clients diagnosed with hepatitis C to the clinic for HCV care, while the clinic referred clients with hepatitis C to ASN for case management. This agreement paved the way for conversations with the clinic about increasing their hepatitis C treatment capacity. The clinic's leadership initially expressed reluctance to take on the responsibility for treating hepatitis C and fear of being overwhelmed by HCV treatment referrals. ASN staff suggested clinic leadership review their electronic health record to identify existing patients who had screened HCV antibody positive to determine whether they had ever received diagnostic testing and, if HCV RNA positive, been treated or cured. The clinic medical director performed such an inquiry and found 96 HCV-positive patients, among whom approximately 40 had incomplete HCV diagnostic testing and only two had been treated. The medical director decided additional in house hepatitis C clinical management capacity was needed.

ASN helped the medical director identify training resources, including in-services by the Pacific AIDS Education Training Center and one of San Francisco's HCV clinician champions and web-based training through the University of California San Francisco Project Extended Community Health Outcomes (ECHO) initiative, which offers free didactic and case-based learning for rural primary care providers to treat hepatitis C. These efforts resulted in the FQHC contacting their existing patients to offer them follow-up HCV diagnostic testing and care and treatment, where indicated—a first for Monterey County—and to establish streamlined HCV testing protocols. Examples of streamlined protocols included a clinic standing order wherein a positive HCV diagnostic test result was automatically followed by pre-treatment tests, including an order for a liver ultrasound needed to assess the stage of liver disease, before the client's first appointment with an HCV-treating primary care provider. One local primary care physician's participation in Project ECHO enabled him to receive approval from a local Medi-Cal managed care plan to prescribe hepatitis C treatment in a primary care setting.

To support HCV treatment implementation in the local FQHC, ASN helped the medical director establish a monthly HCV stakeholder meeting (HCV Charrette), including primary care providers, Medicaid (Medical) managed care plan representatives, pharmacists, pharmaceutical company representatives, and community-based organizations. These discussions facilitated troubleshooting, streamlining, and coordinating linkage to care, treatment authorization, filling prescriptions, case management, and access to care. Work group members identified strategies to increase access to care for people not

covered by the Medi-Cal hepatitis C treatment policy in place at the time.²⁴ Pharmacists and pharmaceutical company representatives offered suggestions for navigating patient assistance programs and other treatment resources. ASN invited guest speakers to the meetings, including clinicians from other local health jurisdictions with expertise treating HCV in PWID and people experiencing homelessness, in an effort to increase the cultural competency of local providers.

C) LESSONS LEARNED

ASN learned the importance of prioritizing HCV testing activities for those settings with the highest positivity rate, including syringe exchange and drug treatment programs, and ensuring access to on-site, experienced phlebotomists. To assure follow-up, they learned to collect in-depth contact information and conduct weekly outreach to provide repeated, unstructured opportunities in multiple settings for finding individuals who had been tested and re-engaging them in care. ASN learned the plusses and minuses of leveraging existing HIV testing data systems for HCV navigation, and identified an outstanding need for better case management platforms. Cultivating local clinician champions proved particularly fruitful, and was made possible by experienced clinicians in other jurisdictions providing inperson and web-based training and by supporting incremental change, with clinicians starting first with their own existing patient panels. Cultural competence with people who inject drugs also proved critical to program success, and was facilitated by actively seeking and heeding ongoing client feedback.

ASN's HCV demonstration project proved helpful in building and sustaining partnerships and increasing hepatitis C awareness among local leaders. After the demonstration projects, ASN received time-limited pharmaceutical company funds for HCV linkage to care activities and continued their partnerships with local HCV clinic champions. However, ASN's ability to sustain its HCV testing and linkage to care capacity and services remained contingent on identifying sustainable resources.

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²⁴ The California Department of Health Care Services Medi-Cal hepatitis C treatment policy can be accessed at https://www.dhcs.ca.gov/Pages/HepatitisC.aspx.

APPENDIX E - SITE-SPECIFIC PROFILE: FAMILY HEALTH CENTERS OF SAN DIEGO





GOAL 2: HEPATITIS C TESTING AND LINKAGE TO CARE

GOAL 3: HEPATITIS C CARE COORDINATION

A) Site Background and Intervention

Family Health Centers of San Diego's (FHCSD) mission is to provide affordable, high-quality health care and support services to all people, with a special commitment to people who are uninsured, low-income, and medically underserved. FHCSD offers a wide range of health care services regionally, including 22 primary care clinics, a teen health center, 5 behavioral health facilities, an outpatient drug treatment program, a syringe exchange program, three mobile medical units, and a pharmacy. FHCSD is the largest health care safety net provider for uninsured people in San Diego County, and the largest comprehensive HIV/AIDS services provider in the San Diego region. FHCSD's hepatitis C virus (HCV) testing and linkage to care demonstration project addressed the whole hepatitis C care continuum, from outreach and testing to linking people to both primary care and hepatitis C care and treatment at FHCSD clinics. The



findings in this profile are limited only to those clients whose HCV testing, linkage to care, and care coordination services were attributed to the CDPH-funded HCV testing and linkage to care demonstration project funds, and do not reflect all FHCSD clients tested, linked to care, or treated for hepatitis C infection during the grant period. FCHSD allocated clients to this project whom they anticipated needed navigation services.

B) METHODS AND RESULTS

Outreach and Testing in Drug Treatment and Community Settings

Based on findings from an assessment conducted for FHCSD by academic partners of which settings would yield the highest rates of hepatitis C positivity, as well as previous experience, FHCSD conducted HCV testing in eight drug treatment programs and numerous other community settings. The HCV testing and linkages team partnered with the FHCSD homeless services outreach team, along with other outside organizations, to conduct joint late night (5pm – 1am) and weekend outreach events, offering HIV and HCV testing and other services in bars, alleyways, parks, homeless encampments, and under bridges. Testing services took place via mobile health van and included rapid HCV antibody testing, which returns

results in 20 minutes, and same-day phlebotomy for diagnostic HCV ribonucleic acid (RNA) testing. Clients with a positive test were linked to FHCSD clinics for hepatitis C evaluation and care.

Offering HCV testing in drug treatment programs and community settings presented unexpected challenges. Some clients who had been court mandated to drug treatment stopped attending medical appointments due to fear of FHCSD notifying their parole officer if they left their drug treatment program early. While confidentiality rules protected the privacy of clients accessing health care, these concerns remained and had to be assuaged to assure successful linkage. Additional challenges arose in finding ways to pay for hepatitis C treatment for people in drug treatment programs where they were still serving prison time, because people in state prison are not eligible for Medicaid (Medi-Cal) until after release. Navigation staff sometimes had difficulty contacting clients in residential treatment programs who had a full schedule of required group education and counseling sessions. Challenges that arose in methadone clinic settings included clients being busy getting their daily dose of methadone before work and not having time for testing, or not having veins needed for a blood draw to conduct HCV diagnostic testing.

FHCSD had challenges locating people experiencing homelessness when their encampments were disbanded, particularly after the major hepatitis A outbreak in San Diego. However, the establishment of a sanctioned tent city following the outbreak temporarily helped facilitate HCV testing in the field. Offering transportation assistance, accompaniment to appointments, and incentives helped to facilitate successful linkage to care for clients tested in drug treatment and other community settings outside the four walls of FHCSD's clinics. Overall, FHCSD screened 1,313 people for HCV antibody, 55 percent of whom were known to have ever injected drugs. Figure 1 shows HCV testing outcomes for clients with a positive HCV antibody result (N=356) and Figure 2 shows linkage to care outcomes for clients with a positive HCV RNA result (N=215).

Figure 1: Number of Clients with Positive HCV Antibody Result Who Were Referred to RNA Testing, Received RNA Testing, and RNA Test Results, by Injection Drug Use History—Family Health Centers of San Diego, March 1, 2016 - June 30, 2018

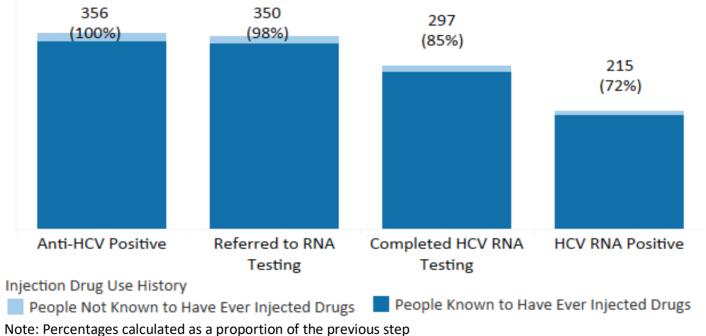
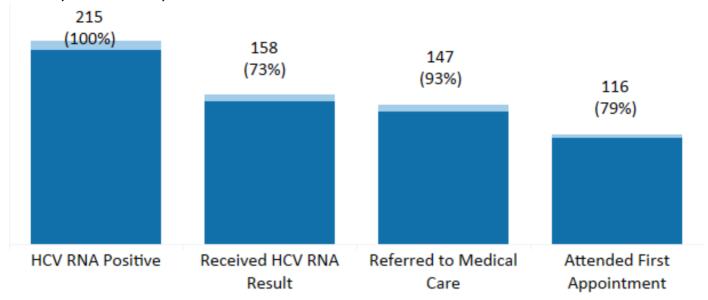


Figure 2: Number of Clients with Positive HCV RNA Result Who Received Their Result, Referral to Medical Care and Attended the First Medical Appointment, by Injection Drug Use History, Family Health Centers of San Diego, March 1, 2016 – June 30, 2018



People Not Known to Have Ever Injected Drugs

People Known to Have Ever Injected Drugs

Note: Percentages calculated as a proportion of the previous step

Internal Capacity Building within a Federally Qualified Health Center with Multiple Locations

The lead infectious disease physician on the project developed standardized talking points for all staff to use when discussing HCV screening, testing, care, and treatment with clients. He also established a weekly huddle with 15-20 FHCSD clinical providers and staff. The weekly huddles were based on the Project Extended Community Health Outcomes (ECHO) model, and included didactic presentations on HCV treatment, along with discussion of practical issues, such as navigation, insurance, prior authorizations, and individual case reviews. Patient navigators met after the huddle to discuss individual cases and to identify solutions and recommendations for clinic leadership. Once trained, clinicians typically dedicated approximately 10 percent of their practice (four hours/week) to treating hepatitis C. For every 2.5 days of total clinician time dedicated to hepatitis C treatment, FHCSD allocated one full-time patient navigator. By the end of the project, FHCSD had become a satellite location of the national ECHO network. The number of in-house prescribing clinicians treating hepatitis C increased from 7 in July 2016 to 11 in June 2018; the number of FHCSD clinics offering hepatitis C treatment increased from 1 to 8 during the same time period.

Family Health Centers of San Diego increased other aspects of their organizational capacity during the project as well. FHCSD began the project sending HCV diagnostic laboratory tests out to a private laboratory for processing, but brought those tests in-house to their internal laboratory during the project, reducing turnaround times from two weeks to 3-7 days and helping to potentially expedite the hepatitis C care continuum. Using an alternate funding source, FHCSD purchased a liver elastography machine, which provides a non-invasive way to determine an individual's stage of liver disease in real time. This information was used to determine an individual's best course of hepatitis C treatment (and

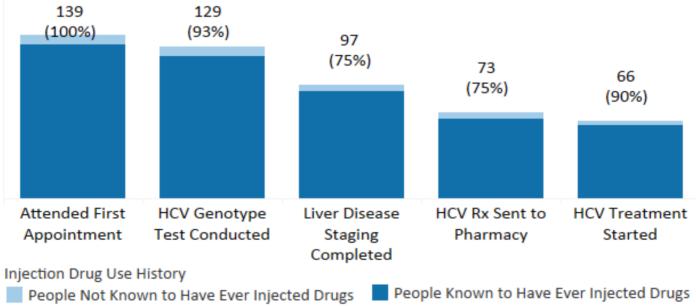
eligibility for the Medicaid treatment guidelines in place at the time)²⁵ and their risk for serious liver disease or liver cancer. As more cases of serious liver disease were detected, FHCSD saw an unmet need and decided to establish a monthly hepatology clinic for people with advanced liver disease, decompensated cirrhosis, hepatocellular carcinoma (liver cancer), fatty liver disease, and other complications.

FHCSD received a federal grant to enroll their prescribing clinicians in training to receive an X waiver, which is needed to prescribe buprenorphine, an evidence-based, biomedical treatment shown to be highly effective for treating opioid use disorders. The number of clinicians with an X waiver to prescribe buprenorphine increased during the project period from 4 to 14. This is a particular important component of offering comprehensive hepatitis C treatment and prevention services because maintenance buprenorphine has been shown to prevent hepatitis C infections among young people who inject drugs by 50 percent. ²⁶ FHCSD also trained their staff in behavior change theory, principles of harm reduction, methamphetamine, and other topics central to serving people who inject drugs well.

Provider turnover proved challenging as mid-level providers who had just been trained to treat hepatitis C in a busy, primary care safety net clinic soon left for higher paying and lower patient volume positions in academic medical centers, leaving FHCSD to restart the hiring and training process over again.

Figure 3 shows treatment starts among those recently and previously diagnosed that were linked to care; and **Figure 4** shows treatment completion rates among those who initiated treatment.

Figure 3: Number of Clients Who Attended the First Medical Appointment, Received Genotype Testing, Received Liver Disease Staging, had a Prescription Sent to the Pharmacy and Initiated Treatment, by Injection Drug Use History, Family Health Centers of San Diego, March 1, 2016 – June 30, 2018

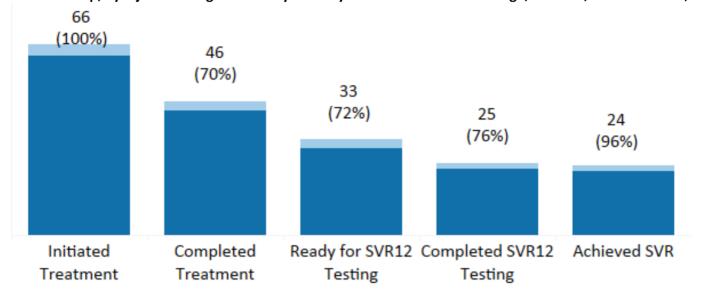


Note: Percentages calculated as a proportion of the previous step

²⁵ The California Department of Health Care Services Medi-Cal hepatitis C treatment policy can be accessed at https://www.dhcs.ca.gov/Pages/HepatitisC.aspx.

²⁶ Platt L, Minozzi S, Reed J, et al. Needle syringe programmes and opioid substitution therapy for preventing hepatitis C transmission in people who inject drugs. Cochrane Database Syst Rev. 2017;9(9):CD012021.

Figure 4: Number of Clients Who Started Treatment, Completed Treatment, 12-weeks Post-treatment, Received Post-Treatment Testing for Sustained Virologic Response (SVR12), and Achieved SVR by Proportion of the Previous Step, by Injection Drug Use History—Family Health Centers of San Diego, March 1, 2016 – June 30, 2018



People Not Known to Have Ever Injected Drugs

People Known to Have Ever Injected Drugs

Note: Percentages calculated as a proportion of the previous step

Patient Navigation and Quality Improvement

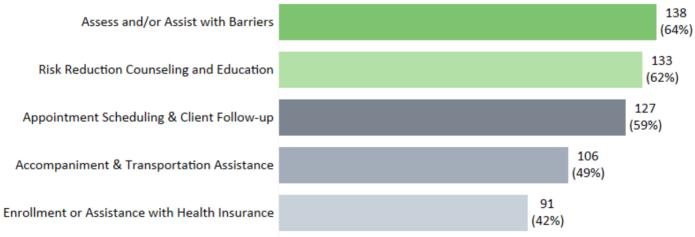
FHCSD used a multi-disciplinary team to provide a wide array of services to support clients and to help them remain engaged in the HCV testing, linkage, care, and treatment process. Enrollment specialists screened clients for insurance eligibility, documented income, explained health insurance options in an impartial manner, and assisted clients with applying for identification and health insurance. Medical assistants (MAs) submitted prior authorization requests to insurers for hepatitis C treatment, assisted clinicians with responding to (often repeated rounds of) treatment authorization denials and documentation requests, scheduled medication refills, and conducted reminder phone calls. Many clients reported not being ready for hepatitis C treatment due to competing issues, including homelessness and intermittent periods of drug treatment and incarceration. Patient navigators provided clients with bus passes, transportation to medical appointments, helped locate clients who had been lost to follow-up, and worked with the MAs to provide referrals to other social services. Staff also used client transportation as an opportunity to prepare clients for their visit, explain the registration paperwork and what to expect, accompany clients to their appointments, and build rapport.

Together, members of the project team identified barriers to client retention in care and modified their protocols to make improvements. Staff modified the client locator form to include more than three fields for asking clients where they might access services or be located. Staff instituted electronic health record alerts to flag when a client accessed any FHCSD clinic location so they could be re-engaged in hepatitis C care. After having clients not show for post-treatment test of cure appointments, staff began scheduling end of treatment and post-treatment appointments at the time of treatment initiation, reinforcing the importance of post-treatment testing during the end of treatment visit, and setting up electronic health record alerts, all of which helped to increase completion of post-treatment virologic testing.

Despite these improvements, patient navigation for hepatitis C care and treatment proved to be time-consuming, both for expected reasons, such as clients facing urgent survival needs for food, housing, and physical safety, and due to unique barriers, such as repeated treatment authorization denials from health insurers. Local Medi-Cal managed care plans covering many FHCSD clients often required multiple rounds of denials and appeals before approving hepatitis C treatment for its members; one plan would only allow one specific gastroenterologist to treat its members for hepatitis C, despite the clinician's office being located far from FHCSD and difficult to access for homeless clients. At times, these dynamics made it difficult for FHCSD staff to both continue testing new clients in drug treatment and other community settings and support existing clients who had already tested hepatitis C antibody positive and who needed to receive follow up diagnostic testing and linkages to care and treatment. Also challenging was having patient navigators split between multiple clinics, which made continuity of care less seamless when a client was seen at a clinic when the patient navigator was not also there.

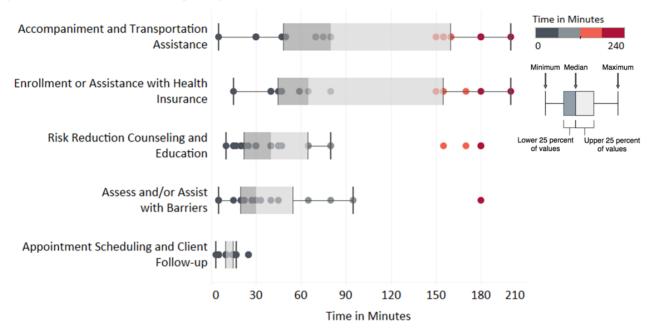
Family Health Centers of San Diego documented some of the activities conducted in providing patient navigation. Among the 1,336 people contacted during outreach, 826 (61 percent) received referrals to substance use disorder treatment, and 772 (58 percent) received referrals to syringe exchange services. Among the 215 clients who tested positive for hepatitis C RNA during the demonstration projects and required additional navigation, 199 (93 percent) received at least one patient navigation service during the demonstration projects, and 170 (79 percent) received at least one referral. **Figure 5** shows the five most frequently utilized services provided to clients and the number of clients receiving those services, among the 215 clients that tested RNA positive during the demonstration projects. Translation services, assistance with treatment authorization and other services were also provided. These numbers are likely underestimates because patient navigation services were not always documented fully or consistently.

Figure 5: Number of People that Received Navigation Services Among Those Who Tested Positive for Hepatitis C RNA (N=215), Family Health Services of San Diego, March 1, 2016 – June 30, 2018



From September 2017 – December 2017, FHCSD recorded the amount of time it took to provide each type of service for patients. A total of 48 clients received at least one navigation service during this time. **Figure 6** shows the median amount of time spent providing that service for each client. These numbers are likely underestimates because patient navigation services were not always documented fully or consistently.

Figure 6: Minimum, Maximum, Median and Interquartile Range (IQR) Number of Minutes, by Service Provided, for People Who Received Navigation Services Among Those Who Tested Positive for Hepatitis C RNA (N=48), Family Health Services of San Diego, September 1, 2017 – December 31, 2017



Data Management and Tools

Multiple tools were used to track program clients and outcomes, in part because FHCSD had funding from multiple funders (including the CDPH Office of AIDS, CDPH Office of Viral Hepatitis Prevention, county behavioral health department, and a pharmaceutical company, to conduct HIV and hepatitis C testing-related activities). The lead clinician on the project used an Excel spreadsheet to track all client test results, insurance coverage, medication prescriptions, and treatment outcomes. However, treating clinicians found that Excel did not have the data management, quality assurance or data management features needed to easily use the spreadsheet to manage a panel of clients at various stages in the hepatitis C care cascade. FHCSD contracted with the San Diego State University, Institute for Public Health to develop and maintain two Microsoft Access databases—one for use by physicians and medical assistants to track all FHCSD clients receiving hepatitis C treatment, and another database which only included those clients whose care was attributed to the HCV demonstration project grant, and which was used to track HCV demonstration project grant deliverables and outcomes. The project-specific database allowed for data cleaning, more accurate grant reporting, and panel management. FHCSD also contracted with their university partner to assist with data management and grant reporting for their demonstration project, which freed up clinic staff time to focus on locating and serving their clients. Even with these tools in place, clinicians and patient navigators had to double enter data into both the FHCSD electronic health record and the project's Access database, and often did not have time to consistently document all of their grant-related activities, leading to gaps in project evaluation data.

C) LESSONS LEARNED

As with other HCV demonstration projects, FHCSD found that drug treatment programs were good locations for finding people living with hepatitis C who were unaware of their infection or out of care, despite some logistical challenges to offering services in these settings. Using a multi-disciplinary team helped FHCSD retain people in hepatitis C care, as did increasing FHCSD's internal capacity to provide HCV diagnostic testing and liver disease staging. Replicating the Project ECHO model in-house nearly doubled FHCSD's hepatitis C treatment capacity. Having data systems to track patient care and for grant reporting was useful in facilitating daily work and informing program quality improvement, but more

robust data systems were needed to handle the complexity of hepatitis C panel management as the size of the program grew.

While a formal qualitative evaluation of FHCSD's efforts was beyond the scope of this project, a number of clients who had initiated hepatitis C treatment appeared to undergo a larger change, expressing interest in improving other aspects of their health, such as by quitting smoking.

FHCSD has disseminated its project findings at national and international conferences, ^{27,28,29,30,31} further advancing the field. The hepatitis C testing and linkage to care demonstration project helped to catalyze larger changes, including the County of San Diego embarking upon a hepatitis C elimination initiative, with the lead clinician for this project as co-chair alongside a county public health official.³²

The experience of an urban federally qualified health center that identifies people in drug treatment programs and community locations and then engages them in a continuum of otherwise in-house services—from diagnostic testing to liver disease staging, care, and treatment—has the potential to be informative to other safety net clinics. This model could be particularly informative to non-clinical drug treatment programs looking to increase their HIV/HCV testing services by partnering with external organizations that have the clinical capacity and infrastructure to offer mobile outreach and testing with linkages to fixed site clinics for medical care. Some aspects of FHCSD's model will be more relevant to some clinics than others, but this case study provides a number of potential points of intervention, such as programmatic and infrastructure changes, for other safety net clinics in large urban areas to consider.

²⁷ Ramers C; Terrault N; Graham C; Sylvestre D; Taylor L; Litwin A; Martin N; Ward J. Hepatitis C Special Interest Group Symposium. Panel presentation on hepatitis C treatment among people who injection drugs at the Annual Association for the Advanced Study of Liver Diseases Meeting, Washington, D.C., October 2017.

²⁸ Ramers C. Integrating Buprenorphine Treatment into Primary Care. Oral presentation at the Annual California Primary Care Association Conference, Anaheim, California, October 2017.

²⁹ Ramers C. Operationalizing Elimination: Curing Hepatitis C in the Patient Centered Medical Home. Poster presentation at the 25th annual Conference on Retroviruses and Opportunistic Infections, Boston, March 2018.

³⁰ Ramers C. Strategic elimination: Efficacy of hepatitis C treatment in people who inject drugs in an urban, underserved clinic in the United States. Poster presentation at The International Liver Congress in Paris, France, April 2018.

³¹ Ramers C. Challenging Cases in Viral Hepatitis. Oral presentation at the Clinical Care Options Hepatitis Symposium, San Francisco, California, May 2018.

³² Ramers C. Sowing the Seeds of an HCV Elimination Movement in San Diego County. HIV Specialist. 2019; April: 14-19.

APPENDIX F - SITE-SPECIFIC PROFILE: HEPLINK LOS ANGELES (LA)









GOAL 3: HEPATITIS C CARE COORDINATION

A) Site Background and Intervention

HepLinkLA was a collaborative project of St. John's Well Child and Family Center (SJWCFC), a network of federally qualified health centers (FQHCs) serving Central and South Los Angeles (LA) and Compton; LA Community Health Project (LACHP), a syringe exchange program; and Tarzana Treatment Centers (TTC), a network of integrated behavioral health treatment centers. SJWCFC is a non-profit community health center offering a broad array of primary care and supportive services to address families' educational, socioeconomic, and mental health needs. TTC is a non-profit organization providing substance use disorder, mental health, and primary care services to adults and youth. TTC operates a psychiatric hospital, residential and outpatient drug treatment centers, and family medical clinics. LACHP combines direct services, outreach, and education to improve



the health of people affected by drug use in LA and to empower people to protect themselves and their communities. HepLinkLA was created specifically to implement this hepatitis C virus (HCV) testing and linkage to care demonstration project in LA County, with a primary focus on clinical care coordination supported by some outreach and testing services.

B) METHODS AND RESULTS

St. John's Well Child and Family Center

Universal, Opt-Out Hepatitis C Screening

SJWCFC instituted a policy of offering hepatitis C antibody screening to all clients, which reduced the burden on health care providers of assessing patient risk factors. All blood samples with a reactive hepatitis C antibody result were automatically tested for hepatitis C ribonucleic acid (RNA), which is needed to diagnose current infection. Universal screening in this primary care setting yielded an overall HCV antibody positivity of three percent, which is lower than that found in drug treatment programs and syringe exchange programs serving primarily people who use drugs but nearly twice the national HCV antibody prevalence estimate of 1.7 percent in the general population during 2013-2016.

Care Coordination

A dedicated hepatitis C care coordinator facilitated hepatitis C care with the support of a multi-disciplinary team comprising a care manager/psychotherapist, linkage to care specialist, and a data specialist/medical assistant. Clients with a positive HCV RNA result received a comprehensive psychosocial assessment of their mental health, substance use, health care, transportation, benefits, and other support needs; education on hepatitis C transmission, test results, and treatment; a care plan; and referrals to other services. Clients needing housing or drug treatment were referred to in-house homeless services team or licensed substance use counselors, respectively. Benefits counselors checked and verified clients' eligibility and insurance coverage at each clinic visit.

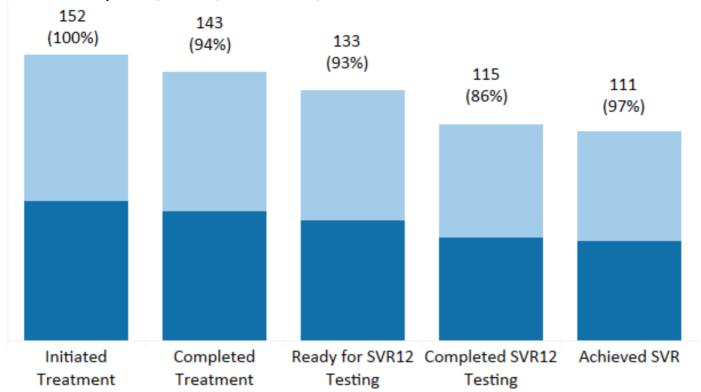
The care coordinator supported all aspects of hepatitis C treatment, reducing the burden on prescribing clinicians. Duties included reviewing laboratory test results, progress notes, and charts to determine whether clients were up to date with laboratory tests, and preparing requests for treatment authorization from insurers. Once clients began hepatitis C treatment, the care coordinator developed no show logs to identify clients with missed appointments and contacted them to identify and address barriers, helping to establish rapport and decrease the cancellation rate. The care coordinator also put flags in the electronic health record for staff to remind clients who came in for another reason of their HCV appointments. Clients who reported transportation barriers received bus tokens or travel arrangements through their insurer.

On-Site Hepatitis C Treatment Supports

At the project's outset, a local Medicaid (Medi-Cal) managed care plan required hepatitis C treatment prescriptions to be written by a gastroenterologist or hepatologist. However, in Year 2, the managed care plan began accepting prescriptions from the infectious disease physician at SJWCFC, increasing their treatment capacity. Hepatitis C prescriptions were initially sent to an off-site pharmacy, which slowed the process of getting medications for hepatitis C treatment. In Year 3, SJWCFC's in-house specialty pharmacy added hepatitis C medications to its formulary, which expedited the turnaround time for filling hepatitis C treatment prescriptions. The specialty pharmacy also successfully treated six clients using directly observed therapy (DOT) during the project's final quarter, putting in place a protocol that could be used in the future for clients with anticipated barriers to adherence, including people experiencing homelessness who may not have a safe place to take or store their medications.

The in-house HIV specialist trained SJWCFC nurse practitioners to treat hepatitis C infection and developed a streamlined hepatitis C treatment protocol, which enabled just one or two treating providers to treat a large number of clients at once. The protocol included standing orders for laboratory panels (such as HCV genotype, fibrosis score, and aminotransferase to platelet ratio index (APRI) scores) needed to evaluate the client's stage of liver disease in preparation for hepatitis C treatment. Ordering these tests in advance of the client's first visit with the prescribing provider enabled the prescribing provider to write the treatment prescription at the client's first visit. The infectious disease physician wrote prescriptions for and evaluated the medical charts and laboratory tests results for all hepatitis C treatment clients, including clients managed by nurse practitioners. The combination of a robust care coordination team, on-site hepatitis C treatment capacity, DOT services, an in-house pharmacy, and a streamlined treatment protocol resulted in high hepatitis C treatment completion rates among both people with (93 percent) and without a history of injection drug use (94 percent) (Figure 1).

Figure 1: Number of Clients Who Started Treatment, Completed Treatment, Received Post-Treatment Testing for Sustained Virologic Response (SVR12), and Achieved SVR, by Known Injection Drug Use History—St. John's Well Child and Family Center, March 1, 2016 – June 30, 2018



People Not Known to Have Ever Injected Drugs

People Known to Have Ever Injected Drugs

Note: Proportions calculated as a percentage of the previous bar.

Los Angeles Community Health Project

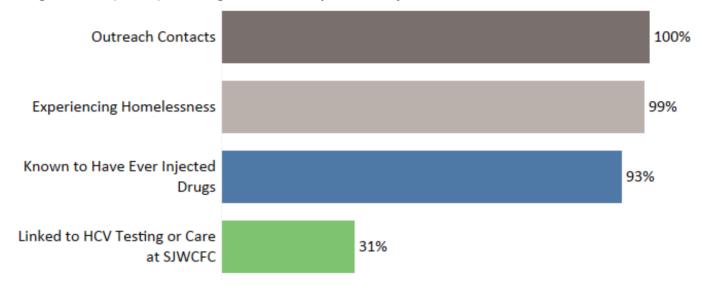
Outreach Partnerships

SJWCFC complemented its primary care-based routine, opt-out HCV testing by partnering with LACHP to offer hepatitis C rapid testing in SJWCFC' mobile clinics. Each week, a SJWCFC linkage to care specialist traveled with an LACHP outreach worker to homeless encampments in the area surrounding that week's rotating SJWCFC mobile clinic location. Together, they conducted outreach and built trust with people experiencing homelessness, offering hepatitis C education, syringe exchange, overdose prevention, and service referrals in English and Spanish along with material supports, such as bus tokens, hygiene kits, condoms, and naloxone (a medication used to reverse an opioid overdose). Clients were linked to the mobile van for hepatitis C rapid testing, hepatitis A vaccination, wound care, and linkages primary and prenatal care. Clients with a reactive HCV antibody test were offered a blood draw for HCV RNA testing and invited to return to the mobile clinic in seven days for their results. SJWCFC and LACHP outreach staff also provided transportation and accompaniment to medical appointments and returned to encampments to remind people linked to care of their upcoming medical appointments.

Among 338 street-based outreach contacts conducted by SJWCFC and LACHP staff, nearly all of those contacted (99 percent) were homeless; 93 percent had ever injected drugs; and approximately one-third (34 percent) were connected to HCV testing or HCV care at SJWCFC (see **Figure 2**). The proportion linked to care may be an underestimate because LACHP follows syringe exchange program best

practices by providing services anonymously to clients who do not wish to disclose their name, and because it took some time for SJWCFC and LACHP to establish systems for information-sharing.

Figure 2: Proportion of Clients Who Were Experiencing Homelessness, Had Ever Injected Drugs, and Whom were Linked to HCV Testing or HCV Care at St. John's Well Child and Family Center (SJWCFC) Among Those Contacted During Outreach (N=338)—Los Angeles Community Health Project, March 1, 2016 – June 30, 2018



Tarzana Treatment Centers

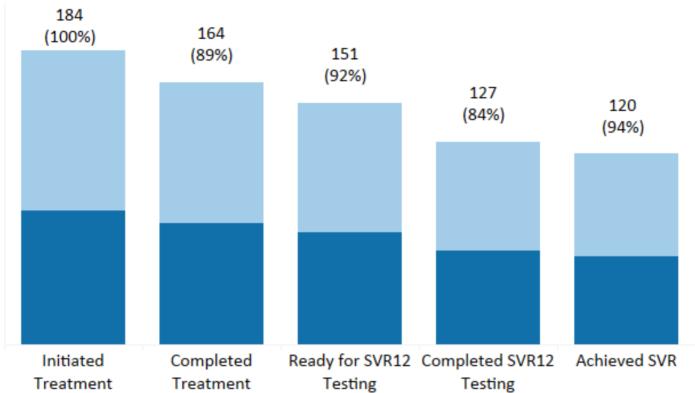
Electronic Health Record-Based Hepatitis C Testing and Care Protocols

TTC focused its testing and care coordination efforts on inpatient and residential drug treatment settings. After taking some time to establish mechanisms for identifying injection drug use history in the electronic health record (EHR), TTC developed a query in its EHR to identify all clients who reported having injected drugs and who did not have a hepatitis C test result on record. Case managers then contacted those clients and offered them rapid hepatitis C antibody testing, which returns antibody results in 20 minutes. TTC preferred using rapid testing over a blood draw because clients in inpatient withdrawal management often left before their blood draw-based HCV antibody test results came back. Clients with reactive rapid HCV antibody test results were offered a blood draw for follow up HCV RNA testing and linked to one of two TTC clinics with hepatitis C-treating clinicians for evaluation and treatment. A nurse care coordinator ordered an ultrasound and laboratory tests at the first care visit, and then referred clients to patient navigators for assessment of barriers to adherence and ongoing support.

TTC also used other EHR features and commercial software packages to improve HCV testing and linkage to care outcomes, including a software application that enabled the hepatitis C care coordinator to send appointment reminders by text message. At the end of Year 2, TTC began using another software product (Fixxer)^{iv} to develop a system for pulling data from its separate primary care and behavioral health EHR systems to create a report listing 1) all clients in the HCV care cascade and their status; and 2) an individualized report to indicate what next steps are needed for each client. Despite these advances, information on injection drug use was not always consistently available in each of the separate EHRs for primary care, mental health, and HIV/hepatitis Care, making it difficult to fully evaluate the proportion of PWID offered hepatitis C testing or linked to care and treatment.

Figure 3 shows the hepatitis C treatment cascade across HepLinkLA by known injection drug use history.





People Not Known to Have Ever Injected Drugs

People Known to Have Ever Injected Drugs

Note: Proportions calculated as a percentage of the previous bar.

Drug Medi-Cal Organized Delivery System

TTC explored ways to leverage Medi-Cal to support hepatitis C care, including the expansion of substance use disorder benefits under the Drug Medi-Cal Organized Delivery System (DMC-ODS). DMC-ODS allowed counties to opt-in to providing a continuum of care modeled after the American Society of Addiction Medicine (ASAM) Criteria for substance use disorder treatment services, including residential, outpatient, and medication-assisted treatment (buprenorphine, methadone, and injectable naltrexone). For clients with previously limited treatment options after three days of withdrawal management, DMC-ODS covered residential treatment (if indicated), providing a stable environment in which clients could obtain follow-up HCV diagnostic testing and, if interested, complete the 8-12 weeks of hepatitis C treatment.

Another benefit newly made available under DMC-ODS was case management, which was defined as "a service that assist[s] a beneficiary to access needed medical, educational, social, prevocational, vocational, rehabilitative, or other community services." Under this new benefit, up to seven hours of case management was covered per client per level of care per month. In anticipation of this change, TTC trained their case managers in hepatitis C and leveraged their efforts to support linking case management clients to HCV care as well as medication assisted treatment for opioid use disorder. The availability of a new broad range of previously non-covered services under DMC-ODS challenged the capacity of TTC to hire, train, or manage staff and manage programs, leading to short-term limitations in

their productivity and capacity while the organization adjusted to accommodate its expanding scope. However, once TTC adapted to the new DMC-ODS funding and service environment, they were able to apply the new case management benefit to support TTC clients through the hepatitis C care cascade.

C) LESSONS LEARNED

Routine, universal, opt-out hepatitis C testing in an urban primary care setting yielded positivity rates nearly double the national average, finding hepatitis C cases without the burden of health care providers having to inquire about patient risk factors. Mid-level practitioners were successfully trained to treat hepatitis C in a primary care setting, and an in-house specialty pharmacy facilitated expedited treatment. Having a dedicated hepatitis C care coordinator proved critical to successful hepatitis C care and treatment in a busy primary care clinic, leading clinic leadership to continue supporting the position after dedicated funding for the HCV testing and linkage to care demonstration project had ended. However, tracking client outcomes and grant deliverables required data entry and management resources not immediately on hand, which necessitated redirecting existing personnel for this purpose who were not necessarily trained in data entry or data management and had competing responsibilities.

Conducting street-based outreach in homeless encampments adjacent to its mobile health clinic enabled SJWCFC to develop trust with a community it had not previously served and enabled LACHP to link to primary care people with whom they had built rapport but who would likely not have been engaged in care. However, sustaining this partnership was difficult when SJWCFC experienced staff turnover and had to redirect staff to other projects when in-kind resources for this project could no longer be sustained. As in other sites, locating people experiencing homeless for appointment reminders proved challenging because homeless encampments were constantly being dismantled and displaced.

Electronic health record based screening, care, and treatment protocols proved helpful in identifying and prioritizing people who inject drugs for hepatitis C testing and linkages to care in a comprehensive substance use treatment program. The creation of a dedicated hepatitis C care coordinator position for this project at TTC was sustained after the funding ended, suggesting the value of one-time investments in hepatitis C care coordination infrastructure. State-supported initiatives aimed at expanding substance use disorder treatment generated both opportunities for synergy with hepatitis C testing and treatment expansion efforts and competing priorities in a time of rapid organizational growth and change.

¹ Hofmeister M, Rosenthal E, Barker L; et al. Estimating Prevalence of Hepatitis C Virus Infection in the United States, 2013-2016. Hepatology. 2018 Nov 6;(e-publication ahead of print).

Wheeler E, Jones TS, Gilbert M, Davidson PJ. Opioid Overdose Prevention Programs Providing Naloxone to Laypersons — United States, 2014. MMWR. June 19, 2015;64(23):631-635.

iii Recommended Best Practices for Effective Syringe Exchange Programs in the United States: Results of a Consensus Meeting. Accessed January 27, 2019 at https://harmreduction.org/wp-content/uploads/2012/01/NYC-SAP-Consensus-Statement.pdf.

iv Product name provided for informational purposes only. CDPH does not endorse any company or its products.

https://www.dhcs.ca.gov/provgovpart/pages/drug-medi-cal-organized-delivery-system.aspx

vi https://www.asam.org/resources/the-asam-criteria/about

vii Los Angeles County Executed Drug Medi-Cal Organized Delivery System Contract. Accessed December 26, 2018 at https://www.dhcs.ca.gov/provgovpart/Documents/DMC-ODS Waiver/Los-Angeles-ODS-Contract Redacted.pdf.