February 2019

EXPLORING STRATEGIES TO SUPPORT HCV PROGRAMMING IN COMMUNITY HEALTH CENTERS

AN EMERGING NEED IN LIGHT OF THE OPIOID CRISIS IN THE U.S

CASE STUDIES AND RECOMMENDATIONS

National Nurse-Led Care Consortium

The National Nurse-Led Care Consortium (NNCC) is a national leader supporting and advocating on behalf of nurse leaders. NNCC is a nonprofit, member-supported organization, and provides a wide range of services to educate and support nurses on the front lines of healthcare. Its mission is to advance nurse-led healthcare through policy, consultation, and programs to reduce health disparities and meet people's primary care and wellness needs.

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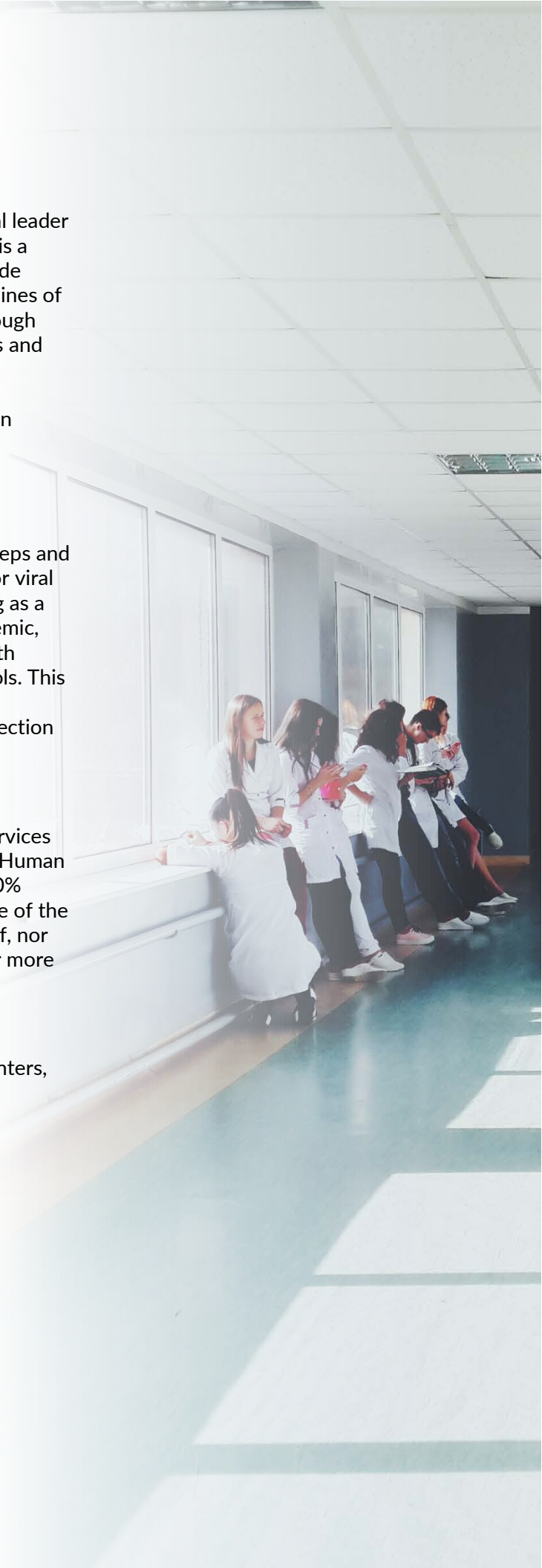

About this Report

The Bureau of Primary Health Care (BPHC) provides action steps and guidelines for health centers on the different stages of care for viral hepatitis. As the Hepatitis C virus (HCV) infection is emerging as a serious public health problem in tandem with the opioid epidemic, health centers have the opportunity to decrease its impact with standardized screening, linkage to care and treatment protocols. This case study highlights how five health centers nationally are addressing the increased rates of HCV infection and its intersection with the opioid epidemic.

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INTRODUCTION

The hepatitis C virus (HCV) is a pressing public health issue, contributing to high rates of morbidity and mortality in the U.S. today.[1] HCV is spread through contact with infected blood. Left untreated, HCV can lead to irreversible liver damage and liver cancer. In 2016, an estimated 41,200 new acute HCV infection cases occurred.[2] Recent CDC surveillance information indicates an increase in incidence across age groups under 60 years old, with 20-29 and 30-39 year olds experiencing the greatest increases.[3]

The Centers for Disease Control and Prevention (CDC) and the U.S. Preventive Services Task Force (USPSTF) recommend prioritizing the "baby boomer" birth cohort (those born between 1945 and 1965) for HCV screening, due to historically highest incidence rates; CDC and USPSTF also recommend screening high-risk populations such as people who inject drugs (PWID).[4]

CDC also notes substantially higher incidence in HCV among PWID, particularly young, rural opioid and heroin users.[5] Some of these "spikes" in HCV infection rates are increasingly linked to the growing opiate crisis[6]; 53% of PWID have HCV infection.

Health centers are community-based and patient-centered organizations delivering comprehensive, primary healthcare services. Additionally, health centers integrate access to pharmacy, behavioral and mental health, substance use, and oral health services in areas where socioeconomic, geographic, or other barriers limit access to affordable health care services.

This publication highlights the varying degrees to which health centers support comprehensive HCV programming, including testing, linkage to care, and treatment services.[7] Clear guidance and recommendations for supporting evidence-based HCV programming at health centers offer promise and a critical opportunity to address the co-occurring HCV and opioid epidemics.

> ***Health centers are poised to address the resurgence of HCV because they often see patients who are at elevated risk of exposure due to behavioral (e.g. injection drug use, unprotected sex) and social-environmental risk factors (e.g. rurality, transient housing, lack of syringe exchange programs).***

Through key informant interviews with HCV health center stakeholders, on-site observations, and a review of state policies, the National Nurse-Led Care Consortium (NNCC) assessed the landscape and scope of HCV testing, linkage to care, and treatment in five health center organizations across the country. This report details these findings, describes an HCV testing and linkage to care pathway for positive patients, and considers the public health significance and impact of HCV infection and the co-occurring opioid epidemic in the US. Real world examples and best practices of HCV programming supported at health centers are also provided.

SCREENING AND TESTING

Health centers often have different HCV screening programs, depending on the availability of resources and patient demographics. Many health centers base HCV screening protocols on CDC guidelines by testing the “baby boomer” age cohort of patients born between 1945 and 1965, and patients who report risk factors associated with HCV. However, this screening approach often misses younger patients who might not report risk factors, such as injection drug use. An alternative screening strategy is universal testing, which includes one-time HCV testing and as needed based on risk factors, for any health center patient 18 and older, to decrease transmission of HCV, avoiding high costs to the health system and moving towards eradication of the disease.

Many health centers are limited by the number of tests they can provide to under- and uninsured patients, given high test costs. One of the biggest issues is the lack of confirmatory testing conducted, leaving both patients and providers misinformed. Health centers also often see patients with co-occurring substance use disorders, and coordinating visits for these patients can be challenging. Some health centers are able to afford rapid HCV tests, which can provide on-site antibody test results. However, reflexive testing with a single blood-draw is more effective in confirming diagnosis. Some health centers have an on-site laboratory to conduct tests, but others may require a lab services partner to confirm results.[8]

Currently, there are several systemic barriers to effective screening, including:

- Variable HCV programming across health centers nationally, allowing many HCV infections to go undetected.
- Limited awareness about current HCV infection patterns. Many new infections are occurring in people younger than the “baby boomer” cohort.
- Current screening protocols are based on the "baby boomer" age cohort as well as risk-based assessments, however risk-based screening misses patients who don't report risk factors.
- Out of pocket costs for uninsured and underinsured patients. Patients may be unable to prioritize paying for medical tests when they do not have symptoms. Fear of a positive test result and a belief that treatment would be unaffordable may add to cost barriers for some patients.

Despite several barriers to screening, increasing the number of patients tested would diagnose more patients at earlier asymptomatic stages of HCV infection. With treatment this would prevent some patients from developing chronic HCV infection and its complications, including liver cancer. Thus, increasing testing and linking to treatment would ultimately improve outcomes in health center patient populations.

LINKAGE TO CARE

Once patients are screened and tested for HCV, linking them to appropriate care is the next phase in the care continuum. Linkage to care includes connecting patients to a treating provider. In some states, the treating provider needs to be a specialist to receive payer reimbursement, while in others a variety of appropriately trained health professionals can treat HCV-positive individuals. Linkage to care can also include connecting patients to behavioral health services, which can sometimes be a prerequisite to insurance approval, since there is a high rate of HCV-positive patients who have co-occurring substance use and mental health diagnoses. Patients who have the support of behavioral health resources and services may have better antiviral medication adherence and thus a better chance to cure their HCV infection.

As with screening and testing, a variety of challenges exist for linking patients to care. Most notably, maintaining continuity of care can be difficult given the frequency of health center visits required during HCV treatment. Patients with active HCV infection may require several pre-treatment appointments to complete the clinical requirements

necessary for the insurance authorization to initiate HCV treatment. Patients receiving antiviral treatment for HCV need to take medication consistently and attend a final visit after 12 weeks to establish completion of treatment. Additionally, health center patients may experience housing instability, or can be difficult to contact (i.e., phone out of service). Support staff at health centers, such as community outreach workers, are essential for linkage to and retention in care; they can locate hard to reach patients in the community and encourage them to come back to the health center for follow up or to continue treatment. Linking health center support staff to the HCV insurance approval process may be more efficient, cost saving, and effective in helping patients access medication and appropriate behavioral health services. However, not all health centers have the resources or capacity to have outreach workers and/or linkage to care coordinators assist with patient follow up and prior authorization of medications for HCV treatment.

HCV TREATMENT ACCESS

New and emerging antiviral therapies have made it easier for primary care providers, with training and support, to treat HCV infection. However, some state-level provider restrictions inhibit the ability to provide care without a specialist. Additionally, variable state Medicaid policies limit treatment for some patients based on degree of liver damage or sobriety requirements.

Figure 1 below includes many of the systemic challenges in accessing HCV treatment. Primary challenges include access to testing and linkage to care services, access to providers with expertise in treating patients with antiviral drug therapies, the cost of care, and payer treatment eligibility guidelines, including provider type, sobriety, and fibrosis score restrictions.

BARRIERS TO HCV TREATMENT ACCESS

- Lack of awareness about current HCV infection patterns
- Risk based screening is insufficient
- Lack of screening programs
- Variable provider education about direct antiviral drug therapies
- Treatment costs
- State HCV policies
- Degree of liver damage
- Reimbursement availability
- Access to insurance

State policy environments have influenced testing, linkage to care, and treatment programs at each health center network to varying degrees. Table 1 on page 16 describes state Medicaid policies for the states represented in this case study; California, Pennsylvania, Massachusetts, Iowa, and Nebraska.

SPOTLIGHTING COMMUNITY HEALTH CENTERS: A REVIEW OF HCV PROGRAMMING ACROSS FIVE U.S HEALTH CENTERS

CHARLES DREW HEALTH CENTER

Charles Drew Health Center (CDHC) provides health care services for individuals and families living throughout Douglas County in Omaha, Nebraska.[9] CDHC serves the whole community, but also provides specialized services to residents of public housing and persons experiencing homelessness. In 2015, the health center served 10,202 patients, with a majority of patients served (90%) living at or below 200% of the federal poverty line.[10] While a majority of Nebraska residents identify as white/Caucasian, about 70% of patients seen at CDHC identify as being part of a racial or ethnic minority.[11] Approximately 45% of CDHC's adult patients are uninsured, and nearly 45% are either Medicaid or Children's Health Insurance Program (CHIP) beneficiaries.[12]

Nebraska HCV Incidence[12]	Testing Process	HCV Test Procedure
<.6 per 100,000	▪ Opt-in ▪ USPSTF risk-based screening ▪ Initiated by nurse	▪ Provider orders blood work ▪ HCV AB: rapid ▪ HCV RNA: PCR, blood draw (in house lab)

HCV SCREENING AND TESTING OVERVIEW

The Nebraska Department of Health and Human Services (NDHHS) has seen a substantial rise in HCV rates since 2012, prompting the development of a hepatitis testing initiative. Charles Drew Health Center, Inc. (CDHC) joined as a testing site in 2016. The goal of the initiative is to increase access to screening, test at-risk patients, and improve linkage to care to provide appropriate interventions for patients in need of HCV treatment. Support from the NDHHS allows CDHC to provide free OraQuick® rapid antibody testing, a finger-stick test that diagnoses antibody positivity in twenty minutes, for HCV and HIV according to CDC risk-based guidelines. Nurses offer the test based on behavioral and birth cohort risks, and patients can opt-in to testing; currently, reminders for HCV screening do not exist in the electronic health record (EHR). Patients with positive HCV antibody rapid test results have blood drawn. Confirmatory tests are sent to an NDHHS lab for results during the patient's initial visit.

LINKAGE TO CARE Once the health center receives positive tests results, the clinical team provides the patient with counseling and HCV education, coordinates follow up appointments, and provides information regarding available resources for treatment. CDHC has limited capacity to treat HCV due to limited provider availability. Furthermore, strict sobriety and fibrosis score restrictions create challenges to treatment in Nebraska. As a result, uninsured patients are referred to the University of Nebraska Medical Center (UNMC) for treatment follow-up, and insured patients work with the icare team to identify a provider for referral.

CDHC's linkage to care team can link patients to on-site supportive services, and provide referrals to HCV treatment and medication assisted substance abuse treatment.

The Nebraska Department of Health and Human Services financially supports the HCV screening program at CDHC, allowing the health center to offer risk-based rapid HIV and HCV screening and confirmatory RNA results at no cost to the patient or the clinic.

While CDHC has some capacity to provide behavioral health and supportive services, patients who need Medication-Assisted Treatment (MAT) for substance use are usually referred to specialized programs outside of the health center. Patients also work with charitable care and financial counselors at UNMC to coordinate payment options for costs accrued through HCV care.

STATE POLICY RESTRICTIONS FOR HCV TREATMENT

Nebraska is among the 19 states that have not yet expanded the statewide Medicaid program.[13] To qualify for HCV treatment in Nebraska, patients must have a fibrosis score of at least F3, and demonstrate considerable liver damage.[14] Patients must also abstain from substance use for at least six months.[15] Currently, there is no restriction on prescribing authority or hepatitis B virus (HBV) co-infection requirement for HCV medication access.

COMMUNITY HEALTH CENTERS OF SOUTHEASTERN IOWA, INC.

Community Health Centers of Southeastern Iowa, Inc. (CHC/SEIA) is a primary care organization (PCO) that uses a patient centered medical home model to provide comprehensive primary care in four largely rural counties (Des Moines, Henry, Lee and Louisa) in the Southeastern Iowa region. According to 2017 Uniform Data System (UDS) data, a majority (83%) of patients are white, and 13% identify as Hispanic/Latino (of any race).[16]

Iowa HCV Incidence	Testing Process	HCV Test Procedure
CDC state surveillance data unavailable[17]	▪ Opt-out ▪ USPSTF risk-based screening ▪ Initiated by MA/clinical staff	▪ Provider orders lab work ▪ HCV Ab: Blood draw ▪ HCV RNA: Blood draw

In August 2015, CHC/SEIA integrated opt-out routine HCV screening into their primary care appointments, using the U.S. Preventive Services Task Force guidelines (e.g., "baby boomer" birth cohort testing plus risk-based testing). This initiative was part of a broader HIV and sexually transmitted infection (STI) screening initiative led by the Iowa Primary Care Association in partnership with Iowa Department of Public Health implemented across nine Iowa health centers, including CHC/SEIA sites. Medical assistants, lab technicians and other clinical staff at each of the four network sites received training on the epidemiology of HCV infection, and implementation of CDC screening guidelines. HCV testing occurs in two stages. In the event of a positive antibody test, the lab at CHC/SEIA automatically runs for RNA if the antibody is detected in the sample. CHCSEIA assumes the cost of the screening for uninsured and under-insured patients and passes on a portion of the cost to the patients based on their sliding fee scale percentage. To streamline the process further, CHC/SEIA is working to implement standing orders so that clinical staff can perform screening for any patients who do not have a testing record in the EMR.

In addition to the primary care setting, CHC/SEIA has a substance abuse counselor on site 3 days a week to refer patients too as needed.

LINKAGE TO CARE

CHC/SEIA uses telemedicine consultation with hepatologists as one way to link HCV patients to a specialist consultation without an increased burden on the patient.

If the confirmatory HCV RNA test shows active infection, CHC/SEIA connects the patient to an in-house primary care provider (PCP), who discusses the patient's HCV diagnosis and treatment options. The PCP then conducts an HCV-relevant medical history screening and physical exam; this includes screening for depression and substance use as well as additional blood tests to document liver function and other relevant clinical factors. This information allows CHC/SEIA sites to start the process to secure prior authorization to treat the patient from the patient's insurance provider (if they are insured). CHC/SEIA also connects HCV-positive patients with substance abuse counseling, if needed, which is provided in-house at one of the clinic locations. The substance abuse counselor can provide a variety of services, including mental health support, harm reduction education, and substance use disorder counseling/treatment (a key factor, since sobriety is required for treatment approval). CHC/SEIA does annual depression and screening, brief intervention, and referral to treatment (SBIRT) screenings to assess alcohol and/or substance misuse with all patients 18 years and older. Upon receipt of insurance approval, with the help of staff members, CHC/SEIA primary care providers begin treatment, with consultation support from two University of Iowa Health Care (UIHC) hepatologists. This consultation arrangement allows health center primary care providers to provide on-site treatment rather than referring the patient to a specialist at UIHC.

STATE POLICY RESTRICTIONS FOR HCV TREATMENT

In 2015, Iowa expanded Medicaid to include households up to 133% of the federal poverty line, increasing patient access to HCV screening and treatment.[18] In 2016, the entire Medicaid program became a managed care system, putting final treatment coverage decisions in the hands of managed care organizations (MCOs), which make treatment decisions based on both state Medicaid policies and the MCOs' own guidelines. Therefore, patients with Medicaid coverage still encounter state policy restrictions on HCV treatment. An HCV-positive patient must have moderate liver damage (F3 fibrosis score restriction), and be sober for three months in order to begin treatment. Iowa policy also requires that an HCV specialist provider supervise HCV treatment.[19]

PROGRAM SUCESSES AND OPPORTUNITIES

HCV screenings across CHC/SEIA sites have increased substantially since integrating opt-out routine HCV screening and testing; over 1,000 HCV screening tests were completed in 2017, a substantial increase over the 373 screenings completed in 2016. Due to the increased number of patients diagnosed with HCV as part of the routine screening project, CHC/SEIA reached out to the Iowa Primary Care Association (PCA) for technical assistance with HCV treatment. The PCA formalized a partnership with UIHC hepatologists to educate providers about direct-acting antiviral treatment regimens for HCV as well as provide consultation for treatment of HCV patients. Because of this training and ongoing consultation support from partner hepatologists, PCPs within the four CHC/SEIA sites began treating newly diagnosed and eligible HCV patients on-site instead of referring to UIHC specialists. Additional technical assistance from the statewide pharmacy supports health centers, providers, and patients in accessing treatment medications and with questions about the medication regimen.

CHC/SEIA has successfully worked with Walgreen's specialty pharmacy to assist with approval on HCV prescriptions, provide support for patients to obtain Medicaid approval for HCV treatment, and assist patients with out-of-pocket Medicare prescription costs (of about $30,000).

SAN YSIDRO HEALTH

San Ysidro Health (SYH), a health center in San Diego County, California, serves the South Bay, as well as El Cajon and Southeast San Diego communities. SYH provides a wide range of medical, dental, behavioral health, and special support to more than 91,000 patients annually. SYH serves a predominantly Hispanic/Latino patient population. Nearly three quarters (72%) of SHY's patients live at/below the federal poverty line, 56% utilize Medi-Cal, and over 30% are uninsured[20].

California HCV Incidence[21]	Testing Process	HCV Test Procedure
<.6 per 100,000	▪ USPSTF risk-based	▪ Opt-in HIV/HCV

HCV SCREENING AND TESTING OVERVIEW

Pre- and post-diagnosis counseling for HCV and/or HIV take place in one session with an HIV/HCV certified California Test Counselor. During this session, an SYH Test Counselor discusses behavioral risks and harm reduction, as well as available resources, using a standardized protocol. Funding from the county Health and Human Services Administration now allows SYH to bundle HIV and HCV OraQuick® rapid antibody testing in the on-site labs, and to conduct blood-based RNA confirmatory testing for HCV Ab+ patients.

A unique feature of SYHC's primary care program is its in-house infectious disease providers with specialized expertise in delivering care to HCV-positive patients.

LINKAGE TO CARE

After a patient with active HCV is identified, SYH's coordinated service delivery method includes the Test Counselor linking the HCV-positive individuals to a Testing Supervisor, both of which are certified in California as Test Counselors, who coordinate linkage to care. In-house infectious disease specialists prescribe antiviral treatment. In addition, a behavioral health consultant and/or substance use counselor assesses behavioral health needs during post-test counseling. If appropriate, these services are offered in the clinic in conjunction with HCV treatment. In the past, an HCV patient navigator assisted patients through HCV treatment and related supported services. Now, given funding constraints, the medical assistant to the infectious disease specialist coordinates patient navigation through the program.

STATE POLICY RESTRICTIONS FOR HCV TREATMENT

Beginning in July 2015, eligibility for antiviral treatment expanded to patients with evidence of light liver scarring and an F2 fibrosis score (rather than F4), patients with HIV or HBV co-infection, and active intravenous drug users (instead of requiring 6 months of sobriety).[22]

PROGRAM SUCCESSES AND OPPORTUNITIES

Adding HCV screening to an existing HIV testing program allows SYH to:

- Utilize existing infectious disease specialists to treat HCV in a highly coordinated way.
- Extend related wrap-around services to patients.

SYH has a supportive partnership with County of San Diego Health and Human Services, which facilitates both antibody and confirmatory testing for RNA patients regardless of insurance status.

WHITTIER STREET HEALTH CENTER

Whittier Street Health Center (WSHC) is a health center located in lower Roxbury, Massachusetts. WSHC provides primary health care and outreach services to nearly 30,000 individuals in the Roxbury and greater Boston areas, including specialized services for residents of public housing.[23] The majority of WHSC patients (90%) self-report being a racial/ethnic minority. Nearly 91% of patients live at or below federal poverty line, about 34% of patients are uninsured, and 35% utilize MassHealth, Massachusetts' combined Medicaid and Children's Health Insurance Program.[24]

Massachusetts HCV Incidence[25]	Testing Process	HCV Test Procedure
>1.9 per 100,000	▪ Opt out ▪ Universal adult testing ▪ Initiated by MA/nurse ▪ Standing order in EMR with prompts	▪ Standing order ▪ HCV Ab test: reflex, blood based ▪ HCV RNA: PCR test, blood based

HCV SCREENING AND TESTING OVERVIEW

WSHC has provided HIV services since 1994 and HCV treatment since 2016. Initially, per USPSTF recommendations, "baby boomers" were prioritized to receive HCV testing (as well as select high-risk populations such as active injection drug users). Subsequently, WSHC incorporated a comprehensive HCV treatment program within their infectious disease program, and integrated opt-out universal HCV testing into routine physical exam visits for their adult patients (18+). A nurse or medical assistant initiates blood-based HCV Ab testing during an outpatient visit, using a standing order in the EMR system.

In 2016, WHSC screened 2,800 patients for HCV, 72% (2,016) of whom were outside the "baby boomer" age cohort, and screened due to behavioral risk.

LINKAGE TO CARE

WSHC's behavioral health department is interdisciplinary, consisting of psychiatrists, psychologists, nurse practitioners, social workers, and licensed mental health counselors. They offer onsite individual, family, couple, and group counseling, as well as medication management services for all ages.

Patients testing positive for HCV are linked to a primary care provider for post-test counseling. The case managers, who have either bachelors or associates degrees, conduct psychosocial and behavioral needs assessments, prepare prior authorizations for treatment, and assist with financial aid, if needed. WSHC has financial counselors who work closely with the medical case managers to help patients to apply for medical insurance. When treatment approval is obtained, the primary care provider links the patient to the on-site infectious disease specialist to begin treatment. The case manager secures prior authorization to begin HCV treatment for the patient, connects the patient with supplemental healthcare services, and schedules the patient's appointments. Additionally, WSHC connects patients to onsite behavioral health services, which cover a broad scope of mental health and substance use treatment modalities.

STATE POLICY RESTRICTIONS FOR HCV TREATMENT

Prior to 2016, in Massachusetts, only patients with advanced liver disease and demonstrated substance use abstinence for at least six months were approved for HCV treatment.[26] However, in 2016, the state eliminated criteria for fibrosis staging and substance use abstinence.[27] In addition, MassHealth does not require specific prescriber qualifications or HIV/HBV co-infection for HCV medication access.[28]

PROGRAM SUCCESSES AND OPPORTUNITIES

Initially, WSHC experienced some challenges in rolling out their HCV treatment program, primarily surrounding changed workflow, such as test ordering and operations across departments. Confidentiality considerations were addressed through ongoing training. Staff were trained in best practices for ordering tests as well as methods for EMR documentation to reduce delays in linking patients to care. WSHC addressed challenges in real time by incorporating a comprehensive HCV treatment program within their existing infectious disease program and integrating universal HCV screening into routine visits for their adult patients. WSHC is now:

- Expanding staff capacity (medical assistants) to screen and order labs.
- Showing effectiveness in linking HCV and/or HIV patients to care, with 100% linkage to care demonstrated among over a thousand patients screened in a six month period.
- Increasing number of patients requesting HCV testing during office visits through its HIV/HCV awareness campaign activities and community outreach efforts.

PHMC HEALTH NETWORK

In 2012, the National Nurse-Led Care Consortium (NNCC), in partnership with Public Health Management Corporation (PHMC), introduced a comprehensive HCV testing and linkage to care model in PHMC's five health centers in Philadelphia county. The PHMC Health Center Network serves primarily at-risk populations, including PWID, patients experiencing homelessness, and public housing residents. In 2016, the network served over 20,000 patients, primarily in ethnic and racial minority communities; 55% were non-Hispanic black, and 26% were Latino/Hispanic. Most (82%) had incomes below the federal poverty line, 56% receive Medicaid, and 28% were uninsured.[29] In 2017, PHMC initiated a partnership with a Temple University Hospital Emergency Department, opening an urgent/primary care clinic adjacent to the ED, and establishing the sixth health center within the network.

Pennsylvania HCV Incidence[30]	Testing Process	HCV Test Procedure
.6 - 1.9 per 100,000	• Opt-out • Universal screening • Initiated by MA • Reminder prompts in EMR	• Standing order • HCV AB reflex to RNA: blood based

HCV SCREENING AND TESTING OVERVIEW

All six PHMC network health centers integrated routine HCV testing into primary care using a medical assistant-initiated, opt-out, laboratory-based model. This protocol includes EMR modifications to prompt, track, report, and facilitate reimbursement for HCV tests. Medical assistants and other clinical staff at PHMC's health centers were provided HCV education and training (i.e. on etiology and epidemiology and test protocols). Use of the standing orders in the EMR allows medical assistants to begin the laboratory requisition for blood-based test for the HCV antibody reflex to RNA quantitative real-time polymerase chain reaction (PCR) test. This minimizes providers' test-ordering burden, reduces costs through negotiated tests prices, and will potentially lead to more patients receiving HCV tests and diagnoses.

LINKAGE TO CARE

Universal testing in PHMC primary care settings increases access to testing without requiring potentially flawed risk assessments, particularly for patients younger than the "baby boomer" cohort.

While PHMC health centers screen and test for HCV, not all six provide on-site HCV treatment, but providers are receiving education and training to treat HCV. PHMC has a linkage-to-care coordinator through the AmeriCorps Volunteers in Service to America (VISTA) program, for all HCV patients; this position has increased the capacity for more patients to be informed of their diagnoses, receive medication, referrals to primary care and specialists (when needed), referrals to onsite behavioral health services, and MAT for opioid use disorder. Once a patient has a confirmed HCV-positive diagnosis, they are connected with an in-house primary care provider (PCP) trained to treat patients with direct-acting antiviral therapy, who collects the patient's medical history and conducts a physical exam. The PCP then orders labs for patients to start the prior authorization process and treatment regimen. The PHMC health center HCV linkage-to-care coordinator begins the prior authorization process for medication approval, which is essential for the patient to begin treatment. The patient is also connected with an in-house licensed behavioral health consultant to review knowledge on HCV and its treatment, discuss their current substance use and behavioral health, and help with any counseling or treatment barrier needs.

STATE MEDICAID POLICY RESTRICTIONS FOR HCV TREATMENT

Pennsylvania expanded Medicaid in 2015. The state also recently enacted a series of policy changes that have eliminated fibrosis score restrictions for HCV-positive patients seeking treatment.[31] Since January 2018, fibrosis scores have been completely eliminated in Pennsylvania, increasing opportunities to identify and treat HCV-positive patients.

Until recently, when the state eased treatment restrictions, most HCV treatment was provided by a trained PCP and supervised by an infectious disease specialist.

PROGRAM SUCCESSES AND OPPORTUNITIES

Since introducing a comprehensive HCV testing and linkage to care model in PHMC's six health centers:

- Over 21,000 HIV and over 20,000 HCV tests have been given (dual HIV/HCV testing substantially increased total number of tests given).
- Over 90% of HCV-RNA positive patients received their confirmatory result; 78% were linked to HCV care by their primary care providers, including, nurse practitioners or physician assistants.
- Nearly 42% of HCV-RNA+ patients were not previously diagnosed, with more than 50% born after 1965

TABLE 1. HCV PROGRAM POLICIES AT A GLANCE

	Charles Drew Health Center	Community Health Centers of Southeast Iowa	San Ysidro Health Center	Whittier Street Health Center	PHMC Health Network
CITY, STATE	Omaha, NE	Burlington, IA	San Diego, CA	Boston, MA	Philadelphia, PA
SCREENING STRATEGY	Opt-in	Opt-out	Opt-out	Opt-in	Opt-out
POPULATIONS SCREENED	USPSTF*	USPSTF*	USPSTF*	Universal-adults 18+	Universal-adults 18+
FIBROSIS RESTRICTION SCORE	F3	F3	F2 or HIV/HBV co-infection	None	None
BEHAVIORAL HEALTH REQUIREMENTS	6 month sobriety	3 month sobriety	Not specified	None	Screening and counseling required
PRESCRIBER REQUIREMENTS	Unrestricted prescriber authority	Specialist must prescribe	Not specified	Unrestricted prescriber authority	No restriction; PCP can prescribe
MEDICAID EXPANSION STATE?	No	Yes	Yes	Yes	Yes

SUPPORTIVE PARTNERSHIPS AND SERVICE INTEGRATION

All of the health centers described have had various partners who supported their screening and/or treatment programs. The following are common themes in the ways HCV programming was made possible:

FINANCIAL SUPPORT OF HCV TESTING

The costs of conducting screening tests can be prohibitive, but many health centers have built partnerships to keep costs down. One health center partnered with lab testing partners who agreed to decreased-cost "bundled" testing for blood Ab and RNA confirmatory tests. Some clinics work with their state health department to provide free (to the clinic) confirmatory HCV RNA testing. In these partnerships, some clinics send blood samples to their state public health labs. As a result, one health center is able to provide free testing to baby boomers and anyone else with risk factors for HCV. Health centers have also partnered with state or local health departments to provide lower cost (or free) "bundling" of rapid HCV and HIV testing.

PROVIDER SUPPORT

Support from specialists and pharmacies can give primary care providers the capacity to treat patients with HCV. Training from infectious disease specialists and/or hepatologists can help prepare primary care providers to start antiviral treatment for HCV, as well as internal education and trainings among peers and other providers. Some health centers utilize telehealth resources, specifically Project ECHO®, initially created to support providers in rural locations, so they could consult with specialists in weekly virtual clinics to enhance HCV knowledge and expand treatment capacity. In addition, other health centers work with specialists, who take referrals or consult if primary providers need assistance with a case. Technical support from pharmacists regarding direct antiviral regimens and advice about medication interactions also play a role in making it possible for primary care providers to treat patients for HCV.

This support can also help control treatment costs. In the case study clinics described, many primary care providers now treating patients with HCV are nurse practitioners or physician assistants. Both PHMC and CHC/SEIA integrated treatment into their clinic workflow and leveraged their diverse group of primary care providers to initiate treatment and manage costs of programming. Additionally, partnerships with pharmacies and medical aid agencies like Americares and Direct Relief may provide medication pricing programs to make treatment more affordable for uninsured/underinsured patients.[32,33]

MEDICAL-LEGAL PARTNERSHIPS

State Medicaid policies are varied and often outdated where eligibility to receive HCV treatment is concerned, reflecting a time when the treatments for HCV were less effective, had more side effects, and could not provide a cure. For example, some state Medicaid policies require that patients have experienced moderate liver damage in order to be eligible for HCV treatment.

A medical-legal partnership (MLP) through the PHMC health network and Pennsylvania Health Law Project (PHLP) laid the groundwork for subsequent expansions in HCV treatment policies in Pennsylvania. The MLP provided assistance for patients around health insurance eligibility, public benefits, and other civil-legal needs of health center patients. The legal aid workers embedded into the PHMC health network noticed patients were denied HCV treatment due their fibrosis score. These observations prompted HCV experts and advocates throughout Pennsylvania to challenge the state Medicaid fibrosis score restriction. Because of this effort and collaboration with PHLP, Pennsylvania Medicaid HCV treatment policies were updated to eliminate the fibrosis score and provider restrictions.[34]

BEHAVIORAL HEALTH SERVICE INTEGRATION

It is standard practice for insurance companies to request behavioral health screening and counseling as part of the approval process for HCV treatment. Screenings identify depressive symptoms, substance use, and other signs of distress. Individuals with HCV have high rates of substance use disorders (SUDs), as well as elevated rates of depression, bipolar disorder, anxiety disorders, and other mental health issues.[35,36] In some states, sobriety requirements of 3-6 months may prevent some individuals with SUDS to be able to be approved for treatment.

A behavioral health assessment for HCV may include:

- Conducting a brief screening of depression, alcohol use, and drug use, and discussing other distress.
- Reviewing basic knowledge of hepatitis C infection, how it impacts the liver, and how the potential HCV agents work to reduce and eliminate the virus.
- Discussing treatment expectations, including sobriety, explaining effective adherence in treatment, discussing past experience taking daily medication and ways to improve daily medication adherence.
- Reviewing motivation for starting treatment and troubleshooting potential challenges to initiating treatment.
- Motivational interviewing for any ongoing substance use or barriers to treatment.

The behavioral health consultant (BHC) may discuss the screening with the primary care provider, and document the assessment and education provided in the EMR. Once treatment begins, the BHC may check in to review engagement with treatment, well-being, and related concerns. For some patients, behavioral health concerns can impede successful treatment. However, ongoing integrated behavioral health services can work to support patients with co-occurring SUDs and HCV and enhance completion rates.

FIGURE 2. HCV SCREENING THROUGH TREATMENT PROTOCOLS

1

HCV screening decisions

There are many factors to balance when determining the appropriate scope for HCV screening programs. Universal adult screening may be most effective in identifying HCV-positive patients where there is known opioid abuse and/or high PWID populations. Alternatively, in communities with low HCV and opioid abuse prevalence, the USPFTF of behavioral risk and baby boomer (1945-1965) cohort screening recommendations may be more feasible based on health center resources.

2

Utilizing EMR systems to streamline HCV testing

EMRs can provide several opportunities to support staff in providing HCV testing, including automatically prompting clinical staff/providers to discuss testing with patients. Additionally, EMR standing orders allow trained health center staff to begin the testing process without requiring the primary care provider signature for each patient's test, saving time, streamlining workflow, and potentially saving costs to the health center.

3

Antibody (Ab) screening

This test identifies people who have been exposed to HCV. Currently, health centers use a finger stick, an Oraquick® rapid Ab test, or a reflex Ab to RNA blood-based test. Patients who are positive for HCV on the Ab test need additional blood-based testing.

4

RNA confirmatory tests

Confirmatory testing, using a blood-draw, determines whether there is active HCV infection. In some cases a confirmatory HCV test is performed as a reflex when the HCV test result is positive.

5

PCP appointment

If RNA tests determine there is a current infection, a PCP meets with the patient to discuss the diagnosis and provide education about HCV and risk reduction. They order additional lab tests to assess liver function and other clinical health indicators, and initiate insurance pre-certification processes. Health centers vary in approach to initiating treatment for uninsured patients. In some cases, patients are referred to staff who assist patients in applying for insurance or financial aid.

6

Liver function test results

Results from liver function lab tests provide important clinical information, and are required to inform treatment access. In some states, for example, Medicaid will only cover antiviral treatment for HCV if a patient has severe liver damage.

7

Behavioral health consultation

While not all health centers utilize a behavioral health consultant, behavioral health and related assessments are critical because of the connection between substance use and HCV risk. In some states, sobriety restrictions on treatment for Medicaid-insured patients mean that a patient may need behavioral health support, and, in some cases, additional services (such as MAT for some patients with opioid use disorders) to qualify for treatment. Additionally, given elevated rates of depressive and anxiety disorders among individuals with active HCV infection, behavioral health support may help patients adhere to treatment, optimizing treatment outcomes.

8

Patient education and initiating HCV treatment

Patients meeting all screening and insurance eligibility requirements receive education on the HCV treatment regimen before beginning treatment. Some health centers have PCPs trained in HCV direct antiviral treatment who are able to oversee treatment. Other health centers link patients to care outside of the clinic or use telemedicine consultation.

9

Ongoing patient engagement

Patients in treatment for HCV need ongoing care to increase the likelihood of being cured. Enhanced supportive services like case management or patient navigation, can help with client retention through the 8- or 12-week treatment period.

10

Treatment completion

Completion of the full 8- or 12-week treatment regimen, typically leads to sustained virologic response, effectively curing most patients of their HCV infection.

11

Demonstrate Sustained Viral Response (SVR)

Patients must have labs drawn at 12 weeks to show SVR after completion of treatment.

12

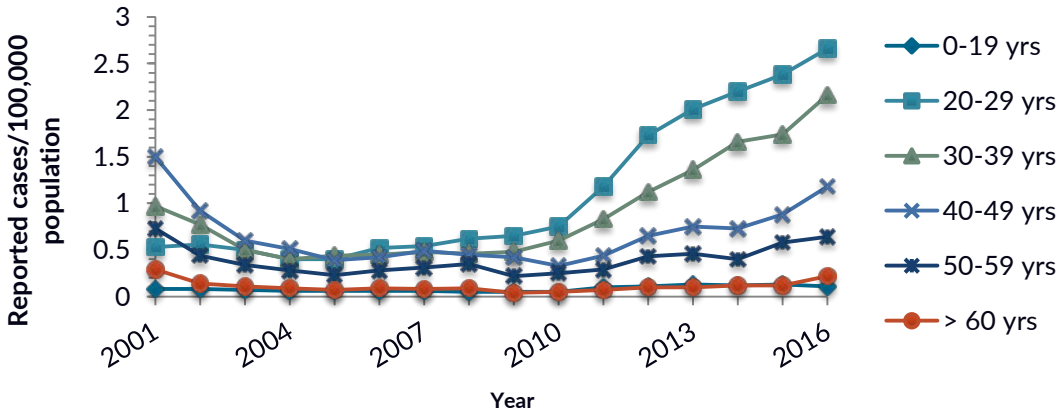
Consider rescreening

PCPs should consider discussing risk for reinfection (on a case-by-case basis) if seen at a future appointment. Some patients may need rescreening for active infection using RNA testing to determine if they have been re-exposed to HCV.

HEALTH CENTER CONSIDERATIONS: RISING HCV RATES AND OPIOID EPIDEMIC

In recent years, the US has seen a significant spike in cases of HCV, particularly in younger adults (see Figure 3 below), in geographically rural locations, as well as amongst PWID populations. As previously mentioned, this rise in HCV cases is occurring in parallel with the opioid epidemic in the US. Health centers are well situated to integrate behavioral health and primary care by delivering on-site management of the infectious disease complications for patients with opioid and substance use disorders.

Figure 3. Incidence of Acute Hepatitis C, by age group United States, 2001-2016[37]



Source: CDC, National Notifiable Diseases Surveillance System (NNDSS)

Screening programs like the ones described in this report provide an opportunity for health center administrators and providers to inform programmatic activity and responsiveness to PWID and other higher-risk populations about substance use, other behavioral health concerns, and risk reduction, regardless of HCV status. Further, integrating behavioral health services into HCV treatment allows patients to address substance use and other behavioral health concerns in concert with physical health care. Several states and insurers require behavioral health counseling and screening for patients to receive treatment for HCV. Additional recommendations for enhancing HCV programming are outlined in the next section.

TABLE 2. STATE POLICIES SURROUNDING ACCESS TO CLEAN NEEDLES

STATE	SYRINGE SERVICES LEGAL	SYRINGE RESTRICTIONS	IMPACT
Nebraska	NOT LEGAL None known to operate in the state	MODERATELY RESTRICTIVE ▪ Pharmacies can sell to adults without Rx[38] ▪ Needles/syringes for street drug use are classified as drug paraphernalia[39]	Resources to reduce HCV transmission rates due to needle sharing are very limited
Iowa	NOT LEGAL However, Harm Reduction Coalition of Iowa operates sites (not in CHC/SEIA service area)	MODERATELY RESTRICTIVE ▪ Pharmacies can sell to adults without Rx[40] ▪ Needles/syringes for street drug use are classified as drug paraphernalia[41]	Resources to reduce HCV transmission rates due to needle sharing are very limited
California	LEGAL Legal and available to SYHC patients[42]	SUPPORTIVE ▪ Pharmacies can sell to adults without Rx Needles and syringes are specifically deemed NOT drug paraphernalia[43]	Access to syringes and needles for prevention of reinfection or transmission of HCV are relatively accessible
Massachusetts	LEGAL Legal and available to Whittier Street HC patients[44]	SUPPORTIVE ▪ Pharmacies can sell to adults without Rx[45] Needles and syringes removed from the list of drug paraphernalia[46]	Access to syringes and needles for prevention of reinfection or transmission of HCV are relatively accessible
Pennsylvania	LEGAL Legal in Philadelphia and Pittsburgh under local laws but not PA law. Services available to PHMC health center patients	MODERATELY RESTRICTIVE ▪ Pharmacies can sell to adults without Rx[47] ▪ Needles/syringes for street drug use are classified as drug paraphernalia[48]	Patients in Philadelphia have increased access to sterile needles and the services provided by the syringe service program, compared to PWID in other areas of the state.

> Health centers are well situated to provide comprehensive health services by integrating behavioral health on-site.

RECOMMENDATIONS FOR ENHANCING HCV PROGRAMMING

This case study outlined several health center systems, as well as similarities and differences in their HCV programming. Recommendations, best practices, and lessons learned for enhancing HCV programming are as follows:

- **UNDERSTAND LOCAL AND HEALTH CENTER PATIENT POPULATION**
  Understanding the local community demographic, as well as health center patient population served, enables health centers to determine priority areas, effectively improving and enhancing patient treatment and care. It also allows health centers to account for one-time and ongoing costs, including estimating coverage (i.e. for test costs) needed for under- and uninsured patients, as well as determining the best approach to screening protocol, i.e., birth cohort and risk factors or universal opt-out screening. Utilizing UDS data alone does not provide the granular detail health centers need to optimally screen and test their patients. Additionally, health centers should look closely at patient information collected through their EMRs, as this is critical to understanding the best approach to HCV programming within that health center. Select EMR data to capture includes:

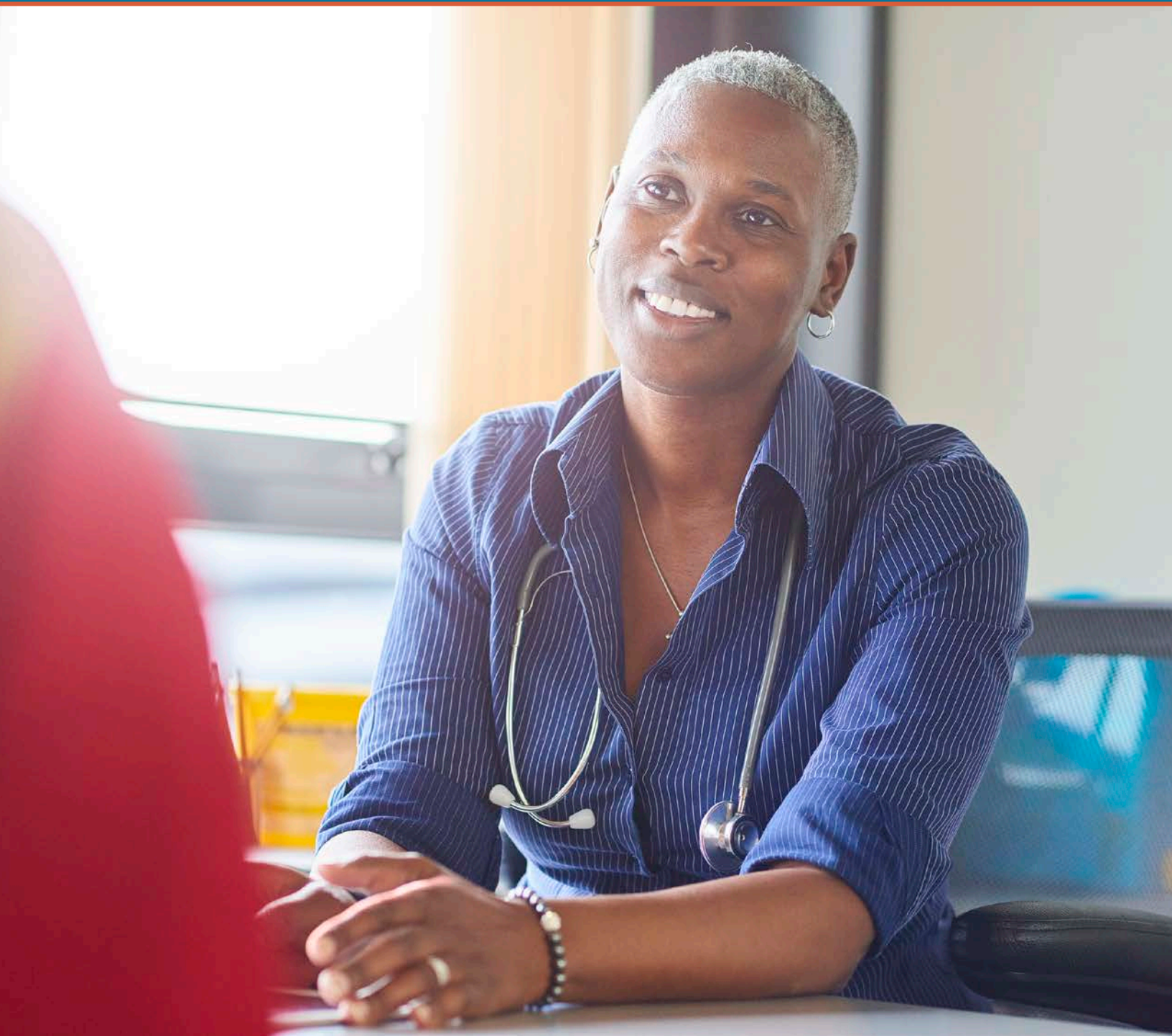
    - Uninsured rates
    - Patients screened and tested for HCV
    - Patient demographics, e.g., sex, age, race, ethnicity
    - Patient history and risk factors associated with HCV
    - Number of HCV-positive patients linked to providers
    - Referrals to outside organizations (if applicable to health centers)
    - Referrals to behavioral health services (if applicable to health centers)

- **EVALUATE THE COSTS OF CURRENT HCV PROGRAM**
  Health centers should estimate and forecast costs associated with HCV programming. This enables health centers to evaluate their programs capacity to provide enhanced universal HCV screening and testing on-site (within the health center), and connects patients to appropriate care.

- **DETERMINE OPTIMAL HCV PROGRAM HEALTH CENTER CAN SUPPORT**
  Not all health centers have the same capacity to implement enhanced HCV programming that includes universal screening and testing, as well as the ability to provide HCV treatment on-site. In order to improve health outcomes for patients, health centers must evaluate their current programming to determine where resources might be allocated most efficiently.

- **LEVERAGE BEHAVORIAL HEALTH INTEGRATION INTO HCV PROGRAM**
  Insurance companies often require that patients attend a screening and counseling appointment with a behavioral health consultant to assess additional HCV treatment needs. Patients who receive treatment for both HCV and behavioral health and/or substance use disorders are more likely to complete treatment. When possible, health centers should consider integrating behavioral health treatment into HCV programmatic activity.

- **IDENTIFY KEY STAKEHOLDERS TO HELP EXECUTE YOUR PROGRAM**
  Health centers often seek partnerships to execute comprehensive programming. Creating a community network of similar organizations on the local, state, and national levels fosters collaboration, creates opportunities to learn from one another, and increases efficiencies in implementing and improving program activity and to address access to health care and treatment for uninsured and under-insured populations.



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NNCC HCV Case Study Acronyms and Abbreviations

BHC - Behavioral Health Consultant
BPHC - Bureau of Primary Health Care
CDC - Centers for Disease Control and Prevention
CDHC - Charles Drew Health Center
CHC/SEIA - Community Health Centers of Southeaster Iowa, Inc.
CHIP - Children's Health Insurance Program
HER - Electronic Health Record
HBV - Hepatitis B Virus
HCV - Hepatitis C Virus
HHS - U.S Department of Health and Human Services
HRSA - Health Resources and Services Administration
MAT - Medication-Assisted Treatment
MCOs - Managed Care Organizations
MLP - Medical-Legal Partnership
NCA - National Training and Technical Assistance Cooperative Agreement
NDHHS - Nebraska Department of Health and Human Services
NNCC - National Nurse-Led Care Consortium
PCA - Primary Care Association
PCO - Primary Care Organization
PCP - Primary Care Provider
PCR - Polymerase Chain Reaction
PHMC - Public Health Management Corporation
PHLP - Pennsylvania Health Law Project
PWID - People Who Inject Drugs
SBIRT - Screening, Brief Intervention, and Referral to Treatment
STI - Sexually Transmitted Infection
SUDs - Substance Use Disorders
SVR - Sustained Viral Response
SYH - San Ysidro Health
UDS - Uniforms Data System
UIHC - University of Iowa Health Care
UNMC - University of Nebraska Medical Center
USPSTF - U.S Preventative Services Task Force
VISTA - Volunteers in Service to America
WSHC - Whittier Street Health Center