

Integrating HCV Services into Opioid Treatment: Supplemental Guide

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HIV, HCV OD SUD data summary: How has the landscape changed?

Since 2020, disruptions in care, physical isolation, logistical barriers, and increasingly unsafe drug supply caused by the COVID-19 pandemic have profoundly impacted health outcomes related to illicit drug use. Opioid Treatment Programs (OTPs) have proven effective in preventing both accidental opioid overdose and HCV transmission; increasingly OTPs are also a venue for treating hepatitis C and reducing reinfection rates among People Who Inject Drugs (PWID) [1]. This brief discusses current data related to health concerns associated with illicit drug use in the United States, including substance use disorders (SUDs), overdose, and injection-drug use attributable HCV and HIV infections.

Substance Use Disorders: The proportion of Americans living with an SUD remained relatively stable between 2015-2019 [2]. However, thirteen percent of Americans reported initiating or increasing substance use to cope with these symptoms in 2020, the first year of the pandemic [3]. Additionally, the COVID-19 pandemic exacerbated many risk factors associated with the development or worsening of SUDs. The CDC states that between April and June of 2020, the number of people reporting symptoms associated with anxiety and depressive disorder rose 30.9%, and symptoms of trauma-and stressor-related disorders rose by 26.4% [3].

Despite evidence of increasing prevalence of SUD, there continues to be a large unmet need for SUD treatment programs. Of the 14.5% of the U.S. population living with an SUD in 2020, only 1.4% received any form of substance use treatment in either inpatient or outpatient settings [4]. More encouragingly, innovations in the regulation of opioid use disorders (OUDs) brought on by the COVID-19 pandemic have yielded promising results. These changes will be discussed in greater detail in the SAMHSA regulations section of this report on page.

Overdose: The CDC estimates that 100,306 drug overdose deaths occurred between April 2020 and April 2021, a 30% rise from the same time period a year earlier and more than twice as much as in 2015 [5]. In addition to opioid misuse, stimulant misuse is also contributing to the climbing overdose mortality rate. There were nearly three times as many deaths involving cocaine in 2020 than in 2015, and more than four times as many deaths involving methamphetamine [6]. The increased mixing of stimulants and opioids is contributing to these increases in overdose fatalities. The number of fatal overdoses involving both cocaine and opioids has outnumbered the number of cocaine-involved overdoses where opioids were not present since 2014. For the first time in 2020, the same was true for overdoses involving both methamphetamine and opioids [6]. These trends are likely caused by a combination of two factors—(1) the rise of unintentional opioid use due to a contaminated drug supply; and (2) more frequent intentional mixing of stimulants and opioids. Interventions to treat stimulant use disorder, such as motivational interviewing and contingency management, have been shown to be effective and implementable in both inpatient and outpatient settings [7]. This suggests there are opportunities to reduce opioid-related fatalities if OTPs integrate programming to treat methamphetamine and cocaine use disorders.

The growing overdose mortality rate has magnified racial and socioeconomic health disparities. In 2020, the highest overdose death rate was among American Indian and Alaska Natives (AIAN). The highest growth in overdose mortalities by racial group, was among the Black/African American population in 2020 at 48.8%, significantly higher than the 26.3% growth experienced by White Americans [8]. The overdose mortality rate among Black/African Americans surpassed that of their White counterparts in

2020 for the first time since 1999 [8]. The Latinx population experienced relatively few overdose deaths, but saw 41% more fatalities in 2020 than in 2019 [8].

Inequitable access to medications for opioid use disorder (MOUD) treatment is one factor driving these health disparities. Methadone treatment facilities are more likely to be based in areas with a high concentration of Black/African American and Latinx residents, and these communities have less access to programs that provide buprenorphine, which are more commonly located in White neighborhoods [9]. While methadone and buprenorphine treatment have been shown to have similar success rates, many people who seek treatment at OTPs find the stringent protocols around methadone treatment to be inconvenient or prohibitive. Expanding options for MOUD with a racial equity lens and relaxing prohibitive regulations could increase uptake of treatment among marginalized racial/ethnic groups, positively impacting the racial disparities in overdose rates.

HCV: Injection drug use continues to be the most frequent route of transmission in the increasing number of new HCV cases [10]. In 2019, CDC estimated that 57,500 individuals were living with an acute HCV infection; up 43% from 2012 [10]. The most significant increase in HCV was seen in people aged 20-39; consistent with the demographic with the highest rate of opioid misuse [9,10]. Despite the rising number of new HCV cases, the amount of people initiating HCV treatment has either leveled off or decreased every year since 2015 [11]. Between 2014 and 2020, the average number of people treated for HCV was 120,000, less than half of what it would take to eliminate HCV in the U.S. by 2030 [11].

The COVID-19 pandemic has also reduced the number of identified new HCV cases. The volume of HCV antibody tests fell 59% in March of 2020, but rebounded to near pre-pandemic levels by July of 2020 [12]. However, the number of antibody-reactive results, RNA-positive results, and number of HCV treatment prescriptions dispensed remained substantially lower in July 2020 than the same time period in 2019 [12]. The recovery in antibody testing paired with low case-findings indicates that people at higher risk of HCV were less likely to access testing and treatment services during the pandemic [12]. OTPs are uniquely poised to provide targeted HCV testing and treatment services given high prevalence rates of HCV among OTP patients.

HIV: HIV diagnoses among people who inject drugs (PWID) rose throughout the country between 2015 and 2019, and CDC estimates that about 10% of new HIV cases overall, can be partially or fully attributed to injection drug use [13]. Recent trends in HIV transmission among PWID reflect growing racial and socioeconomic disparities. In 2019, Black/African Americans accounted for 29% of new HIV infections attributed to injection drug use, despite making up only 14% of the U.S. population [14,15]. Additionally, 43% of the 2,508 new HIV cases among PWID occurred in the South, the U.S. region with the highest poverty rate [15,16].

Despite the rising rate of HIV transmission via drug injection, the use and awareness of PrEP, a medication that lowers the risk of acquiring HIV, remains low among PWID. Research has shown that PWID in OTPs demonstrate high interest and value in PrEP, once made aware of it, and methadone treatment programs that provide PrEP have seen high adherence rates amongst patients [17-19].

Conclusion: Data demonstrates that OTPs can be successful in reducing many risks associated with OUD. OTPs offer an ideal opportunity to test and treat for hepatitis C given the high prevalence population accessing services, and consistent, frequent contacts with patients. Additionally, by expanding options to MOUD and incorporating services to address stimulant misuse, OTPs could help reverse trends in the overdose fatality rate and reduce health disparities in their communities.

COVID-Related Challenges and Considerations

COVID-19 Vulnerability for People Who Use Drugs (PWUD)

The global SARS-CoV-2 pandemic manifested as coronavirus disease 2019 (COVID-19), with its most severe presentation being acute respiratory distress syndrome leading to severe complications and death [20]. Public health experts warned about the devastating impact the COVID-19 pandemic might have on our most vulnerable populations [21]. People who use drugs (PWUD) face unique vulnerabilities in the COVID-19 era because of their specific social and health care needs. They face significant harm from the pandemic and its social and economic consequences, including marginalization in health care and social systems [22]. While relationships between drug use and blood-borne and sexually transmitted infections are well studied, less attention has been paid to other infectious disease outbreaks among PWUD [23].

Disparities and Inequities

COVID-19 disproportionately affects PWUD due to a high prevalence of cofactors that make the disease more severe. This includes unsanitary and/or overcrowded living conditions, stigmatization, incarceration, homelessness, and difficulties adhering to social distancing or self-isolation mandates. The pandemic also has had both short- and long-term effects on essential PWUD services, such as syringe services programs (SSPs) or opioid substitution therapy programs. Importantly, there is substantial evidence of other infectious disease outbreaks in PWUD that were associated with factors that enable COVID-19 transmissions, such as poor hygiene, overcrowded living conditions, and communal ways of using drugs [23].

COVID-19 racial and ethnic disparities are pronounced and can be traced to longstanding systemic inequities [24]. These same inequities also contribute to disparities in overdose and access to substance use treatment, amplifying the risk for Black Indigenous and People of Color (BIPOC) PWUD. Despite levels of drug use similar to or lower than whites, BIPOC PWUD, particularly the socioeconomically disadvantaged, experience a disproportionate number of health consequences from drug use [25]. The most pervasive disparities are observed among Black/African American and Latinx individuals, and where data exist, American Indian, Alaska Native, and Pacific Islander populations. The pandemic has shone a spotlight on health disparities and created opportunities to address the causes underlying these inequities [20].

When infected with COVID-19, persons with SUD are more likely to have a complicated illness course. The combination of COVID-19 infection, an SUD, and a chronic disease or risk factor for chronic disease – which is common among PWUD – presents a complex and layered risk, especially for BIPOC PWUD. For example, PWUD have a high smoking rate, a precursor for multiple chronic physical conditions such as cardiovascular disease, chronic obstructive lung disease, and cancers, all of which put them at risk for acute respiratory distress syndrome and death from COVID-19 [22]. A recent study found specific subpopulations of PWUD with greater odds of COVID-19 infection, including males, older adults, Hispanic persons, non-Hispanic Black persons, non-Hispanic persons of other races, as well as persons with chronic lower respiratory diseases, chronic hepatitis, and diabetes [24]. COVID-19 infection risk can

also vary by type of substance use disorder (SUD); unique opportunities for exposure or spectrums of underlying conditions that confer increased vulnerability may account for this risk [24].

COVID-19 has exacerbated barriers and limited access to effective resources, yet efforts to mitigate the negative impact may be less beneficial to Black/African American PWUD who face economic and structural inequities, and lack consistent technology and internet access relative to their counterparts [26]. Geographic locations that reported data by race and ethnicity indicate that Black/African American individuals and, to a lesser extent, Latinx individuals bear a disproportionate burden of poor outcomes from COVID-19. The most common explanations for this disproportionate burden involve two issues. First, BIPOC communities bear a disproportionate burden of underlying comorbidities. Second, those in urban settings live in more crowded conditions and are less able to social distance and isolate, and are more likely to be homeless [20]. These and other inequities facing Black/African American communities widen the racial disparities for COVID-19 vulnerabilities among PWUD.

Infection risks for fully vaccinated PWUD

Widespread vaccination is vital to limiting the spread of COVID-19 in the United States. Though data on COVID-19 vaccine uptake among PWUD are scarce [27], PWUD are unlikely to be vaccinated for preventable infectious diseases due to structural barriers such as lack of insurance coverage, transportation challenges, and medical stigmatization [28]. Early findings have shown that concerns about vaccine side effects, lack of concern about the effects of COVID-19, insufficient information about the vaccine, and general distrust of the vaccine development and deployment process contribute to low vaccine uptake among PWUD. When adjusted for age, younger PWUD who were experiencing homelessness and unemployment showed greater vaccine hesitancy [28].

For PWUD who are fully vaccinated, the effectiveness of COVID-19 vaccines might be curtailed by compromised immune status and a greater likelihood of exposure. Substance dependency can lead to difficulty adhering to physical distancing measures due to using drugs with others and exposure through congregate settings. Some may also experience immunosuppression from drug use and higher likelihood of comorbidities that can lead to COVID-19 complications (i.e., HIV and viral hepatitis) [21,23,24]. Additional considerations should be made for the potential decrease in vaccine immunity with emerging COVID variants, increased risk of COVID-related hospitalization, and the higher risk of breakthrough infection for people with recent SUD-related medical encounters.

Service Access and Delivery

COVID-19-related reductions and closures of health and social services placed PWUD at disproportionately increased risk for harm and critical treatment disruptions. Some of the most impacted services included syringe service programs, opioid agonist treatment, addiction counseling/self-help group/drop-in services, and withdrawal management and treatment. In addition, access to medical professionals, pharmacies and medications, shelters and housing, and food banks and food services were also compromised. The closing of these essential services PWUD rely on, coupled with the increased overdose risk inherent in isolation that was prescribed for COVID safety, likely contributed to an increase in overdose deaths [29].

One essential service that continued through the COVID-19 pandemic is the prescription of controlled substances such as buprenorphine for the treatment of opioid use disorder (OUD). Federal lawmakers

invoked an exception to the 2008 Ryan Haight Act that required in-person evaluation for such prescriptions. Telemedicine as an alternative, mitigated service interruptions and eliminated initiation delays of up to 12 weeks from pre-COVID times. The DATA 2000 waived clinicians could prescribe after conducting an initial telemedicine visit. Telemedicine also ushered in opportunities to innovate existing models of referral and engagement of PWUD in treatment, which will remain vital to closing the treatment gap and reducing mortality for PWUD [30].

Several key challenges exist in expanding the delivery of essential PWUD services via telemedicine. Inequities and disparities in access continue to prevail. BIPOC persons, rural residents, older adults, and low-income populations have limited to no access to reliable technology. Digital literacy and English fluency also present barriers to telemedicine services. Structural and policy changes to improve digital access and literacy will be critical to expanding the telemedicine model to these under-resourced populations.

Implications and Recommendations

The unprecedented disruptions in treatment and access to critical services have left PWUD vulnerable to unintended adverse effects, such as fluctuations in tolerance levels and substance use behaviors, increased withdrawal symptoms and overdose events, poorer physical and mental health outcomes, and greater risk for COVID exposure. These issues underscore the need for uninterrupted access to treatment and support services; a reduction in the capacity of these services leads to an inadequacy in addressing the needs of PWUD [30].

Researchers and practitioners recognize that the COVID-19 pandemic presents an opportunity for accelerated research and service provision innovations in this area. Selected recommendations to address the inequities and vulnerabilities affecting PWUD include [21]:

- A multi-pronged policy response to improve public health programs that serve PWUD and their communities.
- Investment in addressing social determinants of health, including homelessness and access to technology.
- Funding priority for local efforts in outreach, advocacy, and harm reduction in predominantly Black neighborhoods.
- In addition to telemedicine services, essential services should remain open and flexible to the unique needs of PWUD during COVID-19. At the same time, novel and effective adaptations and interventions should remain available and accessible post-COVID-19.
- Decriminalize PWUD and prioritize harm reduction services during and after the pandemic.

COVID-19 and Medicated Assisted Treatment: What has changed? What is at stake?

Methadone delivery is highly regulated by federal law. Drug treatment advocates argue that these regulations make methadone treatment inaccessible and unfavored for people with substance use disorder who need treatment. Federal regulations stipulate, for example, that only federally qualified opiate treatment programs may dispense methadone for opioid use disorder (OUD) treatment. Prospective patients must have initial in-person appointments to initiate treatment, and initial doses are limited. Further, patients must come to methadone clinics daily for observed dosing when starting treatment. The granting of take-home doses for patients, which would preclude needing to go to the clinic

daily, is extremely limited by federal law. The combination of these regulations, particularly the strict rules about daily or frequent clinic visits, can be challenging to negotiate for patients who are also managing employment, family care, or other responsibilities [31]. The regulations also reduce access to treatment, with patients in rural settings, for example, having to drive up to 90 minutes to reach a clinic [32].

The administration of buprenorphine is less strictly regulated, allowing patients to be prescribed buprenorphine by a licensed primary care provider or addiction medicine doctor, and prescriptions can be filled at regular pharmacies. Several studies have pointed to the racial differences in methadone and buprenorphine uptake, with patients on buprenorphine more likely to be white and of higher socioeconomic status than their non-white counterparts on methadone treatment.[9,33]

The onset of the COVID-19 pandemic prompted sweeping changes in the medication assisted treatment (MAT) regulatory framework, allowing for greater flexibility, as it was no longer safe to have groups of patients congregating at clinic sites for extended periods. Initiating buprenorphine via telemedicine became allowable for the first time. SAMHSA allowed methadone clinics to make blanket exceptions for 28-day take-home medications for “stable” patients and 14-day take-home medications for “less-stable” patients. SAMHSA somewhat narrowly defines a stable patient as, among other things, someone who has adhered to their treatment plan 100% for sixty days, has had negative toxicology reports for 60 days, and is able to maintain stable living conditions.[34]

The loosening of regulations related to telemedicine has increased access to buprenorphine, and the relaxation of take-home protocols reduced barriers to initiating and maintaining methadone treatment. Several studies have found no evidence of increased medication diversion, more frequent overdose, or decreased treatment adherence with the expansion of Medications for Opioid Use Disorder (MOUD) [35,36]. Further, patient satisfaction has increased, with patients reporting appreciation for the increased autonomy and opportunities for more individualized care [37].

Moving forward, SAMHSA will extend the loosening of the take-home regulations for stable patients based on the agency’s definition. But this will only occur after 30-60 days of in-person clinic visits and only in states that concur with the changes. Advocates argue that SAMHSA can and should do more to loosen restrictions further, as the current regulations will continue to widen the racial inequities in methadone versus buprenorphine uptake, maintaining the resulting racial inequities in overdose deaths [38,39].

HCV programmatic advancements and considerations

Lessons from the Learning Community

The Addiction Technology Transfer Center (ATTC) Network Coordinating Office (ATTC NCO) at University of Missouri Kansas City (UMKC) developed *Your Guide to Integrating HCV Services into Opioid Treatment Programs* with the support of SAMHSA. This guide was released in May 2020, and to support implementation of processes for integrating HCV services outlined in the guide, the ATTC Network convened an interactive learning community based on the guide’s content. This learning community consisted of representatives from seven opioid treatment programs (OTPs) of varying sizes in eight different states who participated in sessions every two to four weeks with a combination of didactic and peer-to-peer learning. As baseline, 63.5% of the OTPs were providing HCV testing to patients, with 87% providing testing upon completion of the sessions. All participating programs completed action plans related to service integration at their site and tracked their progress through a set of change indicators.

Reflecting on their learnings at the conclusion of the learning community cycle, participants highlighted the following key lessons:

Patient and staff education are crucial to increase the sense of buy-in needed to fully integrate HCV services into OTPs.

The majority of learning community participants highlighted the importance of centering staff and patient education as a key strategy to support the success of HCV service integration. This training should focus on the basics of HCV prevention, transmission, and treatment, emphasizing that HCV can be cured and, if left untreated, can lead to significant liver damage. Having this information, supported staff and patient buy-in to the importance of addressing HCV in OTPs. Oftentimes, a nurse or other clinical lead would provide the education, although clinical expertise is not necessarily a prerequisite for being a HCV educator. Making education sessions iterative and a required part of patient and staff onboarding further supported project success.

Universal testing simplifies and streamlines the processes.

Learning community participants noted that the majority of OTP patients could be considered high risk for HCV infection, and it was more expedient to implement universal HCV testing as part of the integration process than it was to attempt to identify high risk patients using an assessment. Many learning community participants employed an "opt out" testing model, in which patients were informed upon entering the program that all patients were provided the recommended HCV testing, and they had the option to refuse if they wished. Having a recently confirmed HCV diagnosis was a strong incentive to pursue HCV treatment for many patients. Some participants also noted they utilized contingency management to further support patients' linkage to care processes, incentivizing patients with gift cards or small cash payments for completing subsequent steps and appointments in the HCV treatment processes.

Maximizing efficiency and clarifying roles in the team approach leads to optimal outcomes.

The majority of learning community participants shared that, upon review of their policies and processes for HCV testing and linkage to care, they were able to identify multiple opportunities for streamlining and clarifying the patient flow and staff communication processes. Developing clear and concise protocols and taking a team approach with clearly defined roles for the case managers/recovery counselors, nurses, peer support specialists, prescribing clinicians, and labs supported optimal HCV integration processes.

Learning community participants highlighted a variety of strategies contributing to workflow efficiency. One of the programs had an in-house lab that took on processing all the initial antibody test results. Another program used electronic health records to flag patients who required follow up testing, for example, or support making a treatment appointment. Several participants established formal MOUs with Federally Qualified Health Centers (FQHCs) that agreed to provide HCV treatment for patients. Other programs assigned peer support specialists to follow patients through treatment, or may have clinical providers utilize a telehealth model to advise onsite clinical staff around treating HCV.

It is crucial to have an awareness of state policies and resources related to HCV testing and linkage.

Different states have varying Medicaid restrictions for HCV treatment [40], and it is essential to be aware of policy-driven barriers to HCV treatment that may impact OTP patients, such as sobriety or

prescriber restrictions, and to develop strategies around maneuvering these barriers and communicating them to patients. There may also be additional prior authorization requirements, such as those related to specific preferred regimens, genotyping, or hepatitis B testing that are particularly relevant for programs providing HCV treatment onsite. Some learning community participants also highlighted the importance of patient assistance programs that provide HCV treatment to uninsured patients. Having a strong foundational knowledge of each of these relevant factors aids efficiency in clinic workflows for HCV testing, linkage, and treatment.

Transportation can be a barrier for many patients.

Some learning community participants found that transportation to external appointments related to HCV treatment posed a significant barrier to treatment for their patients. Programs addressed this need in a variety of ways, including transporting patients to appointments themselves or providing bus or taxi/rideshare vouchers.

Hepatitis C Virus (HCV) Services Integration in Opioid Treatment Programs (OTPs): Case Studies

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Integrating HCV Testing into OTP Workflows: Arizona's CODAC Clinic

CODAC is one of Arizona's oldest and most respected community providers of specialty care for mental illness, addiction, and trauma. What began as a grassroots drug abuse prevention program has grown into a multi-faceted organization that provides services across the entire spectrum of behavioral health care. The 380 clinic is located in Tucson, Arizona. In 2018, CODAC turned this clinic into a program that operates twenty-four hours a day, seven days a week. The CODAC team has a goal to complete patient assessments and inductions as quickly as possible, with a target of having a patient onboarded and dosed within a three-and-a-half-hour-window. Medication Assisted Treatment (MAT) is just one of the services that CODAC offers its patients--employment programs, pain management services, including acupuncture, primary care, OBGYN care, psychiatric services, nursing services, and individual and group counseling are also available at the clinic.

This drive to treat the whole patient underpinned CODAC staff's motivation to address HCV inhouse. Staff noticed the high prevalence of HCV infection among their MAT patients and knew that these patients were more likely to complete treatment if it was offered onsite where they already came for methadone every day. CODAC staff started by identifying people from different departments who would play an integral role in HCV treatment protocols. They got feedback from other providers in the community who were treating HCV and began regularly consulting with a Gastroenterologist in the community who was part of Project ECHO, a program that used telehealth and conferencing to increase clinical capacity to treat HCV. They also joined the University of Missouri-Kansas City Addiction Technology Transfer Center's HCV learning community, which was a group of several OTPs from around the USA who were starting to integrate HCV services into their substance use treatment. This peer-based group shared their strategies, successes, and lessons learned.

Training staff onsite about the benefits of curative HCV treatment and of providing directly observed therapy for methadone patients taking HCV meds was one of the activities CODAC staff attribute to helping to move their process along. While completing prior authorization requests for HCV treatment was initially the most intimidating and time-consuming piece of the HCV treatment process, CODAC HCV team members met with a representative from one of the insurance companies that commonly covered

CODAC patients for targeted training and technical assistance. This intervention significantly reduced the time required to successfully complete the prior authorization process from as long as ten hours to about ten minutes.

As a result of having embraced the structural changes described above—identifying an HCV team and each team members' roles, seeking consultation with HCV experts, providing internal trainings about the benefits of HCV treatment, and seeking support to improve the likelihood of prior authorization requests being approved the first time—CODAC has seen impressive results. CODAC continues to work toward universal HCV screening of all patients. In the first five months of 2022, CODAC offered HCV antibody screening to 411, or almost half of its 870 MAT intake patients, identifying 92 patients who were antibody positive, and 38 patients who were RNA positive. CODAC staff encourage other OTPs starting to integrate HCV testing and treatment protocols to seek guidance and support so as not be intimidated by the various steps in the HCV treatment process.

Working with Community-Based Clinical Providers: The University of California San Francisco (UCSF) DeLiver Van and Fort Help Methadone Partnership

The DeLiver van is a program of the UCSF Liver Clinic and functions as a mobile, one-stop shop for HCV testing and treatment for marginalized communities in San Francisco. The DeLiver team partners with community-based organizations, homeless service sites, and drug treatment programs to offer HCV testing and treatment to patients accessing those services. In 2019, The DeLiver van piloted its services in partnership with the Fort Help methadone program in San Francisco, creating a model OTP/liver clinic partnership.

Prior to any testing activities at or near Fort Help, the DeLiver team met with the Fort Help clinic staff to give them information about what the DeLiver van can offer in terms of HCV services, which includes HCV antibody and RNA testing, as well as HCV treatment via telemedicine. They also met with a few Fort Help patients to talk to them about their HCV needs. As Fort Help staff and patients expressed interest in moving forward with a partnership, the DeLiver team next reserved a parking spot outside of the Fort Help clinic and began parking there weekly, offering rapid HCV testing to patients walking in and out of the clinic. If rapid tests were positive, the DeLiver team would do the venipuncture for confirmatory testing that same day, send it to the lab, and disclose the results to the patient when the van returned to Fort Help the following week. If the patient was viremic, DeLiver staff offered counseling around options, and if the patient wanted to be treated by the DeLiver team, DeLiver staff would collect insurance information and pre-treatment labs and have a clinic visit that day. DeLiver would continue to see the patient through the full course of their treatment utilizing a telehealth model on the van. This included discussing a treatment plan about how often they would like their medication and delivering the medications to the patients from the van.

Throughout this process, DeLiver and Fort Help worked together to optimize the testing and treatment opportunities for patients. Fort Help staff would proactively send patients to the van for testing and follow up appointments. Fort Help staff were also responsive to DeLiver's requests to flag patients and send them out when necessary. DeLiver staff attribute the effectiveness of the partnership to early and ongoing communication about each party's respective roles and responsibilities, and efforts to ensure the smooth ongoing functioning of the client identification, testing, and treatment processes.

Fort Help's Mission campus was the pilot site for the DeLiver van, and DeLiver screened 69 patients there, 39 (52%) of whom were HCV antibody-positive. Of the 12 patients who were RNA positive, DeLiver successfully treated and cured 8 patients. The DeLiver van then went to a second Fort Help campus, where they tested an additional 112 patients, 73 (65%) of whom were antibody-positive. At the second campus, DeLiver treated an additional 15 patients of the 27 who were RNA-positive. In the past three years, DeLiver has treated and cured dozens of patients in partnership with a variety of city settings, including methadone programs, shelters and navigation centers, and single-room occupancy hotels.

Dr. Jennifer Price, the Medical Director of the UCSF Liver Clinic and DeLiver program, has the following advice on successfully forming OTP/community clinic partnerships: "Being open to listening and different ideas and being creative is really helpful." Dr. Price notes that insurance barriers can be difficult to overcome in efforts to implement universal HCV screening campaigns, which makes the OTP/clinic partnerships an attractive option.

Dried Bloodspot Testing at OTPs in Oregon

As HCV disproportionately impacts people experiencing substance use disorders, homelessness, and incarceration, the multi-step HCV diagnostic process poses formidable barriers to efficient uptake of HCV treatment. The process can be expensive, time-consuming, and often involves a minimum of two visits before a patient is even diagnosed with HCV. Point of care rapid antibody testing can truncate this process, but the process still involves multiple visits as confirmatory testing is necessary to determine viremia for individuals who test antibody positive. Further, for people who have histories of injection drug use and vein damage, undergoing blood draws can be difficult and/or traumatic.

Dried blood spot testing, or DBS, represents a potential paradigm shift in HCV testing. DBS testing precludes the need for a blood draw as it requires only a fingerstick and blotting of blood on filter paper. The samples are then shipped to a lab where they can be tested for multiple diseases, including HIV, hepatitis B, hepatitis C antibody and confirmatory testing, and syphilis.

Dr. Andrew Seaman, Medical Director of Hepatitis and HIV services at Central City Concern (CCC) in Portland, OR, contends that DBS HCV testing holds particular promise for OTPs for several reasons, including that it requires a fingerstick as opposed to venipuncture, it is highly stable when properly stored, and offers the only non-phlebotomy-based HCV confirmatory testing in the U.S. These features render DBS testing preferable for many patients. Additionally, Dr. Seaman has found OTP administrators amenable to implementing universal HCV screening using DBS because this method can also be used to screen for syphilis, which is required by federal regulation. Routine integration of DBS screening therefore allows methadone clinics to internally screen for all required screening tests and high impact public health diseases like HIV and hepatitis C. Dr. Seaman and Sky Liepold, the CCC outreach worker leading the project, think this may not only improve blood borne pathogen screening rates at OTPs, but may also decrease barriers to opioid use disorder treatment retention. Although the turnaround time between sending samples to the lab and receiving results can be several days, this is generally not a challenge in OTPs as patients regularly return to the clinic for their medication and can be easily identified for results disclosure and linkage processes.

Given these advantages to DBS HCV testing in OTPs, Dr. Seaman is pursuing resources to support the roll out of DBS HCV testing to all OTPs in the state of Oregon. The model for this intervention, a partnership

between CCC and CODA, Inc Opioid Treatment Program in Portland, Oregon, implemented DBS HCV and syphilis testing on 02/22/2022. Patients at CODA are universally offered opt out screening at intake and are given a \$15 gift card at the results disclosure appointment.

This program screened 307 people between 02/22/2022-08/03/2022, 45 of whom were RNA positive for HCV. 12 of these patients were on HCV treatment as of August 2022, though with a 93% treatment initiation rate in the CCC hepatitis C elimination program between 2017 and 2022, this number is expected to significantly increase over time. 42 of the 307 people tested at CODA intake had inconclusive HCV RNA DBS results, generally due to insufficient specimen collected. Of note, when a 50% HCV RNA positivity rate is applied to those 42 inconclusive test results, often halted by insufficient quantity at the confirmatory stage of testing, the rate of presumed HCV RNA positivity within patients completing the intake process at CODA is an estimated 21.5% compared to 1% within the general population. Jennifer Dransfeldt, a Medical Assistant at CODA, describes the sense of satisfaction she gets in supporting program activities, saying, "I feel like I am being a productive member of society. Helping others find a new way to live a healthier and happier life. Freedom!!"

Opportunities to Integrate Overdose Prevention Services with OTP and HCV Services: Interview with Maya Doe-Simkins of the Remedy Alliance

Fatal overdoses continue to be the main cause of unintentional/accidental death in the United States, with opioid overdoses accounting for nearly 75% of drug overdose deaths. An average of 115 people die from an opioid overdose every day, and individuals with substance use disorder (SUD) experience an increased risk of overdose. In this interview, Maya Doe-Simkins of the Remedy Alliance explains the goal of naloxone saturation as a strategy to prevent overdose deaths and discusses various strategies that MAT programs can engage to protect their patients from accidental overdose death.

ATTC NCO Interviewer: *Can you tell me a little bit about the risk of overdose for folks in MAT (medication-assisted treatment) and how that changed over time?*

Maya: I've always known that agonist-based MAT is actually our most effective overdose prevention intervention. The drug supply gets wonkier as prescribed access to any kind of psychoactive medication gets harder and harder. The folks who are on MAT may have co-occurring mental health conditions that might lead them to need to take benzodiazepines, for example. Those are going to be harder to get [prescribed from a doctor]. Street-acquired benzodiazepines these days often contain fentanyl, right? So even though MAT is really protective [against overdose], any engagement in the illicit drug market is more dangerous than it's ever been.

ATTC NCO Interviewer: *What's getting in the way of more successfully preventing overdose and how can substance use treatment help out with that?*

Maya: Fundamentally, it really depends on the provider. And I don't just mean individual clinical providers, but the entire organizational culture and treatment programs, around the ways in which a return to opioid use is acceptable or not acceptable. Trying to be really intentional about the ways in which patients or clients may be mechanisms of amplifying naloxone access via secondary distribution within their communities and within their social networks [will prevent overdose].

The universal provision of naloxone through substance use disorder treatment programs is still not the total norm, and that varies regionally. I think that depends on both culture at programs, but also the kind of mandate by state and federal, and large local government funders. Every single patient or client should get naloxone on a regular basis. And if they ask for more, they should get as much as they want, and they shouldn't be referred out to access that.

ATTC NCO Interviewer: *So getting naloxone into the hands of MAT patients, and doing so regularly, is crucial. Anything else you think is really important?*

Maya: Yeah, I mean, I think that the periods of both induction and tapering are the really tricky periods, they're usually periods where there's a lot of tension between providers and clients. Just frame the incremental increase [of medication] in and of itself, as an overdose prevention strategy. And then also, depending on where the desire or request for tapering, or exiting folks out of treatment comes from, oftentimes, there's this tension with what the patient wants to be done. But I think that proactively preparing for the if, or when, of tapering, in advance of that being something on people's mind is probably another place [to focus on]. The communication [around this process] is clunky and graceless. I think getting a little bit more sophisticated in that messaging proactively is another thing I would consider.

ATTC NCO Interviewer: *Are there any successful overdose prevention integration models that you'd want to highlight specifically around drug treatment programs?*

Maya: My current favorite overdose prevention/harm reduction/treatment program, is out of the Boston Public Health Commission. They moved that central intake activity to the syringe service program. It normalized coming to the syringe service program, and it provided this clear rationale for people to continue to engage in the services at the Harm Reduction Program, despite being in treatment, or not, or intermittently in treatment, or temporarily in treatment. I really like that model.

The other even simpler model is bringing naloxone in-house, harm reduction training for staff, and regular culture shift activities. Sit down with your policies and do what I refer to as a "searching and fearless organizational self-inventory" about how policies are detrimental to, or in conflict with, overdose prevention messaging. It's a lot of work. And I think that a lot of the time, treatment programs are like, well, where's the money for this? Or we don't have a budget for naloxone, et cetera. But one, I feel like states should be providing the budget for naloxone out of the ample federal dollars for naloxone in some way or another, and that having these conversations is not a discrete person's job, it should be integrated into everybody's communications. And whenever people are able to do that, they've discovered that it enhances the therapeutic relationship. So, I don't actually think it's a great idea to kind of separate out that role of like, "overdose prevention person."

ATTC NCO Interviewer: *Talk to me about the concept of naloxone saturation, and why this is a really important time to be leaning into that idea.*

Maya: The concept of naloxone saturation means ensuring that there is naloxone on the scene where there are overdoses. We need to transition from a scarcity mentality to one of abundance with ample

naloxone, giving people at least as much as they asked for, and sometimes more than they asked for. When I first started doing a little bit of work with the Chicago Recovery Alliance, I paid attention to how those guys did orientation to their new staff and volunteers. “We always try to negotiate up for syringes right there, like if somebody comes in and says, I need 10, we say, Well, how about 100?” I think that we need to sort of adopt a similar mindset with naloxone, because, you know, one per every X number of population isn't enough to ensure that there's naloxone at those overdose events. And as overdose events become more complicated because of more polydrug use, and faster because fentanyl is actually speeding up the onset of overdose, the fall back on professional first responders becomes less and less viable as a lifesaving intervention.

ATTC NCO Interviewer: *Tell me about the Remedy Alliance and how you all are working on these issues.*

Maya: The Remedy Alliance/For The People is the next version of the national Naloxone Buyers Club, which the Buyers Club was established back in 2012. In 2012, there were zero branded products. We didn't have any expensive branded products. There were only a few generic manufacturers, there was a [naloxone] shortage that turned into a massive price hike. We're talking about, at that time, the difference between 65 cents per dose to \$15 per dose. So, we negotiated back then, for a super cheap deal to maintain the less expensive price prior to the shortage exclusively for harm reduction programs. And so that bumped along for a decade. The Buyer's Club was something more than a sort of socialist harm reduction, [it was a] collective [that grew] into an actual organization. More recently, we needed to have a more formal structure, so we transitioned to a nonprofit structure. And, we also negotiated with a second pharmaceutical company to offer an inexpensive price for generic injectable naloxone.

So now we have two suppliers. We are exempt from federal wholesale distributor definition because of our structure and the overdose public health emergency. So basically, we have cut out all of the problems that pharma, distributors and prescription status impose on harm reduction programs. We have one prescriber that is working exclusively with us at Remedy Alliance. We have tiered pricing that makes naloxone available to unfunded naloxone distribution groups. There is enough funding to purchase way more naloxone than the country even needs, even at our highest price (though not at the highest branded prices!). There's enough federal money for that. It will depend on the will and investment of decision-makers a little bit at the federal level, but much more so at the state level.

Are you aware of how hepatitis activities are funded in your state? Check in with your local and/or State Health Department!

The CDC [PS-21-2103](#) grant funds 49 states, Puerto Rico, and 8 US cities. These grants are focused on hepatitis disease surveillance, elimination planning, and related activities. Some states received additional funds to support specific activities hepatitis-related targeted to people who use drugs.

Get to know your state or local hepatitis coordinator! They will be interested in how your program is addressing hepatitis C. Here are some helpful inquiries to consider in communication with Health Department viral hepatitis staff.

- What activities are funded under our state/city PS21-2103 grant?

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- What other HD funding streams support or could support hepatitis activities (e.g. HIV, SAMHSA, etc.)?
- Would it ever be possible to utilize unspent/carry-forward funds to support activities related to our OTP HCV screening and linkage program? (e.g. bulk purchasing rapid test kits, phlebotomy certification for staff, etc.)
- Are there community-based organizations or clinical staff you can connect our program to that can better support our efforts to test and treat our patients for HCV?
- Are there any special projects you are aware of related to hepatitis C - such as a health plan that is doing a demo project, a QI effort, or 340B-funded efforts that would be good for us to know about or get involved in?

What is a CLIA certificate and how are they relevant to HCV testing?

In 1988, Congress passed the Clinical Laboratory Improvement Amendments (CLIA), which gave Congress the authority to establish standards for laboratory testing, in order to ensure accuracy and reliability of test results. CLIA applies to all laboratories that are examining “materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings” [41]. OTPs need to be CLIA-certified as these programs regularly conduct patient drug testing and may perform other clinical tests.

Generally, labs are required to have a CLIA certificate for each site where testing occurs, unless it is a mobile unit or the testing location is within a hospital. Labs or testing sites can apply to be part of the CLIA program by completing and submitting [form CMS-166](#). CLIA certificate applications must be submitted to the State Agency of the state in which the laboratory is located. It is recommended to discuss any other state-specific requirements with the state agency.

The purpose of a CLIA waiver is that certain tests can be performed outside of a laboratory setting, which allows for greater flexibility in the use of these tests, which in turn can make testing more accessible. CLIA describes waived tests as “simple laboratory examinations and procedures that have an insignificant risk of an erroneous result.” The Food and Drug Administration (FDA) determines which laboratory tests can be waived through its review of the manufacturers’ CLIA waiver applications. Only tests that are CLIA-waived can be performed by a laboratory with a certificate of waiver [42]. A list of CLIA-waived tests, which includes the OraQuick HCV Rapid Antibody test, can be found on the FDA website [here](#).

FDA Reclassification of HCV Testing

On November 19, 2021, the U.S. Food and Drug Administration (FDA) issued final orders reclassifying two types of hepatitis C diagnostic tests from Class III to Class II [43]. The two types of tests are (1) nucleic acid-based HCV ribonucleic acid devices intended for the qualitative or quantitative detection or genotyping of HCV RNA, and (2) certain HCV antibody devices intended for the qualitative detection of HCV antibodies [44]. Discussions on reclassification have been ongoing since 2018, with several advisory committees and panels working to assess the potential risks, safety, effectiveness, and benefits of the device under the then proposed Class II [45]. This work, coupled with the efforts of other agencies and organizations such as the CDC, is intended to increase access to hepatitis C testing and treatment, ultimately reducing disease transmission and deaths in the United States.

The three classes of devices are class I (general controls), class II (general and special controls), and class III (general controls and premarket approval) [44]. The FD&C Act allows the FDA to reclassify a device into class I or II on its own initiative or in response to a petition from the manufacturer or importer of the device. To change the device's classification, the proposed new class must have sufficient regulatory controls to reasonably ensure the device's safety and effectiveness for its intended use [44].

Reclassification means HCV test manufacturers will no longer have to submit a premarket approval application (PMA) or go through the stringent FDA medical device review process. They can now get clearance through a less taxing premarket notification (510(k)) process, while still adhering to special controls and safety assurances. The special controls in place include labeling stating that the RNA-based diagnostics are not intended for screening donated blood or tissues, as well as certain requirements that manufacturers verify their test designs and provide validation data from clinical performance evaluations [46]. With the reclassification, the regulatory approval process time is significantly shorter, decreasing turn-around time for manufacturing. Additionally, the reclassification may support the potential for more manufacturers to develop these tests, which can increase competition and access to these essential tests [43].

Implications

Hepatitis C virus (HCV) infection is a significant source of morbidity and mortality in the United States. With no existing vaccine or pre-/postexposure prophylaxis available, effective but expedited interventions are vital to treatment [47]. The CDC considers the reclassification of these tests as groundbreaking for hepatitis C diagnostics as it [45]:

- Expedites, and in some cases facilitates, bringing methodologies such as rapid nucleic acid tests and potentially antigen detection tests for diagnosis of current HCV infection to the U.S. market
- Facilitates the development of innovative technologies for point-of-care viral detection assays for diagnosis of current HCV infection
- Decreases cost, increases competition, and provides smaller companies an opportunity to develop new and improved assays, which has the potential to decrease diagnostic device costs

These reclassifications will also benefit the Department of Health and Human Services' [Viral Hepatitis National Strategic Plan](#), as increased access to tests will likely aid patients in seeking the appropriate treatment and likely reduce transmission [43].

Medicaid Policy and HCV Treatment Access: Advocacy and Progress

When the highly effective, direct-acting antiviral medications first became available in 2014, the “\$1,000 per pill” price tag for the lifesaving treatment drew considerable media attention and criticism from patient advocacy groups [48]. The perceived high cost of the treatment prompted insurance payors to establish various criteria around which patients could be prescribed HCV treatment because they were nervous about the cost to treat the large number of Americans who were living with HCV. Treatment restrictions are enforced using prior authorization, a process whereby health care providers must get advance approval from a payor, who will decide whether to cover a medication or service.

Medicaid treatment restrictions are especially relevant because people newly infected with or living with HCV are disproportionately insured under Medicaid, compared with private insurance [49], and commercial insurers often follow the lead of Medicaid policy and adopt similar restrictions. In 2017, the

National Viral Hepatitis Roundtable (NVHR) and the Center for Health Law and Policy Innovation of Harvard Law School (CHLPI) partnered to launch “Hepatitis C: State of Medicaid Access,” a project to track these restrictions and grade state Medicaid plans on their HCV treatment accessibility.

The project focused on three common restrictions: (1) liver disease progression, or requiring a certain stage of liver disease (i.e., fibrosis) be reached before treatment, (2) sobriety requirements, and (3) prescriber requirements, which dictate that only certain healthcare providers are eligible to prescribe HCV treatment. The 2017 full report, available on the [Hepatitis C: State of Medicaid Access website](#), summarizes the widespread use of these restrictions across the U.S.

Over time, the combined forces of (1) advocacy, supported by these reports, and (2) more competitive pricing for HCV medications resulting from additional HCV regimens coming to market, contributed to a general trend toward expanded HCV treatment access in the U.S. The Hepatitis C: State of Medicaid Access January 2022 progress report notes that “33 states have either eliminated or reduced fibrosis restrictions, 29 have loosened their sobriety restrictions, and 28 have scaled back their prescriber restrictions.” [40] Eleven additional states have removed prior authorizations to access HCV treatment for most patients entirely.

While these victories are significant and crucial, restrictions persist in many states. Moving forward, NVHR and CHLPI are now taking a broader approach, and will soon begin tracking additional restrictions based on feedback from patients, providers, and other stakeholders about ongoing barriers to treatment. For example, the group is monitoring whether managed care organizations are adhering to the same policies as fee-for-service organizations as required by law. The group also plans to look at increased barriers to care for individuals seeking retreatment, compared to those seeking initial treatment.

The role of specialty pharmacies in creating barriers to HCV treatment is also increasingly an issue; while specialty pharmacies may provide valuable services, such as prior authorization support and adherence programs, many enact their own treatment access barriers above and beyond those dictated by Medicaid policies, such as requiring that prescriptions be received by mail. This is particularly relevant in the HCV context, as most HCV medications are dispensed via specialty pharmacies and specialty pharmacy barriers often disproportionately impact historically marginalized communities such as people experiencing homelessness.

Typically, decisions about treatment restrictions are made at the state level by each state’s Medicaid Pharmacy and Therapeutics committee, or its Drug Utilization Review Board. Adrienne Simmons, Director of Programs at NVHR, described using the state report cards and the information on national trends to engage these committees and decision-makers around the importance of removing HCV treatment restrictions. In doing so, she highlighted a variety of strategies NVHR has found helpful in its advocacy work on Hepatitis C: State of Medicaid Access, and these strategies may prove instructive for those invested in similar work locally:

1. Determine who has the decision-making power regarding treatment restrictions (e.g., Medicaid, Department of Health, Governor, legislature).
2. Identify internal champions within the state Medicaid program and leverage personal relationships with physicians and pharmacists who serve on relevant committees.

3. Encourage providers and patients to provide testimony about the hardships posed by Medicaid restrictions to relevant committees, boards, or policymakers.
4. Track prior authorization denials and collect data on treatment access issues, including the administrative burden of prior authorizations.
5. Raise treatment access issues in state coalition meetings and elimination planning work groups to support awareness, education, and advocacy efforts.
6. Include the removal of prior authorization in state elimination plan goals and strategies.
7. Send sign-on letters and/or request meetings with the Medicaid, Department of Health, and Governor's Offices.
8. Leverage opinion editorials, letters to the editor, and social media to spread awareness about how treatment access restrictions are impacting the community.
9. Engage with national organizations like NVHR and CHLPI to understand national trends and how to address concerns regarding removing prior authorizations, such as safety and budget impact concerns.
10. Present and publish on treatment access restrictions.

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