Science over Stigma: The Public Health Case Against HCV Treatment Sobriety Restrictions

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Effectively addressing the opioid epidemic in the U.S. depends on our ability to provide appropriate prevention and care services for low-income people who use drugs (PWUDs). First and foremost, ensuring that everyone living in America has access to affordable health insurance is the highest form of non-discriminatory healthcare design and is a critical public health intervention to address the opioid crisis. As the dual heroin and prescription drug epidemics continue, PWUDs of all economic backgrounds will need insurance to access primary health care, substance use treatment, mental health care, wound care and emergency room visits, naloxone, and infectious disease treatment.

Hepatitis C (HCV) is the leading infectious disease killer in the United States. It kills more people than all 60 infectious diseases that the Centers for Disease Control and Prevention (CDC) track combined[1]. Despite lacking a comprehensive national hepatitis surveillance program, available data suggests that up to 70% of HCV infections are among people who inject drugs (PWID)[2]. This can be attributed to the incredibly infectious nature of the blood borne virus, lack of awareness and resources for hepatitis prevention, stigma against people who use drugs, and barriers to accessing curative HCV treatment. To improve the quality of life of people living with HCV, reduce hepatitis-related liver cancer and death, and reduce new infections, PWID must have unhindered access to curative hepatitis C treatment.

With the introduction of curative therapies in 2014, HCV care has been revolutionized. Scientific revolutions are sold by pharmaceutical companies for a very high price - the five HCV direct acting antivirals (DAAs) on the market (Sovaldi, Harvoni, Viekira Pak, Zepatier, Epslusa) cost $54,600-$94,500 wholesale acquisition price per 8-12 week cycle. Despite lower negotiated prices with public and private insurers, there remains fear that the demand for treatment is too great to afford at even the negotiated lower prices. As a result, many private insurance companies and state insurance programs have instituted measures that restrict access to treatment. These measures include restricting treatment for only the sickest people living with HCV, requiring referral to a specialist, and dismissing people who are currently or have recently used drugs as unacceptable to treat. This issue brief will focus on the latter restriction.

Sobriety requirements, which restrict access to curative treatment when there is any evidence of drug and/or alcohol use within an arbitrary timeframe or requires drug and alcohol testing before treatment will be provided, is not based on clinical evidence or

treatment recommendations, has created a significant barrier to treatment.[3] Such restrictions are antithetical to consumer private insurance protections and the federal requirement for Medicaid to provide access to medically necessary treatment.

> One example of insurance requirements related to substance use is Illinois' Medicaid substance use restrictions which states that "individuals must not have evidence of substance abuse diagnosis or treatment (alcohol, illicit drugs or prescription opioids and other drugs listed on the schedule of controlled drugs maintained by the Drug Enforcement Administration) in the past 12 months. Information pursuant to this requirement will be based on department claims records, prescriber's knowledge, medical record entry, state's narcotic prescription registry database, reports from a hospital, an emergency department visit, an urgent care clinic, a physician's office or practice, or another setting. Individuals must also provide documentation of a negative standard urine drug screen report within 15 days prior to submission of the prior approval request[4]."

In 2015, the Centers for Medicare and Medicaid Services (CMS) released guidance clarifying federal Medicaid law. The guidance explicitly stated that restrictions based on sobriety are not clinically based and are at odds with federal requirements to ensure access to medically necessary treatment[5]. Similarly, state insurance regulators are beginning to assess potential discriminatory formulary designs more closely, particularly for plans that must meet Affordable Care Act requirements. Despite this increase in monitoring and oversight, many state Medicaid Directors, health insurance plans, and prescribing physicians maintain that people who use drugs should not be eligible for treatment due to their drug use and perceived risk for reinfection.

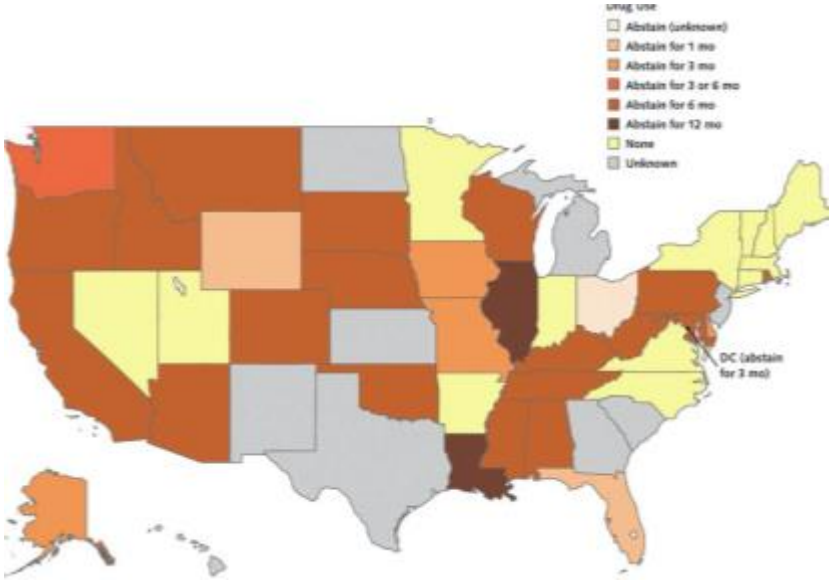

Figure 1 Image: National Viral Hepatitis Roundtable, 2016 Medicaid Sobriety Requirements for HCV Treatment from Hepatitis C: The State of Medicaid Access, November 14th, 2016 http://www.chlpi.org/wp-content/uploads/2013/12/HCV-Report-Card-

This issue brief provides evidence-based arguments that people who currently or formerly use(d) drugs are just as suitable for treatment as non-drug users, supporting the immediate removal of discriminatory restrictions to curative treatment. Additionally, several states have successfully leveraged scientific arguments and community will to remove hepatitis C treatment restrictions. Strategies for success as well as cost-effective and comprehensive models of hepatitis care for PWID will be discussed in the latter half of this document.

Science Over Stigma: An Evidence Base Supporting Removal of Sobriety Restrictions

For the past forty years, the U.S. sociopolitical response to drug use has focused on eradicating drugs through the criminal justice system at the expense of a public health response to drug use. The war on drugs bred abstinence-only requirements which, despite lacking empirical backing, became the standard in substance use treatment and healthcare practice. Today, abstinence-only conditions are weaved into the fiber of every American institution. This vast misunderstanding of drug use often shuts down relationships between healthcare providers and patients who use drugs and creates institutionalized stigma against PWUD. In cases where care is denied to someone based on his/her illicit injection drug use, underlying assumptions about the person's ability to take care of him/herself can be traced back to drug war rhetoric or a single bad encounter rather than medical training or peer-reviewed research. Over 50,000 people in the U.S. died from drug overdose in 2015 and over three million people are living with hepatitis C - the time has come to challenge discriminatory treatment so that PWUDs have access to recovery, clinicians can provide sound medical interventions, and the healthcare system can benefit from long term cost savings.

People Who Use Drugs Can Adhere to Treatment

To combat stigma against PWID and empirically prove the ability of PWID to adhere to HCV treatment, Merck & Co. (pharmaceutical manufacturer of the HCV treatment regimen, Zepatier) funded and conducted a clinical trial called C-EDGE CO-STAR, which was published in August 2016. "The results of this trial show that illicit drug use prior to and during hepatitis C therapy had no impact on the effectiveness of the therapy, and that reinfection was low, at 4%," says Professor Gregory Dore, lead investigator for the clinical trial and a physician at St. Vincent's Hospital in Sydney, Australia. The trial outcomes also show excellent treatment adherence. "At greater than 95%, this is comparable to results in hepatitis C populations that exclude people who use drugs[6]."

Risk of Re-infection for People Who Use Drugs is Minimal

A study published three years earlier entitled *Recommendations for the Management of Hepatitis C Infection Among People Who Inject Drugs* presents several models which suggest that HCV treatment for PWID can lead to significant reductions in HCV prevalence and reduced transmission, and that a recent history of injection drug use does not compromise adherence or treatment completion[7]. The study further suggests that curative treatment is particularly effective when combined with other harm reduction interventions such as involvement in syringe service programming (SSPs) and medication assisted treatment (MAT). A review of several HCV treatment regimens found that HCV treatment formulations (that were available at the time) can be used in PWID on opioid medication assisted therapies. Furthermore, this study submits that HCV treatment among PWID is cost-effective as fewer infections and advanced cases save the health care system considerable savings over time. **Due to these findings, PWID should be a high priority for treatment.**

Appropriate Models of Care Can Better Manage and Support Treatment Among People Who Use Drugs

Models of Care for the Management of Hepatitis C Virus Among People Who Inject Drugs: One Size Does Not Fit All leverages findings that PWID can and should be treated. This research finds that one complication to providing HCV care to PWID is the lack of non-judgmental, culturally competent, and accessible treatment settings for this vulnerable population. Despite the lack of suitable treatment settings, HCV treatment has been successfully provided to PWID through multidisciplinary approaches including community-based clinics, substance use disorder treatment clinics, and specialized hospital-based clinics. These models may be integrated into "all under one roof" primary care settings or occur in specific substance use and community-based health care settings. Research has found that "a high level of acceptance of the individual life circumstances of PWID rather than rigid exclusion criteria will determine the level of success of any model of HCV management[8]."

Reducing community viral load through the combination of the provision of medication and harm reduction services is not foreign to public health and healthcare systems. In the late 1980s and 1990s, the AIDS/HIV epidemic devastated communities vulnerable to the sexually transmitted and blood borne virus. PWID were one such community where, in dense urban areas, the burden of HIV was as high as 50%. In response to high rates of HIV infection and resulting death, many of these cities instituted SSPs which offer sterile syringes and injection supplies, syringe disposal, overdose prevention education, HIV/HCV testing, and linkage to HIV/HCV care. Although the price of HIV drugs can be unattainable by some people living with HIV, systems such as AIDS Drug Assistance Program (ADAPs) and patient assistance programs were put in place to help ensure access to life-saving medications. Because of this well-resourced, open, and accessible healthcare system, physicians and specialists provided treatment to anyone with a confirmed HIV diagnosis. Unfortunately, these systems have not been extended to people living with HCV.

Ensuring that PWID living with HIV were linked to insurance coverage and treatment and virally suppressed in addition to utilizing safe injection practices has had tremendous success. Thirty years later, communities where the HIV burden among PWID was 50% before is now below 10%[9]. Furthermore, PWID living with HIV can stay healthier and live longer due to advancements in HIV treatments. This example of HIV prevention and care demonstrates the ultimate purpose of public health and healthcare systems – to reduce disease and ensure care regardless of the population. It also shows the efficacy of treatment as prevention. Treatment as prevention refers to the decreased number of viral infections which are transmittable in a community. Less possible infections mean fewer infections, so treatment can serve a dual function as prevention in this regard.

Cost-Effective and Comprehensive Models of Care for PWID

HCV treatment as prevention is part of a three-pronged comprehensive hepatitis prevention package geared toward PWID which also includes SSP and MAT. Together, these strategies ensure that PWID are living without HCV, have access to everything they need to prevent new infection while injecting, and have access to substance use medications that decrease injection incidence. Furthermore, these prevention strategies are less costly over time than the lifetime cost of infectious disease treatment and emergency care for drug-related health issues.

Treating PWID now Saves Costs Later

The cumulative cost of treating hepatitis C in America is estimated at $6.5 ($4.3-$8.4) billion and it will peak in 2024 at $9.1 ($6.4-$13.3) billion[10]. To put the health economics of HCV into perspective, the cost of DAA HIV medication can be juxtaposed with the cost of HCV treatment. This is especially poignant since HCV infections in the U.S. vastly outnumber HIV infections.

> "The discounted lifetime cost of treating one person with HIV in the United States is $315,000. The corresponding cost of curing HCV is $58,000--which is only 18% of the total HIV treatment cost. HIV antiretroviral treatment is cost-effective in the United States; HCV treatment is cost saving[11]."

SSPs also create cost savings and public and private payers should invest in these important programs. One syringe costs less than one dollar. Using a sterile syringe and clean injection supplies with every injection episode provides a high degree of protection from contracting bloodborne HCV infection for PWID and could lower overall health care costs. For instance, an Australian study estimated that the Australian government avoided 21,000 hepatitis C infections and saved approximately $738 million in total lifetime hepatitis C treatment costs through SSPs between 1991 and 2000,[12] confirming that it is much more cost-effective to invest in SSPs as a prevention measure on the front end than to treat people on the back end.

HCV Treatment = HCV Prevention

The 2016 federal appropriations package contained language that relaxed restrictions that have been in place for over thirty years barring the use of federal funds for public health programming that reduces the infectious disease consequences of injection drug use. The ban is still in place for harm reduction supplies such a syringes and cookers. These sterile supplies are necessary to prevent hepatitis transmission. Moreover, very few philanthropic organizations in the United States provide funding for SSPs. Many SSPs in the U.S. have sparse operating budgets and are unable to meet the demand for sterile harm reduction supplies. **When HCV prevention interventions are hard for PWID to access consistently, transmissions continue to rise. HCV treatment is an important and necessary prevention intervention to reduce transmission.**

A Combination of Medication Assisted Treatment (MAT) and HCV Treatment Is Essential for PWID

MAT has been proven to reduce viral infection among PWID by 64%[13]. By reducing drug withdrawal symptoms while simultaneously reducing drug cravings, substance use medications can enhance a person's recovery prospects. MAT may also increase a person's HCV treatment outcomes. Strict regulations surrounding the prescribing of MAT have historically caused hesitancy among doctors who already are deterred by the mandate to gain MAT certification and limitations on the number of MAT patients per provider. This federal cap was set at 30 patients in the first year of practice and 100 patients during following years. Two federal initiatives were enacted in 2016 which can accelerate MAT prescribing – the Obama Administration raised the prescribing cap on MAT provision to 100 patients in the first year and 275 in subsequent years, and Congress passed the Comprehensive Addiction and Recovery Act (CARA) which expands the MAT provider base to physician assistants and nurses. **Both substance use treatment and hepatitis C treatment need to be expanded to meet the hepatitis prevention and care needs of PWID.**

Science Informing Policy: States and Plans Are Deciding to End Discriminatory Plan Designs

Ten state Medicaid programs have removed the sobriety restriction within their plans. This has been accomplished by applying pressure on state insurance offices to make a state plan amendment, bringing lawsuits against state insurance offices for the denial of care, and Managed Care Organization (MCO) contracts. New York and Pennsylvania built strong inter-disciplinary coalitions that lobbied their state insurance office to remove hepatitis treatment restrictions in their Medicaid state plan (the agreement between a state and the federal government on which healthcare will be provided, to whom, and how it will be reimbursed). These coalitions featured communal educational events,

lobbied their state insurance officials, and engaged in direct action campaigns to remove discriminatory healthcare restrictions.

Washington and Florida residents brought law suits against their state Medicaid program on grounds that the state was denying medically necessary treatment, and that the denial of medication had caused them harm. These lawsuits prompted state Medicaid programs to reverse their sobriety policies along with other restrictions on barring curative treatment access. Similar lawsuits were brought in other states, challenging both Medicaid and commercial payers, and several states currently have pending lawsuits. Precedence is being set for using litigation to gain access for PWID to curative medication.

Competition on the treatment market is increasing as new HCV DAA drugs come to market. Advocates are hopeful that competition will continue to drive prices down. To further ease public and private payers' anxieties about cost, there are now many state Medicaid programs and commercial plans that have begun providing curative treatment to PWID, proving that restrictions can be lifted in a cost-effective way. The fear of bankruptcy has not manifested. Given these economic arguments, data that supports high adherence and treatment outcomes among PWID, the availability of complimentary hepatitis prevention interventions for PWID, and state hepatitis advocacy successes, regulations that block PWID from curative hepatitis treatment should be removed immediately.

Non-discrimination Starts with Access to Insurance

To receive equal access to treatment, low-income people who use drugs must receive equal access to insurance. Widespread access to health insurance and coverage of substance use/ mental health services are the first steps in addressing institutional stigma towards PWUD. Health insurance coverage accelerates a person's chances of recovery and success. As defined by the Substance Abuse and Mental Health Services Administration (SAMHSA), "recovery is a process of change through which individuals improve their health and wellness, live a self-directed life, and strive to reach their full potential.[14]" By providing coverage of overdose reversal drugs, medication assisted treatment, out-patient counseling services, emergency room care, infectious disease treatment, and primary care; health insurance and non-discriminatory medical service provision should be the cornerstone to our nation's response to drug use.

Restrictions that limit access to prevention and care services for PWID are discriminatory and at odds with our nations values and public health interests. People who use drugs deserve high quality, readily available and culturally competent prevention, care and treatment and a cure to HCV.

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