



December 9, 2024

Dear Colleague Letter Title: Advancing HIV and viral hepatitis testing with point-of-care diagnostics for people with substance use disorder

Dear Colleague:

As the Assistant Secretary for Mental Health and Substance Use and leader of the Substance Abuse and Mental Health Services Administration (SAMHSA) and the Director of the Centers for Disease Control and Prevention (CDC), we urge the public health and substance use disorder (SUD) treatment communities to increase the number of people with SUD who are tested and treated for HIV and viral hepatitis.

In the United States, an estimated 2.4 million people have hepatitis C,ⁱ 1.2 million people have HIV,ⁱⁱ and 660,000 people have hepatitis B.ⁱⁱⁱ Roughly 2 percent of those with HIV also have hepatitis B.^{iv} Injection drug use is a risk factor for all three infections and is the most commonly reported risk factor for new hepatitis C virus (HCV) and hepatitis B virus (HBV) infections. Further, one in four people with HIV who inject drugs also have hepatitis C.^v One in seven people with HIV,^{vi} one in three people with HCV infection,^{vii} and one in two people with HBV infection do not know they have it.^{viii} According to the National Substance Use and Mental Health Services Survey, only a third of our nation's 15,000 substance use disorder treatment facilities offer HIV, HCV, or HBV testing.^{ix} This represents thousands of missed opportunities to ensure everyone knows their HIV, hepatitis C, and hepatitis B status and to link individuals to lifesaving treatment.

To increase the identification and treatment of all people with HIV and viral hepatitis, CDC recommends that all adults receive HIV, HBV, and HCV testing at least once in their lifetime.^x CDC also recommends:

- [HIV testing](#) at least once a year for people who share needles, syringes, or other drug injection equipment (for example, cookers) or exchange sex for drugs or money
- Routine periodic [hepatitis C testing](#) for people with ongoing risk factors, including people who currently inject drugs and share needles, syringes, or other drug preparation equipment
- Routine periodic [hepatitis B testing](#) for people who inject drugs
- Clients without hepatitis B immunity, including adults age 19–59 and adults 60 and older with [risk factors](#), should be [vaccinated](#)

Testing is the first step to accessing lifesaving treatment. For example, hepatitis C treatment with oral direct-acting antivirals is curative in >95% of cases, prolongs life, is very well tolerated, and confers cost savings to the healthcare system by preventing HCV-related complications. Yet too few people are diagnosed, and only one-third of people with diagnosed hepatitis C have been

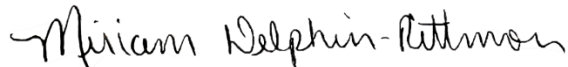
treated or have naturally cleared the virus.^{xi} At the end of June 2024, the [FDA cleared a fingerstick point-of-care \(POC\) HCV RNA test](#) for use in Clinical Laboratory Improvement Amendments (CLIA)-waived settings. This new POC test has the potential to revolutionize provider workflows and significantly reduce barriers to hepatitis C testing and treatment. Prior POC tests for the HCV antibody have only been able to diagnose previous exposure and not current infection, requiring multiple visits to test and connect people to treatment. Since the test takes 60 minutes or less to run, the new POC HCV RNA test can facilitate same-day diagnosis and rapid treatment initiation for hepatitis C. CDC recommends [direct HCV RNA testing](#) for people who might have been exposed to HCV within the past six months. Co-located hepatitis C treatment or highly accessible treatment through telehealth, mobile units, or warm handoffs to hepatitis C treatment providers is essential to actualize the benefit of POC HCV RNA testing. POC HCV RNA testing has the potential to significantly improve HCV testing and treatment rates in settings where people with SUD seek care.

People with SUD are at increased risk for HIV, and SUD treatment improves both HIV and SUD-related health outcomes. There are several [FDA-approved POC tests for HIV](#) that can be run on fingerstick whole blood or oral fluids in CLIA-waived settings. We reiterate an [earlier appeal](#) to increase POC HIV testing in SUD treatment programs. Linking people with HIV to treatment is essential to prolong their lives and prevent HIV transmission, and those who test negative may benefit further from being connected with [HIV pre-exposure prophylaxis \(PrEP\)](#) and [syringe service programs](#).

Integrating HIV and viral hepatitis testing in SUD treatment settings improves treatment initiation, especially when treatment is co-located, and is in line with [SAMHSA's 2023–2026 Strategic Plan](#), which prioritizes the integration of behavioral and physical healthcare. SAMHSA and CDC encourage SUD treatment facilities to integrate HIV and viral hepatitis testing, including POC HIV and HCV tests, into the services they offer their clients. Those who test positive should be connected to HIV or HCV treatment or offered on site when feasible. Information on integrating [HIV](#) and [HCV](#) into SUD treatment is available. HCV POC testing may be an allowable expense for SAMHSA grant recipients—reach out to your SAMHSA Government Project Officer to assess feasibility; a budget revision may be necessary.

More than one million Americans are on medications for opioid use disorder, and millions more receive SUD treatment each year. It is our collective responsibility to ensure that they access screening and lifesaving treatment for HIV and viral hepatitis. Advancements in diagnostics are the first step to increasing testing, but we need your help to implement and use these new tools. Please consider integrating these POC diagnostics into your practice. With your help, we can increase HIV and viral hepatitis screening to ensure that no more families and communities have to lose loved ones to these preventable and treatable diseases.

Sincerely,



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Director, Centers for Disease Control
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ⁱ Hall, Eric W et al. “Estimating hepatitis C prevalence in the United States, 2017-2020.” *Hepatology* (Baltimore, Md.), 10.1097/HEP.0000000000000927. 13 May. 2024, doi:10.1097/HEP.0000000000000927

ⁱⁱ “HIV Surveillance Supplemental Report: Estimated HIV Incidence and Prevalence in the United States, 2017–2021,” 2023

ⁱⁱⁱ Bixler D, Barker L, Lewis K, Peretz L, Teshale E. Prevalence and awareness of hepatitis B virus infection in the United States: January 2017–March 2020. *Hepatology Commun* 2023;7.

^{iv} Bosh, K A et al. “HIV and viral hepatitis coinfection analysis using surveillance data from 15 US states and two cities.” *Epidemiology and infection* vol. 146,7 (2018): 920-930. doi:10.1017/S0950268818000766

^v Ibid.

^{vi} “HIV Surveillance Supplemental Report: Estimated HIV Incidence and Prevalence in the United States, 2017–2021,” 2023

^{vii} Lewis, Karon C et al. “Estimated Prevalence and Awareness of Hepatitis C Virus Infection Among US Adults: National Health and Nutrition Examination Survey, January 2017-March 2020.” *Clinical infectious diseases: an official publication of the Infectious Diseases Society of America* vol. 77,10 (2023): 1413-1415. doi:10.1093/cid/ciad411

^{viii} Bixler D, Barker L, Lewis K, Peretz L, Teshale E. Prevalence and awareness of hepatitis B virus infection in the United States: January 2017–March 2020. *Hepatology Commun* 2023;7.

^{ix} Substance Abuse and Mental Health Services Administration. (2023). National Substance Use and Mental Health Services Survey (N-SUMHSS) 2022: Annual Detailed Tables (SAMHSA Publication No. PEP23-07-00-002). Rockville, MD: Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration. Retrieved from <https://www.samhsa.gov/data/>.

^x <https://www.cdc.gov/hiv/nexus/hcp/diagnosis-testing/index.html>; <https://www.cdc.gov/hepatitis-b/hcp/diagnosis-testing/index.html>; <https://www.cdc.gov/hepatitis-c/hcp/diagnosis-testing/index.html>

^{xi} <https://www.cdc.gov/mmwr/volumes/72/wr/mm7226a3.htm>.