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VIEWPOINTS

The Urgent Need to Implement Point-of-Care RNA Testing for Hepatitis C Virus to Support Elimination

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Hepatitis C virus (HCV) elimination is an important global public health goal. However, the United States is not on track to meet the World Health Organization's 2030 targets for HCV elimination. Recently, the White House proposed an HCV elimination plan that includes point-of-care (POC) HCV RNA testing, which is currently in use in many countries but is not approved in the United States. POC HCV RNA testing is crucial for implementing community-based testing and for enabling test-and-treat programs, assessing cure, and monitoring for reinfection. Here, we review the status of POC HCV RNA testing in the United States, discuss factors that are needed for successful implementation, and issue specific public health and policy recommendations that would allow for the use of POC HCV RNA testing to support HCV elimination.

Keywords. hepatitis C; point-of-care testing; molecular diagnostics; laboratory testing.

Hepatitis C virus (HCV) elimination is an important global public health goal. HCV is now a readily curable infection due to highly effective and well-tolerated short-course direct-acting antiviral (DAA) therapy; prior treatment cost concerns have largely been overcome in the United States. However, curative DAA treatment remains underutilized, and studies examining population-level progress through the HCV care continuum consistently identify early continuum gaps in HCV testing. In 2021, the US Department of Health and Human Services introduced the first national plan for HCV elimination, and 13 states have either written or implemented initiatives to meet elimination goals [1]. Achieving HCV elimination will require overcoming several barriers. Notably, people with HCV (and particularly those who inject drugs) experience stigma and discrimination, have lower access to healthcare in general, and may have frequent interactions with criminal legal systems where health services are suboptimal [2].

A key barrier to elimination is the complexity of the HCV diagnostic process. HCV surveillance often relies on HCV antibody prevalence data (reflecting exposure) with estimation methods required to infer the proportion with active infection. Currently, standard clinical practice is to conduct an antibody test to screen for exposure and then follow up with an HCV RNA polymerase chain reaction (PCR) test, or "viral load," to confirm a diagnosis of current active HCV. Individuals who spontaneously clear the virus or who successfully complete HCV treatment will remain positive on antibody testing for life yet remain susceptible to recurrent infection. Only HCV RNA PCR is effective for diagnosing recurrent infection in these individuals. As the proportion of treated HCV infections increases, public health agencies will have decreased ability to soundly estimate the prevalence of active infection using antibody-only surveillance.

Here, we argue that the absence of a commercially available point-of-care (POC) HCV RNA assay in the United States is a major hindrance to HCV elimination. The technology for POC HCV RNA testing is in widespread use internationally but remains unavailable in the United States because of the lack of regulatory approval and commercial availability. We also discuss the opportunities for implementation of POC HCV RNA testing and the challenges that need to be addressed to support the rollout of this technology in the United States.

THE HCV AND INJECTION DRUG USE SYNDEMIC

The HCV epidemic has codeveloped with a sustained rise in injection drug use in the United States; the 2 epidemics interact in specific socioeconomic contexts as a syndemic. Incident HCV infection is strongly associated with drug injection and continues to increase, commensurate with the emergence of fentanyl and its analogues [3]. There is a unique opportunity to leverage current state and federal initiatives to address both HCV elimination and the harms associated with injection drug use. For example, resources from the opioid settlement funds could be directly leveraged to fund HCV elimination activities.

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Integrated initiatives could include enhanced HCV surveillance among those with substance use disorder (SUD) and use of POC RNA testing to allow for easier integration of HCV- and SUD-related activities to simultaneously enable HCV elimination and reduce the harms associated with drug use.

IMPORTANCE OF POC RNA TESTING TO SUPPORT HCV ELIMINATION

The difficulty of confirming an HCV diagnosis adversely impacts the ability to achieve HCV elimination. Population-level HCV care outcomes, such as those for human immunodeficiency virus (HIV), are often conceptualized as a "care continuum," where each step is necessary before the subsequent step can be achieved. Thus, testing is necessary for diagnosis and ultimately for treatment. US-based studies have shown that 28%–93% of individuals with positive antibody tests do not receive follow-up RNA testing [4]. This gap is larger among younger people and those who currently inject drugs, particularly among those who have recently initiated injection drug use [5, 6]. These populations have high rates of HCV infection and high likelihood of transmitting to others and therefore are key populations to diagnose and treat both for their individual outcomes and for preventing transmission. Furthermore, the coronavirus disease 2019 (COVID-19) pandemic likely increased the risk for HCV transmission due to increased injection drug use, drug injection supply shortages, and economic hardship and resulted in decreased HCV testing and treatment, resulting in the potential for more transmission [7, 8].

Laboratory-based solutions have shown promise in improving the gap between testing and diagnosis but are insufficient to reach the most critical populations. One solution is "reflex testing," where patient samples obtained by phlebotomy and with positive antibody test results automatically undergo HCV RNA testing at a laboratory [9]. Evidence suggests that reflex testing can improve care continuum outcomes, but gaps remain [10, 11]. For instance, populations at high risk for undiagnosed HCV are also least likely to be engaged in regular healthcare. Also, many of those who use drugs and have HCV are not in drug treatment and therefore may be less likely to receive testing by phlebotomy. People who inject drugs may have specific difficulties with venipuncture because of difficult venous access. Another strategy is testing for RNA in dried blood spots, which has the advantage of not requiring venipuncture but is generally not implementable as a "point of care" test, resulting in similar issues of loss to follow-up after testing.

Historically, POC antibody testing has been used to reach marginalized populations for screening. POC antibody testing remains an important and cost-effective component of screening programs. A recent economic evaluation from Australia found that a combined strategy of POC antibody testing for treatment-naive patients with follow-up POC HCV RNA and direct POC RNA for already treated patients was the most economically efficient approach at seroprevalence levels <74% [12]. In addition, POC RNA testing can enable a complete HCV diagnosis in settings where phlebotomy is unavailable and enhance the effectiveness of screening programs at detecting recurrent infections in high-risk populations. Current POC technology is not a panacea. The wait time for a result, which can be 1 hour more, may still be too long for some patients, and the equipment is not easily portable for mobile programs but, nonetheless, represents a major improvement over traditional testing.

From a societal perspective, investments in the POC testing infrastructure may be cost-effective. Indeed, the same Australian study suggested that any of several POC RNA strategies are likely to be cost-effective compared with venipuncture-based strategies as long as there are modest increases in treatment uptake [12]. Two Canadian studies found that POC testing strategies for people who inject drugs or in prison settings were likely to be cost-effective or cost-saving compared with the standard of care of venipuncture-based testing [13, 14].

CURRENT STATE OF POC HCV RNA TESTING IN THE UNITED STATES

As of this writing, no POC HCV RNA testing platform is available for clinical use in the United States, even though this technology has been approved for use abroad since 2018 [15]. The technology to perform POC molecular testing has been supported by US public research investment. The totality of US public investment for the Cepheid GeneXpert molecular diagnostic platform, for example, was estimated to be more than $250 million [16]. Despite this significant public investment, companies such as Cepheid that have developed POC HCV RNA testing platforms have not sought regulatory approval in the United States. In general, regulatory pathways for molecular POC testing have been onerous. As a result, these critical technologies have been unavailable to medical providers, public health programs, community-based organizations, and patients who would benefit from their use.

In December 2021, the US Food and Drug Administration (FDA) reclassified HCV testing to class II, which allows manufacturers to seek approval through a less burdensome and less costly regulatory pathway. To further incentivize approval, HCV RNA is included as part of the Rapid Acceleration of Diagnostics (RADx) Independent Test Assessment Program, a fast-track program supported by the FDA and the National Institutes of Health and created to facilitate the development and distribution of COVID-19 molecular testing. A request for proposals that was launched in January 2023 is soliciting HCV POC RNA tests with the goal of accelerating the validation and authorization of these diagnostic tests [17]. Indeed,

the use of POC testing using the RADx program is a key pillar of the Biden Administration's HCV elimination program agenda, as built into the White House 2023 budget proposal [18].

IMPLEMENTATION OF POC HCV RNA TESTING: OPPORTUNITIES AND CHALLENGES

The regulatory approval of 1 or more POC HCV RNA tests is only the first step toward widespread implementation but an important and addressable one. Several key questions remain before POC HCV RNA testing can be used as a tool to support HCV elimination in the United States.

Determining the Role of POC HCV RNA Testing in Clinical Care

POC HCV RNA testing has been used in several distinct aspects of HCV diagnosis and management. The least intensive of these is conducting initial screening at nonclinical sites, thus being able to differentiate current active HCV infections from cleared or treated infections and referring patients who are RNA-positive to an off-site clinical provider. This approach also allows community programs, which often have engaged and trusted relationships with their clients but also limited resources, to focus their attention on coordinating referrals for only those clients who need it. POC HCV RNA testing has been used to provide confirmatory testing in settings such as pharmacies, mobile vans, community-based programs, and jails or prisons [19]. This has the potential to increase testing uptake, especially at locations that cannot offer venipuncture for standard testing. For example, a cluster-randomized trial of pharmacies in Australia and the United Kingdom found that 86% of patients interested in HCV testing received testing at POC-equipped pharmacies versus only 13% who were seen at pharmacies that made referrals to external laboratories [20]. This approach has the advantage of avoiding venipuncture as part of the diagnostic process and a faster time to definitive diagnosis. However, the overall care continuum outcomes would still depend on each subsequent step, including linkage to care, treatment initiation, and treatment completion.

POC testing also allows for HCV testing of individuals at risk for reinfection, that is, either people who have spontaneously cleared HCV or those who have already been treated. As the United States aims to expand HCV treatment for people who inject drugs, it is expected that the population susceptible to reinfection will increase, likely necessitating increased use of HCV RNA testing by community-based testing programs to diagnose new infections [21, 16].

Another strategy is the integration of POC RNA testing into on-site HCV treatment programs that are conducted at community sites. There are models published from treatment programs in primary care settings, syringe service programs, mobile units, homeless shelters, prisons, and overdose prevention centers [22–27]. A recent systematic review and meta-analysis of 45 studies quantified the potential impact of POC HCV RNA testing. Of 15 897 patients who received POC HCV RNA testing, 83% initiated treatment at an on-site treatment program. In comparison, of the 4487 patients included in the comparator arms, 69% initiated treatment (pooled odds ratio, 1.32; $P < .0001$) [28].

Most of the above-mentioned programs ultimately required venipuncture for HCV treatment workup (eg, testing genotype, liver function, testing for coinfections) and as part of the clinical protocol for treatment. In the United States, venipuncture-based HCV RNA testing may be required by payers as part of prior authorization processes, further limiting the utility of POC-based testing as part of clinical management. Treatment strategies that are completely free of venipuncture are possible, for example, combining POC testing for HCV, HIV, and hepatitis B virus (HBV); transient elastography for liver disease assessment; and pangenotypic fixed-dose treatments that obviate the need for genotype, baseline renal function testing, or on-treatment monitoring [29]. Clinical studies of such strategies are required, as well as incorporation into US treatment guidelines.

Other innovative strategies have been studied, but only in small pilot studies with little comparative data available. POC RNA testing enables same-day diagnosis and thus enables "rapid treatment" models where treatment could be provided the same day or the next day [30]. However, multiple implementation barriers exist, including the ability to rapidly acquire medications without insurance restrictions that require additional workup. An all-POC strategy that includes HCV antibody testing, HCV RNA testing, HIV testing, HBV screening, pregnancy testing, and fibrosis staging can identify individuals eligible for "simplified" treatment algorithms with pan-genotypic treatments [31]. Several pilot studies have examined this approach, all of which evaluated mobile or community-based treatment models and reported treatment uptake rates of 79%–93% [32–35]. The ongoing TEMPO clinical trial, which is being conducted at syringe service programs in Australia, is expected to provide evidence for such a model compared with the standard of care [36]. In the United States, processes to streamline insurance approval would be needed to enable rapid treatment models and could be built into state or federal public health plans, as they have for HIV.

Pricing, Ancillary Costs, and Reimbursement

The direct costs of a POC HCV RNA testing program include the up-front investment in the testing platform, ongoing purchases of supplies, and maintenance contracts with equipment vendors. The price of these platforms is not yet known, as no approved product has come to market in the United States. A recent Canadian economic study estimated $13 813 as the 10-year amortized cost of equipment and maintenance using the Cepheid GeneXpert platform and $18 as the per-test price

[14]. An Australian study, which also included the cost of training and labor, estimated a $111 per-test cost for POC HCV RNA testing [12]. However, costs in the United States are likely to be different because of different pricing strategies as well as differences in reimbursement and may be too high for community programs without a dedicated funding model.

Despite evidence of societal cost-effectiveness, from a programmatic perspective, a high initial investment and the potential for unreimbursed costs may deter the widespread uptake of this technology. In addition to the direct costs of equipment, supplies, and maintenance, implementing a POC RNA testing program requires staff training and sufficient space and electricity to store and run equipment. Additionally, programs that do not currently perform other in-house laboratory testing would need to obtain a Clinical Laboratory Improvement Assessments certificate of waiver, which is an added administrative and financial cost. These costs may be substantial and not affordable for community-embedded programs in which this testing would have the most benefit. A concerted programmatic effort, such as that undertaken in Australia, may be needed to disseminate the equipment and fund the training needed to ensure the uptake of this technology in community programs [37].

In the United States, in contrast to countries with national healthcare systems, programs may need to rely on insurance reimbursement to support HCV testing activities. Payer reimbursement for POC RNA testing is likely to vary by state and insurance type. Community programs, in particular, may not have a billing infrastructure and the expertise for services that are traditionally the purview of clinical laboratories or medical offices. Even if a fee-for-service payment were guaranteed, the high initial investment might be prohibitive for many programs. A funding model for POC HCV RNA testing thus would need to be sufficiently robust to allow for both upfront investments in the technology and also for the indirect costs of testing.

Surveillance Infrastructure to Enable Reporting and Epidemiology

The growth of POC-based RNA testing would require adjustments to current public health surveillance mechanisms. In general, HCV disease surveillance occurs via mandated laboratory reporting of positive and, in some cases, negative HCV tests. Reporting of HCV RNA testing has been a cornerstone of public health surveillance for determining the state of the "care continuum" and is written into several jurisdictional elimination plans [38, 39]. HCV RNA testing conducted outside of clinical laboratories may hinder these efforts. Lessons can be learned from the COVID-19 pandemic. The rise of rapid home antigen testing led to the likely underestimation of COVID-19 case rates [40]. The implementation of POC testing programs for HCV RNA should account for the need for public health reporting. To the extent that such testing programs occur in conjunction with (or funded by) local health departments, reporting of positive and negative test results can be required, similar to what is required of conventional clinical laboratories. Testing platforms can use information technology such as automated reporting to ease the burden on program staff. However, developing standardized reporting systems will likely require significant investments. Health departments would need to ensure that reporting is not such a burden as to disincentivize launching a testing program and that the staffing and administrative costs of case tracking and reporting are included in funding and/or reimbursement models.

SUMMARY AND IMPLICATIONS

If implemented at scale, the diagnostic innovation provided by POC HCV RNA testing would be an important tool for HCV elimination and an important surveillance strategy for the injection drug use epidemic. Of the 11 countries predicted to achieve WHO elimination targets by 2030, 8 have established programs using POC HCV RNA testing. Delays in bringing these products to market in the United States, despite significant public investment into their development, have been discouraging and constitute barriers to HCV elimination. Recent policy initiatives as part of the COVID-19 response and the 2023 White House budget's HCV elimination plan are important steps toward regulatory approval in the next year. In preparation for this, we recommend several actions by public health programs, professional societies, and federal agencies:

- A federal HCV elimination plan should include a funding model for community-based testing programs that use POC tests, including consideration of staffing, overhead, and logistical costs.
- Insurance reimbursement for POC testing should be encouraged via development of specific billing codes for this purpose and incorporation into the Medicare fee schedule.
- State and local public health departments should incorporate POC testing into their surveillance plans by determining standards for reporting POC tests.
- Federal agencies should fund rigorous clinical research to evaluate the safety and effectiveness of POC testing in innovative care models, such as rapid-treatment start models or all-POC strategies. Professional societies should prepare to incorporate POC RNA testing into clinical guidance based on available evidence.

POC HCV RNA testing may be a necessary tool, but it is not sufficient to simply have invented it. A robust implementation plan that incorporates the financial resources and clinical data needed to support the population-scale implementation and maximize the benefits of this technology must be developed

alongside the technology so that we can achieve the promise of HCV elimination.

Notes

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