



Barriers and solutions to increasing access to point-of-care HCV testing

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HEPATITIS C POINT-OF-CARE
TESTING FORUM

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Partners



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Coordinator Malu performs point of care tests for hepatitis C and HIV at IN Mouraria, a harm reduction centre in Lisbon, Portugal.

Executive Summary

Point-of-care testing holds immense promise in simplifying diagnosis and care pathways, improving access to treatment, and ultimately reducing the global burden of hepatitis C virus (HCV) infection. However, several barriers impede the widespread adoption of point-of-care HCV testing. This report draws on real-world experience from international HCV testing programs and presents consensus recommendations for overcoming barriers to implementation and expanding global access to high quality point-of-care HCV testing from the INHSU Hepatitis C Point-of-Care Testing Forum, Paris 2023.



Solutions to Governance Barriers

1. Improve regulatory approval pathways and harmonise regulatory submissions
2. Raise awareness about the importance of point-of-care testing and the need to improve regulatory pathways among health ministries
3. Identify programs for multi-pathogen testing and demonstrate cost-effectiveness
4. Engage with the International Medical Device Regulators Forum (IMDRF) to reclassify HCV point-of-care testing diagnostic devices



Solutions to Workforce and Quality Assurance Barriers

1. Co-design appropriate training programs with the workforce, whilst meeting regulatory training and compliance requirements
2. Develop cost-effective systems that support training and connectivity, whilst maintaining regulatory compliance, operator competency and analytical quality
3. Enhance understanding of the value of quality assurance, increase quality control product availability and suitability, and simplify quality assurance report formats



Solutions to Health Information Systems Barriers

1. Standardise data exchange and messaging protocols, regulatory compliance, with greater vendor collaboration to improve interoperability
2. Improve adherence of commercially available IT products with data security regulations
3. Advocate for increased funding for IT infrastructure and connectivity and improved linkage with existing laboratory partners



Solutions to Financing Barriers

1. Establish sustainable financing mechanisms and strengthen evidence-based investment cases
2. Integrate HCV point-of-care testing with existing programs and realise cost-optimisation opportunities



Solutions to Service Delivery Barriers

1. Provide governments with cost-effectiveness data to encourage greater investment
2. Advocate for existing point-of-care testing services to be leveraged for HCV testing
3. Tailor training for various HCV point-of-care testing providers, including peer workers for low complexity tests
4. Streamline technology platforms that enable data collection and linkage

Background

An estimated 57 million people are living with chronic hepatitis C infection globally [1].

Although great advances have been made in the treatment of HCV, with curative pangenotypic DAA therapies that are highly effective and straightforward to administer, the burden of HCV remains high and the World Health Organisation (WHO) estimates that in 2019, 290,000 people died from HCV related cirrhosis and liver cancer [2]. The WHO goal to eliminate HCV as a major public threat by 2030 includes targets to increase HCV diagnosis, linkage to care and treatment [2]. Globally, HCV testing and diagnosis remains low and there are still many barriers to linkage to care which have led to a decline in treatment initiations with DAA therapy.

Several interventions have been demonstrated to increase HCV case finding, testing, diagnosis, and linkage to care [3] however, coverage of interventions to enhance the HCV care cascade also remains low. HCV point-of-care testing (for both antibodies and RNA) are key interventions demonstrated to improve the HCV care cascade [3] and have been associated with reduced time

from screening to treatment initiation and increased treatment uptake [4].

Molecular-based, point-of-care finger-stick RNA tests that detect current HCV infection within one hour enable diagnosis and treatment in a single visit [5,7], simplifying care pathways, removing the need for venous blood collection, and reducing loss to follow up [4,8,9]. The 2022 WHO updated recommendations for service delivery and diagnostics for HCV infection state the need for radical simplification of care pathways to reach elimination targets [10]. Specifically, decentralisation, integration with existing care services, task-sharing to expand access to diagnosis, and using HCV point-of-care testing may help to streamline care pathways [7].

Barriers to the implementation and scale up of point-of-care HCV testing

Despite strong examples of HCV point-of-care program delivery internationally [11], barriers to scale up and broad adoption of point-of-care testing for HCV remain. These include lack of knowledge at a

national leadership level, limited evidence to guide policy development, restrictive inflexible regulatory approval pathways relative to technological offerings, a lack of infrastructure to support high-quality training and workforce competency, lack of cost-effective quality management processes, a limited offering of robust, but versatile health information systems, and limited understanding of service delivery models that include task shifting among the health workforce and enable testing pathways in various settings.

The International Network on Health and Hepatitis in Substance Users (INHSU) convened a HCV Point-of-Care Testing Forum for those working in hepatitis C point of-care testing research and implementation at the Global Hepatitis Summit in Paris in April 2023. Following the forum, this report draws on experience from key stakeholders to outline barriers and solutions for increasing access to point-of-care testing in 5 key areas:

1. Governance
2. Workforce and Quality Assurance
3. Health Information Systems
4. Financing
5. Service Delivery



Current diagnostic pathways for HCV testing often include multiple visits - a HCV antibody test to detect previous exposure and an RNA test to confirm active infection - resulting in frequent loss to follow up particularly in people who inject drugs and people in prison who already face many barriers to care, such as:

- Complex / inadequate health service delivery
- Poor global coverage of harm reduction services
- Experiences of stigma and discrimination leading to avoidance of services
- Poor venous access
- Short stays / prison transfers

1. Governance Barriers and Solutions

Robust governance is integral to effective implementation and scale-up of HCV point-of-care programs. Strong leadership and policies are required to support point-of-care HCV testing implementation globally, and regulatory approval pathways influence the introduction of technologies and further innovation.

Barrier 1.1

HCV point-of-care testing does not feature in most national HCV plans and policies stemming from poor understanding of the benefits of point-of-care testing.

Solution:

1. Raise awareness among ministries of health of the importance of HCV testing guidelines and ensure guidelines include point-of-care HCV testing
2. Raise awareness among ministries of health of the importance of diagnostic testing and ensure national strategies are developed, consistent with the 2023 World Health Assembly resolution to strengthen diagnostics capacity
3. Conduct pilot studies to build the evidence-base for policy development
4. Engage in governmental processes to dedicate greater investment in diagnostics infrastructure and service delivery, including point-of-care testing
5. Develop an education and communications plan to raise awareness of point-of-care testing and communicate value to policy makers

Stakeholders and actions required:



Government and Funders:

- Develop testing guidelines and national policies that include HCV point-of-care testing



Researchers and Academic Institutions:

- Gather and disseminate data demonstrating point-of-care testing effectiveness, impact, acceptability, and cost-effectiveness



Community and Advocacy Groups:

- Contribute to studies demonstrating effectiveness, advocate to governments to strengthen diagnostics capacity



Healthcare Providers and Institutions:

- Contribute to studies demonstrating effectiveness and cost-effectiveness
- Advocate for delivery of point-of-care HCV testing in different settings (e.g. drug treatment, harm reduction centres, mental health services, mobile clinics, prisons)
- Advocate for point-of-care inclusion in testing guidelines



Industry and Manufacturers:

- Conduct and fund studies to improve data on effectiveness and cost-effectiveness of point-of-care HCV testing
- Advocate to governments to strengthen diagnostics capacity

Barrier 1.2

There is a lack of coordination across programs utilising point-of-care testing platforms.

Solution:

1. Identify programs currently using point-of-care platforms that could potentially deliver multi pathogen testing, including HCV
2. Capitalise on the call for simplified, decentralised, and integrated care models by global policy organisations (e.g. WHO)
3. Present effectiveness and cost-effectiveness data to demonstrate the benefits of integrated testing programs

Stakeholders and actions required:



Government and Funders:

- Identify programs currently using point-of-care platforms and assess their potential for incorporating multi-pathogen testing, including HCV
- Develop and implement policies that promote collaboration and information sharing among different health programs



Researchers and Academic Institutions:

- Generate robust data on the effectiveness and cost-effectiveness and efficiency of multi-pathogen testing and cross-program coordination
- Share research findings with policymakers and healthcare stakeholders to inform decision-making



Community and Advocacy Groups:

- Engage with policymakers and healthcare providers to ensure that community preferences and needs are considered in the development of diagnostic strategies



Public Health Organisations and Non-Governmental Organisations (NGOs):

- Advocate for multi-pathogen testing and cross-program coordination in addressing health threats, including HCV
- Collect and disseminate data on the effectiveness, cost-effectiveness, efficiency gains of coordinated efforts in point-of-care testing



Regulators and Standards Bodies:

- Work with diagnostic device manufacturers to establish clear and efficient approval pathways for multi-pathogen testing devices



Industry and Manufacturers:

- Develop and market multi-pathogen point-of-care testing closed-cartridge and user-friendly devices that can seamlessly integrate with various healthcare programs
- Engage with regulatory authorities to streamline the approval process for these devices and provide evidence of their accuracy and reliability
- Collaborate with health departments and healthcare providers to tailor devices to meet specific programmatic needs

Barrier 1.3

There is a lack of harmonisation of regulatory submissions from device manufacturers.

Solution:

1. Advocate to regulatory bodies to harmonise data requirements for regulatory submissions
2. Advocate to regulatory bodies to recognise HCV point-of-care testing evidence from comparable overseas regulators
3. Increase collaboration with experts in other infectious diseases to address regulatory changes

Stakeholders and actions required:



Government and Funders:

- Advocate for harmonisation of regulatory requirements at national and international forums, emphasising the importance of timely access to accurate HCV point-of-care testing
- Collaborate with industry stakeholders to compile and present data on the benefits of regulatory harmonisation, such as faster access to innovative technologies



Regulators and Standards Bodies:

- Respond positively to industry feedback and actively work toward harmonising data requirements for regulatory submissions
- Establish communication channels with international regulatory bodies to share information and align standards



Industry and Manufacturers:

- Engage with regulatory bodies to advocate for standardised data requirements for regulatory submissions of HCV point-of-care testing devices
- Share best practices and data submission templates within the industry to encourage consistency in regulatory submissions



Point-of-care testing inside NSW Users and AIDS Association's (NUAA) needle and syringe service in inner Sydney, Australia.

Barrier 1.4

Regulatory approval pathways can slow down the introduction of technologies and further innovation due to lack of information or samples for regulatory submissions.

Solution:

1. Create an international reference panel for assessment of new assays and a network of labs to rapidly assess HCV point-of-care testing performance

Stakeholders and actions required:



Government and Funders:

- Advocate for the importance of regulatory harmonisation and the establishment of these mechanisms at an international level



Researchers and Academic Institutions:

- Contribute scientific expertise to the development of evaluation protocols and standards for HCV point-of-care testing



Community and Advocacy Groups:

- Advocate for the establishment of these international mechanisms
- Raise awareness about the importance of regulatory pathways that support innovation and rapid access to new technologies



Public Health Organisations and Non-Governmental Organisations (NGOs):

- Champion the creation of an international reference panel and a network of labs
- Mobilise resources and expertise to facilitate the establishment and operation of these mechanisms
- Provide technical assistance to countries and regions in setting up their own reference panels and lab networks



Regulators and Standards Bodies:

- Work closely with international partners and stakeholders to develop standardised evaluation protocols for HCV point-of-care testing devices
- Collaborate with manufacturers to establish clear guidelines and requirements for regulatory submissions



Industry and Manufacturers:

- Collaborate with government health departments and international health agencies to provide necessary data and samples for regulatory submissions
- Support the establishment of the international reference panel by contributing technical expertise

Barrier 1.5

The current classification of HCV point-of-care diagnostic devices by the International Medical Device Regulators Forum (IMDRF) is based on the highest public health risk, this is stymieing device development and slowing regulatory approvals.

This classification is not reflective of the availability of HCV treatments that can lead to cure in almost all people who receive therapy.

Solution:

1. Advocate to the IMDRF to down classify HCV point-of-care testing devices as has been done by the United States Food and Drug Administration

Stakeholders and actions required:



Regulators and Standards Bodies:

- The International Medical Device Regulators Forum (IMDRF) should organise a working group to thoroughly evaluate the classification of HCV point-of-care testing devices
- Seek input from stakeholders, including device manufacturers, regulatory authorities, and public health experts, to make informed decisions



Researchers and Academic Institutions:

- Share research findings with regulatory authorities and the IMDRF to inform their decision-making processes. Collaborate with public health organisations to assess the potential impact of down-classification on disease control



Community and Advocacy Groups:

- Advocate for down-classification. Collaborate with other stakeholders to ensure community voices are heard in discussions with the IMDRF



Public Health Organisations and Non-Governmental Organisations (NGOs):

- Advocate for down-classification based on the changes in the HCV therapeutic landscape, changes in clinical HCV management, treatable nature of HCV infection, and potential benefits to disease control and public health
- Raise awareness among policymakers and the public about the importance of down-classification



Hepatitis C Nurse
Vanessa Ahenakew
Points to a Rapid Test.
Photo taken as part of
Connecting with Care,
Ahtahkakoop, Canada.

2. Workforce and Quality Assurance Barriers and Solutions

Implementing point-of-care HCV testing programs requires a trained and competent workforce and effective quality assurance processes.

Barrier 2.1

Point-of-care testing operator training and competency must be acceptable to a multidisciplinary workforce.

Solution:

1. Co-design point-of-care testing training programs with the intended workforce and align expectations of training (time to complete, delivery modes) with compulsory regulatory elements. Consider leveraging successful training models of other point-of-care testing programs either in country or internationally
2. Ensure online, self-paced modules are available as training modalities for busy clinic staff, and provide opportunities at each stage of the training for operator feedback and self-assessed competency
3. Allocate appropriate levels of funding for operator capacity building, especially in areas of high workforce turnover

Stakeholders and actions required:



Government and Funders:

- Allocate appropriate funding to support capacity building of operators and the development and continual improvement of training programs and ongoing competency assessment
- Monitor the effectiveness of the training and competency programs
- Encourage collaboration between training program developers and testing providers



Training Program Developers and Educators:

- Collaborate with the point-of-care testing workforce to co-design training programs
- Develop online, self-paced modules
- Establish quality assessment indicators and feedback mechanisms at all stages of training



Healthcare Providers and Institutions:

- Advocate for and actively engage in the co-design of training programs.
- Allocate resources for training programs
- Support staff in participating in training, including allowing time for completion of training modules, competency assessment and re-training needs
- Collect feedback from staff and communicate their needs to program developers
- Ensure that the training and ongoing competency aligns with the facility's point-of-care testing protocols
- Develop clear processes for the initiation of re-training activities

Barrier 2.2

Suitable quality control (QC) and quality assurance (EQA) materials are often not readily available.

Solution:

1. Improve QC/EQA product availability, product specifications and management processes to meet point-of-care testing needs and reduce cost
2. Ensure availability of QC products (negative, variable positive, and variable genotype patterns) suited to point-of-care testing specifications. Negative QC material is important in non-laboratory settings to detect biological contamination
3. External quality assurance report formats should be simplified to allow easy interpretation by point-of-care testing operators. Point-of-care testing operators should be alerted to discordant Quality Control and External Quality Assurance results in real-time via software alerts
4. Increase demand for QC and EQA products to prompt market competition and reduce costs
5. Include in-built quality checks in cartridges as additional quality tier
6. Incorporate EQA/QC materials for multiplex immunoassays (MIAs) in development

Stakeholders and actions required:



Government and Funders:

- Allocate appropriate funding to embed quality control and quality assurance regimes
- Encourage collaboration between training program developers and quality product manufacturers



Industry and Manufacturers:

- Include in-built quality checks in cartridges as additional quality check tier
- Manufacture cost-effective quality products, in accordance with regulatory protocols with matrix matched specimens, extended stability, suitable storage, transport and preparation requirements
- Incorporate EQA/QC materials for multiplex immunoassays (MIAs) in development to facilitate multi diagnoses thus allowing for greater integration across health system programs and further reducing point-of-care testing costs



Training Program Developers and Educators:

- Collaborate with the point-of-care testing workforce to co-design specifications of quality products suitable for use in point-of-care testing environments
- Establish quality assessment indicators and provide continual monitoring and feedback to manufacturers



Healthcare Providers and Institutions:

- Advocate for and actively engage in the co-design of easy-to-use quality materials
- Allocate resources for training programs
- Support staff in participating in quality testing and reporting
- Collect feedback from staff and communicate their needs to quality product manufacturer



3. Health Information Systems Barriers and Solutions

Implementing point-of-care HCV testing programs requires strong health information systems, including optimal IT connectivity and reporting mechanisms.

Barrier 3.1

There is a lack of investment in IT infrastructure to enable health information exchange and efficient workflows.

Solution:

1. Advocate for increased funding to support IT infrastructure

Stakeholders and actions required:



Government and Funders:

- Fund the development of IT infrastructure to facilitate point-of-care testing; collaborate with healthcare facilities to provide funding and support for IT infrastructure improvements



Researchers and Academic Institutions:

- Develop and evaluate new IT infrastructure to support point-of-care testing



Healthcare Providers and Institutions:

- Allocate budget to invest in IT infrastructure

Barrier 3.2

There is a lack of 'plug and play' standards and a lax development approach to interoperability across devices and supporting infrastructure.

Solution:

1. Develop standardised data exchange protocols and interoperability standards specific to HCV point-of-care testing

Stakeholders and actions required:



Regulators and Standards Bodies:

- Actively engage with device manufacturers to develop standardised data exchange protocols, data security, and interoperability standards
- Establish an independent body to certify and test the interoperability of devices and systems, ensuring they meet the 'plug and play' standards



Industry and Manufacturers:

- Prioritise interoperability and data security in product development
- Actively collaborate with IT standards bodies to ensure devices adhere to the agreed-upon standards



Healthcare Providers and Institutions:

- Healthcare procurement agencies should drive change through procurement contracts specifying interoperability and alignment with 'plug and play' standards

4. Financing Barriers and Solutions

Funding is required to enhance the scale-up of point-of-care HCV testing. Financing refers to revenue raising, purchasing goods and services, and pooling resources.

Barrier 4.1

Bilateral and multilateral funding has been limited; there has been some recent catalytic funding in low-and-middle income countries, however this is insufficient for large scale scale-up.

There is a lack of strong country-level investment cases advocating for funding allocation to HCV point-of-care testing.

Solution:

1. Establish a sustainable financing mechanism for point-of-care HCV testing
2. Evaluate the cost-effectiveness of HCV point-of-care testing strategies and implement appropriate tiered diagnostics appropriate to specific sub-populations to reduce overall costs
3. Provide those involved in policy shaping with stronger evidence-based investment cases that support allocating funding to HCV point-of-care testing over other priorities
4. Understand the role that external non-governmental organisations (NGOs) play in supporting countries to locate and present country data, particularly in resource constrained countries

Stakeholders and actions required:



Government and Funders:

- Commit to prioritising HCV testing as a public health initiative. Engage with advocates, researchers, and NGOs to review the evidence-based investment cases for HCV point-of-care testing
- Allocate a portion of the national healthcare budget to support the scale-up of point-of-care HCV testing
- Collaborate with international organisations and donors to advocate for increased funding. Collaborate with local healthcare institutions to gather relevant data on HCV prevalence, disease burden, and potential cost savings from early detection
- Identify cost-effective diagnostic solutions for the specific population



Public Health Organisations and Non-Governmental Organisations (NGO):

- Provide technical assistance and guidance to countries in developing their HCV testing programs
- Mobilise resources to support the establishment of HCV testing programs in low-and-middle-income countries
- Advocate for HCV testing as a global health priority and encourage increased funding and support for HCV testing initiatives. Facilitate knowledge sharing and best practices among countries



Government and Funders:

- Increase funding for HCV testing programs in low- and-middle-income countries through bilateral and multilateral channels. Consider innovative financing mechanisms to attract private sector involvement
- Support capacity-building efforts to support scale-up in recipient countries

**Researchers and Academic Institutions:**

- Conduct local studies to generate country-specific data on cost-effectiveness. Share findings with national health authorities, international organisations, and advocates
- Engage in capacity building to improve the collection and analysis of HCV-related data

**Community and Advocacy Groups:**

- Collaborate with healthcare providers to advocate for funding allocation and policy changes. Educate the public and policymakers about the economic and person-specific benefits of HCV point-of-care testing

Barrier 4.2

Opportunities for device and delivery cost optimisation are not being utilised due to lack of understanding of potential for integrating HCV within existing point-of-care programs or developing new point-of-care programs that cover multiple diagnoses.

In addition, opportunities for enhancing pandemic preparedness through increased investment in hepatitis elimination infrastructure are not being realised [12].

Solution:

1. Integrate HCV point-of-care testing with existing point-of-care testing programs to increase diagnostic capabilities and access cost savings
2. If there are no existing point-of-care testing programs in a location, providers should strongly consider establishing programs that integrate hepatitis with diagnostic platforms for other infections, for example HIV/STIs/tuberculosis, depending on population screening needs
3. Identify opportunities for integrating HCV point-of-care testing in plans to build capacity for pandemic preparedness and response.

Stakeholders and actions required:**Government and Funders:**

- Evaluate the existing healthcare infrastructure and identify opportunities for integrating HCV point-of-care testing into other diagnostic programs
- Allocate resources and funding to support the implementation of decentralised and integrated testing programs

**Researchers and Academic Institutions:**

- Conduct studies to evaluate the effectiveness, cost-effectiveness, and impact of integrated point-of-care testing programs
- Share data with policymakers to support integrated testing approaches

**Community and Advocacy Groups:**

- Advocate for integrated testing programs that can provide comprehensive healthcare services to patients
- Collaborate with healthcare providers to ensure that patients have access to integrated testing services

**Healthcare Providers and Institutions:**

- Assess the feasibility of integrating HCV testing with existing point-of-care programs, such as those for tuberculosis or HIV
- Advocate for the adoption of integrated testing approaches within their healthcare facilities
- Invest in staff training to ensure healthcare professionals can effectively operate multi-diagnosis point-of-care devices
- Collaborate with NGOs and community groups to ensure that patients have access to integrated testing services

**Public Health Organisations and Non-Governmental Organisations (NGO):**

- Provide technical guidance and best practices for integrating HCV testing into existing point-of-care programs

**Industry and Manufacturers:**

- Offer support and technical assistance to healthcare facilities for the implementation of integrated testing solutions

5. Service Delivery Barriers and Solutions

Simplifying, and disinvesting from existing testing pathways requires new models of care and a restructuring of service delivery. Service delivery is broad, for the purposes of this paper the INHSU Forum expert panel conceptualised service delivery as the way in which HCV diagnostic services are provided to people. This includes tailoring services to target populations, task shifting among members of the health workforce, and establishing testing pathways in various settings.

Barrier 5.1

There is a lack of political will and/or funding to transition pilot HCV point-of-care testing projects to sustained programs.

Solution:

1. Provide governments with cost-benefit and cost-effectiveness data that demonstrate savings generated by point-of-care testing programs
2. Leverage existing point-of-care testing services being used in other disease areas to increase efficiency and ability to scale HCV point-of-care testing programs

Stakeholders and actions required:



Government and Funders:

- Engage with HCV point-of-care testing projects and request cost-benefit and cost-effectiveness data
- Explore the potential for cross-utilisation of point-of-care testing infrastructure, resources, and expertise to scale up programs



Researchers and Academic Institutions:

- Conduct studies to evaluate the cost-benefit and cost-effectiveness of point-of-care testing programs
- Share data with policymakers to support the adoption of point-of-care HCV testing into practice and policy



Community and Advocacy Groups:

- Compile and disseminate cost-benefit and cost-effectiveness data from HCV point-of-care testing projects



Healthcare Providers and Institutions:

- Generate and disseminate clear cost-benefit and cost-effectiveness data from all HCV point-of-care testing programs

Barrier 5.2

There are a lack of service providers willing or able to take on HCV point-of-care testing. There is inadequate knowledge/expertise within primary care and inadequate capacity/interest among specialty providers.

Solution:

1. Provide tailored operator training to a range of HCV point-of-care testing providers, including those working in community settings and those from affected communities
2. Understand that peer workers can provide high quality, responsive and respected care and are an asset to the workforce, work to engage peer workers in low complexity point-of-care testing delivery

Stakeholders and actions required:



Government and Funders:

- Allocate resources for the development and implementation of tailored operator training programs. Establish guidelines and incentives for engaging peer workers in point-of-care testing delivery



Researchers and Academic Institutions:

- Conduct research on the impact of operator training programs on competency and capacity to perform point-of-care HCV testing
- Evaluate new models for delivery of training for point-of-care HCV testing that facilitate increased adoption and implementation into practice



Public Health Organisations and Non-Governmental Organisations (NGO):

- Identify potential peer workers within affected communities who can be trained to deliver HCV point-of-care testing
- Raise awareness about the importance of peer workers in HCV care



Community and Advocacy Groups:

- Actively engage in training programs and express interest in contributing to HCV point-of-care testing delivery. Provide input on how to make services more responsive and community oriented



Healthcare Providers and Institutions:

- Create pathways for healthcare workers and peer workers to be trained and integrated into the point-of-care testing workforce. Meanwhile, professional healthcare associations to advocate for and endorse operator training for HCV point-of-care testing
- Support the integration of peer workers into point-of-care testing teams



Industry and Manufacturers:

- Collaborate with training providers to support the development of training materials specific to their products

Barrier 5.3

Systems are required to ensure that data from decentralised models of care are collected and collected and recorded into health records.

Solution:

1. Implement simple, high-quality, technology platforms that have common elements and enable linkage across health services

Stakeholders and actions required:



Government and Funders:

- Invest in technology platforms for health data collection and record-keeping. Establish standards and guidelines for data collection and ensure interoperability between various health services



Healthcare Providers and Institutions:

- Adopt and integrate the recommended technology platforms into decentralised models of care. Ensure all results are promptly entered into health records and shared with relevant services
- Provide regular training and support to ensure effective use of platforms



Industry and Manufacturers:

- Health Information Technology (IT) companies should develop high-quality technology platforms that are specifically designed for data collection and health record integration. These platforms should be customisable to meet the unique needs of different healthcare providers and settings. The costs of these programs need to ensure that systems are scalable, particularly in low- and middle-income countries

Key components of Point-of-Care Testing Programs

There are a range of components that contribute to successful point-of-care testing program implementation and several good practice case studies globally demonstrating effective program delivery.

An optimised framework for the delivery of point-of-care testing programs that focuses on patient-centred care, co-design and community-led initiatives has been developed [12]. This includes the need for defined site selection criteria, appropriate clinical governance, policy and guideline application, risk assessment and quality management, point-of-care operator training, connectivity and reporting systems, and supply management.

Program framework for point-of-care testing [13]

The implementation of a decentralised point-of-care testing model is feasible and has been demonstrated to be effective. Key enablers for successful implementation include national policies, strong governance, champions from various sectors, funding, flexible connectivity systems, and a trained, competent, and well supported workforce.



Examples of Pilot HCV Point-of-Care Testing Programs

Community Outreach | Catalonia

The HepBClink model is a community-based test-and-treat strategy that brings together HBV and HCV education, screening and simplified access to treatment for migrants.

WHO ACCESSES THE SERVICE?



768

MIGRANTS*

from Pakistan, Senegal and Romania.

*March 2021 - August 2022

WHAT SERVICES ARE OFFERED?

- HCV education, information provision
- HCV testing, diagnosis and treatment
- Liver disease assessment
- Referral to other HCV services
- HBV testing and diagnosis
- Translation support

Education sessions are led by community health agents from the target countries, in-language.



Testing for HCV Ab and HBV sAg is offered using point-of-care tests. If positive, DBS test for confirmatory testing.



If DBS is positive, conventional blood work is undertaken, including FIB-4 score.



Clients are treated at the international health unit or referred to a tertiary hospital if they have advanced liver disease

Community health agents support clients through the process.



HCV antibody prevalence was 1.4%, 0.6% and 3.7% for migrants from Romania, Senegal and Pakistan, respectively (n=16/768, 12 new diagnoses). The prevalence of HCV-RNA was 0.7%, 0.3% and 1.2%, respectively (N=6, all new diagnoses); 4 (66.6%) of them were linked to care, and two initiated and completed antiviral treatment in specialist care. The prevalence of HBsAg was 1.4% for migrants from Romania, 8.2% for Senegal and 0.9% for Pakistan (n=30/768, 20 new diagnoses). Among them, 14 (70%) were linked to care, tested DNA-HBV positive through routine testing. Subsequently, 10/14 (71.4%) attended a visit with the hepatologist at the reference hospital, and none met antiviral criteria.

WHAT INTERVENTIONS DO WE USE?



On-site testing



Point-of-care HCV antibody testing



Dried blood spot testing



Reflex HCV RNA testing



Pre-test counselling and education



Patient navigation

KEY BARRIERS

1. Building trust was more challenging with migrants from Romania than Pakistan and Senegal
2. Follow up to assess linkage to care and treatment was challenging because the population is highly mobile
3. Cost effectiveness data is required to assess sustainability

KEY ENABLERS

1. The use of community health agents, community leaders and civil society from the same countries as those screened
2. The use of rapid, point-of-care tests and DBS sample collection
3. Multidisciplinary collaboration with all involved parties.
4. Direct collaboration with public health agents.

This study was funded by Instituto de Salud Carlos III through the project "PI19/0568" (Co-funded by European Regional Development Fund "A way to make Europe").

A Mobile HCV Testing Clinic | Copenhagen

A peer-led organisation in Copenhagen, motivated by personal challenges in accessing HCV testing and treatment services, acquired a van and converted it into a mobile HCV testing clinic.

WHO ACCESSES THE SERVICE?

 **10**
CLIENTS PER DAY*
The van is open for testing one day a week.

WHAT SERVICES ARE OFFERED?

- HCV education, information provision
- Peer support
- HCV testing
- HCV diagnosis
- HCV treatment

Participants receive an HCV antibody test from a mobile clinic. If positive, clients then receive an RNA test using an Xpert® HCV Viral Load Fingerstick test, also in the van.



Those who test positive for HCV RNA receive peer-assisted referrals to a hospital clinic for further care.

The van operates every Tuesday from 11am-4pm and is located between a drug consumption room and food service outlet.



The van also operates as a needle syringe service.

Over a two-year period, 742 individuals were tested. 28% were antibody positive and 55% of this group tested positive for HCV RNA. 80 people began treatment and 79 achieved SVR.

WHAT INTERVENTIONS DO WE USE?



On-site testing



Point-of-care HCV antibody testing



Point-of-care HCV RNA testing



Dried blood spot testing



Reflex HCV RNA testing



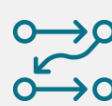
Fibroscan



Pre-test counselling and education



Peer support



Patient navigation

KEY BARRIERS

1. Initial funding challenges
2. Initial hesitation about treating people who inject drugs due to concerns about adherence and reinfection risks
3. Resistance to involving those with lived experiences in testing
4. Knowledge gaps about HCV among staff at OAT clinics and shelters making outreach challenging
5. Convincing skeptical institutions of the relevance of the testing services

KEY ENABLERS

1. Partnering with healthcare professionals bolstered credibility, enabling collaboration with researchers and clinicians for funding applications
2. Intensively raised HCV awareness in the social sector and OAT clinics nationally
3. Engaged politicians with van visits and liaised with the health ministry
4. Invested in extensive advocacy to promote mission and approach
5. Emphasised importance of lived experience to improve testing process and ensure community trust

A Micro-Elimination Campaign | Pakistan

A house-to-house micro-elimination campaign in the Malir district of Karachi, a high burden area for HCV infection, using HCV Ab screening with self-tests followed by confirmatory testing and treatment by field teams.

WHO ACCESSES THE SERVICE?

 **125-150**
CLIENTS PER WEEK*

Average screening rate of 25-30 households daily

WHAT SERVICES ARE OFFERED?

- HCV education, information provision
- Peer support
- HCV testing and diagnosis
- HCV treatment
- Liver disease assessment
- Referral to other HCV services

An awareness campaign is run in the area before screening begins.

People are informed about a small incentive to complete the test.

Commencement of DAA treatment if RNA positive



For people not at home, an Ab self-test is left with the most senior house member present.

Those who test positive on the self test are contacted and invited to the medical facility for confirmatory testing



1,184 participants were allocated to the self-test arm. Of this group 1,026 participants completed and reported testing for HCV (compared to only 223 out of the 1,001 in the control arm)

WHAT INTERVENTIONS DO WE USE?



On-site testing



Point-of-care HCV antibody testing



Financial incentives



Reflex HCV RNA testing



Pre-test counselling and education



Peer support

KEY BARRIERS

1. Cost of the test kit is a barrier to future implementation in LMICs
2. A substantial number of individuals were not at home on multiple occasions
3. Education about performing the test
4. For some patients, difficulty in correctly reading the very light test line
5. There is a fair bit of tobacco chewing practice in this area which could affect the test results
6. Some (very few) subjects refused to be tested because they were worried about the implications of a positive test

KEY ENABLERS

1. The ability to test remote populations may offset potential cost barriers
2. Use of a video demonstration on a smart phone was helpful, in addition to pictorial material
3. Field staff did re-read the test kits to understand the level of difficulty
4. Clear instructions about rinsing the mouth and letting it dry out were provided
5. The Union Council officials were helpful in convincing some of those who households who had refused to participate earlier

Examples of National HCV Point-of-Care Testing Programs

National Point-of-Care HCV RNA Testing in Harm Reduction Services in Georgia

The population of Georgia is 3.7 million, with an estimated 51,000 people who inject drugs. There are 14 needle and syringe program sites, nine mobile harm reduction sites and over 100 harm reduction workers nationally.

- Point-of-care HCV RNA testing is provided at five harm reduction centres using on-site GeneXpert systems, followed by integrated DAA treatment, which is also provided on-site
- Between 2019-2022 4,773 people were tested for HCV RNA at a harm reduction centre, 1,878 (39%) of those were RNA positive and 871 (47%) of those commenced DAA treatment

National Point-of-Care HCV Testing England

In England, HCV point-of-care testing is provided by 22 HCV Operational Delivery Networks (ODNs). Point-of-care testing is available in all networks and a combination of DBS antibody testing, oral antibody testing and GeneXpert RNA testing has been used across various settings as part of a comprehensive testing program.

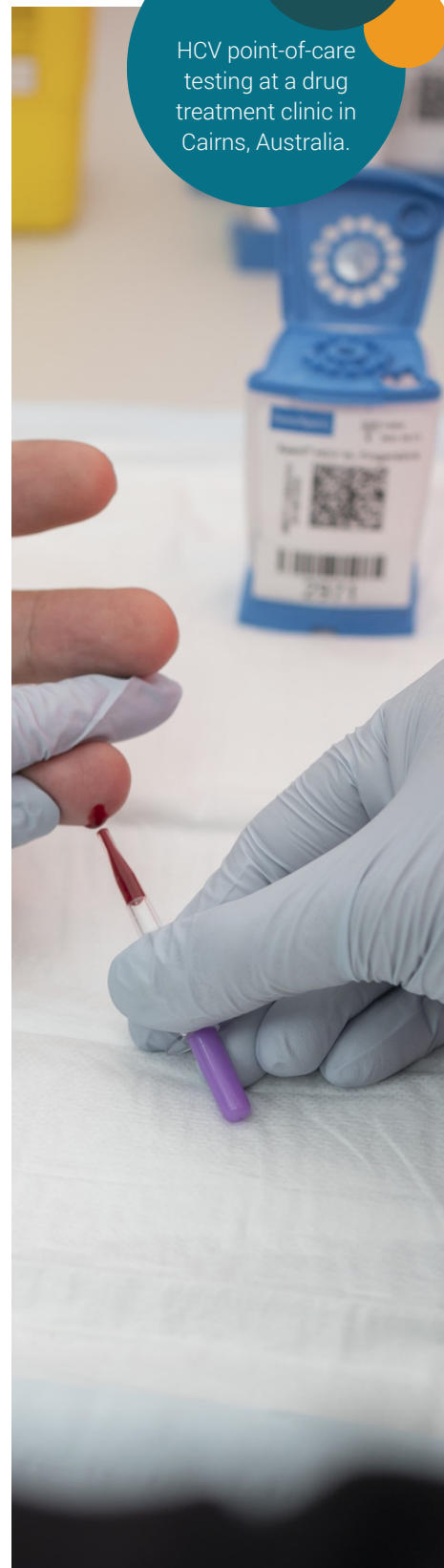
- Implementation models include community outreach, peer-delivered mobile testing, emergency department testing, prison reception testing and intensive prison test and treat programs.

National Australian Hepatitis C Point-of-Care HCV Testing Program

The National Australian Hepatitis C Point-of-Care Testing Program covers 90 sites nationally and plans to conduct 60,000 molecular-based and/or antibody HCV tests from 2022-2024. Sites include drug treatment clinics, needle and syringe programs, prisons, mobile outreach models, homelessness services, Aboriginal Community Controlled Health Organisations, and mental health services.

- The program includes provision of, standard operating procedures, deployment, set-up of GeneXpert platforms for point-of-care RNA testing implementation, technical/operator support, blood collection devices and test cartridges, point-of-care operator training (delivered to healthcare workers, including peer workers), a quality assurance program, device connectivity, and a research and evaluation framework.

HCV point-of-care testing at a drug treatment clinic in Cairns, Australia.



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Hepatitis C nurse, Inês Marinho, performs a hepatitis C point of care test as part of the CRESCER REACH_U project in Lisbon, Portugal.