

# Have a Heart, Save My Liver!

## Why Hepatitis C Virus Care Remains Inaccessible

May 2023

### What Is the Burden?

Available evidence suggests that by 2040, viral hepatitis deaths will outnumber HIV, tuberculosis, and malaria deaths combined if viral hepatitis is not appropriately addressed.<sup>i</sup> In the absence of proactive national strategies to raise awareness, actively engage with communities to scale up hepatitis C virus (HCV) screening uptake, and decentralize HCV care to make it more accessible, particularly among key populations with the highest HCV burden, countries will not be able to find the missing millions of people living with HCV.

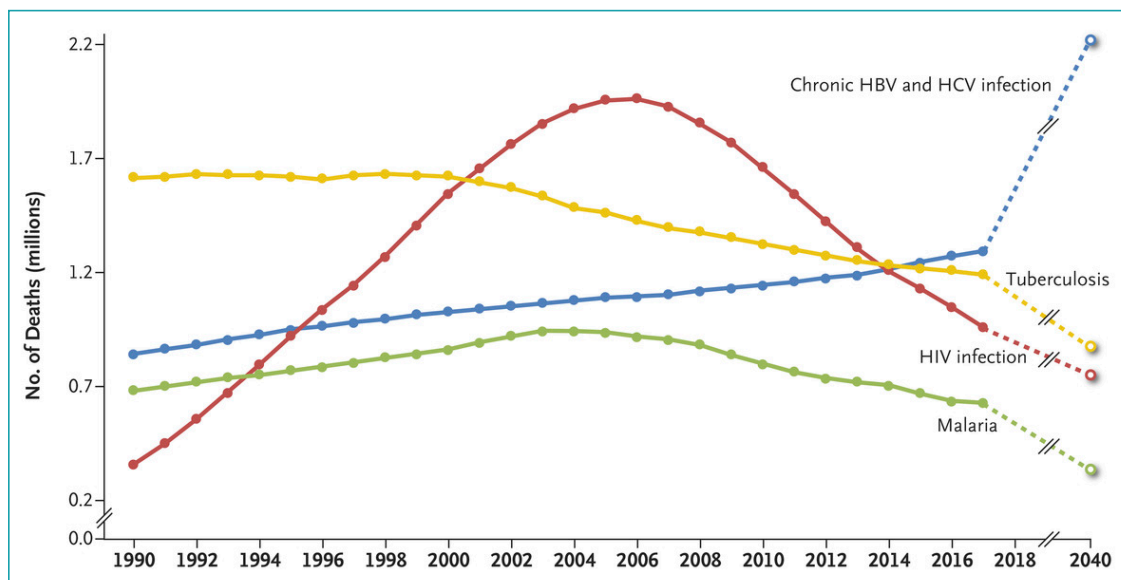
Seven years into the Global Health sectors strategy on HIV, viral hepatitis, and STIs (GHHS) for 2016–2021, in which the World Health Organization (WHO) set out a strategy to eliminate viral hepatitis by 2030,<sup>ii</sup> only 21% of the 58 million people estimated to be living with HCV have been diagnosed, and about 400,000 people die from the disease each year.<sup>iii</sup> Low- and middle-income countries account for about 75% of the global HCV burden,<sup>iv</sup> with India, Pakistan,

Nigeria, and China alone being home to over 50% of people living with HCV.<sup>v</sup>

While about 30% of people who contract HCV clear the virus spontaneously within six months,<sup>vi</sup> the vast majority — about 70% — develop chronic HCV, and 15%–30% of that population risk developing cirrhosis within 20 years.<sup>vii</sup> People with chronic HCV are usually asymptomatic for decades after infection and sometimes symptoms only appear when severe liver disease occurs.<sup>viii</sup> As a result, late diagnosis is common, with people only seeking care when there are serious complications like cirrhosis and liver cancer.

Based on WHO Guidelines,<sup>ix,x</sup> key populations with the highest HCV burden include people who use and inject drugs, people in incarceration, men who have sex with men, and trans people. Other populations that could be targeted in national HCV elimination programs include people living with the hepatitis B virus, people on dialysis, pregnant people, migrants, people who are homeless, and people over 40 or 50 years old.

### Worldwide Deaths from Chronic Viral Hepatitis as Compared with Deaths from Tuberculosis, Human Immunodeficiency Virus (HIV) Infection, and Malaria.



Source: DL Thomas. N Engl J Med 2019;380:2041-2050.

## What Progress Has Been Made?

### HCV is the only chronic infectious disease that can be cured with 8–12 weeks of treatment.

As a result, the disease can be controlled and eliminated with appropriate national strategies that address stigma and prioritize key populations for diagnostics and treatment with all-oral pangenotypic direct-acting antivirals (DAAs). Generic versions of DAAs are commercially available, and cost less than \$100 in a few countries.<sup>xi</sup>

However, based on Polaris Observatory studies, only 11 countries (Australia, Canada, Denmark, Egypt, Finland, France, the country of Georgia, Japan, Norway, Spain, and the United Kingdom) are on track to achieving the HCV elimination goals by 2030. An additional 22 countries are expected to meet these goals between 2031 and 2050.<sup>xii</sup>

## HCV Elimination Challenges

Although HCV can be cured with all-oral pangenotypic DAAs, several factors still hamper access to HCV care in most low- and middle-income high-burden countries. First, there is a general lack of political will and championship at the national and global levels to fund and prioritize HCV elimination. Because the HCV burden is highest among marginalized and stigmatized population groups — like people who use and inject drugs, men who have sex with men, people living with HIV, and people in incarceration — some of whom are criminalized instead of being prioritized by national health strategies, HCV is not prioritized in national healthcare programs.

Second, the complex process involved in HCV diagnostics poses a significant barrier to scaling-up diagnostics in several countries. This process includes high diagnostics costs, centralization of diagnostics services in tertiary or reference hospitals, numerous steps in the diagnostics process, multiple clinic visits, and delays in treatment initiation following a positive HCV diagnosis.

Third, originator and generic DAAs are not widely available in several countries.<sup>xiii</sup> This is the case with Glecaprevir/Pibrentasvir; for example, a pangenotypic originator DAA that offers the shortest treatment duration and can be used to form a salvage regimen for people who have failed treatment on other DAAs, yet it is almost exclusively registered and commerciality available in high-income countries and no generic version is available. Even in

some of the countries where other pangenotypic DAAs like Sofosbuvir/Daclatasvir and Sofosbuvir/Velpatasvir are registered, supply is sometimes limited and the treatments are exorbitantly priced, including generic options. Other factors like lack of awareness and a clear strategy to find the missing millions of people with HCV, intellectual property barriers such as patents and drug regulatory challenges also impede several countries' access to DAAs.

To address some of these challenges, the WHO's 2022 Updated Recommendations on the Treatment of Adolescents and Children with Chronic HCV Infection and Updated Recommendations on Simplified Service Delivery and Diagnostics for Hepatitis C Infection both provide additional guidance for national governments to consider and adopt in a bid to meet the HCV elimination goals.

## SUMMARY OF WHO GUIDELINES ON HCV CARE<sup>xiv</sup>

### Decentralization, integration, and task sharing

- Provision of HCV testing and treatment services at the same site through decentralization of care to lower-level facilities.
- Integration of HCV care into other services like primary care, harm reduction programs, prisons, and HIV services.
- Promotion of task sharing through delivery of HCV testing, care, and treatment by appropriately trained nonspecialist doctors and nurses.

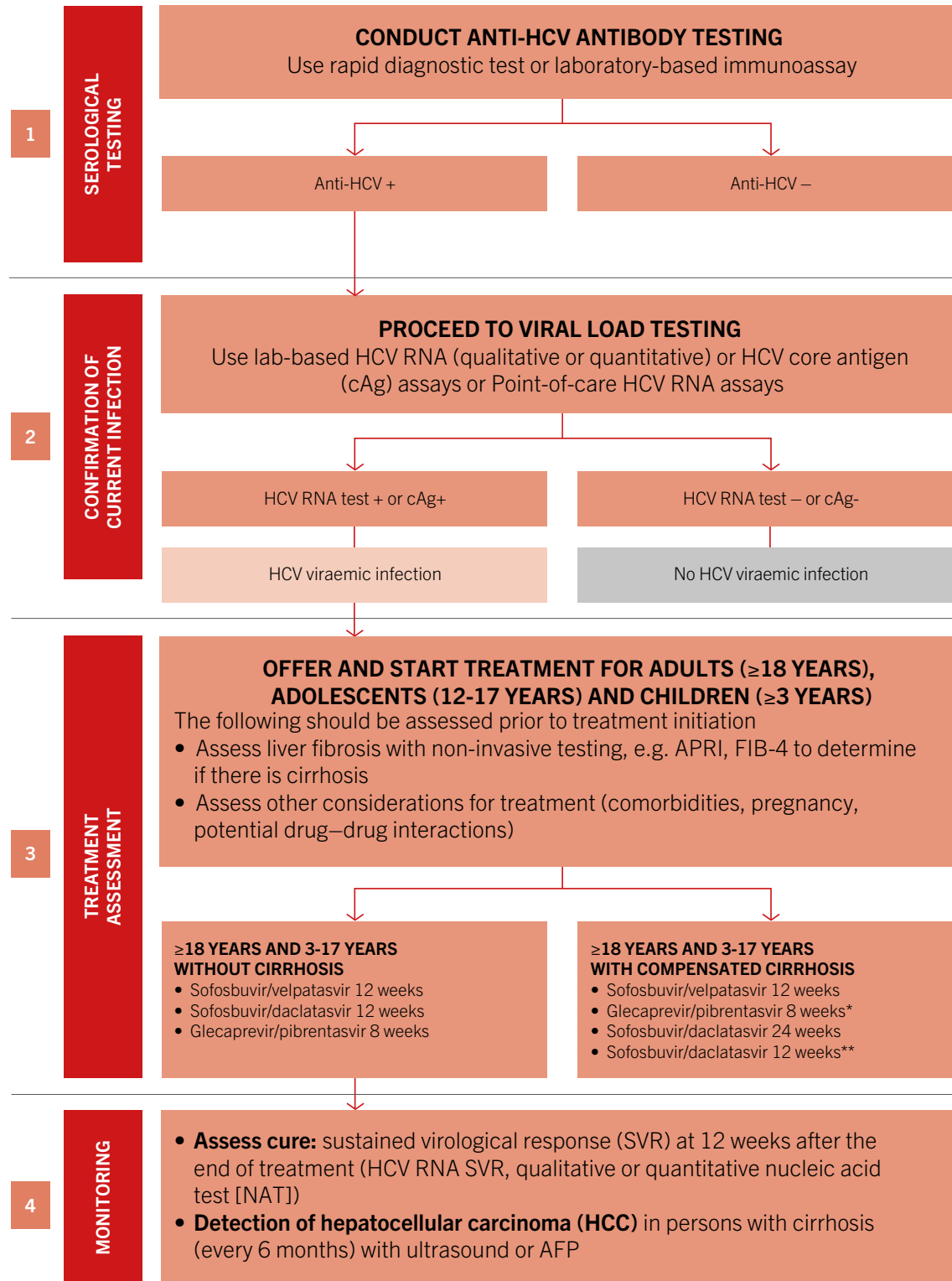
### HCV diagnostics

- Use point-of-care (POC) HCV RNA viral load and reflex HCV RNA viral load testing.
- Simplification of the HCV diagnosis, treatment, and monitoring algorithm.

### Treatment of Chronic HCV

- Every adult diagnosed with an HCV infection (except during pregnancy) should be initiated on treatment with existing DAAs irrespective of disease stage.
- Every adolescent and child down to three years of age with chronic HCV should be initiated on treatment with existing DAAs irrespective of disease stage.
- Adolescents and children with chronic HCV weighing >25 or 30 kg can use existing adult doses of the recommended DAA regimens, while those weighing less may require specific pediatric dosage and formulations.

# SUMMARY ALGORITHM FOR THE DIAGNOSIS, TREATMENT AND MONITORING OF CHRONIC HCV INFECTION IN ADULTS, ADOLESCENTS AND CHILDREN ≥ 3 YEARS



Source:WHO Updated Recommendations on Treatment of Adolescents and Children with Chronic HCV Infection: Policy Brief, 2022, 8.

## DAA TREATMENT OPTIONS AND TREATMENT DURATIONS

| Age groups                   | Recommended pangenotypic DAA regimens |                      |         | Non-pangenotypic DAA regimen (in settings with minimal GT3 infection) <sup>2</sup> |
|------------------------------|---------------------------------------|----------------------|---------|--|
|                              | SOF/DCV <sup>1</sup>                  | SOF/VEL <sup>2</sup> | G/P     | SOF/LED  |
| Adults (18 years and above)  | 12 weeks                              | 12 weeks             | 8 weeks | 12 weeks   |
| Adolescents (12–17 years)    | 12 weeks                              | 12 weeks             | 8 weeks | 12 weeks   |
| Older children (6–11 years)  | 12 weeks                              | 12 weeks             | 8 weeks | 12 weeks   |
| Younger children (3–5 years) | 12 weeks                              | 12 weeks             | 8 weeks | 12 weeks   |

<sup>1</sup> In those without cirrhosis. Treatment for 24 weeks is recommended in those who are treatment-experienced or with compensated cirrhosis. May be considered in settings where genotype 3 is known to be highly prevalent (>10%).

<sup>2</sup> For use in those with genotype 1, 4, 5, or 6 infection.

Source:WHO Updated Recommendations on Treatment of Adolescents and Children with Chronic HCV Infection: Policy Brief, 2022, 7.

### Focus of This Policy Brief

**This policy brief presents online survey data from 23 countries on some of the key HCV diagnostics and policy barriers that inhibit access to HCV care in low- and middle-income countries. The diagnostics barriers covered in the survey included:**

- the number of clinic/health facilities visits required to get confirmatory HCV test results,
- how long after a positive HCV diagnosis treatment is initiated,
- whether all HCV diagnostics services required before treatment initiation are provided at a single facility,
- the availability of HCV reflex testing,
- the level of care at which HCV diagnosis services are provided, and
- whether HCV genotyping is required.

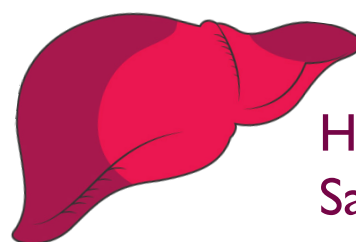
**The policy barriers covered in the survey included:**

- availability and implementation of policies to prioritize HCV elimination such as domestic funding,
- integration of HCV into HIV or sexual health programs,
- harm reduction initiatives,
- awareness raising, and
- other HCV-specific policies at the country level.

As countries pledge and mobilize resources to catalyze bold national viral hepatitis elimination strategies,<sup>xv</sup> this policy brief aims to serve as a resource for key in-country data on HCV treatment access barriers and how these barriers can be addressed. We hope it will also serve as a starting point for engagement between health advocates and policymakers as we work together to develop appropriate strategies to address HCV diagnostic and treatment barriers.

### Methodology

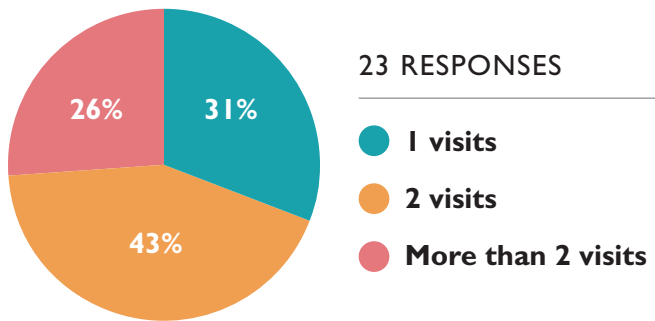
The data for this policy brief was crowdsourced and collected between January and April 2023 using a short data collection survey that was widely shared through email communication and on social media platforms by partners working on access to global health technologies.<sup>xvi</sup> The data was collected through a google form that asked specific questions relating to implementation of a simplified HCV diagnostics pathway and policies at the national level to prioritize HCV elimination. We recognize the limitations of the crowdsourced data and reliance on countries where we have in-country partners and networks.



**Have a Heart,  
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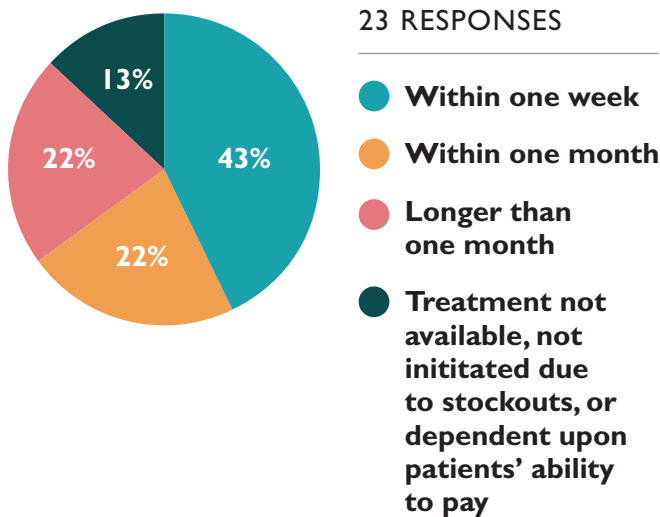
## BARRIERS RELATING TO HCV DIAGNOSTIC SERVICES

### I. Number of clinic/health facility visits required to obtain confirmatory HCV test results



Based on the data collected, of the 23 countries surveyed, 31% (seven countries) provide confirmatory HCV test results after one visit to health facilities, 43% (ten countries) provide results after two visits, and 26% (six countries) required more than two visits to health facilities. Patients are lost to follow-up when multiple clinic visits are required to obtain confirmatory tests results.

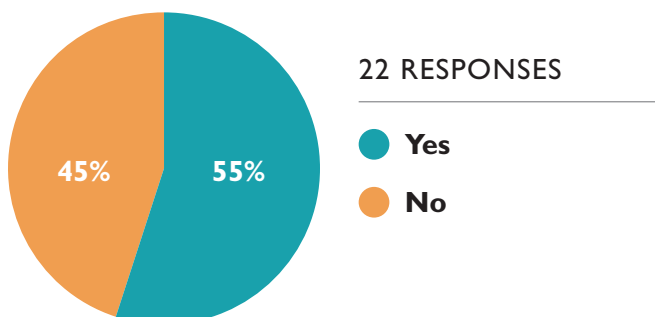
### 2. Turnaround time between HCV diagnosis and treatment initiation



The data collected shows that 43% of countries (ten) initiate treatment within one week of the HCV diagnosis, about 22% (five) initiate treatment within a month, and about 22% (five) take longer than one month to initiate treatment. In 13% of countries (three), treatment is either not available, is sometimes not initiated due to stockouts, or is dependent on patients' ability to pay.

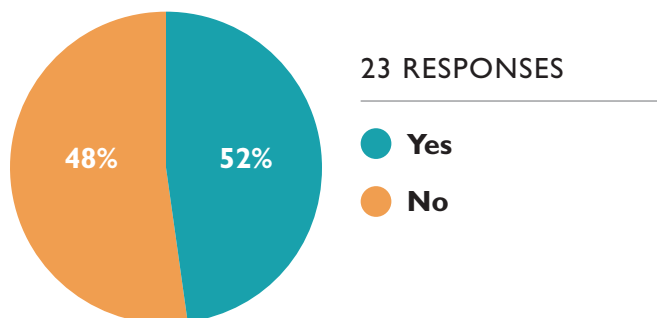
Early treatment initiation prevents complications such as liver damage and cirrhosis as well as further transmission, resulting in savings to health systems. Marginalized communities with high HCV burden like people experiencing unstable housing, people who use drugs, and people in prison and other detention settings are in constant fear of prosecution and stigma and are often on the move. If treatment is not initiated soon after a positive HCV diagnosis, these patients may be lost to follow-up.

### 3. Provision of all HCV diagnosis services in single facility



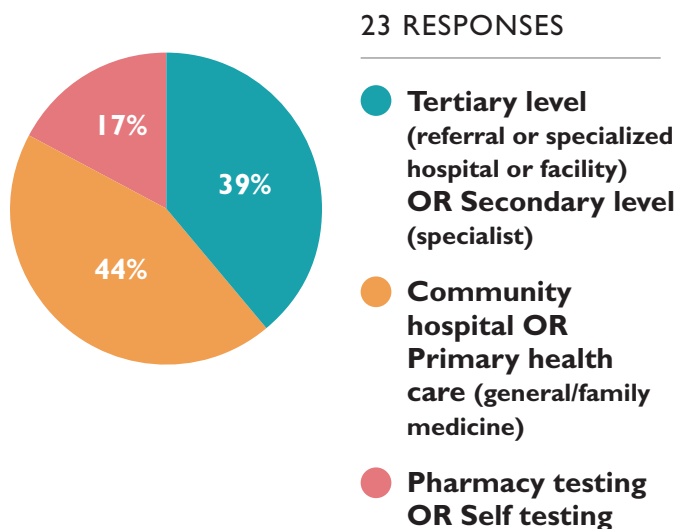
Only 55% of the countries (12) offer all diagnostic services needed before treatment initiation in a single facility, meaning that patients in many countries need to visit different health facilities before obtaining a confirmatory HCV diagnosis. Simplifying and decentralizing the HCV diagnostic and treatment algorithm as recommended by the WHO is key to ensuring that more people seek, receive, and complete HCV care services.

#### 4. Availability of HCV reflex testing



The data show that 52% of countries (12) do not offer reflex testing. Reflex testing uses one blood sample to perform an antibody test and, if the test is positive, a confirmatory test using the same blood sample. Without reflex testing, patients have to return to the clinic and have another blood sample taken. Reflex testing is recommended by the WHO because it simplifies HCV diagnostics by reducing time to results, the frequency of visits to health facilities, the number of blood samples drawn from patients, and enables early treatment initiation. Multiple health facility visits are associated with high loss of patients to follow-up.

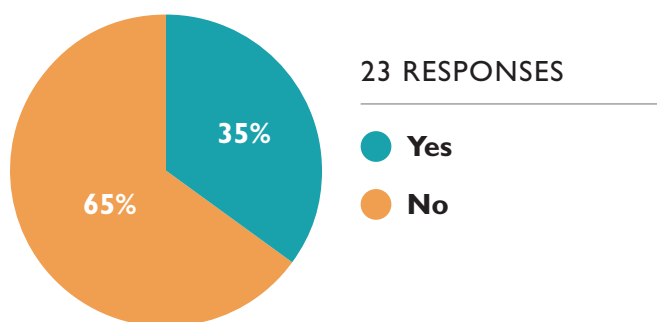
#### 5. Decentralization of HCV diagnostics services



HCV diagnostic services are still highly centralized, with 39% of countries (9) offering these services only in tertiary or secondary levels of care (specialist/reference hospitals and clinics), 44% (10 countries) offering them in the primary and community levels of care, and only 17% (4 countries) providing pharmacy and self-testing.

Decentralization of HCV testing services is recommended by the WHO because it brings testing closer to communities, eliminates barriers such as long trips to health facilities, and can engage the community in microelimination efforts.

#### 6. HCV Genotyping requirement

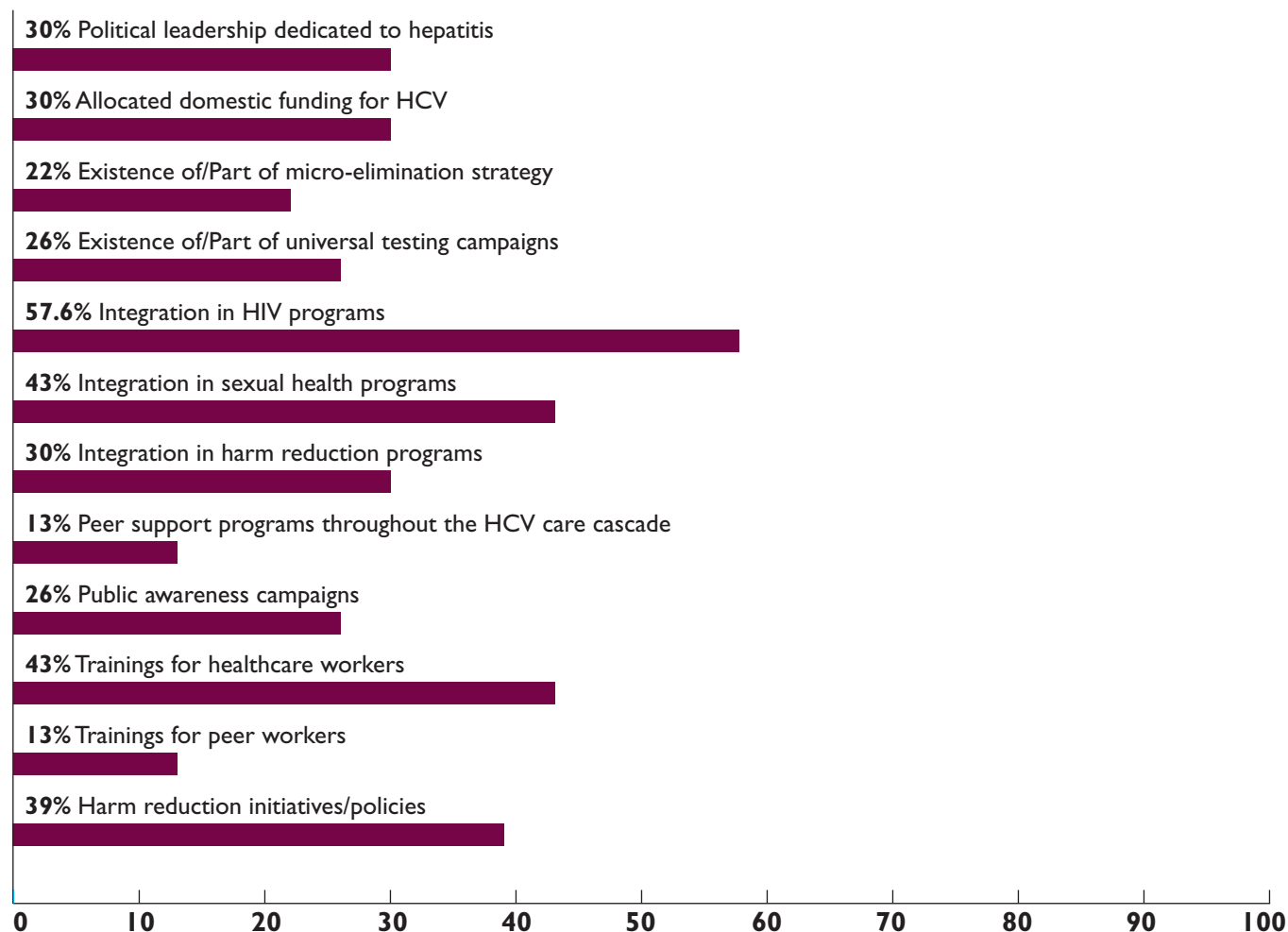


HCV genotype testing is still required and included in the HCV diagnostic algorithm in 35% (eight) of the 23 countries surveyed. HCV genotyping is not recommended by the WHO when pan-genotypic DAAs — which are the recommended standard of care — are used for HCV treatment. In addition, HCV genotyping is expensive both for health facilities and patients, causes unnecessary delays in treatment initiation, and is mainly available in centralized health facilities, requiring unnecessary travel.

## BARRIERS RELATING TO NATIONAL POLICIES TO PRIORITIZE, CONTROL, AND ELIMINATE HCV

### 7. Elements of HCV elimination present/implemented at the national level

23 RESPONSES



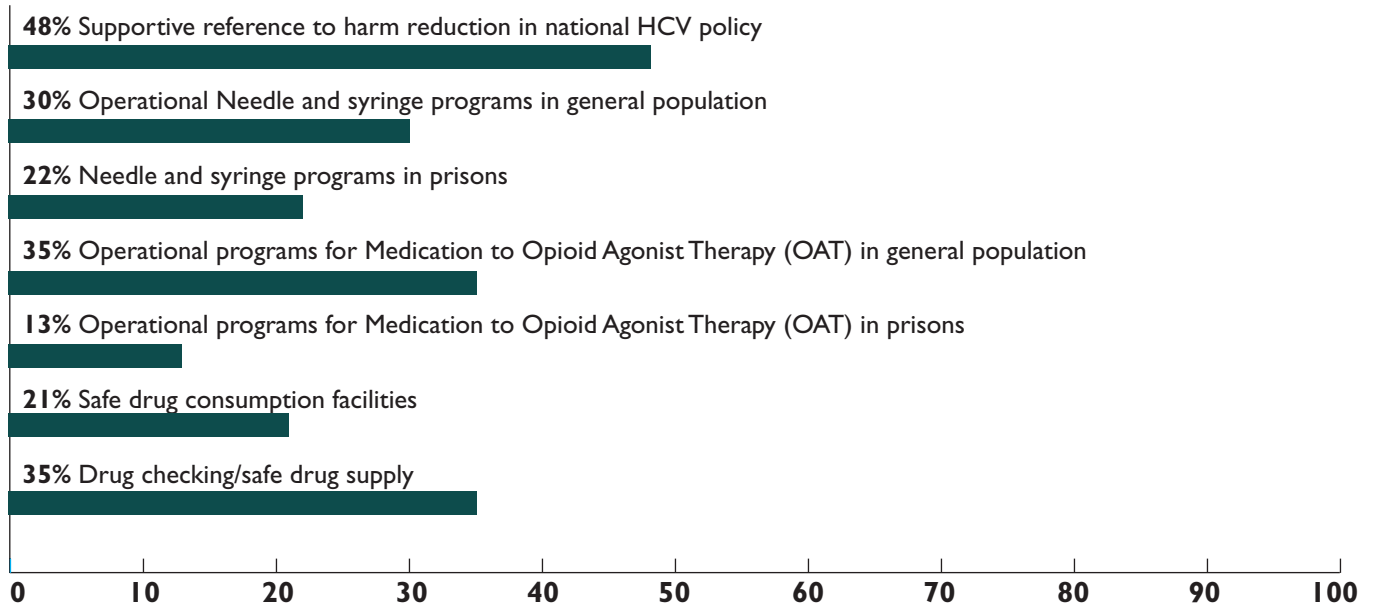
About 30% (7 countries) have some form of political leadership dedicated to viral hepatitis, and about 30% (7 countries) have some domestic funding allocation for HCV either simply mentioned or actually implemented in the national hepatitis program. Only about 22% (5 countries) have an HCV micro elimination strategy, and interestingly, over half (57.6% or 13 countries) have integrated HCV into HIV programs.

In addition, 39% of the countries (9) have harm reduction initiatives/policies, 30% (7 countries) have integrated HCV into harm reduction programs, and 43% (10 countries) have integrated HCV into sexual health programs. Only 26% of countries (6) have public awareness campaigns on HCV, 43% (10 countries) have training for healthcare workers on HCV, and 13% (3 countries) have training for peer workers either mentioned or implemented in the national hepatitis program.



### 8. Harm reduction strategies included/implemented at the national level

23 RESPONSES



Of the 23 countries surveyed, 48% (11 countries) reported having supportive reference to harm reduction in national HCV policy, 30% (7 countries) reported having operational needle and syringe programs (NSP) in the general population, while about 22% (5 countries) reported having operational NSP in prisons.

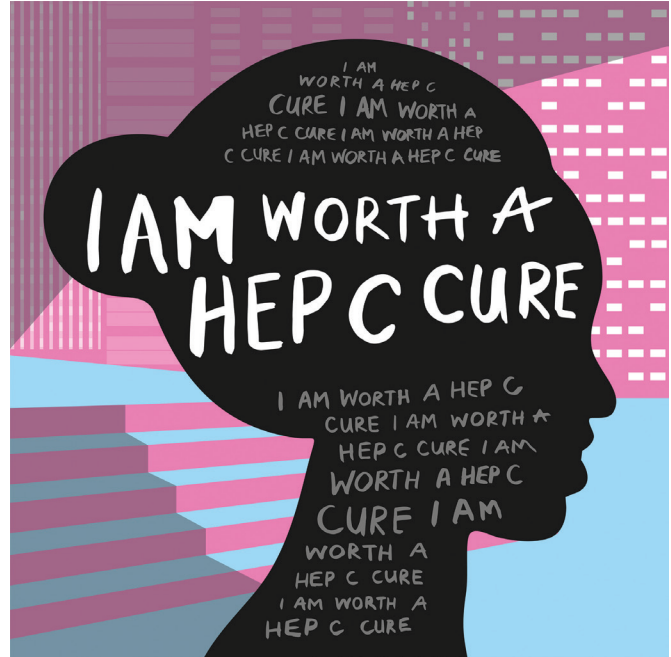
Referring specifically to opioid agonist therapy (OAT), only 35% (8 countries) have operational programs for medication to OAT in the general population, while 13% (3 countries) have OAT programs in prisons. About 21% (5) of the surveyed countries provide safe drug consumption facilities, while 35% (8 countries) have drug checking/safe drug supplies.



## Conclusion

As the target year for viral hepatitis elimination, 2030, approaches, we demand that:

- The global community and national governments work together to raise funding for HCV elimination, to find the missing millions of people living with HCV, and to scale up HCV diagnostics, especially among high-burden key populations.<sup>xvii</sup> Having a clear idea about the demand for DAAs would serve as a leverage to re-engage with generic manufacturers and negotiate more affordable prices for health systems and patients.
- Given that HCV remains asymptomatic for several decades while causing avoidable liver damage, national hepatitis programs should continuously raise awareness about HCV, subsidize HCV screening programs to encourage more people to screen, with a particular focus on key populations.
- Countries adopt WHO recommendations on decentralization of care to lower-level health facilities accessible to all; integrate HCV care into primary care, harm reduction programs, prisons, and HIV services; and task sharing through delivery of HCV testing, care, and treatment by appropriately trained non-specialist doctors and nurses.
- Countries review HCV diagnostics algorithms to include POC HCV RNA viral load and reflex HCV RNA viral load testing, eliminate requirements for HCV genotype testing, and to initiate treatment at the same site and during a single visit.
- Countries put in place systems to record epidemiological data regarding HCV diagnosis, treatment, and care to track and guide policies and allow communities to understand and advocate for the best care.
- National regulatory authorities review and amend policies that prevent registration of generic Daclatasvir, even if the originator drug is not registered, by relying on its registration in other countries. This will ensure that all approved generic DAAs are available on the market, promote competition and drive down treatment costs.



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- <sup>viii</sup> Moorman AC, Xing J, Rupp LB, et al. Late diagnosis of hepatitis virus C infection, 2014–2016: Continuing missed intervention opportunities. *American Journal of Managed Care*. 2019 August; 25 (8).
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- <sup>xii</sup> CDA Foundation. Countries/territories achieving relative or absolute impact and programmatic target – HCV. 2023. <https://cdafound.org/polaris-countries-maps/>.
- <sup>xiii</sup> Treatment Action Group. Have a heart, save my liver! Where is the cure registered? 2021 September. <https://www.hepcoalition.org/en/advocate/campaigns/have-a-heart-save-my-liver/article/have-a-heart-save-my-liver-where-is-the-cure-registered>.
- <sup>xiv</sup> World Health Organization. Updated recommendations on simplified service delivery; World Health Organization. Updated recommendations on treatment of adolescents.
- <sup>xv</sup> The Hepatitis Fund. Global resource mobilization conference. 17 May 2023. <https://endhep2030.org/global-resource-mobilization-conference/>.
- <sup>xvi</sup> Latin America (LATAM): Brazil, Mexico, Guatemala; Middle East and North Africa (MENA): Egypt, Algeria, Morocco; Asia: Indonesia, Yemen, Bangladesh, India, Nepal, Malaysia; and sub-Saharan Africa: Kenya, Mozambique, Nigeria, Mauritius, Tanzania, South Africa, South Sudan, Uganda, Cameroon, Zambia, Côte d'Ivoire.
- <sup>xvii</sup> This includes people who use and inject drugs, people in incarceration, men who have sex with men and trans people, people living with the hepatitis B virus, people on dialysis, pregnant people, and people over 50 years old.