Perspectives of People with HCV Lived Experience and Healthcare Providers on Potential Long-Acting Therapies

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Background

Hepatitis C virus (HCV) is the only chronic viral infectious disease that can be cured and requires just 8–12 weeks of treatment. Yet, of the 50 million people estimated to be living with HCV globally, only 36% were diagnosed between 2015 and 2022, only about 20% received curative treatment and approximately 242,000 died.[1] Low- and middle-income countries (LMICs) account for 89% of the global HCV burden,[2] with China, India, Nigeria, and Pakistan alone being home to over 50% of people with HCV.[3] While in high-income countries and parts of Eastern Europe and Southeast Asia unsafe injecting drug use is the most common mode of HCV acquisition — contributing to 43.6% of new infections globally[4] — the leading modes of HCV acquisition in Africa and other parts of the world include unsafe injection practices in health settings, unscreened blood transfusions, and inadequate sterilization of medical equipment.[5] Across the board, marginalized populations such as people who inject drugs, people in carceral settings, and people who are unstably housed are disproportionately affected by HCV.[6] These marginalized population groups are often confronted with several competing priorities causing them to deprioritize healthcare, and frequently face challenges navigating the healthcare system, especially when this requires multiple clinic visits as is the case with HCV. Worse still, these populations are rarely prioritized in healthcare programming further compounding their limited engagement with the healthcare system.

Recent advances in long-acting drug delivery such as the approval of long-acting injectable therapies, including, cabotegravir and rilpivirine (Cabenuva), lenacapavir (Sunlenca) for HIV treatment; and cabotegravir (Apretude) — popularly referred to as CAB-LA — for HIV prevention, plus the prospect of a once yearly lenacapavir for HIV prevention currently under investigation,[7] could revolutionize chronic viral infection treatment and prevention, potentially paving the way for their elimination.

In the case of HCV, a long-acting single injectable cure would significantly reduce loss to follow-up by ensuring that people are diagnosed and cured during a single health encounter.[8] Given the recent expansion of point of care (PoC) testing in some LMICs, this would facilitate a test-and-cure approach to HCV elimination. For prevention, long-acting buprenorphine approved for the treatment of moderate to severe opioid use disorder (OUD) helps reduce opioid cravings and withdrawal symptoms thus reducing risky behaviors, such as unsafe injecting drug use, which is a major driver of new HCV infections.[9]

Unitaid's Commitment to HCV Elimination

Available evidence suggests that by 2040, viral hepatitis deaths will outnumber HIV, tuberculosis, and malaria deaths combined if viral hepatitis is not appropriately addressed.[10] Until the recent U.S. government freeze on global health funding,[11] HIV, TB, and malaria have historically had funding support through the United States Agency for International Development (USAID) and the President's Emergency Plan for AIDS Relief (PEPFAR), with additional support from the Global Fund. Despite its nascent threat, no similar dedicated global initiative has ever existed for viral hepatitis.

In a bid to contribute towards addressing the enormous gap in viral hepatitis elimination and ensure equitable access to innovative LATs, the global health agency, Unitaid, is supporting two major initiatives to ensure equitable access to innovative LATs for HCV prevention and treatment in LMICs. The first involves the integration of HCV testing and treatment within harm reduction programs; and piloting the use of low dead space syringes and long-acting buprenorphine in 10 countries.[12] The second initiative is the LONGEVITY consortium[13] which is developing a long-acting version of a combination of two existing direct acting antivirals (DAAs) used to cure HCV — glecaprevir/pibrentasvir (G/P) currently exclusively registered and used in high-income countries — for use in LMICs. If the safety and efficacy of long-acting G/P are established, the HCV treatment landscape would radically change as long-acting G/P would provide an additional option to the treatment toolbox in LMICs, enabling people diagnosed with HCV to choose between the current standard of care involving 8-12 weeks of pills/tablets and this innovative single injectable cure. In addition, a long-acting single injectable cure will offer people with HCV the chance to select a treatment option that works best for them, thereby providing an opportunity to address and eliminate pill/tablet fatigue, improve treatment adherence, prevent relapses arising from treatment interruption, and resulting in more constant plasma levels in the bloodstream. This will also provide privacy to people with HCV who may be vulnerable to stigma.

While the research and development into a long-acting G/P is in the pre-clinical stage,[14] the LONGEVITY research team sought to understand the preferences, acceptability, and challenges of people at higher risk of HCV; healthcare providers; and policy makers vis-a-vis various long-acting HCV treatment modalities. To this end, the LONGEVITY research team conducted two surveys. The first was a survey of HCV treatment prescribers and policy makers in LMICs assessing their preferences and perceived feasibility of three different long-acting modalities for HCV cure compared to the current standard of care.[15] The second was a survey of potential end users of long-acting G/P in three HCV high burden LMICs namely, Egypt, Ethiopia and India, to understand the barriers and facilitators to three long-acting treatment preferences.[16]

What End Users Think About a Potential Long-Acting HCV Cure

Survey Characteristics

The HCV end users survey was a descriptive, cross-sectional survey designed to measure facilitators and barriers to three long-acting HCV treatment modalities, namely: an intramuscular injection, an implant and a micro array patch (MAP), and preferred administration methods. This survey was translated into Arabic, Amharic, and Hindi and administered in-person at health facilities that monitor and treat people with HCV in Egypt (100 people) and Ethiopia (150 people), and among people who use drugs in India (150 people), — aged 18 years or older — majority of whom had been diagnosed with HCV.

Patient Survey: Clinical Characteristics

- 92% diagnosed with HCV
  - → Of diagnosed, 61% treated
  - → Of treated, 88% cured
- 20% also a person living with HIV
- Of people who inject drugs (PWID), 89% had injected within the past year:
  - → 61% within the past 3 days
  - → 8% within the past week
  - → 5% within the past month
  - → 26% within the past year
- 56% of PWIDs over the past year were concerned that an injection for HCV treatment might spoil injection locations for drugs

Characteristics, n (%)		Egypt (n=100)	Ethiopia (n=150)	India (n=150)	Total (n=400)
Respondents diagnosed with HCV	Yes	100 (100%)	132 (88%)	137 (91%)	369 (92%)
	No	0 (0%)	18 (12%)	13 (9%)	31 (8%)
Of diagnosed, treated for HCV	Yes	100 (100%)	73 (55%)	52 (38%)	225 (61%)
	No	0 (0%)	49 (45%)	85 (62%)	144 (39%)
Of treated, cured of HCV	Yes	98 (99%)	54 (84%)	37 (71%)	189 (88%)
	No	1 (1%)	10 (16%)	15 (29%)	26 (12%)
HCV Treatment Method	Pills	70 (71%)	71 (97%)	50 (96%)	191 (85%)
	Interferon Injections	12 (12%)	1 (1%)	0 (0%)	13 (6%)
	Pills and Injections	17 (17%)	1 (1%)	0 (0%)	18 (8%)
	Not sure	0 (0%)	0 (0%)	2 (4%)	2 (1%)
History of injecting illicit drugs into veins or skin	Yes	1 (1%)	2 (1%)	150 (100%)	153 (38%)
	No	98 (99%)	148 (99%)	0 (0%)	246 (62%)
Concern HCV injection might spoil injection location for drugs	Yes	0 (0%)	0 (0%)	76 (56%)	76 (56%)
	No	0 (0%)	1 (100%)	59 (44%)	60 (44%)

Figure 1

Willingness to Try LATs

Overall, of the three long-acting treatment modalities, the injectable ranked highest as the most preferred long-acting modality end users would be willing to try (78%) if this worked just as well as the 12 weeks of daily oral pills/tablets. However, among respondents from Egypt wherein 98% of people with HCV have been cured with daily oral pills/tablets, there was less willingness to try any of the long-acting modalities.

Willingness to Try LA Modalities

We now want to ask you about 3 new ways to take medication for hepatitis C infection. We want your thoughts on this even if you do not have HCV, have already been treated for HCV in the past, or are currently receiving HCV treatment.

Survey Question: If an injection (an implant, and a MAP) worked just as well as taking pills, would you be willing to receive an injection (an implant, and a MAP) for hepatitis C treatment if needed?

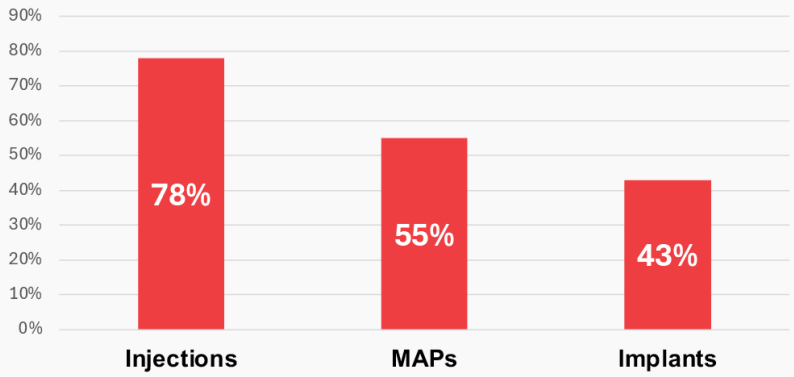

Figure 2

Most Preferred HCV Treatment Option

When asked to rank their most preferred HCV treatment options, 61% of survey participants selected pills/tablets — the current standard of care for HCV treatment — followed by injection at 28%. The low number of respondents who chose the MAP and the implant is reflective of their current unavailability or scarce use in most LMICs.

Most Preferred LAT Option

Survey Question: Which way of taking medicine seems the best to you? Rank in order...

Top Results:

→ 61% Pills
→ 28% Injection
→ 6% Microneedle Patch
→ 6% Implant

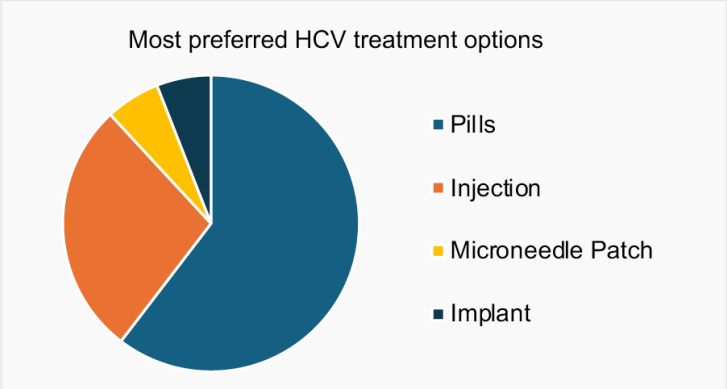

Figure 3

Least Preferred HCV Treatment Option

Interestingly, flipping the above question around, when asked to rank their HCV long-acting treatment modalities starting from the least preferred option, MAPs ranked top as the least preferred HCV long-acting treatment modality (50%) followed by implants (38%) and pills (10%), meanwhile injections ranked lowest as the most least preferred HCV long-acting treatment modality (2%). This clearly indicates a high preference for a long-acting injectable cure for HCV among respondents.

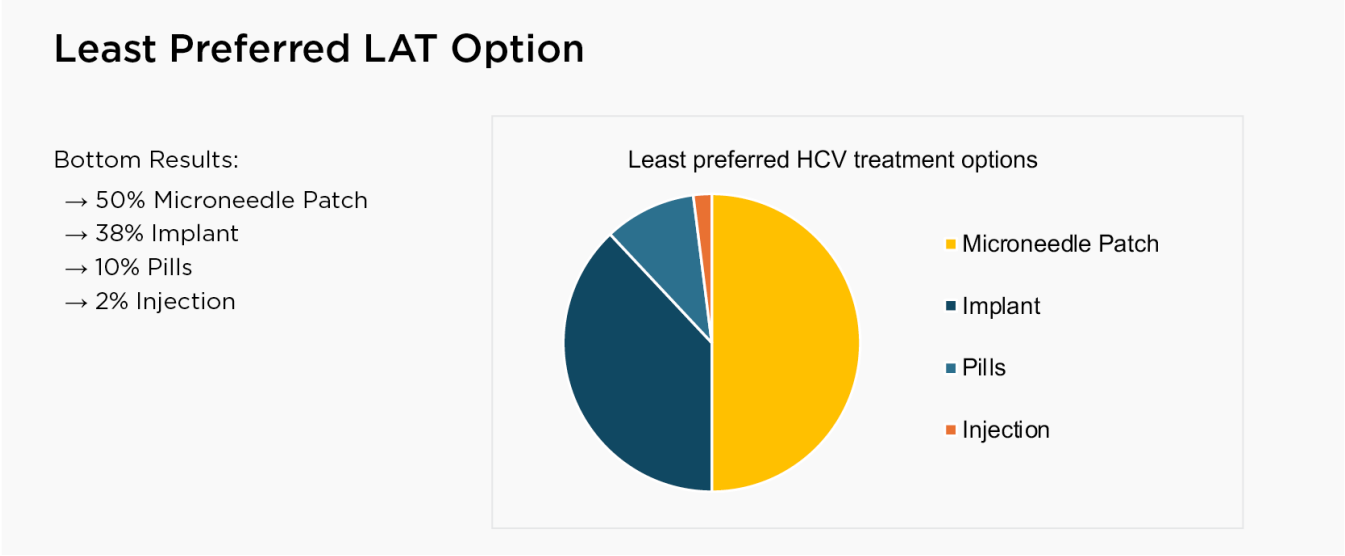

Figure 4

Reasons for Preferring a Long-Acting Injectable HCV Cure

According to most respondents, a single long-acting injectable cure presents several benefits over pills/tables. Namely 63% indicated that injections are very beneficial because they are easier than taking pills, while 52%, 50%, and 45% indicated that injections are beneficial because they are: more effective than pills/tablets; have fewer side effects than pills/tablets; and provide discretion compared to pills/tablets respectively.

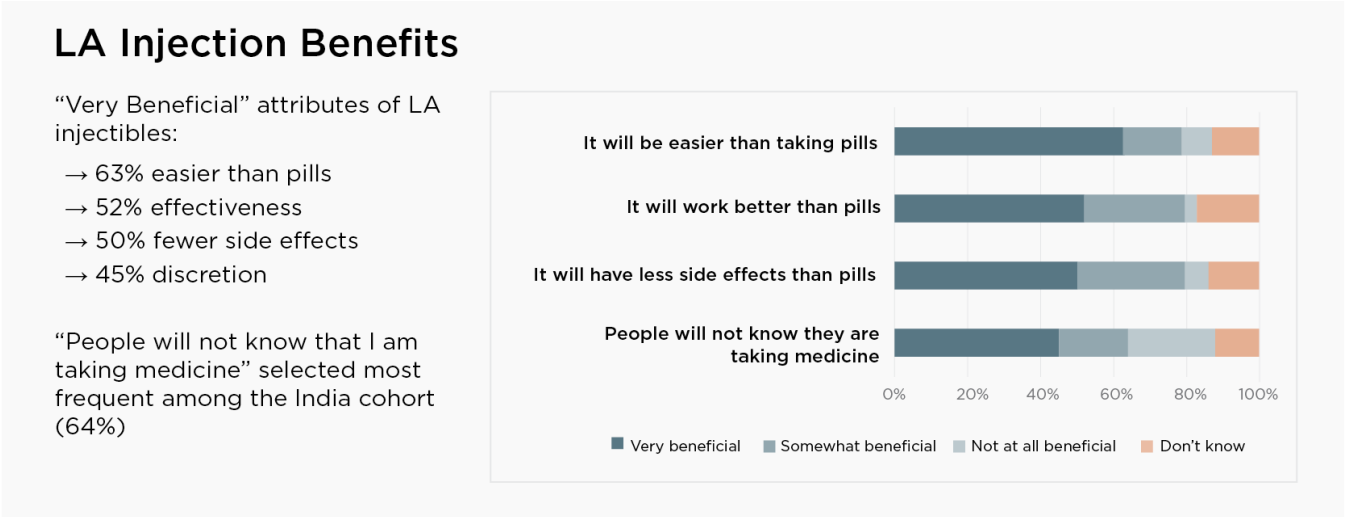

Figure 5

Respondents' Concerns with a Long-Acting Injectable HCV Cure

Aside from the overall enthusiasm and the benefits expressed over a potential long-acting injectable HCV cure, respondents also expressed some concerns. Up to 53% were "very concerned" that a long-acting injectable HCV cure might not be effective, while 44% were "very concerned" that side effects from the injection might last longer than taking pills/tablets, and 48% were "somewhat concerned" that the injection might be painful. Another concern which arose particularly among people who inject drugs was that an injectable HCV cure would spoil self-injection location for drugs. Clearly, in anticipation of the rollout of these LATs, there is a need for increased advocacy and community engagement on their comparably high efficacy profiles and bioequivalence to currently available DAAs, and their potential side effects. While clarity on the potential side effects and injection site pain would be established when the LAT is developed and its safety and efficacy are demonstrated in clinical trials, now is the time for broad dissemination of, and engagement on, the survey results to discuss some of these concerns, address community questions, and ensure that people have the information they need to make well-informed choices.

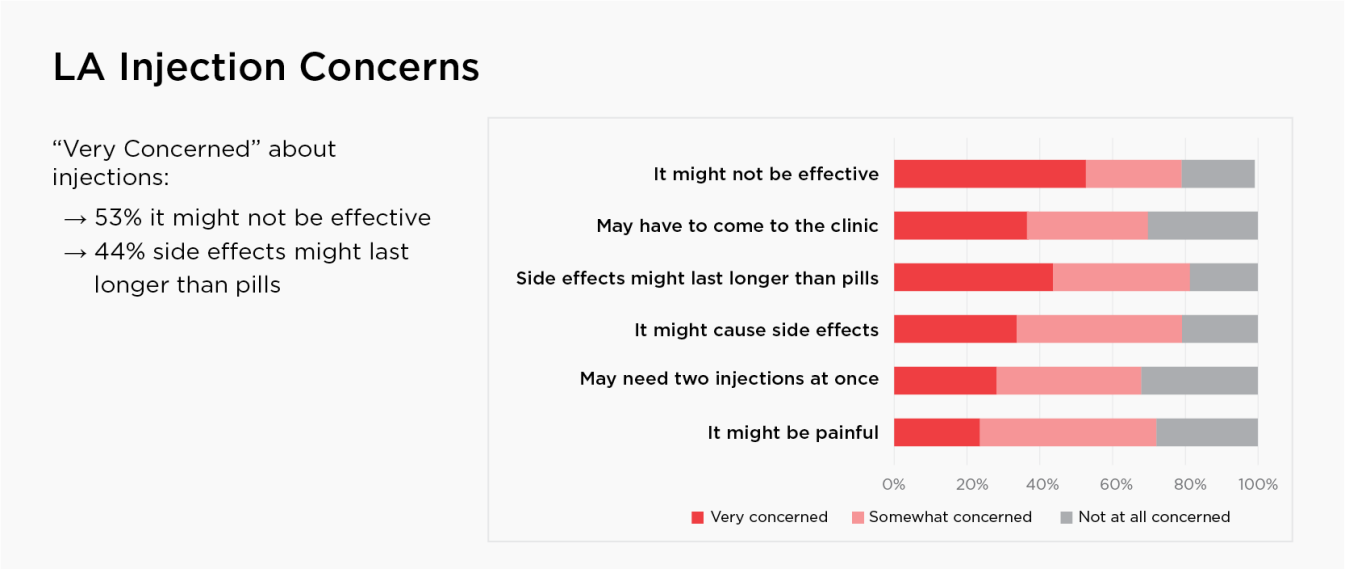

Figure 6

What Providers and Policy Makers Think about a Potential Long-Acting HCV Cure

Survey Characteristics

The healthcare providers and policy makers' survey was also a cross-sectional survey focused on the same three long-acting modalities. However, unlike the end users survey which was administered in-person and on-site at various facilities in three countries, this survey was disseminated online — on professional listservs, social media platforms, and through targeted direct communication — in English, French, Portuguese, Russian, and Spanish. The survey was completed online on Research Electronic Data Capture (REDCap) by people who self-identified as HCV treatment prescribers and policy makers in LMICs between October 2022 and February 2023.

As indicated on the map below, there was great representation from LMICs across all regions and respondents included 122 healthcare providers and 50 policy makers. In terms of respondent roles, of the 122 healthcare providers, 87 (71%); 37 (30%); 56 (46%) identified as specialist providers primarily in HCV care; general health care providers with occasional HCV care; and trained other providers on HCV care and treatment respectively. Of the 50 policy makers, 28 (23%); 37 (30%); 33 (27%); and 23 (19%) identified as developing guidelines for HCV treatment; advising on national treatment guidelines; conducting research on HCV treatment; and developing HCV related treatment policies in my country respectively.

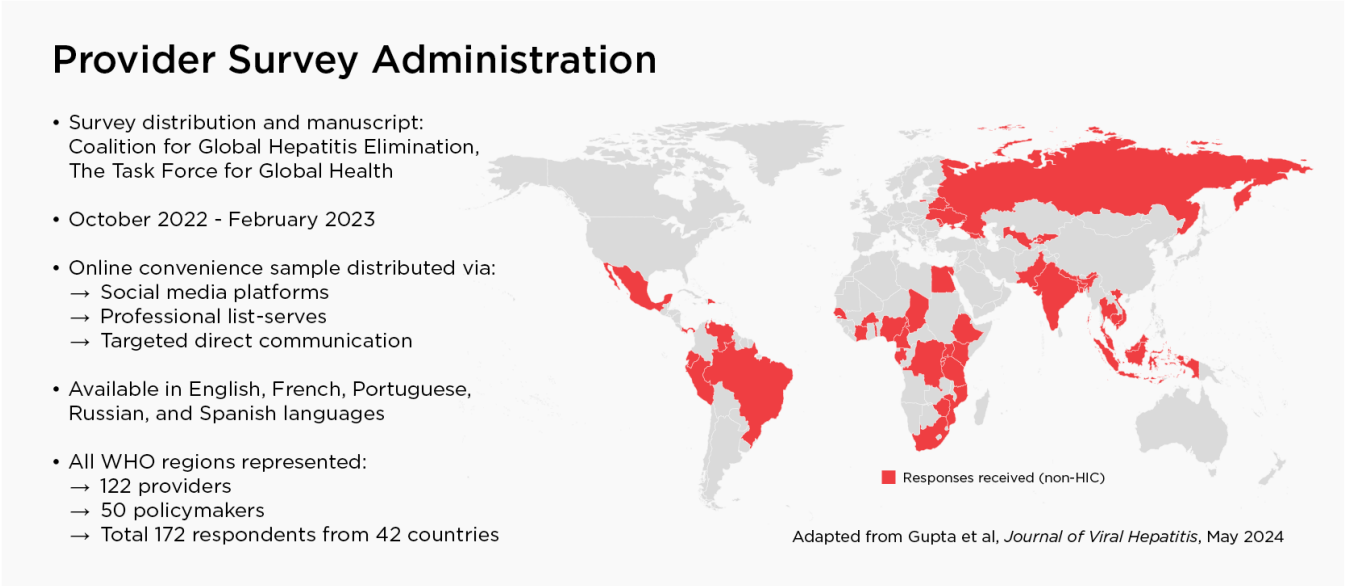

Figure 7

Perspectives on End Users' Preferred Long-Acting HCV Cure Modality

Healthcare providers and policy makers were asked to share their perspectives on the proportion of people diagnosed with HCV (end users) they thought would prefer any of the three long-acting treatment modalities to currently available DAAs, assuming no additional cost to end users (or if these were priced similarly to currently available DAAs). Based on the survey responses, 43% of respondents indicated that 75-100% of end users would prefer a long-acting HCV treatment modality to daily oral pills/tables, and 24%

indicated that 50-74% would prefer a long-acting HCV treatment to daily oral pills/tables. When asked specifically about a long-acting injectable HCV cure, 64% of respondents indicated that this long-acting modality would be preferred by end users.

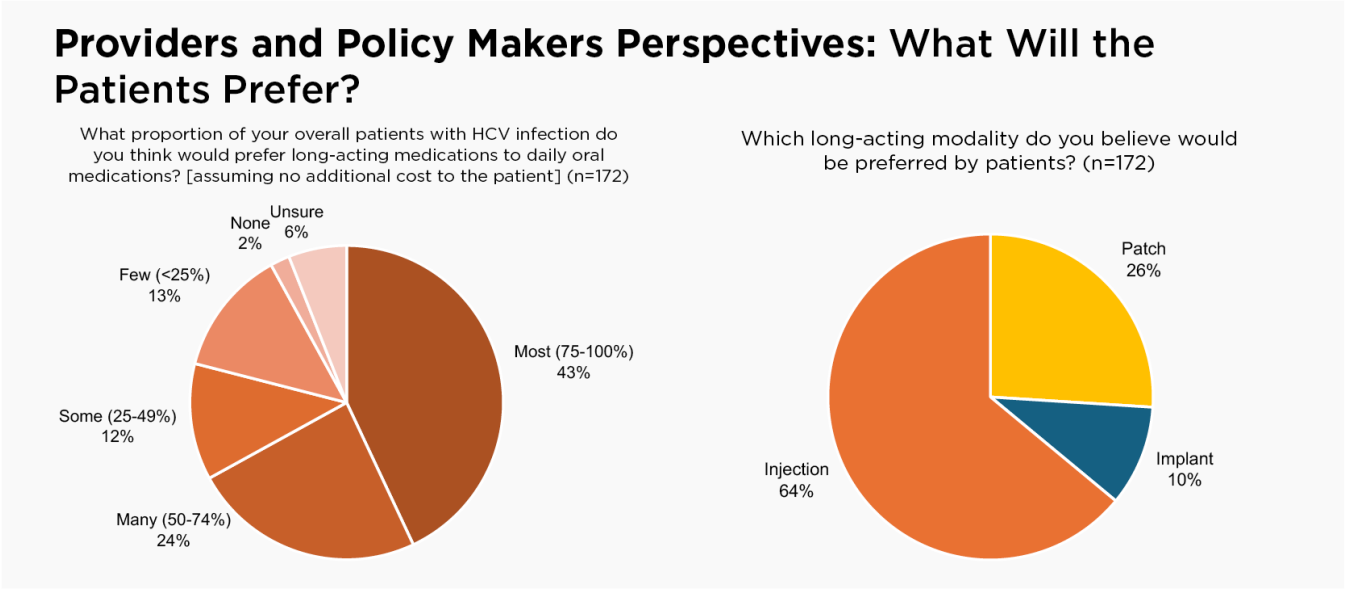

Figure 8

Top Factors Influencing Long-Acting HCV Treatment Preferences

Narrowing down to healthcare providers, when asked about the top factors influencing their preference for long-acting HCV treatment, 88% chose "improved patient satisfaction or quality of life", 87% chose "improved adherence and treatment success", 84% chose "improved efficacy" and 80% chose "fewer side effects". In terms of end-users (or patient) characteristics that would influence their decision to prescribe a long-acting HCV cure, 76% of healthcare providers chose the "patient has failed previous HCV treatment", 75% chose the "patient does not routinely engage in medical care", and 70% chose the "patient is HIV coinfected, is incarcerated, plus social determinants of health."

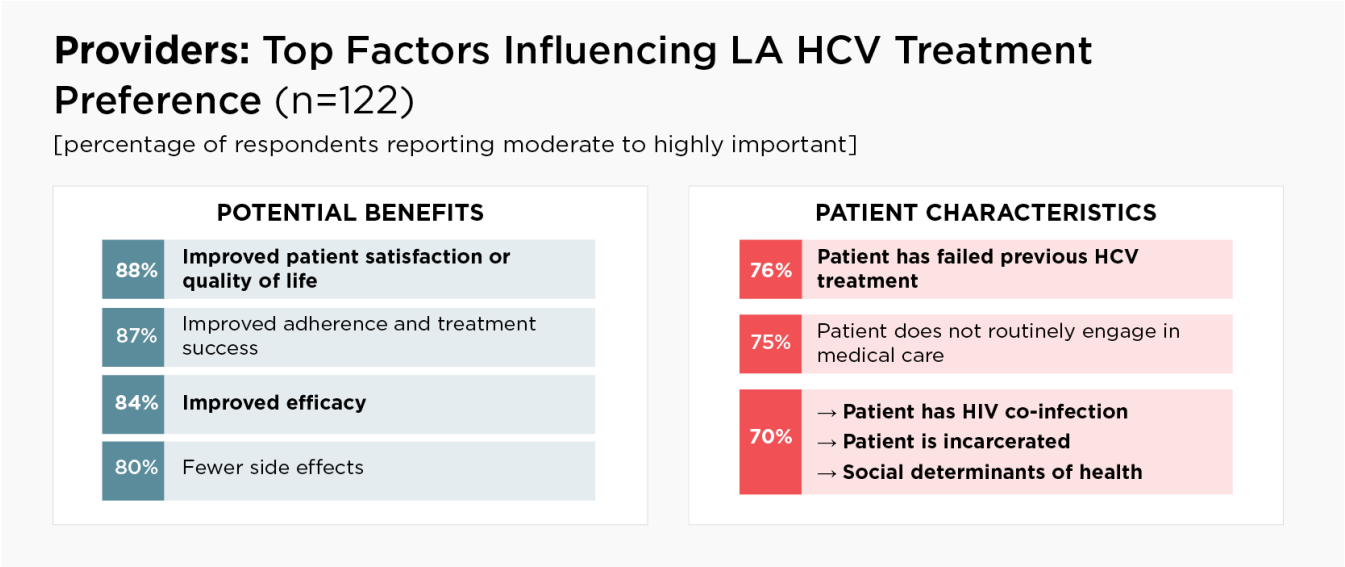

Figure 9

Policy Makers' Top Factors Influencing Long-Acting HCV Cure Introduction

Among the top factors that would influence the adoption of a long-acting HCV cure, 86% and 84% of the 50 policy maker respondents chose "lower cost to the health system and improved patient satisfactions or quality of life" and "improved adherence, lower cost to patients and decreased HCV spread in the community," respectively. In terms of greatest obstacles to the introduction of this innovative therapy, 70% of policy makers chose "cost of the drugs", while 46% indicated that the "approval process and concerns over side effects or drug-drug interactions" would be the greatest obstacles. Additional obstacles included "patient preferences or perceptions" (40%) and "storage and distribution requirements" (38%).

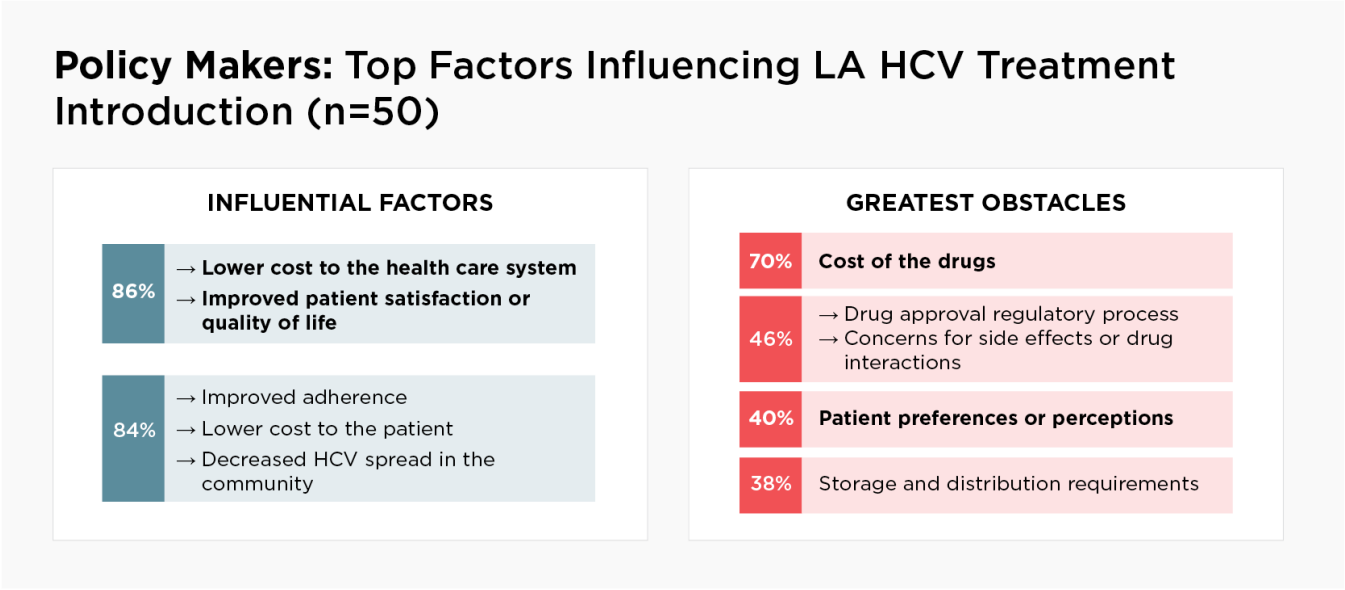

Figure 10

Based on the surveys, despite overall high enthusiasm for a potential single injectable HCV cure, numerous barriers currently stand in the way of this innovative therapy. These barriers need to be addressed for long-acting G/P to be accessible to everyone who needs it.

These include:

- *The multi-step process involved in HCV diagnosis,* despite WHO recommendations on a simplified approach to HCV diagnosis, including the use of self-testing, reflex testing, and PoC ribonucleic acid (RNA) assays in addition to laboratory-based RNA assays among priority populations at decentralized facilities in primary care settings such as harm reduction sites and prisons to ensure same day diagnosis,[17] it still takes between one to eight weeks for people to obtain HCV confirmatory tests results in most LMICs. This requires multiple visits to — sometimes different — health facilities just to receive a diagnosis. Given that HCV can be asymptomatic for one to two decades, a great number of people simply give up in the process and are lost to follow-up.
- *Highly centralized HCV diagnostic and treatment services*, in the vast majority of LMICs, while HCV screening is available in decentralized settings, confirmatory testing (in the form of PCR or RNA test) and treatment services are in centralized health facilities with specialists, requiring people to travel long distances for a diagnosis and for treatment

initiation. Aside from the time investment, transportation costs to these facilities also pose a barrier. Due to conflicting priorities in the lives of people at higher risk of HCV, namely, people who inject drugs, people in carceral settings, and people who are unstably housed, highly centralized HCV care services are a disservice.

- *High cost of DAAs despite efforts to lower prices*, in May of 2023, the Clinton Health Access Initiative (CHAI) and The Hepatitis Fund concluded an agreement with Viatris and Hetero, the leading World Health Organization (WHO) prequalified generic manufacturers of DAAs to reduce the price of sofosbuvir/daclatasvir (SOF/DAC) — the most affordable DAA that cures HCV within 12 weeks. Under this agreement, Viatris and Hetero committed to reducing the price of SOF/DAC to US$60 Ex Works per treatment course in all LMICs.[18] Yet, the cost of DAAs remains prohibitively high in many countries. For example, people with HCV in Vietnam, pay nearly US$1000 for SOF/DAC, and people in the Philippines and Kyrgyzstan pay US$800 and US$874, respectively.[19] In addition to SOF/DAC, other DAAs recommended by WHO to be co-administered with SOF to cure HCV include Velpatasvir and Ravidasvir. Ensuring the approval and availability of all these different treatments in countries is critical as this will create competition in the DAAs market, resulting in lower prices.

Barriers to HCV Care Identified through the End-User Survey

Number of Visits Needed to Diagnose and Treat HCV	
2-3	47 (27%)
4-5	55 (32%)
6-7	27 (16%)
8-10	5 (3%)
10+	3 (2%)
Depends on risk factors	32 (19%)

Timeline to DAA Treatment Initiation Following a Positive HCV Diagnosis	
Same day	16 (9%)
Within one week	55 (32%)
Within one month	61 (35%)
Within one year	23 (13%)
Most do not initiate	17 (10%)

Patient Out-of-Pocket Costs	
$0	50 (29%)
<100 USD equivalent	21 (12%)
$101-300 USD equivalent	21 (12%)
$301-1,000 USD equivalent	38 (22%)
>$1,001 USD equvalent	19 (11%)
Unsure	22 (13%)

Figure 11

- *Cumbersome treatment monitoring procedures*, according to the updated WHO guidelines, pangenotypic DAAs which cure all HCV genotypes are recommended, and the only required tests following a positive HCV RNA test are: a liver function test to determine if liver damage has occurred, a comorbidities test (including HIV and Hepatitis B virus), a pregnancy test (as exiting treatments have not been approved for use during pregnancy and breastfeeding), and an assessment of potential drug-drug interactions. This is followed by a sustained virologic response test 12 weeks after treatment completion to confirm cure.[20] Additional tests such as genotype testing before treatment initiation and viral load testing during treatment, both of which are costly and unnecessary, are sometimes required either by health insurance providers or healthcare providers. These additional tests significantly complicate and increase diagnosis and treatment costs often paid out-of-pocket by most people in most LMICs.

- *Limited awareness about HCV among healthcare providers and the wider population,* general awareness about HCV is limited, resulting in low demand and uptake of screening services. Coupled with the fact that clinical symptoms of HCV infection sometimes appear after one to two decades of chronic infection when advanced liver disease has occurred, many people show up for care very late — having potentially infected other people.

Paving the Way for Access to a Long-Acting HCV Cure

While long-acting G/P is still in the preclinical research and development stage, ensuring timely and equitable access to this promising single injectable HCV cure in LMICs once it is developed and proven to be safe and efficacious requires partnerships and continuous engagement among all stakeholders, including governments and policy makers; healthcare providers; drug and diagnostic device manufacturers; civil society and community members; funders; and researchers to address the above barriers through:

- *Full adoption of WHO recommendations on simplification of diagnosis by countries,* including the use of reflex testing and PoC RNA assays in addition to laboratory-based RNA assays — especially among marginalized populations, such as people who inject drugs, and hard-to-reach communities with limited access to healthcare and high rates of loss to follow-up; decentralization of HCV testing and treatment to lower-level health facilities such as primary care settings;[21] HCV care integration with other services, such as harm reduction and other evidence-based measures for people who inject drugs and HIV services; and task-sharing to ensure the delivery of care and treatment by nonspecialists and nurses.[22] This will contribute towards finding the missing millions of people with HCV, result in increased demand for DAAs, and create a certain and sustainable market for generic manufacturers who are pulling out of the HCV treatment market due to low demand for DAAs.[23]
- *Elimination of cumbersome treatment monitoring procedures* such as genotype testing and viral load testing during treatment, and the use of pan-genotypic DAAs.
- *Awareness raising in healthcare settings*, given that unsafe injection practices in health settings, unscreened blood transfusions, and inadequate sterilization of medical equipment constitute the leading modes of HCV acquisition in LMICs, there is dire need to invest in robust comprehensive prevention measures including improved safety of medical injections and procedures, and continuous training for healthcare providers in LMICs. Continuous training should also include HCV diagnosis, treatment, and care among nonspecialists such as nurses to broaden the pool of providers who can diagnose, treat, and manage HCV in LMICs.
- *Strong political leadership in viral hepatitis* and increased domestic and global financial resource allocation for its elimination, including catalytic funding for diagnosis, prevention, awareness raising, and treatment are all needed. This political leadership and prioritization of viral hepatitis elimination is also needed to seize available opportunities to make use of economies of scale to access low-cost diagnostics and DAAs, including the adoption of harmonized and simplified diagnosis and treatment guidelines for children and adolescents down to three years.[24]

- *Ministries and departments of health need to address the barriers faced by populations most affected and at higher risk of HCV,* provide and fund harm reduction programs, strengthen community and civil society engagement, work with affected populations and civil society in the viral hepatitis response, and support community engagement, advocacy, and peer-led service delivery.[25]
- *Research institutions need to advance the HCV vaccine research agenda*, and current investments in global health and equitable access to long-acting technologies need to be scaled-up.
- *Universal health coverage*, now more than ever before, governments need to recognize that health is a precondition for, and an outcome and indicator of, the social, economic and environmental dimensions of sustainable development, and fully invest in universal health coverage. This will ensure that everyone has access to the full range of quality health services they need — from health promotion to prevention, treatment, rehabilitation, and even palliative care across the course of life — when and where they need them, without financial hardship. Without universal health coverage people will continue to use up their life savings, sell assets, or borrow and be pushed into poverty as they pay for needed health services out of pocket — destroying their futures and often those of their children.[26]

The abrupt freeze in USAID, PEPFAR, and GAVI programs funding that were already allocated through Congressional appropriation without notice should serve as a wakeup call, particularly to governments in countries that were heavily reliant on foreign aid for healthcare, to reconsider their national healthcare strategies. Now more than ever before, the need for additional initiatives aimed at ensuring global equitable access to healthcare, including innovative long-acting health technologies cannot be overemphasized. In the case of the African region, full implementation of the Abuja Declaration[27] in which African governments set a target of allocating at least 15% of their national budgets to improve healthcare would be a great starting point.

Endnotes

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