WHO HAS ACCESS TO HEPATITIS C TESTING? LIBERATE OUR DIAGNOSTICS!

INTRODUCTION

Accurate, high-quality data on the hepatitis C virus (HCV) continues to be a struggle for countries that are scaling up testing services and linking people to treatment and care, as part of implementing their national hepatitis plans. There is very little in-country information about the availability and pricing of HCV diagnostics and how licensing and pricing barriers may affect how governments determine coverage of testing services. Crowd-sourced data from the free, public database, mapCrowd, has been collected between 9 April and 30 October, 2019 from 44 countries, provided by 60 mapCrowd contributors.

To supplement their contributions, we conducted a review of the scientific literature and managed to gather updated data related to the availability and pricing in public and private sectors of the following HCV tests:

- Lab-based enzyme immunoassays (EIAs)
- Antibody rapid diagnostics tests (RDTs)
- Dried Blood Spot (DBS) testing
- Quantitative and qualitative HCV viral load polymerase chain reaction (PCR)
- Nucleic acid testing (NAT) DNA/RNA platforms
- Core antigen
- Genotyping
- FibroScan liver disease staging tests

Based on this data, we summarize key findings, noting that in-country contributors provide project-specific data and may not provide a comprehensive view of the national HCV diagnostics landscape.[1]

More information about HCV diagnostics is available in the Activist Guide to Hepatitis C Virus Diagnostics, available at: http://www.treatmentactiongroup.org/content/activist-guide-hepatitis-c-virus-diagnostics-10-2019

The issue brief aims to provide supplemental evidence for advocates on HCV diagnostics availability and pricing, which could help inform national and regional campaigns

mapCrowd

THE MAJORITY OF PEOPLE ARE UNDIAGNOSED AND UNTREATED

Generic versions of direct-acting antivirals (DAAs), which effectively cure a person with hepatitis C in 12 weeks, have demonstrated bioequivalent safety and efficacy as branded medications.[2] Generic competition has reduced prices to less than US$100[3], even much lower in Egypt, India, and Pakistan. Hepatitis C is becoming more visible, with an estimated 111 countries creating viral hepatitis plans.[4]

Availability of affordable DAAs is still a challenge for upper middle-income countries, such as Algeria, Brazil, and China, which are excluded from Gilead's voluntary licenses. Moreover, even countries that fall under the voluntary license are met with registration delays due to lengthy regulatory processes, such as national authorities requiring local bioequivalence studies. Stalling the registration processes has been a delay tactic used by Gilead and sub-licensees to control the market block generic competition in countries. Without a clear path to increasing affordable treatment access, and despite creating national plans, most governments show a trend of lacking political will, limiting any new funding for implementing HCV responses, and failing to remove treatment and diagnostics restrictions.

Limited coverage of diagnostics tests by public health systems in low- and middle-income countries is another trend, in which exorbitant out-of-pocket costs prevent patients from completing the steps necessary to confirm diagnosis, start, and complete treatment. Diagnostics costs have contributed to the majority of people living with chronic HCV being left undiagnosed and untreated. Less than 20 percent of people living with HCV have been diagnosed worldwide; of those, less than 5 percent are people living in low- and middle-income countries.[5] According to some modeling studies[6], eliminating hepatitis C by 2030, will depend on the WHO target to diagnose 90 percent of people living with HCV infection. In other words, **benefits from comprehensive harm reduction services and universal access to generic treatment won't be realized, unless countries scale up diagnoses.**

SIMPLIFYING AND DECENTRALIZING DIAGNOSTICS

The 2018 WHO HCV Guidelines recommended simplifying and decentralizing the steps needed to confirm a person's HCV diagnosis and start on early treatment.[7] It will be several years before there are simpler, high quality, inexpensive, rapid tests on the market that can confirm diagnosis in resource-limited settings and at community sites where people most disproportionately affected by HCV receive their services, such as pharmacies, harm reduction, sexual health clinics. Until then, there are several types of existing tests and a variety of models of care to simplify and decentralize the testing pathway. [8]

Diagnosing hepatitis C is a two-step process requiring antibody screening and virological (also known as confirmatory) testing. There are other tests used to determine the hepatitis C virus subtype (known as genotype) and the extent of liver damage that a person has—these tests inform the optimal treatment regimen and duration of treatment for a person. At the end of treatment, usually 12 or 24 weeks, a test to confirm sustained virological response (SVR), or the curative rate, and taken as a viral load test should be offered.

Table 1. Key HCV Diagnostics[9]

Screening: HCV antibody test	- Determines whether a person who is apparently healthy and without any symptoms might have an infection or a disease - Looks for HCV-fighting antibodies that the immune system produces - Two methods: either a **rapid diagnostic test** (RDT) that uses oral fluid (saliva) or blood from the veins or from a fingerstick, or a lab-based **enzyme immunoassay** (EIA) that uses blood or plasma samples.

Virological/ confirmatory: Viral load (qualitative or quantitative), or core antigen test	- Confirms—or rules out—whether someone has hepatitis C disease
	- Looks directly for the virus
	- Two types of tests: viral load (called RNA or nucleic acid test, NAT) or core antigen
	- **Viral load tests** have 2 types:
	  - **Qualitative** checks whether there is HCV in the bloodstream. The test result is either positive (virus is detectable) or negative (virus is undetectable).
	  - **Quantitative** measures the amount of HCV in the bloodstream. These tests, while not available in every country, are used during HCV treatment to see if it is working.
	- **Core antigen** is another type of virological test that detects HCV in the bloodstream earlier than viral antibody tests—two weeks after infection.
	- Core antigen is simpler and should be less expensive than viral load testing.
	- Core antigen is only available in large lab settings (hospitals) and less sensitive, meaning it might miss some infections.

Genotype test	- With 6 known subtypes of the hepatitis C virus, genotype testing determines which genotype a person has and to help doctors prescribe optimal treatment regimen and treatment duration. - 2018 WHO HCV Guidelines recommend eliminating genotype tests if pangenotyic DAAs are used and available in countries.[10]

Liver disease (fibrosis) staging test	- Liver disease staging tests are important to know the type and length of treatment for a person.
	- Liver biopsies should no longer be used.
	- **Non-invasive liver disease staging tests** are recommended:
	  - **APRI or FIB-4** liver function tests, which are less expensive lab-based tests, are recommended for resource-limited settings
	  - **FibroScan** is a non-invasive, ultrasound imaging test that looks at liver stiffness using sound waves. FibroScan is more expensive and not as widely available in low- and middle-income countries, yet the examination can take 5 minutes and return results immediately.

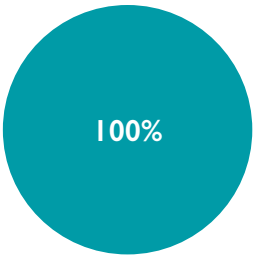
Confirmation of cure/ SVR test: Viral load[11]	- A viral load test is recommended to confirm that a person achieved SVR, or the curative rate, after completing treatment at 12, or 24 weeks (for patients with cirrhosis). - There is not enough data to know whether core antigen tests can confirm SVR, therefore viral load tests are recommended. - Patients who did not achieve SVR would be considered as failing treatment and would be assessed and counseled for other treatment regimens, or other medical interventions in cases of liver failure. - Follow up testing and counselling is recommended for people who are at risk of reinfection or who have advanced liver disease to monitor for liver cancer.

WHAT HEPATITIS C DIAGNOSTICS ARE AVAILABLE IN COUNTRIES?

The mapCrowd database has crowd-sourced information in at least one section of questions for an estimated 111 countries. However, information on the availability of HCV tests varies, depending on the familiarity of the types of diagnostics, how easy to obtain the data, and at what stage countries are in implementing their HCV responses. The pricing data reflects the prices that governments agencies pay for diagnostics, not patients' out-of-pocket costs. Yet how much governments pay per test affects decisions on which tests to cover by the public health system or whether there are waiting lists before a person can start the necessary steps to diagnosis.

Of 111 countries, between 34 and 45 percent of the countries have data on the availability of HCV antibody testing (RDT and EIA, respectively).

mapCrowd questions: Is laboratory-based HCV antibody testing available? Price in public market and in private market?

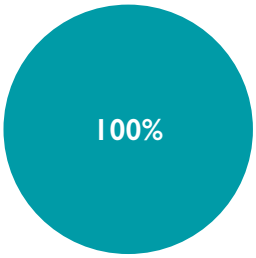


Total: 50 country responses

Yes: 50[12]

And 40 countries where at least one price has been filled-in and updated, data ranges from the minimum public sector price at US$0.99 (Cambodia) to the maximum at US$28.50 (United States) per test with an average price at US$10.

mapCrowd questions: Is HCV antibody rapid testing available? Price in public market and in private market?



Total: 38 country responses

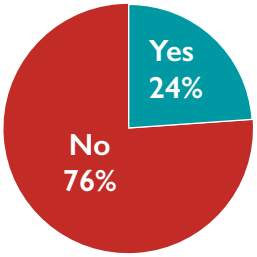
No: 1 country (Bulgaria)

Yes: 37[13]

And 24 countries where at least on price has been filled-in, data ranges from the minimum public sector price at US$0.23 (Pakistan) to the maximum at US$27 (Germany) per test with an average price at US$8.7.

Dried blood spot testing is a method of blood sample collection and may not yet be validated and approved for HCV antibody or off-label viral load testing in countries. Therefore, there were only 5 countries with available DBS testing.

mapCrowd questions:
Is dried blood spot testing[14] available? Price in public market and in private market?



Total: 21 country responses

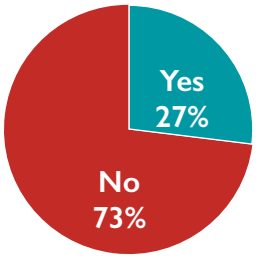
No: 16 countriers[15]

Yes: 5[16]

There was no mapCrowd information on DBS prices.

Information on viral load testing platforms was more limited, with only 13.5 percent of countries having available data. Both qualitative and quantitative viral load (NAT/PCR) platforms are captured in the responses.

mapCrowd questions: Are NAT/PCR platforms available for HCV testing?



Total: 15 country responses

No: 4 countries[17]

Yes 11 countries[18]

The different types of NAT/PCR platforms available in the countries were collected in mapCrowd or from the literature review, however, the price per test for each specific platform was not detailed. Rather, the price per viral load test (qualitative and quantitative), per GeneXpert cartridge, and per reagent were taken as average estimates. Public and private sector prices were compared, if data was provided.

For a lower-income country, such as Cambodia, the viral load testing platform may be donated for use in the public sector. Yet the sustainability of national programs is put to the test if maintenance, cartridges (US$18) and reagents (US$95) must be furnished by public health budgets. Roche and Cepheid may have the most commonly available viral load platforms in low- and middle-income countries. Their platforms also diagnose other diseases, such as HIV, yet they may be licensed exclusively to perform disease-specific tests. The price negotiated for an HIV test may not be offered at the same price for HCV, even though they are both used on the same diagnostic platform.

Cepheid's GeneXpert can diagnose HBV, TB and sexually transmitted infections. GeneXpert is used in 130 countries for HIV and TB,[19] and concessional high burden developing countries (HBDC) pricing for public sector programs, based on the MTB/RIF tuberculosis cartridge, was negotiated in 2012 at US$9.98 if sales volumes met projections of over 4.7 million tests annually.[20] For the HCV cartridge, the price has been lowered to US$14.90 per cartridge for all lower-income countries[21], yet government agencies in middle-income countries may be paying more. Table 2 shows how country procurement officials may have negotiated lower prices depending on the size of the national epidemic and whether they could combine the cartridges with those for other diseases (i.e., bundled volumes). Launched in 2019, the "Time for US$5" campaign[22] calls on Cepheid to reduce the price of GeneXpert MTB/RIF tuberculosis cartridges to a target price of US$5, including maintenance and service costs, and with the possibility to expand the target price to HIV, HCV, and STI cartridges.

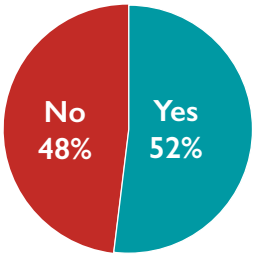
Furthermore, neighbors or countries with similar economic statuses may be paying more to confirm diagnoses. Government agencies in Rwanda, classified as a middle-income country, pay a significantly different price than Uganda, classified as a low-income country (US$87 vs. US$131, respectively) for viral load tests (see Table 2).

Table 2. Availability and comparative prices (paid by payors) of NAT/PCR platform tests in select countries, in (USD)[23]

Country	Available NAT/PCR platforms	Per test	Per cartridge (relates to GeneXpert only)	Per reagent
Cambodia	CAP/CTM or Cobas 4800/6800/8800 (Roche) m2000 (Abbott) GeneXpert (Cepheid)	30 (public sector)	18 (public sector)	95 (public sector) 60 (private sector)
Egypt	CAP/CTM or Cobas 4800/6800/8800 (Roche)	22 (Qual., public sector) 56 (Quant., private sector)	Not applicable	No data
Iran	CAP/CTM or Cobas 4800/6800/8800 (Roche) GeneXpert (Cepheid)	9 (Qual., public sector) 38 (Quant., public sector) 40 (Qual., private sector) 93 (Quant., private sector)	38 (public sector) 92 (private sector)	No data
Lebanon	CAP/CTM or Cobas 4800/6800/8800 (Roche) m2000 (Abbott) Panther (Hologic) GeneXpert (Cepheid)	179 (Qual., public sector) 132 (Quant., public sector) 198 (Quant., private sector)	No data	No data
Nigeria	CAP/CTM or Cobas 4800/6800/8800 (Roche) m2000 (Abbott) GeneXpert (Cepheid)	47 (Qual., public sector) 47 (Quant., public sector) 74 (Qual., private sector) 47 (Quant., public sector)	No data	No data
Pakistan	CAP/CTM or Cobas 4800/6800/8800 (Roche) m2000 (Abbott) GeneXpert (Cepheid)	11 (Qual., public sector) 21-57 (Qual., private sector) 59-112 (Quant., private sector)	13 (public sector)	No data
Philippines	GeneXpert (Cepheid)	130 (Qual., public sector) 142 (Quant., private sector)	No data	No data
Rwanda	CAP/CTM or Cobas 4800/6800/8800 (Roche) m2000 (Abbott) GeneXpert (Cepheid)	99 (public sector) 87 (Qual., private sector) 87 (Quant., private sector)	No data	49 (public sector)
South Africa	GeneXpert (Cepheid)	93 (Quant., public sector) 171 (Quant., private sector)	No data	No data
Uganda	GeneXpert (Cepheid)	16 (Qual., private sector) 131 (Quant., private sector)	No data	No data
United States	CAP/CTM or Cobas 4800/6800/8800 (Roche) m2000 (Abbott) Panther (Hologic)	79 (Qual., public sector) 65 (Quant., public sector) 329 (Qual., private sector) 329 (Quant., private sector)	Not applicable, Cepheid's GeneXpert not FDA-approved	No data

Information on HCV core antigen testing was available in 24 percent of countries having available data.

mapCrowd questions: Is HCV core antigen testing available? Price in public market and in private market?



Total: 27 country responses

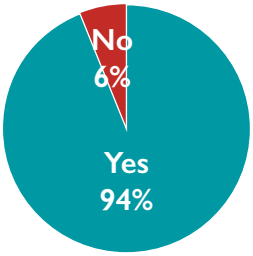
No: 13 countries[24]

Yes: 14 countries[25]

There is a lack of pricing transparency for core antigen, and limited mapCrowd data on price per core antigen test. Cameroon Yet other sources[26] show a price range of US$25-30 per HCV core antigen test, using the Abbott ARCHITECT platform.

Genotyping has been present throughout the pegylated-interferon era and continues to be used as more tolerable, oral DAAs are replacing the older treatment; 42.3 percent of countries have available data.

mapCrowd questions: Is HCV genotyping available? Price in public market and in private market?



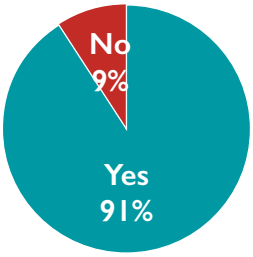
Total: 47 country responses

No: 3 countries[27]

Yes: 44 countries[28]

Data ranges from the minimum public sector price at US$17 (France) to the maximum at US$473 (United States) per test.

mapCrowd questions: Is liver fibrosis staging through Fibroscan available? Price in public market and in private market?



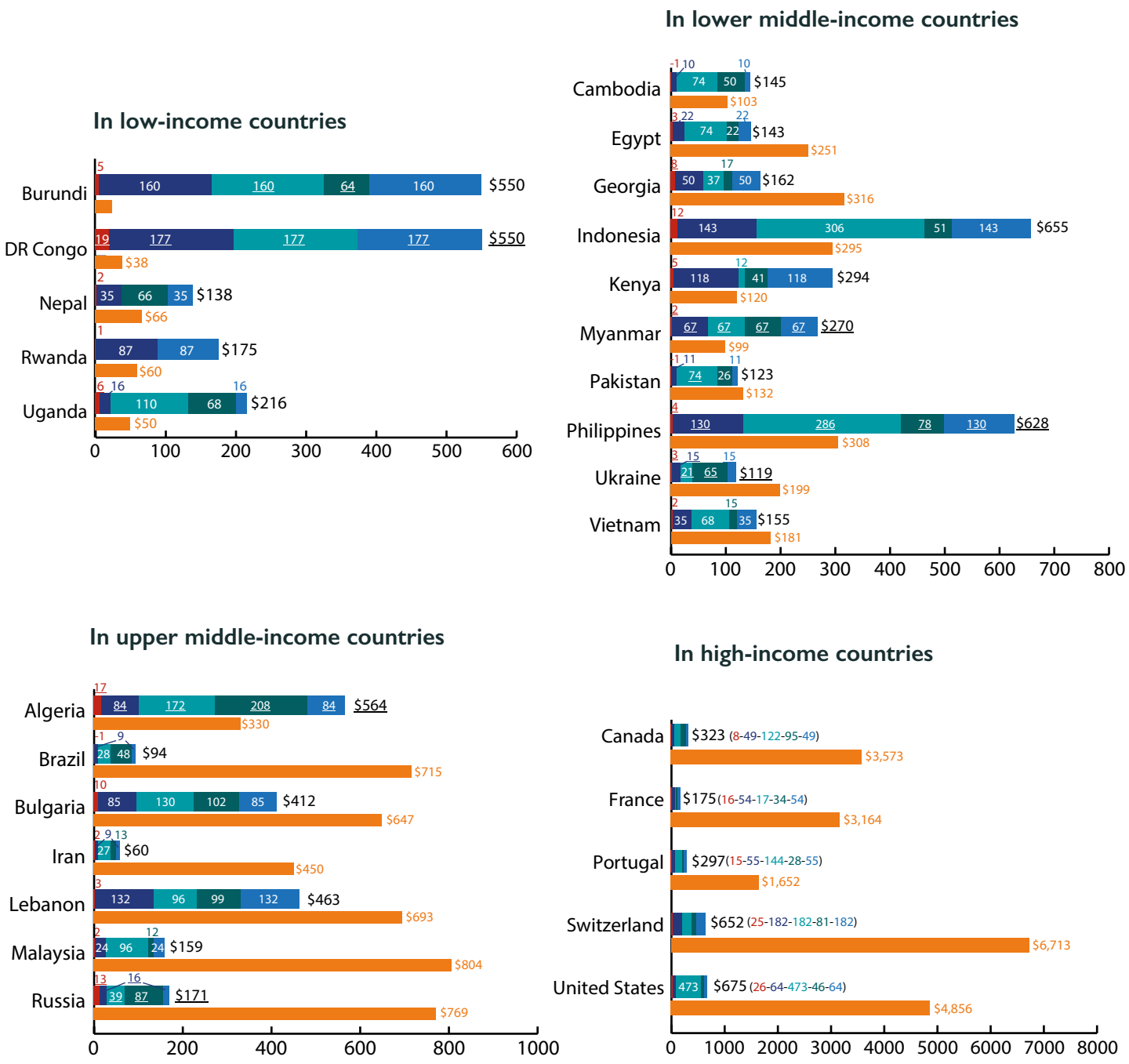
Total: 44 country responses

No: 4 countries[29]

Yes: 40 countries[30]

Data ranges from the minimum public sector price at US$12 (Malaysia) to the maximum at US$102 (United States) per test.

Figure 1. HCV diagnostics prices in select countries, in (USD), compared to monthly GNI per capita (%)



PRICE COMPARISON OF KEY HCV DIAGNOSTICS IN SELECT COUNTRIES

Based on mapCrowd data, if the key HCV diagnostics in Table 1 were made available in 27 select countries, we can compare prices and estimate the total amount needed to cover the diagnostics pathway. We compared the prices of 5 key tests: antibody, virological, genotype, liver disease staging, and SVR tests. We privileged the complete set of prices in the public sector when available. For some countries (Algeria, Myanmar, DR Congo, Philippines, Russia, and Ukraine), prices were only available in the private sectors. For this comparison, we chose the least expensive antibody test (laboratory-based EIA antibody testing or rapid diagnostic tests) and the least expensive viral load test (it could be qualitative or quantitative).

For the comparison, we assume countries are not using pangenotypic DAAs, therefore genotype testing is included. FibroScan is costlier and not as widely used in low- and middle-income countries, compared with average APRI or FIB-4 lab-based tests (ranging from US$0.83 to US$3.70).[31] However, we chose to include FibroScan, as a non-invasive liver disease staging test because it can be used as a portable, point-of-care option for use in mobile clinics, in remote settings, operated by trained community healthcare workers, and not reliant on laboratory technicians. In Rwanda, both genotyping test and Fibroscan are not available. In Nepal, genotyping test is not available and in DR Congo, FibroScan is not available. The total test packages do not include the cost of treatment, human resources, staff training, and operational costs for testing sites.

Figure 1 provides a glimpse at the exorbitantly priced HCV diagnostics, particularly for public health sectors in low- and middle-income countries, when compared with monthly gross national income (GNI) per capita. Diagnostics prices may not be a barrier in upper middle-income and high-income countries, such as Brazil, Iran, Russia, and Malaysia.

Yet in many low- and middle-income countries the total costs for a person to confirm diagnosis can amount to or exceed one month's income.

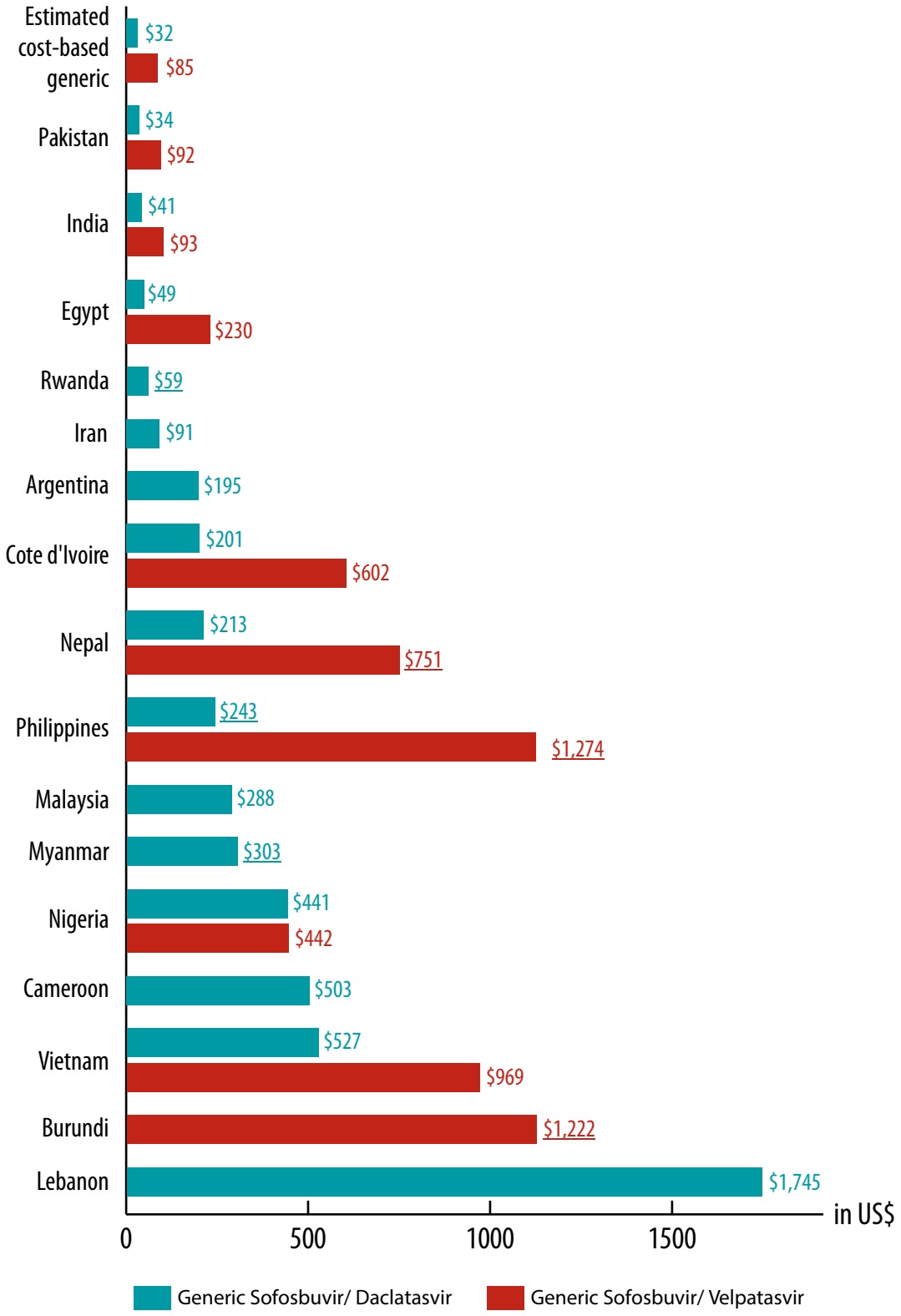
The total costs of the 5 tests vary across countries: of the 27 selected countries, the least expensive package is available in Iran at US$60[32] ; the same package costs 11 times more in the United States at US$675. Across all countries, HCV antibody tests remain the least expensive part of the testing package. By comparison, genotyping and FibroScan tests represent 50 percent or more of the total cost of this package in 18 of the 24 selected countries.

The prices reflect those paid by government agencies, yet public health systems may not fully cover the cost and may require patients to pay out-of-pocket. Surveyed healthcare workers and community members in India (Delhi, Manipur) and Morocco strongly agreed that out-of-pocket costs were barriers to confirming diagnosis.[33] Out-of-pocket expenses do not reflect transportation, lost wages, childcare, and other costs associated with attending clinic visits.

According to mapCrowd data, in Pakistan's public health sector, antibody and viral load tests are free of charge for patients; they do not pay out-of-pocket. In Egypt's public health sector, civil servants are 100% covered by the national program. For people who cannot pay, they can choose to stay in the public health system, but they may wait longer to be tested than in the private system. In Brazil, the antibody and viral load tests are generally free of charge but there are long wait times. In Iran, the quantitative viral load on PCR platforms, genotyping, and Fibroscan are not covered by public health insurance, and patients do need to pay out-of-pocket.

In most high-income countries, such as France, all the diagnostics are covered by the social security system and costs are not barriers to diagnosis.

Figure 2. Price comparison of 12-week course of generic pangenotypic DAAs in (USD)



Price in the private sector

PRICE COMPARISON OF PANGENOTYPIC DAAS IN SELECT COUNTRIES

Scaling up diagnostics requires a reliable, affordable, high quality supply of DAAs—pangenotypic DAAs are most optimal. People who are diagnosed need to have a clear path to starting on treatment as early as possible. There are many strategies for affordable treatment access that countries can use, including volume-based price negotiations, through companies' voluntary licenses, government use or compulsory licenses, and several types of legal challenges, such as opposing the patent on a medicine or biomedical technology. Inclusion in originator companies' voluntary licenses is often promoted as guaranteeing lower medicines prices. Yet in the mapCrowd database, the lowest prices are found in countries where local generic manufacturing exists (e.g., Egypt, India, Iran, and Pakistan) and/or countries which have challenged the patents on sofosbuvir, invoked a compulsory license or used other legal strategies to protect generic competition (e.g., Argentina, Egypt, and Malaysia).

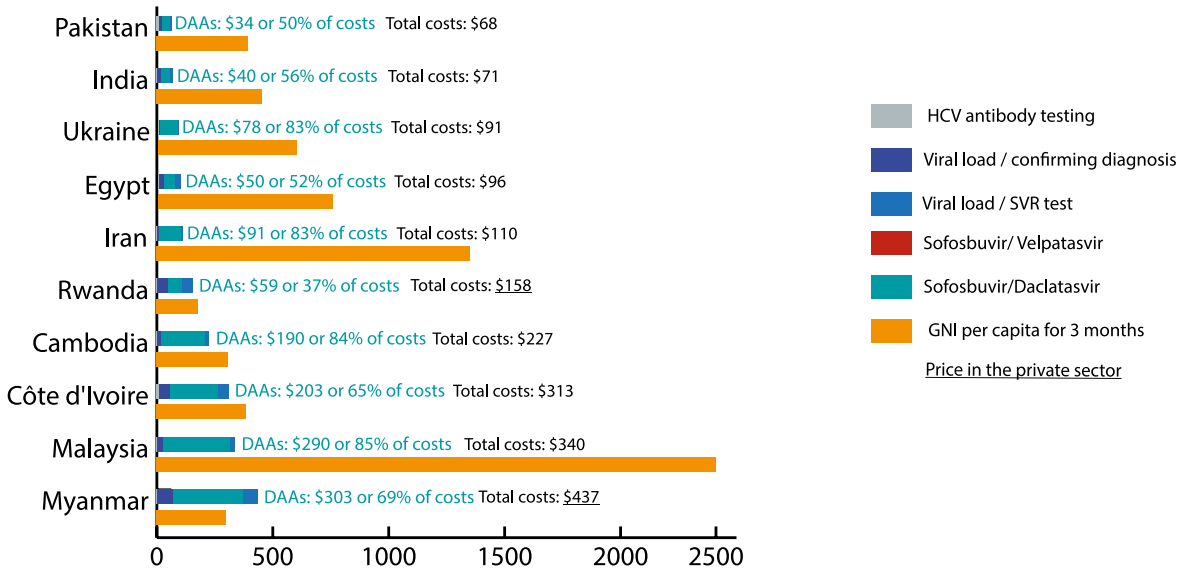
When comparing generic sofosbuvir/velpatasvir and sofosbuvir/daclatasvir, sofosbuvir/daclatasvir remains the cheapest pangenotypic DAAs available worldwide, both in fixed dose combination (available in at least 10 countries), or by adding one sofosbuvir pill to one daclatasvir pill.[34] Generic sofosbuvir/velpatasvir, licensed or sub-licensed to manufacturers under Gilead's voluntary license, is consistently more expensive than generic combinations of sofosbuvir/daclatasvir when both are available in a country. MapCrowd contributors provided actual prices in select countries for as low as US$34 and US$92 for a 12-week course of sofosbuvir/daclatasvir and sofosbuvir/velpatasvir treatment, respectively (see Figure 2). These prices get closer and closer to University of Liverpool's projections of US$32 for a 12-week course of sofosbuvir/daclatasvir and US$85 for a 12-week course of sofosbuvir/velpatasvir.[35]

Generic sofosbuvir/daclatasvir is found in countries included in the Medicines Patent Pool's voluntary license: Burundi (no data yet), Cameroon, Côte d'Ivoire, India, Myanmar, Nepal, Nigeria, Pakistan, Philippines, Rwanda, and Vietnam.

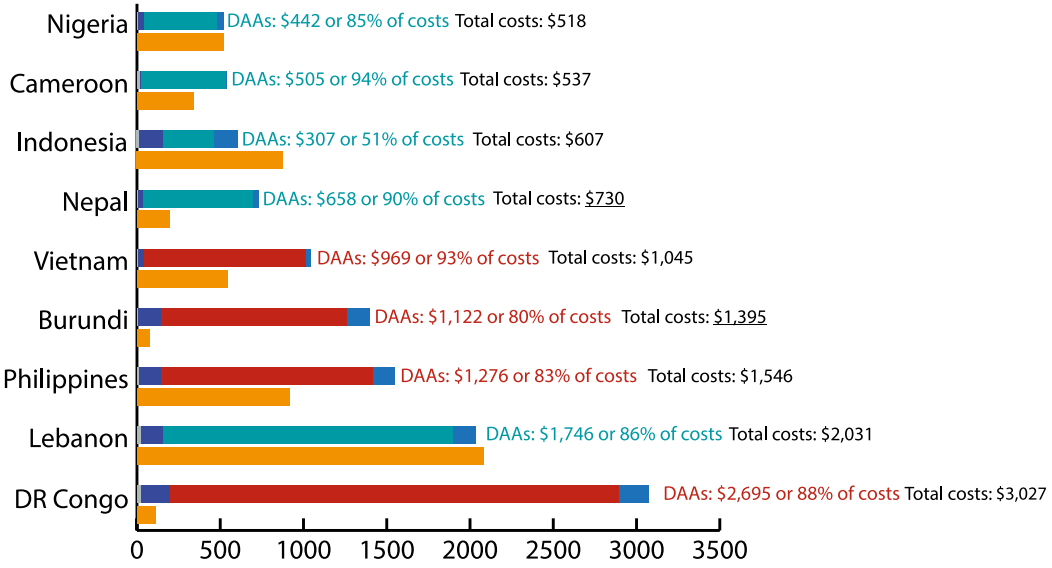
Generic sofosbuvir/velpatasvir is found in countries included in Gilead's voluntary license: Burundi, Cameroon, Côte d'Ivoire, India, Malaysia, Nepal, Nigeria, Pakistan, Philippines, Rwanda, and Vietnam.

Figure 3. Test-and-treat costs among countries (in USD)

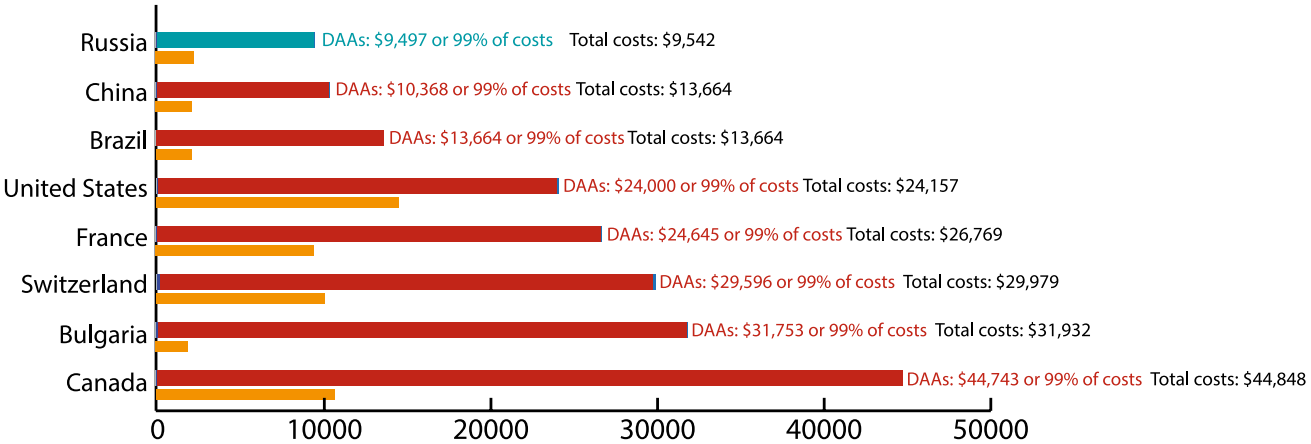
Countries where test-and-treat costs < US$500



Countries where test-and-treat costs between > US$500 and < US$4,000



Countries where test-and-treat costs >US$9,000



PRICE COMPARISON OF TEST-AND-TREAT PROGRAMS IN SELECT COUNTRIES

Despite the plummeting prices of generic pangenotypic DAAs, most countries' HCV responses are anemic, lacking political will, government action, and new, dedicated funding. **Misassumptions about the diagnostics and treatment costs could be behind governments' stalled efforts.** If testing and treatment is simplified and decentralized, in line with 2018 WHO Guidelines, there could be fewer steps and fewer costs for each patient.

We compared 29 countries, based on best available, reliable mapCrowd data. We selected the cheapest available, public sector prices per 'key HCV test' in each country, then added to one of the generic pangenotypic DAA combinations. The key HCV tests included in this analysis are: HCV antibody (EIA or RDT, whichever is the least expensive), and viral load tests for confirming diagnosis and SVR as 'proof of cure'. To simplify the diagnostics pathway, pangenotypic DAAs would be used and genotype testing could be skipped.

While core antigen testing could be less expensive than viral load, it requires a centralized lab setting, such as a hospital. Rather, point-of-care viral loads could be used until there is a WHO prequalified, high quality, point-of-care core antigen test on the market. Also, we did not include liver disease staging, such as FibroScan, as this is not the cheapest option in resource-limited settings.

The rough calculations of the costs that a country would bear to test-and-treat one person are points for discussion when comparing with long-term healthcare costs for people with advanced liver disease, liver cancer, or other serious conditions. The lowest test-and-treat costs in one income class could be used for similar countries to compare and strive towards, particularly when negotiating prices with diagnostics companies. If Rwanda's government pays less than US$200 to test-and-treat a person, this could be used as a reference to analyze costs in a country with similar economic status. There are many unique variables to Rwanda's lower costs; this includes decentralized screening and viral load testing, leveraging the HIV infrastructure, healthcare training, and financing for its HCV programs, and access to affordable DAAs.

The size of a country's HCV epidemic also factors into how tests are priced (volume-based pricing), yet this can no longer be an excuse for government apathy and inaction. Bundling HIV, HBV, HCV, TB, and STI tests to use on a multi-disease platform can help with price negotiations. It might be possible to negotiate with diagnostics companies, if unwilling to reduce prices, to contribute towards the cost of generic DAAs. Or countries could pool procurement of the tests and medicines needed for their HCV responses through the Global Drug Facility or the WAMBO procurement platform.

> *There is immense structural violence and other health systems barriers that prevent people from knowing their HCV status; the cost to test-and-treat should not be one of them.*

DIAGNOSTICS ADVOCACY DEMANDS

For governments and in-country implementing partners:

■ Simplify the diagnostics pathway and increase patients' linkage and retention in care by

- skipping:
  - antibody tests in high-prevalence populations and start with confirmatory testing
  - HCV viral load monitoring (only use at week 12 or 24 to confirm SVR)
  - genotype testing, if pangenotypic DAAs are used
- increasing access to:
  - pangenotypic DAAs
  - 'one-stop shops' that offer a range of services: HIV/HBV/HCV screening, testing, and treatment; harm reduction services; and referrals to mental health and other social services.

■ Ensure increased number of patients who are screened and tested by:

- implementing surveillance studies to understand countries' local epidemics and to better estimate what the costs would be to test-and-treat at the national level
- purchasing and integrating HCV tests on open licensed, multi-disease diagnostics platforms,
- fast-tracking regulatory requirements for in-country registration process for diagnostics
- demanding companies to divulge transparent and disaggregated pricing on the total costs of diagnostics, and/or demand all-inclusive pricing in the *ex works* price
- minimizing the layers of distribution, ensuring transparency and accountability along the global and domestic supply chains to reduce costs, and excluding taxes on public goods.

For companies:

■ Ensure transparency of:

- pricing on the total costs of diagnostics
- service/maintenance costs for instrument-based platforms.

■ Drastically reduce the prices of tests regardless of volumes and eliminate maintenance fees on point-of-care diagnostics platforms!

■ Prioritize the development of:

- dried blood spot protocols and submit them for stringent regulatory authority approval
- point-of-care RNA and HCV core antigen tests with acceptable diagnostic accuracy.

■ Include community and civil society organizations in the design, research, and implementation of diagnostics, which could address affordability, simplicity, and community-friendly testing settings.

For donors:

■ Invest and prioritize development of point-of-care RNA and HCV core antigen tests with acceptable diagnostic accuracy;

■ Promote operational research of point-of-care RNA and HCV core antigen tests as soon as possible to understand their advantages/disadvantages when used in routine settings and in resource-limited countries;

■ Include in diagnostics procurement budgets hepatitis C test instruments, reagents, and commodities;

■ Promote the sharing of multiplex platforms across different programs, and offer cross-disease instead of vertical funding;

■ Central procurement platforms, such as Global Fund's WAMBO and the Global Drug Facility, should cover diseases beyond HIV, TB, and malaria;

■ Demand transparent price information available via these platforms to improve domestic procurement negotiations;

■ Utilize good practices for procurement.

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Treatment Action Group (TAG)

TAG is an independent, activist and community-based research and policy think tank fighting for better treatment, prevention, a vaccine, and a cure for HIV, tuberculosis, and hepatitis C virus (HCV). TAG works to ensure that all people with HIV, TB, or HCV receive lifesaving treatment, care, and information. TAG is comprised of science-based treatment activists working to expand and accelerate vital research and effective community engagement with research and policy institutions. TAG catalyzes open collective action by all affected communities, scientists, and policy makers to end HIV, TB, and HCV.

For more information, please visit: www.treatmentactiongroup.org

Médecins du Monde

Present in France and in 80 countries, Médecins du Monde (MdM) is an independent international movement of activists who provide care, testify, and accompany social change. From its 388 innovative medical programs and advocacy based on facts, MdM places people who are excluded and their communities in the capacity to access health while fighting for universal access to care.

For more information, please visit: www.medecinsdumonde.org

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11. *Ibid.*

12. Countries where Laboratory based antibody testing is available: Algeria, Armenia, Australia, Azerbaijan, Bangladesh, Belgium, Brazil, Bulgaria, Burundi, Cambodia, Cameroon, Canada, China, Democratic Republic of Congo, Cote d'Ivoire, Egypt, France, Georgia, Germany, India, Indonesia, Iran, Ireland, Kenya, Korea, Rep., Lao PDR, Lebanon, Malaysia, Morocco, Myanmar, Nepal, Netherlands, Nigeria, Pakistan, Philippines, Poland, Portugal, Russia, Rwanda, South Africa, Sweden, Switzerland, Tanzania, Thailand, Tunisia, Uganda, Ukraine, United Kingdom, United States, Vietnam

13. Countries where Antibody Rapid testing is available: Algeria, Brazil, Burundi, Cameroon, China, Democratic Republic of Congo, Côte d'Ivoire, Egypt, France, Georgia, Germany, Indonesia, Iran, Kenya, Lao PDR, Lebanon, Malaysia, Morocco, Myanmar, Nepal, Nigeria, Pakistan, Philippines, Poland, Portugal, Russia, Rwanda, South Africa, Sweden, Switzerland, Tunisia, Uganda, Ukraine, United States, and Vietnam.

14. Dried blood spot (DBS) testing has been used for HIV and other testing and developed and validated for HCV in some countries. DBS uses a blood sample that is obtained by pricking the finger or heel, then preserved and dried on filter paper. DBS can be easily shipped from a remote testing site to a lab for analysis.

15. Countries where dried blood spot testing is not available: Algeria, Bulgaria, Burundi, Cameroon, Egypt, Georgia, Iran, Lebanon, Malaysia, Nigeria, Pakistan, Philippines, Poland, Rwanda, Switzerland, and Tunisia.

16. Countries where dried blood spot testing is not available: France, South Africa, Uganda, United Kingdom, and the United States.

17. Countries where NAT/PCR platforms are not available: Burundi, the Democratic Republic of Congo, Côte d'Ivoire, and Nepal.

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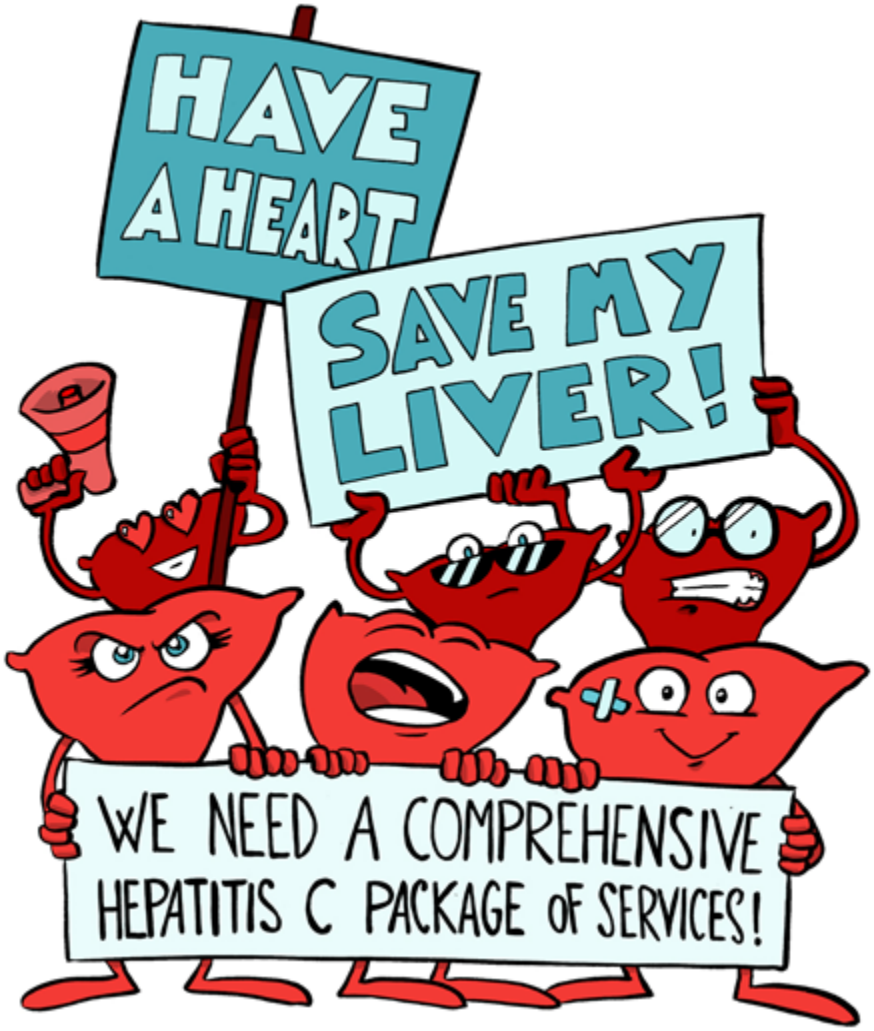

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