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IMPACT STORY: PAVING THE WAY TO HEPATITIS C ELIMINATION

The problem

Hepatitis is a blood-borne disease widely under-diagnosed and untreated, especially in low- and middle-income countries. According to the World Health Organization (WHO), 71 million people suffer from chronic hepatitis C virus (HCV) infection globally (nearly twice the number of people living with HIV). An estimated 400,000 people die each year from HCV-related liver disease, and while mortality from HIV is now declining, mortality caused by HCV is on the rise. Rates of HIV/HCV co-infection are high, because some routes of transmission are shared. People co-infected with HIV/HCV are more vulnerable because they progress faster to life-threatening disease.

New medicines offer a significant opportunity to strike back against HCV. Up until 2015, treatment of HCV was complex, with limited efficacy and severe side effects. New medicines called direct-acting antivirals (DAAs) have revolutionized HCV treatment. Combinations of these new medicines, which are generally well-tolerated and effective, can cure over 95% of HCV infections in 12 weeks. In 2016, the World Health Assembly adopted an ambitious goal to eliminate viral hepatitis, including HCV, as a public health problem by 2030. However many challenges remain.

In many low- and middle-income countries, diagnosis of HCV is limited by a lack of awareness on the part of doctors and patients, few if any testing facilities, and inadequate resources for HCV testing services. Another challenge is that diagnosis of

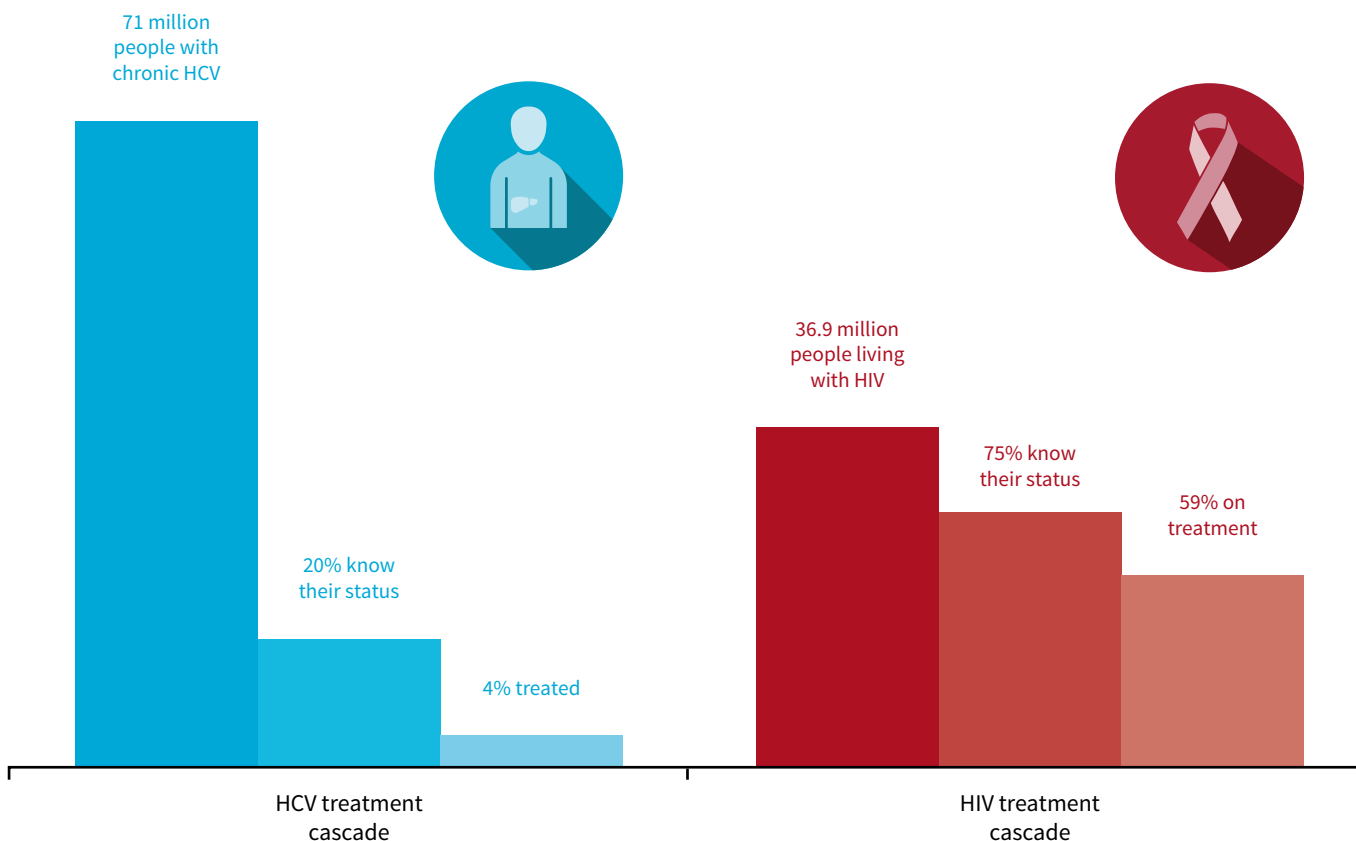
HCV requires a two-step process, first to detect the presence of HCV antibodies, and a second test, to distinguish people who have cleared the virus from those who have a chronic infection. Current HCV diagnostic tools are relatively expensive and sub-optimal, and are often only available in central laboratories in major cities, far from where many patients live. The tests are also inadequate for diagnosing patients co-infected with HIV/HCV making it particularly challenging to identify (and thus to treat) HCV infection in people living with HIV. Comparable to the early days of HIV therapy, access to revolutionary medicines is hampered by high drug prices and slow registration of generic drugs in countries. As a result only a small proportion (20%) of people infected with HCV know their status and only 4% have received treatment worldwide.

Unlike for HIV, TB and malaria, there are no established international funding mechanisms to help finance the response to HCV. Hence, the primary funders of HCV programmes will be national governments themselves. This makes finding affordable ways to diagnose and treat HCV even more urgent. Rapid, point-of-care diagnostics are needed to ensure that people are properly diagnosed and linked to care. Widespread availability of low-cost, generic direct-acting antivirals (DAAs) and decentralization of treatment services to lower levels of the health-care system will be required to meet the target to treat 80% of all persons with chronic HCV infection.

The main contributors to Unitaid are: France, United Kingdom, Brazil, Norway, Chile, South Korea, Mauritius, Madagascar, Spain and Bill & Melinda Gates Foundation.

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Double the amount of people living with chronic HCV as with HIV, yet only 4% are accessing treatment



Sources: Global HIV & AIDS statistics in 2017, UNAIDS 2018; Global Hepatitis Report 2017, WHO.

What is Unitaid doing?

Unitaid is supporting the global goal to eliminate HCV through a set of complimentary investments, which draw on expertise of different implementing partners who are well-positioned to tackle the barriers to HCV diagnosis and treatment. To date Unitaid has invested US \$60 million in HCV grants:

- To **address diagnostic challenges**, Unitaid is supporting a project by the **Foundation for New Innovative Diagnostics (FIND)** to develop simplified rapid tests and point-of-care diagnostics, including tests for HCV/HIV co-infection, and to identify more efficient ways to deliver HCV testing services in low- and middle-income countries;
- To simplify and decentralize treatment, Unitaid has invested in a grant to **Médecins Sans Frontières (MSF)** to provide

research data on **the best and most affordable ways to deliver HCV testing and treatment** services, as well as to make HCV treatment more affordable;

- To make HCV medicines more affordable, Unitaid is investing in the **WHO prequalification programme and Medicines Patent Pool (MPP)**, whose efforts are critical to increasing the availability of quality generic HCV drugs in low- and middle-income countries;
- To ensure **scale-up of HCV services**, Unitaid is investing in a **Coalition PLUS (CPLUS) grant** that is engaging with civil society organizations and local decision makers to increase awareness, foster political will and generate demand for HCV care.

Our projects and results so far

Simplified and more affordable treatment



MSF - Simplifying HCV treatment in low and middle-income countries

- Demonstrated how **simplified models of care can treat people co-infected with HIV and HCV** in resource-limited settings.
- Negotiated a **low price for a full treatment course** - US\$ 120, down from US\$ 1,780.
- Data generated by the project demonstrated that a combination of two drugs, sofosbuvir and daclatasvir, can treat different genetic variations of HCV. These data informed 2018 WHO guidelines for care and treatment of people diagnosed with chronic HCV, which will help simplifying diagnosis and treatment of HCV worldwide.

More affordable medicines



Catalysing the introduction of generic HCV medicines in low and middle-income countries

- The **WHO prequalification programme** assured the quality of generic DAA, and of a rapid diagnostic test.
- The **Medicines Patent Pool (MPP)** enabled the supply of quality generic HCV medicines in low and middle-income countries.
- MPP signed agreements to speed up introduction of **generic daclatasvir** and facilitated competitive production of a generic pipeline medicine (ravidasvir), and its partners are developing a generic formulation of sofosbuvir/daclatasvir.

Increased awareness and demand generation



CPLUS - Increasing awareness, fostering political will and creating demand for new treatments

- **Made significant contribution in lowering the price of HCV medicines**, direct-acting antivirals (DAA), in four countries by addressing intellectual property barriers.
- Successfully **advocated for testing and treatment of stigmatized populations**, such people who inject drugs, in two countries.
- Influenced governments to adopt policies that **facilitate the scale-up of HCV treatment**.

Better diagnostics



FIND - Developing better point-of-care diagnostic tools for hepatitis C and HIV co-infection

- Aims to bring to the **market new point-of-care and rapid diagnostic tests** that can also diagnose HCV in people living with HIV.
- Aims for **affordable, faster diagnosis of HCV**, which helps address loss to follow up among hard to reach populations.
- Helps countries **decentralize testing** in a cost-effective way so it can be performed by less-specialized health workers.

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What impact are we aiming for?

Thanks to the effort of Unitaid and partners, all the building blocks are in place to achieve the WHO target for elimination of viral hepatitis by 2030. These efforts now need to be scaled up. Making generic DAAs more widely available in low and middle-income countries, decentralizing and simplifying diagnosis and treatment of HCV, and eliminating HCV genotype testing, could allow countries to prioritize HCV treatment. This in turn could result in 2.1 million fewer deaths from HCV-associated cirrhosis and liver cancer by 2030.

Using less-expensive generic DAAs to treat HCV infection would generate long-term savings for health systems because fewer people would reach advanced stages of the disease and require expensive treatment. By some estimates, treatment of HCV with generic DAAs could reduce lifetime health care costs by \$1,300¹ for every person treated—a very worthwhile public health investment that could pay for itself over time.

What are the remaining challenges?

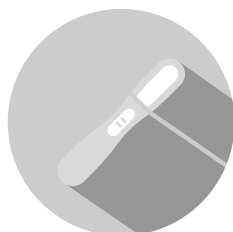
Today, over 60% of people with HCV live in countries that could access generic DAAs at an affordable price, making it possible to initiate and scale up treatment programmes. However, not all countries have taken advantage of this opportunity, due to lack of adequate financing and political will. To provide treatment to every single person with chronic HCV infection it would cost at least US\$ 11 billion, assuming US\$ 150 per full course of treatment, and not taking into account any costs associated with diagnosis, or health care delivery. Several middle-income countries have started to domestically finance and scale up DAA treatment and develop plans in line with the WHO goal of elimination by 2030. However, to

achieve HCV elimination targets, investments will need to increase, and in most cases, those increases will have to come from domestic sources because of the lack of international financing for HCV programmes. Unitaid is currently one of the few donors for HCV.

Through its investments, Unitaid is working with countries to simplify and decentralize the diagnosis and treatment of HCV to make scale-up more feasible. Unitaid is also encouraging coordination among partners working on HCV, and supporting the WHO's Global Hepatitis Programme to bolster the response to HCV.

Essential steps towards elimination of HCV

Diagnosis



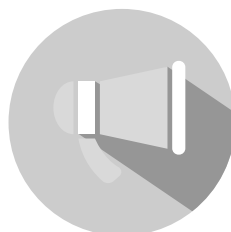
Better diagnostic tools and more effective ways to deliver testing services

Treatment



More affordable quality medicines

Demand



Increasing awareness among providers and patients

Scale-up



Financing and scaling-up HCV diagnosis and treatment

Unitaid and partners

Countries and partners

¹Aggarwal R, et al. (2017) Cost-effectiveness of hepatitis C treatment using generic direct-acting antivirals available in India