Access to HCV treatments: hurdles not barriers

Viral hepatitis kills as many as tuberculosis, HIV, or malaria. Nevertheless, the global response has lagged pitifully behind that for other leading causes of mortality. While the development of direct-acting antivirals (DAAs) for HCV—which is responsible for around 700 000 deaths per year—has been widely heralded as a long-awaited turning point, unaffordable pricing has pushed the race to tackle the virus firmly back in the starting blocks.

On Oct 27, WHO launched its first global report on access to HCV drugs, providing information for countries and health authorities to identify and procure the appropriate treatment at affordable prices, based on the experiences of 13 pioneering countries. Despite the availability, since 2013, of 8–12 week DAA regimens that can cure HCV in more than 90% of chronically infected people, WHO reports that less than 1% of these people have access to treatment, mostly in high-income countries (HICs). But progress has been made: more than 1 million people are receiving or have received treatment with DAAs in low-income and middle-income countries (LMICs) to date.

This report follows recent steps to push HCV to the top of the global health agenda. The World Health Assembly's Global Health Sector Strategy on Viral Hepatitis for 2016–21 established the goal of eliminating viral hepatitis by 2030—an ambitious target that requires scaling up treatment to reach 80% of those with HCV. In April, 2015, several DAAs were added to the WHO Model List of Essential Medicines, emphasising HCV treatment as a priority health-care need, as also highlighted in *The Lancet*'s Commission on essential medicines policies.

With unprecedented transparency, WHO's report reveals striking differences in drug pricing between countries. At the extreme ends of the spectrum, a 28-day supply of sofosbuvir costs $16 368 in Romania, but a generic version is available for $15 in Pakistan. Pricing bears little relation to the extremely low costs of production, and rarely tallies with national income and disease burden. For example, the total cost of treating all patients, adjusted for currency differences and national wealth, ranged from 10·5% of the annual cost for all medicines in the Netherlands to 190·5% in Poland. Unmanageable pricing has led most countries to restrict treatment to those with the most severe liver disease. This has resulted in named-patient importation of generic DAAs in HICs, while falsified products have been noted in some low-income countries.

The WHO report lays out practical steps to increase access, including generic production, leverage, strategic procurement, and competitive bidding. Harnessing the lessons learned from the early days of HAART, generic competition is likely to be the most efficient way to drive down prices. However, whether a country can procure generic medicines depends on whether patents are filed and granted, and if granted, whether the country is included in voluntary licensing agreements. So far, Gilead has granted licenses for sofosbuvir and ledipasvir to several generic manufacturers in India, allowing 101 LMICs to procure the drugs, and Bristol-Myers Squibb has entered a license agreement for daclatasvir with the Medicines Patent Pool, covering 112 countries. Countries where patents have not been filed or granted, such as Egypt, have been able to locally produce generic versions, further driving down costs. For countries outside these agreements, the task is more complex. Governments must look to other means to ensure affordable access, including price regulation and negotiation, pooled procurement, and compulsory licensing.

While cost is the major factor restricting access, further complexities compound the situation. Genotyping and staging of liver disease are necessary to determine the correct treatment regimen. Low awareness, stigma and discrimination, and lack of decentralised care are further obstacles to providing access for all. One of the most successful examples, Egypt, has the highest prevalence of HCV in the world, but has also treated more people with HCV than has any other LMIC. High awareness and political will has driven efficient and early price negotiations and local production of generic DAAs, and predominance of a single genotype has simplified this process. In countries not included in licensing agreements, such as Thailand, civil society groups have filed patent oppositions and garnered political support, leading to price negotiations.

There is no single solution; each country faces unique challenges. Nevertheless, the successes to date show that cost can no longer be an excuse to withhold treatment, but is merely a hurdle to be surmounted. The responsibility for overcoming these hurdles now lies with national governments, who must negotiate better deals. We hope WHO's report provides the impetus to maintain the initial momentum, and motivates other countries to join the race. ■ *The Lancet Gastroenterology & Hepatology*

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For more on the **global burden of viral hepatitis** see *Lancet* 2016; **388:** 1081–88

For more on **WHO's Global Report on Treatment Access to HCV Drugs** see http://apps.who.int/iris/bitstream/10665/250625/1/WHO-HIV-2016.20-eng.pdf?ua=1

For the **Global Health Sector Strategy on Viral Hepatitis for 2016–2021** see http://apps.who.int/iris/bitstream/10665/246177/1/WHO-HIV-2016.06-eng.pdf?ua=1

For more on ***The Lancet*'s Commission on essential medicines policies** see http://www.thelancet.com/commissions/essential-medicines

For more on **personal importation of generic therapies** see *Lancet* 2016; published online Nov 7. http://dx.doi.org/10.1016/S0140-6736(16)32051-7