nature medicine

The price of good health

Efficacious new drugs to treat hepatitis C virus infection offer the potential to halt this epidemic. But their exorbitant cost may prove prohibitive for most patients in need. Strong patient and government advocacy will be necessary to ensure that accessibility to treatments is a right, not a privilege.

According to the World Health Organization, 150 million people are chronically infected with hepatitis C virus (HCV), and 350,000 die each year from liver damage associated with the infection. In the United States alone, at least 3 million people are believed to be infected, most of whom do not know it. And although ~20% of infections resolve spontaneously, ~80% do not, and most chronic HCV infections eventually worsen. So the recent development of direct-acting antivirals (DAAs) offers great potential to both halt the global spread of infection and prevent further liver damage in infected individuals.

Pegylated interferon plus ribavirin has long been the mainstay of HCV therapy, but the long treatment course (24–48 weeks) and severe flu-like side effects make patients reluctant to seek or complete treatment, exacerbating patient health and the emergence of resistant virus. Moreover, not all treated patients clear the virus.

In 2013, the US Food and Drug Administration (FDA) approved two DAAs for the treatment of HCV. In combination with interferon and/or ribavirin, the DAAs show higher efficacy rates—90% in some settings—with a shorter treatment course and fewer side effects than the standard therapy. Yet these new drugs, simeprevir, from Janssen Therapeutics, and sofosbuvir, from Gilead Sciences, will cost $66,000 and $84,000 respectively, for 12 weeks of treatment. Notably, these prices do not account for the additional costs of interferon or ribavirin (~$15,000–30,000, depending on the treatment course), pharmacy dispensing fees, tests and doctor visits. Nor do they reflect the estimated manufacturing costs—which do not exceed ~$270 for a 12-week course of treatment (*Clin. Infect. Dis.* **58**, 928–936, 2014). Instead, the pricing may represent the cost of competing for a piece of the HCV drug market: in 2011, Gilead paid $11 billion for the company that developed sofosbuvir. And the price of these new drugs is anticipated to set the bar for DAAs still under development.

In spite of years of effort, there is no vaccine to prevent or treat HCV infection, and no way to determine who will clear the infection and who will not. So the DAAs are the best options by far for patients to achieve a cure and prevent progressive liver damage and HCV-associated cirrhosis and liver cancer. But their benefit relies on accessibility to treatment, and the treatments' high cost could restrict accessibility to only the wealthiest patients and nations.

In February, at the first meeting of the HCV World Community Advisory Board in Bangkok, Thailand, a group of 38 activists from 22 countries implored six pharmaceutical companies to lower the high price of HCV drugs, hoping to inspire the cost reductions seen with antiretroviral therapies for the treatment of HIV/AIDS. The activists asserted that the current cost renders the drugs out of reach for low- to middle-income countries, in spite of patient assistance programs or licensing deals that the companies may offer. The drug companies have not yet committed to uniformly lowering their prices.

Unlike the case for HIV in the late 1980s, HCV has no ardent core of activists to gain enough traction to exert pressure on drug companies. The disease is slow to progress, with symptoms occurring 20–30 years after infection. As a result, most individuals do not know they are infected until liver damage is apparent. And even in the case of a positive HCV diagnosis, many patients have been reluctant to seek treatment given the debilitating side effects of interferon therapy—particularly when they are asymptomatic without treatment. So the disease lacks the momentum and voice that the HIV/AIDS epidemic achieved. And yet, with 3–4 million new HCV infections per year, the rate now exceeds that of new HIV infections. In contrast, funding for HCV from the US National Institutes of Health in fiscal year 2013 was $101 million, compared with almost $3 billion for HIV/AIDS.

With HCV therapies capable of eradicating the infection, patients should not have to measure the value of their health against the cost of drug treatment. Clearly, more potent advocacy is required to improve both government investment in research and treatment and negotiation of fair pricing strategies with pharmaceutical companies. Investing in infectious diseases should be an ongoing global commitment, as money spent today in delivering cures, particularly in the instance of widespread diseases such as HCV and HIV, is money gained later in enhanced health gains, productivity and fiscal growth. This February, 27 countries agreed to engage in new efforts to detect and control infectious disease outbreaks, and US president Barack Obama intends to request an additional $45 million from the US government to apply to these efforts. One argument for the undertaking is that many countries are ill prepared for an outbreak of a new disease. But the commitment needs to be sustained and extended to ensuring affordability of treatment options in the event of any outbreak. You can't prevent or cure what you can't afford to treat.