



Hepatitis C eradication: A long way to go

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Abstract

Hepatitis C virus (HCV) is a major global health problem with high morbidity and mortality. About 185 million people are living with HCV, of which 80% are living in low and middle income countries. With the development of new highly effective treatments for HCV, it is considered that the eradication of HCV may only be one step away. The major problem with new treatment options is its high price. The price of sofosbuvir-based treatment for one patient in the United States is US\$85000-110000, while the actual

production cost of a 12 wk direct-acting antiviral regimen is less than US\$250. Another major hindrance in HCV eradication is the lack of quality management of blood transfusion screens. Due to the lack of HCV screening, 75% of people in the United States with HCV infection are unaware of their positive HCV status. The control of massive HCV pandemic will require a significant financial investment, political will, and support from medical, pharmaceutical, and civil organizations around the globe.

Key words: Hepatitis C virus; Treatment; Diagnostics; Screening; Transfusion

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Core tip: With the availability of new direct-acting antivirals for hepatitis C virus (HCV), some people think that eradication of HCV may be only one step away. There are a number of issues that need to be overcome to win the fight against HCV. Although the cost of HCV treatment is reduced for certain countries, cost remains a big problem for low and middle income countries for the treatment of a large number of patients. In low income countries, 47% of blood transfusions are from laboratories with no quality management in place. There is a lack of knowledge and awareness about HCV among healthcare providers, policy makers, general public, and at risk populations.

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TO THE EDITOR

Hepatitis C virus (HCV) is a major health problem around the globe. About 185 million people are

living with HCV, of which 80% are living in low-income and middle-income countries^[1]. One third of chronically infected HCV patients develop cirrhosis and hepatocellular carcinoma. It is estimated by the World Health Organization (WHO) that the annual number of deaths caused by HCV related liver diseases ranges from 350000 to 500000^[2]. Treatment with pegylated interferon and ribavirin is the treatment of choice in several countries. The therapy has limited response with a number of side effects. The cost of this therapy is US\$ 4000 for one patient^[3,4].

With the availability of new highly effective HCV treatments, it is considered that the HCV elimination may be only one step away^[5]. We think that the elimination of hepatitis C is not so much easy even with the development of new highly effective therapies, but there are many issues to address before achieving the global eradication of HCV.

The new generation of direct acting antiviral (DAA) drugs has demonstrated high treatment response with minimal adverse effects. The major problem with new drugs is their affordability. The price of sofosbuvir based treatment for one HCV patient in the United States is US\$85000-110000^[6], while the actual production cost of a 12 wk regimen of DAA is less than US\$250^[7]. Several European countries are negotiating the price for new HCV drugs. The French health minister warned that the high price of treatment will impose high burden on the social security system. The high treatment response of new DAA has been linked with adherence to proper treatment regimen. In clinical trials, sofosbuvir (Sovaldi) showed a discontinuation rate of 2%.

Seventy two percent of the world's poorest people live in middle income countries, and 90% of these patients pay for medications out of pocket. Some countries have an insurance scheme in place, but these do not always cover the cost of HCV diagnostics and treatment^[1]. Middle income countries are an attractive market for pharmaceutical companies. Gilead has a licensing agreement with seven Indian companies to manufacture generic HCV medicine at a reduced price for 91 developing countries. Egypt and Pakistan have 11 million and 10 million people living with HCV, respectively. It will cost approximately US\$5 billion, even with the reduced price of sofosbuvir, to treat half the patients in either country. This price does not include the expenses used for laboratory monitoring, hospital visits, and medications to manage adverse events. There is dire need to make HCV treatment affordable for a large number of HCV patients. According to the Centers for Disease Control (CDC), one premature death is prevented for every three virological cures^[8]. We can learn drug affordability from the example established for the affordable treatment of HIV. About 10 million people receive antiretroviral therapy for HIV at a cost of \$100 per person annually^[9].

The major route of transmission of HCV is blood

and blood products^[10]. It was reported by WHO that 47% of blood donations in low income countries are from laboratories with no quality assurance^[11]. Large numbers of labs are using rapid tests and third generation enzyme immunoassays (EIA) for HCV detection. The window period for HCV detection by third generation EIA test is 66 d compared with 4 d for HCV detection by nucleic acid amplification technology (NAT)^[12]. CDC recommends the use of highly sensitive EIA or rapid test for HCV screening and use of another assay to confirm further positive results^[13]. Efforts are needed to establish cost effective NAT laboratories for effective HCV diagnosis.

People with HCV infection remain asymptomatic for long periods during which infection may be transmitted to other persons. Seventy five percent of people in the United States with HCV infection are unaware of their infection^[14]. There is a need for HCV screening programs for both general and at risk populations, including intravenous drug users (IDUs), people with a history of using blood products or unsafe injections, those with piercings and tattoos, prisoners, and homeless people. There is also a need to provide proper prevention, diagnosis, and treatment facilities to the detained population.

In a multinational study to forecast the prevalence of HCV by 2030, it was observed that HCV associated morbidity and mortality can be greatly reduced by increasing diagnosis and the number of individuals getting higher efficacy treatment^[15].

Lack of knowledge and awareness about HCV are observed among healthcare providers, policy makers, the general public, and at risk populations. Forty percent of global HCV infections are due to unsafe injections and improperly sterilized medical equipment^[16]. Health care providers need education and training to reduce the risk of disease transmission by malpractice. It was observed in a recent study that only 5.5% of HCV positive IDUs of India were aware of their status and only 1.4% of HCV positive IDUs had received treatment for HCV^[17]. Massive awareness programs are needed to decrease the future burden of HCV on society.

There is insufficient understanding about the seriousness of this public health problem, so inadequate public resources are allocated for the prevention and control of HCV. There is a need to develop a global strategy for HCV eradication. More than 10 million people are on their feet due to the global polio eradication initiative, and the global incidence of polio has been reduced by 99%^[18]. The control of massive HCV pandemic requires financial investment, political will, and support from medical, pharmaceutical, and civil organizations around the globe.

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