

Hepatitis C: Policy Recommendations for Addressing a Growing Epidemic

INTRODUCTION

Across the world, an estimated 71 million people are living with the hepatitis C virus.¹ If left untreated, hepatitis C infection can cause chronic and debilitating liver disease, including fibrosis, cirrhosis, and cancer. In 2015, hepatitis C infection contributed to 30% of viral hepatitis-related deaths, amounting to ~400,000 lives lost. Recognizing the seriousness of this public health problem, governments, through the World Health Assembly, have adopted the global health sector strategy on viral hepatitis, which aims to eliminate hepatitis C by 2030.²

Of the 36.7 million people living with HIV (PLHIV), the prevalence of those with evidence of prior hepatitis C infection is 6.2%. Hepatitis C infection rates have been especially high among people who inject drugs (PWID) who are HIV positive, with upwards of 80% of this population in some surveys having both infections.³ Co-infection is an urgent public health issue that could jeopardize the progress made in addressing the HIV epidemic.

Key Messages:

- About 71 million people worldwide are living with hepatitis C.
- Untreated hepatitis C can cause liver cirrhosis, cancer, and death.
- About 6.2% of the 36.7 million people living with HIV (PLHIV) are co-infected with hepatitis C.
- Among people who inject drugs who are HIV positive, more than 80% also have hepatitis C.
- Liver disease caused by hepatitis C is becoming a leading cause of death among PLHIV.
- Highly effective direct-acting antiviral (DAA) medicines have made global hepatitis C elimination a realistic possibility; however, access to these drugs remains severely limited.
- Countries need improved national hepatitis C surveillance systems to better understand their epidemic, and national programs for prevention, screening, diagnosis, and treatment.
- Hepatitis C programs should be integrated with HIV and harm reduction programs.
- Countries need to ensure rapid registration of DAAs and to build skills of non-specialist healthcare providers in diagnosing and treating hepatitis.

Infection with hepatitis C

Hepatitis C is a virus transmitted by exposure to infected blood through sharing of contaminated injecting equipment among PWID, transfusion of contaminated blood products, or unsafe healthcare procedures involving unsterilized medical equipment. Hepatitis C can also be transmitted sexually and from an infected mother to her baby. There is no vaccine against hepatitis C, making prevention, testing, and treatment initiatives critically important.

From infection to liver failure

The human immune system can clear the virus by itself in about one out of every four people with hepatitis C infection, in a process known as *spontaneous clearance*. Those who do not get rid of the virus within six months have what is called *chronic hepatitis C infection*. Out of 100 people who have chronic infection, about 30 may never develop liver problems (see Figure 1), but they can still transmit the hepatitis C virus to others. The other 70 people may develop some liver damage, but they may have no or only mild symptoms. After about 20 years, 10 to 15 of these 70 people will have developed cirrhosis (scarring of the liver), and five to seven of them will go on to develop liver failure or liver cancer. Because most people with hepatitis C have no noticeable symptoms, the disease is considered a “silent” infection that can be unknowingly transmitted to others and may not be detected until it has already caused significant damage to the liver.

The burden of hepatitis C and HIV in the Asia-Pacific

The WHO’s Western Pacific region⁴ has approximately 14 million people living with chronic hepatitis C infection, and the South-East Asia region has approximately 10 million.⁵ However, fewer than 10% of people living with chronic hepatitis C infection in low-income countries have been diagnosed.⁶

Co-infection with hepatitis C and HIV doubles the risk of mother-to-child transmission of hepatitis C,⁷ and is associated with higher hepatitis C virus levels in the body and more rapid progression of liver disease.^{8,9} Notably, 62% of PLHIV with hepatitis C co-infection in one regional study in Asia had moderate or significant liver fibrosis, indicating liver disease progression.¹⁰

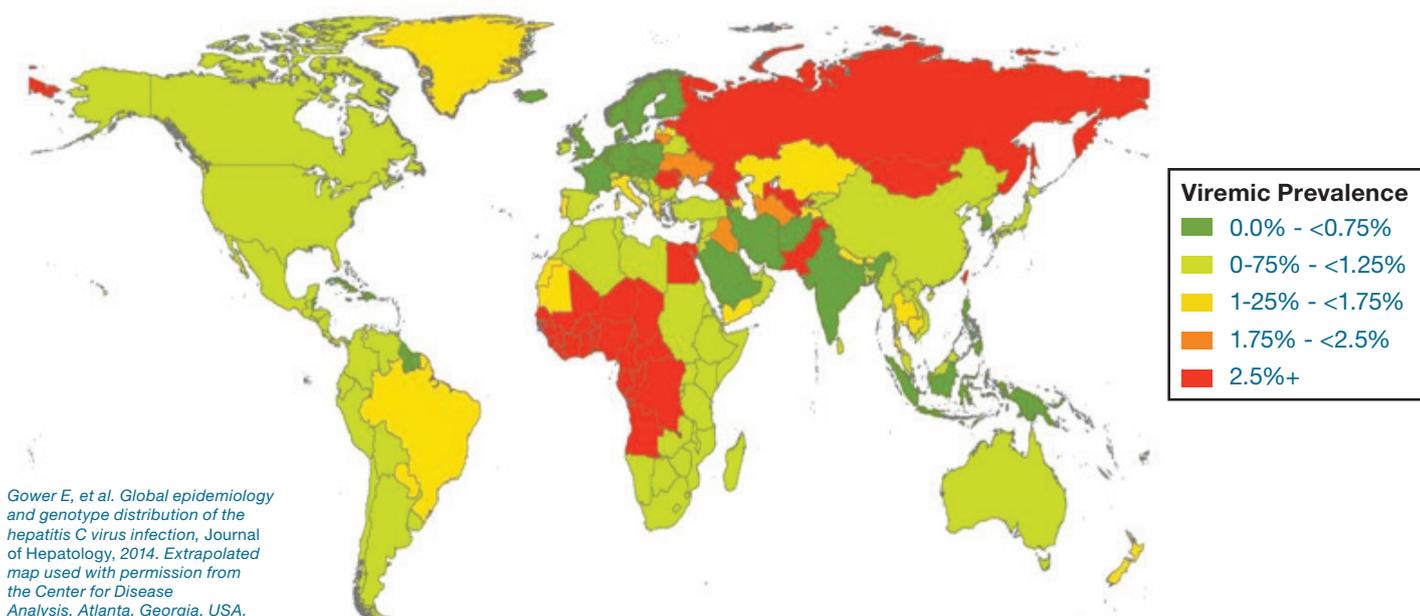
The human and financial costs of hepatitis C

The global hepatitis C epidemic is responsible for substantial health and economic burdens on individuals, communities, and countries across the world (see Figure 2). In India, cases of advanced liver disease and cirrhosis have been projected to peak at 169,000 and 1.2 million, respectively, by 2031.¹¹ This would represent massive increases in these conditions of 220% and 145%, respectively, from 2015 to 2031. In Australia, the number of people with chronic hepatitis C is expected to peak at 255,500 by 2030. The percentage of those with chronic hepatitis C who have cirrhosis or more advanced liver disease would more than double from 7% in 2013 to 18% in 2030, while associated costs are projected to increase from US\$224 million to US\$305 million per year.¹²

Figure 1. Disease progression of hepatitis C virus



Figure 2: Global prevalence of chronic hepatitis C infection



An opportunity to treat and cure hepatitis C

The development of potent and highly effective hepatitis C treatment using direct-acting antivirals (DAAs) has made global hepatitis C elimination a more realistic possibility. Treatment for 8 to 12 weeks with a two-drug combination of DAAs has been shown in clinical trials to cure more than 95% of patients.

DAAs have greatly simplified treatment of hepatitis C, which has required different medicine combinations and regimens depending on the type of virus being treated. The distribution of the six genotypes¹³ of hepatitis C varies across the region. For example, Vietnam and Indonesia have more people infected with genotypes 1 and 6, which are considered relatively easy to treat. In India, Malaysia, and Thailand there are more people with genotype 3, which is considered harder to treat. Some DAAs are recommended for only specific genotypes, necessitating expensive individual patient genotype testing prior to initiating treatment. However, newer “pan-genotypic” DAA regimens can cure most people regardless of the genotype of their infection.

National health programs can achieve long-term public health benefits by treating and curing people with hepatitis C, both to prevent the development of serious liver disease that would require costly medical care and to reduce the potential for new infections.

Guidelines on hepatitis C care and treatment from professional societies such as the American Association for the Study of Liver Diseases (AASLD) and the European

Association for the Study of the Liver (EASL), as well as the World Health Organization (WHO), highlight the importance of treating both HIV and hepatitis C. Most of the WHO-recommended DAAs can be co-administered with commonly used HIV medicines in lower- and middle-income countries. However, although PLHIV are living longer due to greater access to antiretroviral therapy, liver disease caused by hepatitis C is becoming a leading cause of their deaths.^{14,15}

The benefits and challenges of investing in hepatitis C cure

With the availability of a cure for hepatitis C, countries have the opportunity to reduce the tremendous economic and human burdens of this disease. A cost-effectiveness analysis in India showed that hepatitis C treatment increased life expectancy by 8 years and reduced lifetime healthcare costs by US\$1,309 per person cured. Treatment would become cost-effective in India within only two years, and national treatment programs could be cost-saving within 5 to 10 years. For every 10,000 people treated, this translates to preventing 3,850 cases of liver cirrhosis, 2,500 cases of liver cancer, and 4,550 liver-related deaths.¹⁶

Countries such as Australia that have initiated programs for diagnosis and treatment of hepatitis C have achieved impressive results over the past two years. In March 2016, Australia’s Pharmaceutical Benefits Scheme commenced a treatment plan using only DAAs. By December 2016, 32,400 people, constituting 14% of the total population infected with hepatitis C, had begun treatment. From 2014 through 2016, 70% of people with cirrhosis had begun treatment.¹⁷ If this rate of

diagnosis and treatment is continued, by 2030 Australia will have averted 37,950 new hepatitis C infections, 11,990 cases of liver cancer, and 10,350 liver-related deaths, enabling it to meet WHO elimination targets before 2028.¹⁸

Many low- and middle-income countries in the region can access low-cost generic DAAs through a voluntary license mechanism,¹⁹ which has been in place since September 2014. Through rapid price reductions, by March 2018, the cost of a 12-week treatment course using Indian generic DAAs became as low as US\$67.²⁰ Unfortunately, few Asian countries that are authorized to purchase generic DAAs have processes for importing these medicines. In addition, some of the countries that have been excluded from these licenses (e.g., China for sofosbuvir; Thailand, Malaysia for daclatasvir) have millions of people with hepatitis C who cannot afford treatment. New strategies to expand access to these lifesaving medicines are desperately needed to give them the opportunity for a cure.

Conclusions

HIV treatment scale-up has changed the trajectory of the epidemic in many countries, transforming HIV into a manageable chronic disease. Creating access to affordable HIV treatment required aggressive advocacy. Adopting similar approaches to hepatitis C treatment could result in substantial expansion of access to DAAs.

POLICY RECOMMENDATIONS

Globally, approximately 3 million people had been treated for hepatitis C with DAAs by the end of 2016.²¹ However, in that same year, there were another 1.75 million people newly infected.²² Despite growing evidence that hepatitis C treatment is a sound investment with valuable social and economic returns, the vast majority of those who need it cannot access treatment, limiting the potential impact of global treatment scale-up. With the rapid developments in medicines that can cure hepatitis C and policies promoting their use, it is imperative to secure political commitments and investments toward the elimination of hepatitis C. We therefore urge national governments to take the steps below to improve access to care and treatment.

- **Establish national surveillance systems for hepatitis C.** It is essential for country programs to understand their own local hepatitis C epidemics in order to design effective strategies to address them.
- **Establish national viral hepatitis programs.** Countries should establish national viral hepatitis programs with clear plans for achieving targets for prevention, screening, diagnosis, and treatment of hepatitis C, as well as for increasing awareness of the disease among general and key populations.

- **Integrate HIV and harm reduction programs with hepatitis C programs.** Given the prevalence and disease progression of hepatitis C among PLHIV and PWID, these populations should be prioritized for outreach and access to care. Existing programs that have successfully integrated HIV and harm reduction for PWID provide opportunities to add on care and treatment for hepatitis C.
- **Build skills of non-specialist providers to enable task-sharing to facilitate expansion of hepatitis C treatment.** The availability of pan-genotypic DAA regimens has made the diagnosis and treatment of hepatitis C much easier to manage. If we are to meet global targets for eliminating hepatitis C by 2030, then it is essential to build the skills and scope of work of general healthcare providers to diagnose and treat people with hepatitis.
- **Approve fast-track registration of pan-genotypic DAAs.** Slow progress in national approval of DAAs has delayed availability of these medicines at the local level. Rapid approval and registration of these medicines by national regulators will broaden access to treatment, promote competition, and lower costs.

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