Scaling up access to highly effective hepatitis C treatment for HIV infected people: not “mission creep” but “mission critical” for the Global Fund’s response to HIV

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THE OPPORTUNITY: New, powerful oral direct acting antivirals (DAAs) including sofosbuvir (Solvadi) and Harvoni present a truly revolutionary public health opportunity: preventing millions of people with hepatitis C virus (HCV) from dying of liver disease, and setting the world on a course to HCV eradication. These recent therapeutic breakthroughs will make hepatitis C remarkably easy to cure, regardless of HIV status. Several clinical trials have demonstrated HIV co-infection is no longer a poor prognostic factor for response to treatment with DAAs; combinations of these drugs can cure HCV in 12 weeks—or even less time.¹ DAAs are a massive advance over the former standard of care, which is based on injectable medicine that is difficult to administer and tolerate, provide relatively low cure rates, and require costly diagnostic and monitoring tests.

Brand name versions of new DAAs are costly—for now. But DAAs could be mass-produced at a profit for a fraction of the prices paid in high-income countries. Experts estimate that a 12-week treatment course of sofosbuvir + daclatasvir, a highly-effective (cure rate: 84-100%), safe and tolerable regimen that can be co-administered with WHO-recommended antiretroviral agents could be produced for less than US $125.00.²,³ This combination will greatly simplify hepatitis C treatment, since it obviates the need for pre-treatment genotypic testing, and minimal safety and efficacy monitoring are required.

THE EPIDEMIOLOGY: An estimated 7 million people with HIV are co-infected with hepatitis C virus, representing 16% of people living with HIV globally. In some countries, prevalence of co-infection is much higher. For example, MSF has identified very high co infection rates among some cohorts including 15.7% in Mozambique, 10.3% in Kibera, Kenya and 31% in Kachin, Myanmar. Among people who acquired HIV through contaminated injection equipment, co-infection with hepatitis C routinely reaches 90%, and hepatitis C treatment is included in the WHO/UNAIDS/UNODC package of HIV prevention, treatment and care interventions for people who inject drugs. The Global Fund invests extensively in HIV programs in countries where HIV and hepatitis C co-infection is widespread. DAAs offer an unprecedented opportunity to deliver life-saving, curative treatment to people with HIV and hepatitis C co-infection. Being cured reduces liver-related, AIDS-related and all-cause morbidity and mortality—thereby maximizing survival benefits from antiretroviral therapy.⁴,⁵,⁶,⁷

THE NATURAL HISTORY OF CO-INFECTION: Hepatitis C is widely prevalent among, and deadly for people living with HIV, especially people who inject drugs and men who have sex with men. DAAs are life-saving, and will cure hepatitis C in these extremely vulnerable populations, whose human rights are routinely violated.

Hepatitis C co-infection increases hospitalization rates among HIV-positive people, and worsens cardiovascular disease, bone loss and neurocognitive impairment (complications that are also associated with HIV).⁸,⁹,¹⁰,¹¹ HIV accelerates hepatitis C progression and doubles the risk for cirrhosis, especially in people with a low CD4 cell nadir.¹²,¹³,¹⁴ In turn, hepatitis C is associated with increased risk of liver-related and AIDS-related illness and death among co-infected people.¹⁵,¹⁶,¹⁷ Co-infection also puts pregnant women at increased risk of transmitting both hepatitis C and HIV to their newborns, although access to antiretroviral treatment attenuates these risks.

With the widespread use of antiretroviral therapy, which reduces the risk of HIV-associated opportunistic infections, hepatitis C-related liver disease has started to overtake AIDS-defining illnesses as a leading cause of death in some countries.

THE GLOBAL FUND’S POLICY: The Global Fund is currently debating whether or not to permit countries to spend Global Fund funding on DAAs for co-infected patients, and expand beyond limited current programs. Like other priority co-morbidities including sexually transmitted diseases and other parasitic, viral, or bacterial infections, the Global Fund already invests in country programs supporting treatment and prevention for hepatitis C in HIV positive people.

These programs have supported treatment in Georgia, Ukraine, Macedonia and Belarus. Although for very limited numbers of people, the fact that some support for treatment was available has had significant impact mobilizing civil society engagement, demonstrating feasibility of treating co-infected methadone patients and people who inject drugs, advocating for national treatment protocols that include drug users and methadone patients, and galvanizing price reductions such as those secured in Georgia and Ukraine. This synergy between expanded treatment access, equity, human rights, civil society engagement, and increasing value for money is very strongly aligned with the Global Fund’s current strategy. The Global Fund also has a human-rights-based strategy to focus on vulnerable and most risk populations, which explicitly includes people who inject drugs and men who have sex with men. Singling out and excluding a co-infection that is particularly debilitating and life-threatening for these key populations violates both human rights and the Global Fund’s stated commitments.
THE GLOBAL FUND MUST ACT: Backing away from treating hepatitis C—especially with the advent of highly effective, safe, and tolerable regimes that dramatically simplify treatment and cure—would be the wrong decision, for the wrong reasons. The Global Fund will be rejecting the human rights imperative of saving the lives of people on antiretroviral treatment, by leaving them to die from liver disease. Such a decision sends a regrettable signal to other donors, including UNITAID, which has already expanded their project focus to include hepatitis C diagnostics and medicines. No partner, however, realistically holds the reach and leverage of the Global Fund.

Instead of caving in to qualms about high drug prices, the Global Fund should learn lessons from HIV—and work as a leader with partners now to expand and pool country demand and take all actions needed to drive down price, in particular through promoting generic competition, to help bring down the cost of these game-changing medicines.

The Global Fund should recognize that DAA costs are already decreasing, after only minimal pressure. Egypt and India are already using Gilead’s $900 differential sofosbuvir price. Gilead’s recently announced sofosbuvir voluntary license will cut the price of that medicine in 91 low- and middle-income countries where many co-infected persons live. Further price reductions are possible, and highly likely. Expanded volumes will accelerate price reductions, because economies of scale will make the market more attractive to competitors and increase pressure on manufacturers—brand name and generic. Indeed, in the HIV market the Global Fund has historically played an important role in providing exactly this incentive while working to expand generic competition through market shaping efforts.

The Global Fund could set a powerful example, instead of creating a self-fulfilling prophecy, by supporting countries who provide a technically sound case for using Global Fund resources to invest in hepatitis C treatment for co-infected people. Failure to support hepatitis C treatment will allow the epidemic to continue spreading while abandoning some of the world’s most marginalized people to die from a curable infection. This will undermine progress created by scaling up antiretroviral treatment, disregard national autonomy in prioritizing the response, undermine the Global Fund mission and ignore the needs of people suffering with a deadly but curable co-infection.

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1 Rockstroh JK. Does HIV remain a risk factor for achieving sustained virologic response (SVR) under DAA-based modern HCV therapy? *Clinical Infectious Diseases*. 2014 Aug 18; pii: ciu662.