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Increasing Access to Hepatitis C Treatment in Rwanda: The Promise of Rwanda's Existing HIV Infrastructure

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Introduction

For decades, access to treatment for hepatitis C virus (HCV) has been limited in low-resource settings. Untreated chronic HCV infection can lead to cirrhosis of the liver, liver failure, and hepatocellular carcinoma. These long-term consequences are a major contributor to global mortality, estimated at half a million lives per year [1]. The greatest burden is estimated to be in sub-Saharan Africa and Asia, with HCV prevalence rates estimated around 3% in sub-Saharan Africa [2]. Across Africa, challenges in access to HCV treatment occur from access to diagnostics, treatment, and appropriate laboratory monitoring. HCV testing is not offered universally free of charge in any country in Africa, which is a major barrier for accessing care [3], and an epidemiological challenge lies in HCV's asymptomatic infection. Within sub-Saharan Africa, HIV and HCV co-infection are a particular challenge. Until recent years, treatment regimens for HCV were complex, requiring extensive laboratory monitoring and a difficult regimen lasting nearly one year [4] that succeeded in sustained virological response in only about half of patients in both high-income and low- and middle-income settings [5]. In the past two years, several new treatments have emerged for the treatment of HCV using direct-acting oral antivirals [6]. In 2014, ledipasvir/sofosbuvir, a once-daily oral antiviral, was approved for use to treat HCV genotype 1. In clinical trials, an 8 to 12 week course of ledipasvir/sofosbuvir demonstrated sustained virological response in 94% to 99% of patients with limited side effects [7,8]. However, ledipasvir/sofosbuvir was introduced on the market at a cost of about $90,000 per patient per cure. With an extremely efficacious and highly simplified regimen, the potential exists to leverage robust systems for HIV treatment in sub-Saharan Africa to deliver HCV oral therapy if treatment is affordable [9].

The Rwandan health system is well set up to deliver HCV care. HCV prevalence in Rwanda's general population is unknown, but has been estimated around 4% [10]. Studies on higher-risk groups found HCV antibodies were present in 5.7% of known HIV-positive adults [11] and 1.3% of healthcare workers in a tertiary facility [12]. Older treatment regimens in Rwanda were prohibitively expensive and reached very few patients. In July of 2015, the first national treatment guidelines for HCV and hepatitis B were released in Rwanda [13]. Building upon Rwanda's strong system for HIV care poses the potential of great success in addressing HCV in the country and saving thousands of lives. Twenty-five years ago the country faced a growing HIV epidemic and annual per patient costs for lifetime ARV treatment over $6,000 [14] with a GDP per capita of less than $600. However, today, in a global environment that has supported affordable ART access, the country was one of the first to achieve universal access to ART and has seen tremendous gains in life expectancy [15]. Now, the country is building on their system of integrated HIV care in the public health system and taking similar progressive action to address HCV. Advocacy is underway nationally to ensure access to therapies for patients with insurance, however global advocacy is needed to reduce the highly inflated cost of oral antivirals and increase access globally [16]. A pilot study funded by Gilead Sciences with donated ledipasvir/sofosbuvir is set to start in Rwanda in early 2016, bringing oral antiviral therapy to HCV patients for the first time in Rwanda. The study will help to demonstrate the ability of a low-income country to deliver the new HCV care and better understand the laboratory needs to monitor treatment with the simplified therapy. It is also an opportunity to study the effectiveness of ledipasvir/sofosbuvi in treating HCV genotype 4, which is the most prevalent type in Rwanda. However, this pilot study will serve only a fraction of the people with HCV infections in the country and efforts to increase widespread access are still underway.

There is hope that greater access will be possible as Gilead, the drug manufacturer of ledipasvir/sofosbuvir and other oral HCV treatments available at the moment, has taken a lead in developing programs and partnerships to help ensure access to new HCV medicines for patients in low- and middle-income countries. In August 2015, Gilead Sciences announced several licensing agreements with generic manufacturers to produce HCV medicines for 101 low- and middle-income countries [17]. The company is working with national governments to set pricing agreements based on a country's disease burden and economic means. Quick action to bring new HCV drugs to global markets at a rate that is affordable to patients may help to curb the growing epidemic of HCV in Africa and the subsequent burden of liver disease [18]. The efforts to decrease costs by Gilead to date are commendable and show a stark contrast to the slow fight to lower the costs of ARTs in the mid-2000s that cost millions of lives. However, although the reduction in price of ledipasvir/sofosbuvir is greater than 90% of the initial cost of $90,000 per patient per cure, $400 for a poor patient is a fortune. The burden of HCV falls on often already marginalized populations, such as people who inject drugs, prisoners, and individuals living with HIV, many of whom are unaware of their HCV infection and whose voices need support in the global arena. Addressing the burden of HCV will require more global partnerships and the political will of countries to support efforts to bring HCV treatment to their people through developing policies and guidelines that enable HCV treatment and continuing to commit resources to ensure health systems have the capacity to deliver HCV treatment well. Global action was too slow for

HIV, losing millions of lives when treatment was available, but for HCV we can do better and act quickly to prevent unnecessary deaths from a curable infection.

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