HIV/HCV Co-infection: Overcoming Barriers to Treatment

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A critical step in the eradication of hepatitis C virus (HCV) infection is access to effective therapy. With the advent of interferon-free regimens, HCV providers and patients gained hope that the success seen in clinical trials could be translated to the real world. However, the exorbitant cost of the new direct-acting antivirals limits access to these medications to the general HCV population, especially underserved patients with public insurance. We used a descriptive qualitative approach to detail the measures necessary and challenges faced by an inner-city nursing team in Washington, DC to obtain the new direct-acting antivirals. Significant time and dedication on the part of providers and staff was required to assist patients with the process of obtaining direct-acting antivirals.

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Hepatitis C virus (HCV) is a major public health burden, chronically affecting more than 3 million people in the United States and approximately 185 million people worldwide (Kohli, Shaffer, Sherman, & Kottilil, 2014). In contrast, 1.2 million people in the United States and more than 35 million people worldwide are living with HIV (Centers for Disease Control and Prevention [CDC], 2015a). HCV disproportionately affects people living with HIV. A CDC (2015a) report indicated that about 25% of people living with HIV in the United States are co-infected with HCV. However, it is a challenge to understand the true burden of infection, given that state-by-state HCV

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prevalence estimates are hindered by insufficient screening (Yehia, Schranz, Umscheid, & Re, 2014) and poor nationwide reporting mechanisms (CDC, 2015b). In the District of Columbia (DC), HIV and HCV remain at epidemic levels according to a report by the District of Columbia, Department of Health HIV/AIDS, Hepatitis, STD and TB Administration (2014). The report showed that, of the 650,000 DC residents (U.S. Census Bureau, 2015), 16,469 had tested positive for chronic hepatitis C between 2009 and 2013, while 16,423 residents are known to be living with HIV as of December 2013. Moreover, institutional statistics from a large, inner-city hospital in Washington, DC reported the prevalence of HCV in patients born between 1945 and 1965 (otherwise known as the birth cohort) from 7.8% to 10% of the population (Geboy et al., 2014). Despite poor reporting of HCV incidence, both known and projected estimates outline the high prevalence of HCV in Washington, DC.

Due to the staggering rates of HIV and HCV in DC, in 2009 the Washington, DC, Department of Health and the National Institutes of Health (NIH) entered into partnership and birthed the DC Partnership for HIV/AIDS Progress (DCPFAP). The partnership brought clinical research and subspecialty care for HIV and viral hepatitis to underserved inner-city community clinics. The goal of DCPFAP is to bring clinical trial opportunities to underserved populations in Washington, DC. Through this program, approximately 1,124 patients with HCV have been referred for evaluation, and 430 have participated in NIH clinical trials for HCV, including a community study that is a collaboration between NIH, Gilead, and two local Federally Qualified Health Centers. During the evaluation of patients for clinical trials, it was apparent that there were patients who either did not qualify for clinical trials due to stringent inclusion and exclusion criteria, or did not want to participate in clinical trials. Because the ultimate goal was to ensure that everyone obtain treatment, the DCPFAP clinical team decided to try to get newly approved direct-acting antivirals through public and private insurance for some of the HCV-infected patients not being treated through clinical trials. This article documents the experiences and challenges that were encountered in obtaining direct-acting antivirals through both public and private insurance.

Methods

Over many decades, HCV treatment has made tremendous strides from the weekly injection and daily pill burden of interferon and ribavirin to a more tolerable direct-acting antiviral regimen. The goal of HCV treatment is cure. Previous regimens had poor cure rates and were often not well tolerated due to major side effects from interferon products and ribavirin, including severe depression and psychiatric symptoms, which precluded many patients from receiving therapy, especially individuals with mental illness. The new interferon-free regimens with direct-acting antivirals have far fewer, if any, side effects (Brennan & Shrank, 2014). In 2013, the U.S. Food and Drug Administration approved the first direct-acting antivirals, simeprevir and sofosbuvir, as a combination treatment, and the following year approved ledipasvir/sofosbuvir (U.S. Food and Drug Administration, 2014). With the advent of these interferon-free regimens, the hope is that more people will have access to the medications and be cured of HCV. However, this hope has been thwarted by the exorbitant cost of the medications. The cost of simeprevir for a 12-week course is approximately $66,000 USD, while sofosbuvir is $1,000 USD per pill or $84,000 USD for a 12-week treatment course. Both simeprevir and sofosbuvir must be used in combination with other medications, so the total cost of treatment exceeds the cost of the direct-acting antiviral therapy alone. Ledipasvir/sofosbuvir is the recently approved fixed-dose combination direct-acting antiviral therapy that can be used for treatment of HCV genotype 1. It costs $1,125 USD per pill or $94,500 USD for a 12-week course (Hepatitis C Online, 2014a; 2014b; 2014c).

A descriptive, qualitative approach was used to examine the process of obtaining these newly approved direct-acting antivirals for 34 patients (see Table 1) from February 2014 to July 2015. This time frame was chosen because it documented the experiences of the DCPFAP clinical team obtaining the newer direct-acting antivirals with higher rates of cure and fewer side effects.

All 34 patients were served by inner-city clinics in Washington, DC, where the majority of patients were African Americans with incomes below the poverty