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## An Estimate of the Cost of Hepatitis C Treatment for the Brazilian Health System

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### ABSTRACT

**Objectives:** Hepatitis C therapy in Brazil is expensive due to the cost of antiviral drugs and demands on medical resources. The objective of this study was to estimate the direct costs per patient of chronic hepatitis C therapy in a Brazilian setting. **Method:** A microcosting study from a public health system perspective. The costs included were those of antiviral drugs, secondary medicines, diagnostic tests, visits to physicians and other professionals, hospitalization, nurse, and pharmaceutical care. All costs were priced in 2010. The values were converted to US \$ (2010). **Results:** The total direct cost of hepatitis C treatment per patient with interferon alpha (IFN) plus ribavirin (RBV) was US \$982.25, with peginterferon alpha (PEG) 2a 180 µg plus RBV was US \$10,658.08, and with PEG 2b 120 µg plus RBV was US \$12,597.63, taking into account entire treatment according to Brazilian guidelines and assuming that all patients completed full

treatment. The antiviral drugs are the most expensive element of the cost of treatment, totaling more than 40% of the medical costs of IFN plus RBV therapy and more than 88% of PEG plus RBV therapy. Calculating an average of 10,000 treatments per year, the total direct cost is US \$90,346,772.39. According to the Ministry of Health, 90% of the annual total cost of hepatitis C treatment is accounted for by antiviral drugs. **Conclusions:** In Brazil, antiviral drugs are the most expensive component of hepatitis C treatment. The cost of follow-up and support to patients is minimal compared with the cost of antiviral drugs.

**Keywords:** direct cost, hepatitis C, hepatitis C treatment, interferon.

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### Introduction

Infectious diseases are a very significant public health issue in Brazil, not only in terms of overall morbidity but also due to the financial burden and extra demands placed on medical resources [1–3].

Hepatitis C virus (HCV) infection is a serious public health problem as 80% to 85% of HCV carriers develop a persistent infection. Cirrhosis, end-stage liver disease, and hepatocellular carcinoma are the most significant clinical consequences of chronic HCV infection [4]. Moreover, patients with chronic HCV infection require periodic ambulatory care to monitor and treat their condition. As a result, studies show that patients with chronic HCV infection [5] consume a substantial and escalating amount of health care resources.

Treatment for 24 or 48 weeks with interferon alpha (IFN) or peginterferon alpha (PEG) is recommended for people with HCV infection, according to viral and clinical characteristics.

The primary aim of treating chronic hepatitis C is to clear HCV, in order to improve quality of life and reduce the risk of cirrhosis and hepatocellular carcinoma [6].

In Brazil, the public health system provides treatment for chronic HCV infection, including the use of IFN, PEG, and ribavirin (RBV). In 2007, the amount allocated to drugs in the Brazilian Ministry of Health budget was 10.7% and the specialized component of pharmaceutical services accounted for 42% of this expenditure [7]. Another study revealed that Brazil's national system to treat hepatitis C had an annual budget of US \$14,553,293.90 in 2002 and US \$31,633,149.41 in 2007 for medicines [8].

The treatment of HCV infection is expensive and almost 50% of all patients who undergo this treatment are not cured, representing a low cost-effectiveness ratio. The treatment can cause many side effects such as flu-like symptoms, fatigue, hemolytic anemia, neutropenia, depression, irritability, concentration loss and memory disturbances, skin irritation, and weight

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loss [9]. These side effects are the most significant obstacle to adherence [10].

Available data indicate that patients who are adherent and receive at least 80% of their total PEG and RBV doses for at least 80% of the duration of treatment have significantly higher rates of sustained viral response (SVR) when compared with patients with lower levels of adherence [11]. Studies show that patients are more likely to adhere to and complete therapy when there is ongoing support by a clinical team [12].

In a systematic review of studies of treatment of chronic HCV infection in Brazil, the rates of discontinuation varied between 4.5% and 44.4%. Meta-regression to evaluate the association between rates of no SVR and rates of noncompletion found a linear association and demonstrated that an increase of 10% in the discontinuation rate decreased SVR by 4.1%. According to this analysis, discontinuation of treatment is a major reason for the observed differences in rates of SVR in clinical settings compared with clinical trials [13].

In view of the fact that the rate of treatment discontinuation is indirectly related to service organization, this study aims to estimate the cost of chronic HCV infection therapy in a Brazilian setting from the perspective of the Brazilian National Health System. The subject of this study was a group of patients treated in a specialist public health center for HCV infection, cared for by a multidisciplinary team in accordance with Brazilian guidelines.

## Methods

A microcosting study from the perspective of the Brazilian public health system was carried out to identify the direct cost of treatment per patient. The study included the cost of antiviral drugs, treatment of side effects, diagnostic tests, the administration of injectable drugs, outpatient visits to specialist physicians and other professionals, and hospitalization due to treatment. These costs were estimated taking into account the entire treatment in accordance with Brazilian guidelines and assuming that all patients completed full treatment.

### Antiviral Drugs

The antiviral drugs and the duration of treatment were estimated according to Brazilian guidelines [14], and the costs of IFN, PEG, and RBV were those used by the Ministry of Health in 2010. These drugs were purchased through a public bidding process organized by the Ministry of Health.

### Treatment of Side Effects

The drugs used by patients to control side effects and their duration of use in the HCV infection therapy were identified from the prospective cohort study that was carried out in a specialist public health center in Florianópolis between 2005 and 2008 with 111 patients. A multidisciplinary team monitored patients weekly. Data were collected by a pharmacist who monitored patients [15].

The drugs used to treat the side effects resulting from HCV infection treatment were divided into two groups. The first included epoetin alpha and colony-stimulating factor for the control of anemia and neutropenia. The second group included other drugs to control side effects such as fatigue, headache, myalgia, rigors, fever, nausea, insomnia, and depression. The costs of epoetin alpha and colony-stimulating factor are based on Ministry of Health figures. The costs of others drugs are based on figures from the municipality of Florianópolis.

### Diagnostics Tests

The diagnostic tests for HCV infection were identified according to Brazilian guidelines [14]. The diagnostic tests were divided into initial tests and monitoring tests. The initial diagnostic tests included blood cell count, platelet count, alanine transaminase, aspartate transaminase, prothrombin time, bilirubin, albumin, creatinine, uric acid, fasting glucose, thyroid-stimulating hormone, anti-HIV, antigen of the hepatitis B virus, beta human chorionic gonadotropin (women), liver biopsy, HCV genotyping, HCV gene quantitative for patients and use of PEG, and qualitative HCV. The follow-up diagnostic (monitoring) tests included complete blood cell count, platelet count, alanine transaminase, aspartate transaminase, creatinine, thyroid-stimulating hormone, HCV qualitative, and HCV quantitative [14]. The cost of diagnostic tests was taken from the Ministry of Health's database [16].

### Administration of Injectable Drugs

According to Brazilian guidelines, all patients undergoing HCV infection treatment should have medication administered in specialist clinics [17]. Therefore, it was assumed that all patients underwent the administration of injectable drugs in specialist clinics and the cost of this procedure was taken from the Ministry of Health database [16].

### Outpatient Visits to Specialist Physicians and Other Professionals

Visits to specialist physicians for routine follow-ups were estimated according to Brazilian guidelines [14]. Nursing care was calculated according to the frequency of the administration of injectable drugs. Pharmaceutical follow-ups were calculated monthly during the period of treatment. Outpatient visits to other professionals were estimated by using the prospective cohort of patients [18]. The cost of outpatient visits to physicians and other professionals was taken from the Ministry of Health database [16].

### Hospitalizations

The number of hospitalizations associated with HCV infection treatment was identified in a retrospective cohort [18]. The data were identified from the medical records of 188 patients who received treatment between 2003 and 2006 at a specialist clinic in Florianópolis. The cost of treating each patient was calculated according to the procedures described on the patient record. The cost was taken from the public health system database for hospital procedures [16]. The average cost of hospitalization per day was calculated by dividing the cost of all hospitalizations for full-time care by the number of days of hospitalization.

Our methodological approach set out to 1) identify the resources used, b) estimate costs from a public health system perspective, c) calculate the cost per patient, and d) calculate the Ministry of Health's estimated expenditure.

All resources identified were multiplied by the probability of being used by patients. The sum of the total costs is equivalent to the total direct cost taking into account all patients who received full treatment. All costs were based on prices from 2010. The figures were converted to US \$ (2010), R \$1.00 = US \$0.57, according to the exchange rate on July 30, 2010 [19].

Data on the number of patients with HCV infection in Brazil between 2000 and 2009 were compiled according to the epidemiologic database [20]. The number of patients who have undergone HCV infection treatment in Brazil was estimated according to the number of units of IFN and PEG distributed by the Ministry of Health. By taking the number of patients diagnosed and treated annually in Brazil, we can estimate the annual budget to treat patients with HCV infection in Brazil.

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