Clinical pathway for the treatment of chronic Hepatitis C, a look and a complement from the perspective of pharmaceutical services

Mónica Ledezma-Morales, 1* Pedro Amariles M., 1 Claudia Marcela Vargas-Peláez, 2 Francisco Augusto Rossi Buenaventura. 2

1. Grupo Promoción y Prevención Farmacéutica at the Universidad de Antioquia in Medellín, Colombia

2. Fundación IFARMA in Bogotá D.C., Colombia

*Correspondence: monica.ledezma.morales@gmail. com.

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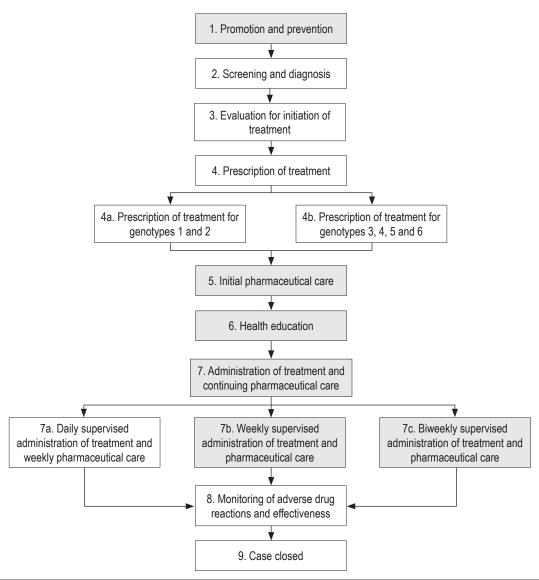
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Dear editor:

When the Statutory Law on Health (Law 1751 of 2015) went into effect, (1) health became enshrined as an autonomous fundamental right. Its provision has been guaranteed and regulated, and protective mechanisms have been established. In addition, a change of focus was generated in health care policy that has defined Primary Health Care as the basis of Comprehensive Health Care Policy (PAIS - Política de Atención Integral en Salud) within the framework of the General System of Social Security in Health (SGSSS - Sistema General de Seguridad Social en Salud). PAIS implementation guidelines have been defined in the Comprehensive Health Care Model and in the Comprehensive Health Care Pathways which aim to articulate various actors in the SGSSS including the Benefit Plan Insurance Entities, the Health Promotion Institutions, and the secretariats of health in order to guarantee timely and quality access to the health services required by citizens. (2)

In accordance with the guidelines established in the PAIS in mid-2017, the Ministry of Health and Social Protection made its first centralized purchase of direct-acting antivirals for the treatment of hepatitis C. It purchased sofosbuvir/ledipasvir, sofosbuvir and daclatasvir. In addition, a clinical pathway for treatment of chronic hepatitis C was established. It seeks to "standardize care based on the best available evidence, improve health outcomes and make the use of the most efficient resources." (3) Undoubtedly, this innovative strategy for management of high-priced medicines within the framework of the SGSSS has improved access to treatment and the consequent cure of patients with hepatitis C. This was demonstrated in the High Cost Account published in July, 2018. (4) However, there are still difficulties regarding timely and continuous access to treatment and provision of health services especially for patients in the subsidized regime and for vulnerable people such as street people, IV drug users, and the incarcerated population who are not generally affiliated with the SGSSS.

In this context, it is necessary to look for options that can address the problem of hepatitis C on several fronts with actions that strengthen Primary Health Care and prevent the progression of chronic liver disease. These should include hospitaliza-



Promotion and prevention: We propose collective information and education activities regarding hepatitis C and the application of a Primary Care checklist by Health Promotion Institutions to evaluate behavior or exposure to hepatitis C risk and to determine the need for screening tests.

Pharmaceutical care: This should include pharmacotherapeutic follow-up through interviews with patients; validation of pharmacotherapy; reviews of drug interactions, effectiveness and safety analysis; evaluations of problems related to real or potential drugs; evaluation of adherence; immunization history evaluations; reviews of the existence of medication orders and laboratory tests; participation in multidisciplinary staff; administrative accompaniment; and performance of pharmaceutical interventions derived from study findings that can be addressed to the patient or to health care personnel.

Health education: Education for patients and their families in general issues related to the disease including mechanisms of transmission, complications, prevention of reinfection, therapeutic objectives, precautions, forms of drug administration and storage, examinations to evaluate drug safety and effectiveness, frequency of administration, management of adverse reactions to medications, and importance of adherence.

Administration: Considering that clinical practice has detected patients for whom supervised daily treatment is not necessary, we propose that drugs be dispensed on a weekly or biweekly basis according to evaluations of adherence and sociodemographic conditions. Adherence could be supervised by telephone or internet.

Pharmacovigilance: Although the current clinical pathway contemplates monitoring of adverse reactions, we propose that pharmaceutical personnel participate in this process. According to their classification, the mild and/or moderate adverse drug reactions can be treated with over-the-counter medications and managed under the direction of a pharmaceutical chemist expert in hepatitis C after agreement with medical specialists. Similarly, there is a need for a follow-up consultation between 6 and 12 months after reaching a sustained virological response. This is especially important in populations susceptible to reinfection such as IV drug users, people living with HIV, men who have sex with men, and patients on hemodialysis.

Figure 1. Clinical pathway for the treatment of chronic hepatitis C, complemented with interventions and activities of pharmaceutical services. Gray boxes indicate processes proposed as complements to the current clinical pathway). Source: adaptation of: Ministry of Health and Social Protection. Clinical pathway for the treatment of hepatitis C. Bogotá, Colombia: Institute of Technological Evaluation in Health Ministry of Health and Social Protection; 2017

tion for decompensation and provisions for subsequent health expenditures. In this sense, the implementation of Promotion and Prevention activities focused on populations that have been identified as being at risk for hepatitis C would allow for timely screening and improve rates of diagnosis and early treatment. These populations include people over 60 years of age, people who received transfusions or donations of organs before 1996, IV drug users, and people who have been tattooed or had piercings in places that do not meet basic sanitary requirements. (3) Recently, the publication of the new Comprehensive Care Pathway for Promotion and Maintenance of Health by the Ministry of Health has taken a step in this direction. It includes a paraclinical package for people 60 years and over that has tests for hepatitis C. (5)

Since patients with hepatitis C are highly susceptibility to problems related to medications due to their ages, multiple pathologies, polypharmacy and social characteristics, the inclusion of pharmaceutical care within Primary Health Care could support medical activity to monitor the safety and effectiveness of treatments. It would also help provide continuity to health care provision. Pharmaceutical care provides a comprehensive view of the patient that allows identification of her/his needs related to hepatitis C or underlying diseases, and communicates them to the health care personnel responsible for the patient's care. (6) It also allows for strict monitoring from screening/confirmation of infection to cure. Evidence of successful implementation of care programs for patients with chronic hepatitis C exists in the experiences of pharmacists in the United States and Spain. (7-11) These experiences could serve as models to be integrated into the clinical pathway established by the Ministry of Health and Social Protection.

In an effort to contribute to achievement of the best health care outcomes for patients with hepatitis C, we have presented a proposal to complement the clinical pathway with interventions and activities of pharmaceutical services (Figure 1). Prospective studies aimed at evaluating the benefits of this complement to the health care pathway could provide evidence of improvement of access to treatment, demonstrate the clinical outcomes of patients with chronic hepatitis C, and compare those outcomes with outcomes currently achieved.

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