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## BARRIERS TO HEPATITIS C TREATMENT

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### Abstract

Despite the availability of highly effective therapy for hepatitis C virus (HCV) infection, few patients receive treatment. Barriers arising at multiple levels, from diagnosis to specialist referral, may impede the delivery of hepatitis C care. At the patient level, lack of awareness, fear of side effects, poor adherence, and comorbid conditions may prevent treatment. For providers, limited knowledge, lack of availability, and communication difficulties may be problematic. At the government and payer level, a lack of promotion, surveillance, and funding may interfere. Each of these barriers needs to be addressed if wider implementation of antiviral therapy is to be achieved.

### Keywords

Hepatitis C/therapy; health services accessibility; delivery of health care; barriers to care

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Recent advances in the treatment of hepatitis C virus (HCV) infection have produced antiviral therapies capable of higher cure rates and shorter treatment durations. For the 130 million to 170 million persons worldwide with chronic HCV infection, current therapies offer a greater than 60% likelihood of sustained virologic response (SVR), regardless of viral genotype.<sup>2-5</sup> However, for effective therapy to be delivered, long-standing barriers to treatment need to be addressed. Furthermore, with increased costs, higher rates of adverse events, and complicated treatment algorithms, newer agents may present even greater challenges to patients and physicians. An understanding of existing barriers to HCV treatment is important to help guide initiatives aimed at improving treatment rates and, ultimately, outcomes.

### Establishing Current Treatment Rates

Only a small minority of HCV-infected persons receives treatment. The proportion of patients treated with antiviral therapy has been estimated in academic, community, and Veterans Affairs (VA) hepatitis C cohorts (Table). Treatment rates ranged from 1.1% in a Vancouver inner-city population to 30% at a university-affiliated VA.<sup>6,7</sup> Market research from the United States suggests that less than 10% of persons with known infection have been treated.<sup>8</sup> Likewise, market uptake of interferon (IFN) in Europe indicates an average treatment rate of 3.5%.<sup>9</sup> Treatment rates may be higher among countries where government-sponsored surveillance and treatment programs are available, such as in France and other European countries<sup>10,11</sup>.

Numerous barriers related to patient, provider, government, and payer factors may effectively prevent the delivery of HCV care. These barriers arise at multiple points beginning from the time of infection to the delivery of antiviral therapy (Figure).

## Patient Factors

Patient-related factors are a common source of treatment deferral and include limited awareness, poor adherence to physician recommendations, economic or social pressures, treatment fears, psychiatric disease, and injection drug use.

## Knowledge and Awareness

Between 65% and 75% of patients with chronic HCV infection are unaware of their infection,<sup>12</sup> representing the single greatest barrier to treatment. Further, among infected or at-risk persons, knowledge related to HCV is poor. Confusion regarding modes of transmission, disease complications, and interpretation of HCV screening tests is common.<sup>13-15</sup> These deficiencies may contribute to missed treatment opportunities, continued transmission, and poorer health outcomes.<sup>12</sup>

## Non-adherence

Though identification of infection may represent the largest barrier to treatment initiation, patients frequently fail to seek treatment once the diagnosis is established. Among patients referred for evaluation of HCV, between 24% and 57% will not attend their initial subspecialty evaluation.<sup>16-18</sup> Likewise, patients may demonstrate a lack of adherence to the subsequent evaluation process, missing clinic appointments and failing to obtain recommended diagnostic testing.<sup>19</sup> This finding is recognized by treating physicians, 80% of whom cited patient non-adherence as a barrier to high-quality service in the United Kingdom (UK).<sup>20</sup> There are multiple reasons for this lack of adherence. Notably, patients may not recognize the urgency to treat an essentially asymptomatic disease.<sup>21</sup> Furthermore, significant economic and social pressures may contribute.

## Economic and Social Pressures

Persons with HCV are more likely to be uninsured compared to individuals without HCV. Data from the National Health and Nutrition Examination Survey (NHANES III) indicate that 29.6% of HCV-infected patients in the United States are uninsured, compared to 12.2% of persons without infection.<sup>22</sup> Further, uninsured persons are less likely to have contact with a healthcare professional, reducing the likelihood of diagnosis and treatment. Though a lack of health insurance is a major barrier to treatment, economic pressures are not exclusive to the uninsured. A cross-sectional study of HCV patients referred to a tertiary care center found that one-half of patients cited personal financial resources as a barrier to care, despite 90% of patients possessing medical coverage.<sup>23</sup> Fears of missed work obligations may further contribute to financial insecurity.<sup>24</sup>

In addition to financial pressures, patients cite multiple social factors as reasons for deferring therapy. These include family obligations, lack of social support, social rejection, and stigmatization.<sup>23-25</sup> More than half of HCV patients report feeling stigmatized, primarily due to the association between HCV and HIV, promiscuity, and/or substance abuse.<sup>25,26</sup> These patients have higher levels of anxiety, worsened quality of life, and difficulty coping.<sup>26</sup> Furthermore, patients may feel stigmatized by their physicians,<sup>27</sup> further reducing the likelihood of treatment adherence.

## Fears of Treatment

For those patients who present for evaluation, fears related to antiviral therapy figure prominently into their decision to pursue treatment. An important consideration among HCV patients is the risk to benefit tradeoff related to treatment.<sup>24</sup> Though a desire to eradicate a chronic, progressive infection may seem intuitive, patients may be unable to look beyond the short-term risks of therapy, particularly side effects. Among patients deferring HCV therapy, nearly two-thirds cite a fear of side effects, coupled with the asymptomatic nature of their disease, as the primary reason for deferral.<sup>21</sup> These findings are supported by an international study of treating physicians, who rated patients' fear of side effects as the most important barrier to HCV treatment.<sup>28</sup> Similar findings were noted in a survey of UK physicians.<sup>20</sup>

Fears of treatment-related side effects are not without merit. Virtually all patients will experience a treatment-related side effect, ranging from mild constitutional symptoms to significant hematologic abnormalities.<sup>2-5</sup> Adverse effects greatly impact quality of life and may lead to dose reductions and treatment discontinuation. While these fears are valid, they may also be heightened by the availability of inaccurate or skewed information.<sup>29</sup> Therefore, it is imperative that patients receive appropriate pre-treatment education and counseling to allay such fears. In addition to side effects, patients express concerns regarding treatment duration and effectiveness.<sup>19-21</sup>

## Psychiatric Disease

Psychiatric illness represents a significant barrier to HCV treatment. Adverse psychiatric effects, including irritability, depression, and mood swings, are common complications of IFN use. Between 21% and 58% of patients will develop significant depression with IFN therapy.<sup>30</sup> Furthermore, HCV-infected patients have a higher prevalence of preexisting psychiatric illness.<sup>31</sup> Recognizing the risks of IFN, clinicians frequently defer therapy for patients with underlying psychiatric illness.<sup>7</sup> Unfortunately, these patients are unlikely to obtain treatment after initial deferral.<sup>32</sup> However, the presence of psychiatric illness is no longer considered an absolute contraindication to therapy.<sup>30</sup> When treated with a multidisciplinary approach, including regular psychiatric monitoring, patients with psychiatric disorders can achieve comparable outcomes to those without psychiatric illness.<sup>33</sup> In a randomized, controlled trial, participants initially deferred from therapy due to substance abuse or psychiatric illness were more likely to become eligible for subsequent antiviral therapy after enrollment in a multidisciplinary intervention compared to those receiving standard of care.<sup>34</sup>

## Injection Drug Use

Injection drug use is a frequent mode of HCV acquisition, accounting for a high proportion of new cases worldwide, and 60% of incidence cases in the United States.<sup>30,35</sup> Active use of injection drugs is a common reason for HCV treatment deferral.<sup>18,36,37</sup> One reason is the high prevalence of depression and psychiatric illness among intravenous drug users (IDUs).<sup>38</sup> Additionally, concerns regarding poor patient adherence, increased risk of adverse effects, and post-treatment reinfection may lead to deferral.<sup>39</sup> Intravenous drug users have poor awareness of current treatments, with fewer than half recognizing that HCV is a curable disease.<sup>40,41</sup> However, between 70% and 80% of IDUs express a willingness for treatment.<sup>40-42</sup> Furthermore, favorable treatment outcomes have been demonstrated in both active IDUs and those receiving methadone maintenance.<sup>33,43,44</sup> Therefore, treatment for these patients should be considered in the setting of close monitoring and adjunctive psychiatric and substance use counseling.<sup>30</sup>

## Provider Factors

Barriers to hepatitis C treatment may arise at the provider level, including primary care physicians and subspecialists. Key barriers to treatment include lack of knowledge and awareness, limited specialist availability and/or lack of referral, and communication issues.

### Knowledge and Awareness

Healthcare professionals have demonstrated key knowledge deficits related to HCV prevalence, risk factors, prevention, and management.<sup>12</sup> Among primary care providers, this may be attributable to a lack of experience. In a nationwide survey of primary care physicians, 73% of respondents reported seeing 5 or fewer HCV patients in the preceding year, with 44% reporting no experience with HCV treatment.<sup>45</sup> Though most physicians correctly identified risk factors for HCV, only 59% reported regularly screening for these risk factors. Similar deficiencies in HCV testing have been noted in studies of family practitioners and obstetrics and gynecology providers.<sup>46,47</sup> Knowledge of HCV was likewise inadequate among drug-treatment providers.<sup>48</sup> Among patients with HCV, perceived physician incompetence is a known barrier to care.<sup>27</sup>

### Specialist Referral and Availability

Primary care physicians infrequently refer HCV patients for subspecialty evaluation. Only one-half of HCV-infected patients are referred to a specialist for evaluation and management.<sup>6,49</sup> For patients with normal liver tests, the likelihood of referral is below 30%.<sup>45</sup> Furthermore, for those patients referred for treatment, the availability of specialists presents an additional barrier. It is estimated that 80% of chronic HCV patients are managed by 20% of gastroenterologists.<sup>8</sup> Specialists are concentrated within academic medical centers or government-designated Centers of Excellence, limiting the availability of local treatment providers. As a result, patients may face long-distance travel, extended wait times, and a lack of scheduling flexibility.<sup>20,50</sup> While academic hepatologists may be more adept at managing adverse effects and limiting dose reductions, the number of patients with chronic HCV may exceed their availability.<sup>8</sup> Efforts to expand the availability of specialist expertise via telemedicine have shown promise.<sup>51</sup>

### Communication Issues

Negative interactions with HCV treatment providers may serve as an additional barrier to treatment. In a cross-sectional study of 322 HCV patients treated at a tertiary care center, 41% reported communication difficulties with their physicians.<sup>27</sup> Specifically, patients felt rushed, misled, or not listened to. Patients may question a physician's competence, or feel stigmatized by these interactions. Healthcare workers are known to harbor negative views of injection drug users, characterizing them as manipulative and unpleasant.<sup>12</sup> As a result of these interactions, patients may feel discouraged, less likely to listen to physician recommendations, and more inclined to defer therapy.

### Government and Payer Barriers

Governments and payers are critical to delivering HCV services, implementing surveillance programs, disseminating information, and increasing public and provider awareness. Though patient and provider factors receive the greatest attention, obstacles arising at the government and payer level are likewise important. In an international study of HCV providers, lack of treatment promotion and insufficient funding were noted as significant government level barriers.<sup>28</sup> Likewise, lack of insurance coverage, high out-of-pocket expenses, and excessive paperwork were cited as payer-level barriers. In a separate study of UK physicians, more than two-thirds of respondents reported inadequate funding as a barrier

to quality HCV care.<sup>20</sup> These sentiments were echoed in the recent Institute of Medicine report on the prevention and control of viral hepatitis in the United States.<sup>12</sup> Specifically, the committee noted the poorly developed surveillance system, inadequate educational initiatives, and fragmented viral hepatitis services in this country. To address these issues, increased resource allocation and improved collaboration between government, healthcare, and educational stakeholders are needed. In the European Union, government sponsored screening and surveillance programs have greatly increased diagnosis rates of HCV infection<sup>10,11</sup>.

## Looking forward: Direct Acting Antivirals

The recent introduction of the direct acting antivirals (DAA) boceprevir and teleprevir has changed the current treatment paradigm for patients with genotype 1 infection. Among treatment-naïve patients, overall SVR rates exceeding 70% are now possible, with the added potential for abbreviated treatment duration.<sup>4,5</sup> For patients concerned about efficacy and duration, the introduction of these agents may increase treatment appeal. However, these benefits must be balanced against increased treatment complexity, higher rates of adverse events, and the potential for drug-drug interactions.<sup>52</sup> It remains to be seen how the availability of triple therapy will influence current treatment barriers.

## Conclusions

Multiple barriers to the diagnosis, evaluation, and delivery of hepatitis C treatment serve to limit the widespread uptake of antiviral therapy. Though recent advances in HCV treatment offer the potential for high cure rates and shorter treatment durations, long-standing obstacles to treatment must be addressed. Poor awareness, misguided and exaggerated fears, relative contraindications, and insufficient funding all contribute to strikingly low treatment rates. Recognizing the global burden of infection, there is a critical need to reduce current barriers to hepatitis C treatment.

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## Abbreviations

<b>HCV</b>	Hepatitis C virus
<b>VA</b>	Veterans Administration
<b>UK</b>	United Kingdom
<b>NHANES</b>	National Health and Nutrition Examination Survey
<b>HIV</b>	Human Immunodeficiency Virus
<b>IDU</b>	injection drug user
<b>DAA</b>	direct acting antiviral, IFN interferon

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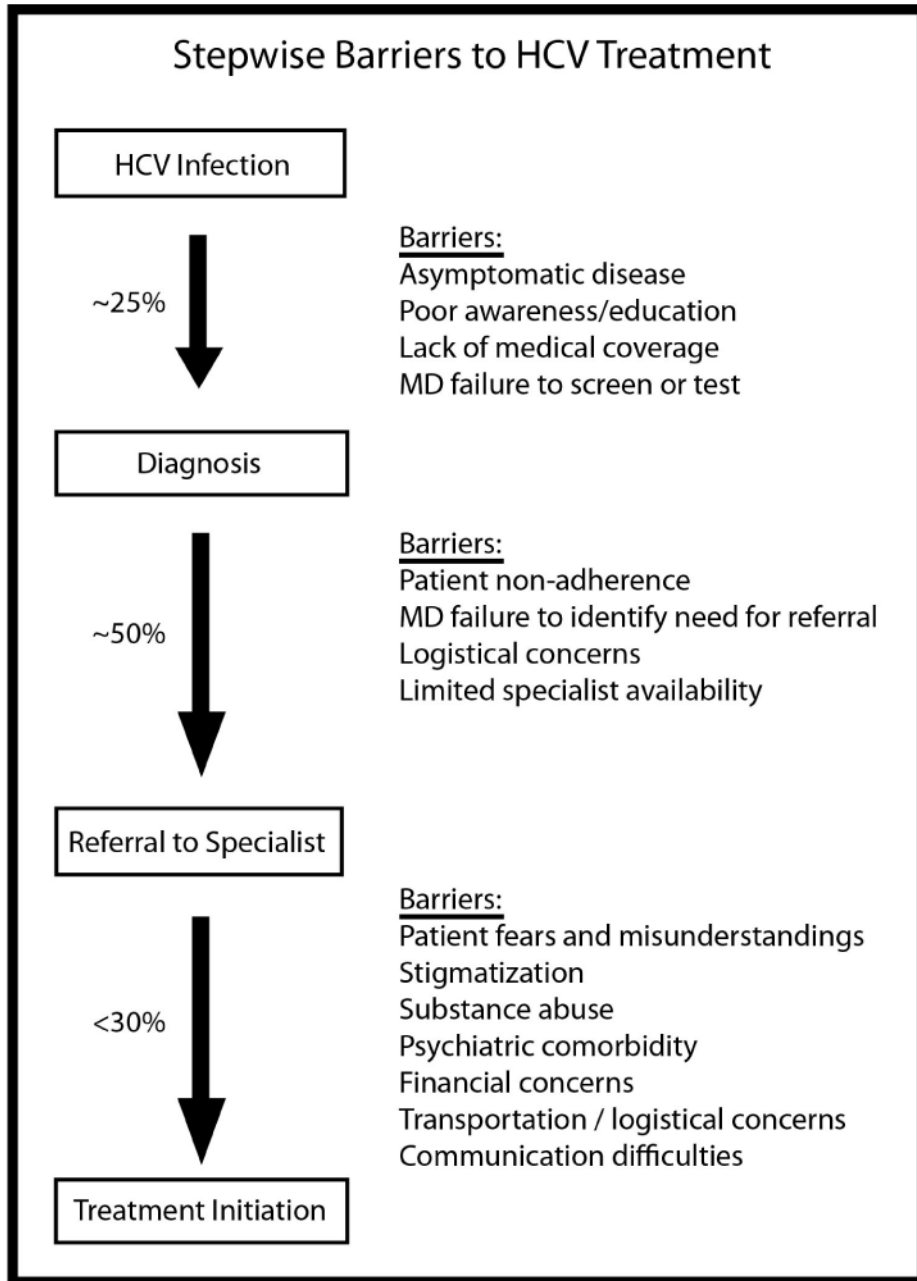
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**Figure.**  
Stepwise Barriers to Hepatitis C Treatment

**Table**

## HCV Treatment Rates in Clinical Practice

Author	Year	Cohort/Setting	# Of Patients	Treatment Rate (%)
Grebely <sup>6</sup>	2009	Community-based inner city cohort	1,360	1.1
Butt <sup>53</sup>	2010	VA National Patient Database	134,934	11.9
Cawthorne <sup>17</sup>	2002	St. Louis VA	557	13.8
Rocca <sup>37</sup>	2004	Olmstead County Hepatitis C Registry	366	15.0
Bini <sup>54</sup>	2005	24 VA medical centers	4,084	17.7
Groom <sup>18</sup>	2008	Minneapolis VA	520	23.8
Evon <sup>32</sup>	2007	Academic medical center	433	25.2
Morrill <sup>36</sup>	2005	Primary care clinic	208	27.4
Falck-Ytter <sup>19</sup>	2002	Teaching county hospital	293	28.3
Butt <sup>16</sup>	2005	Pittsburgh VA	354	29.4
Rowan <sup>7</sup>	2004	Houston VA	580	30.0

VA, Veterans Administration