REVIEW

Ethical Issues in the Treatment of Hepatitis C

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Background & Aims: **Four million Americans are infected with hepatitis C virus (HCV), making it the most common blood-borne infection in the United States. Members of disadvantaged groups such as prisoners and those with psychiatric disorders have a higher prevalence of HCV infection than the general population. Ethical, clinical, economic, and social barriers often prevent these patients from receiving the effective antiviral treatments now available. These barriers to care have received little attention in the literature, and yet, knowledge of the ethical and social justice aspects of HCV treatment can enhance the quality of gastroenterologists' patient care.** ***Methods:*** **This article analyzes 5 clinical-ethical arguments frequently presented for limiting patient access to HCV treatment: risk/benefit balance, justice, compliance, cost-effectiveness, and discrimination.** ***Results:*** **Appropriate psychiatric and substance use intervention can result in a favorable cost-effectiveness and risk/benefit balance for treating members of disadvantaged groups. Although members of disadvantaged populations might exhibit higher rates of psychiatric side effects and poorer compliance with antiviral regimens, collaborative care can improve adherence and reduce adverse effects. The principle of justice might warrant treatment of these populations if the rate of adherence and risk/benefit balance is not significantly different than in other populations. Discrimination against persons with hepatitis C often reduces access to care among prisoners and other stigmatized groups.** ***Conclusions:*** **This analysis suggests that if gastroenterologists and mental health and substance abuse professionals actively collaborate, access to antiviral therapy for HCV can, in many cases, be safely and effectively expanded to disadvantaged populations.**

Hepatitis C virus (HCV) is the most common blood-borne infection in the United States. Prevalence estimates from 1988–1994 in the United States indicate that 3.9 million persons have been infected with HCV, of whom 2.7 million have chronic HCV infection.[1–3] Hepatitis C accounts for 8,000–10,000 deaths annually and is the leading indication for orthotopic liver transplantation in the United States.[3,4] There has been a steady improvement in the effectiveness of antiviral therapies for HCV during the last 13 years, with more than 50% of patients now attaining a sustained viral response (SVR) to combined therapy with pegylated interferon and ribavirin.[5] Members of vulnerable and disadvantaged populations such as intravenous drug users, prisoners, veterans, members of ethnic minorities, and persons with substance use and psychiatric disorders have a high prevalence of HCV. Rosenberg found rates of HCV in persons with serious mental illness to be 19.6%, 11 times the overall population rate. Among intravenous drug users, the rate of HCV positivism might be as high as 95%.[6] There are, however, formidable clinical, ethical, social, and economic barriers that restrict the availability of these beneficial treatments to members of disadvantaged groups.[7–9]

Although government agencies and academic institutions have increasingly recognized the public health ramifications of disadvantaged persons' lack of access to antiviral therapy, there has been almost no corresponding recognition of the ethical aspects of the availability and administration of HCV treatment. A literature search of the MEDLINE, BIOETHICSLINE, and PsycINFO databases retrieved only 5 articles dealing with ethical dimensions of HCV care in the United States apart from transplant considerations and not a single article devoted to ethical issues involved in HCV treatment.[10–13]

Notwithstanding this lack of scholarly attention, knowledge of ethical issues and skill in addressing the potential dilemmas involved in the care of HCV patients are important for gastroenterologists who manage the bulk of HCV patients. Incorporating an assessment of ethical concerns into the care of HCV patients might improve quality of patient care, increase patient compliance and satisfaction, provide protection for physicians in case of adverse events or malpractice litigation, and help

Abbreviations used in this paper: HCV, hepatitis C virus; HIV, human immunodeficiency virus; SVR, sustained viral response.

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1542-3565/05/$30.00
PII: 10.1053/S1542-3565(05)00183-7

ensure providers' adherence to the highest standards of professionalism and social responsibility.

Background

The epidemiology of HCV in disadvantaged populations reinforces the ethical significance of both public policy and medical decision making around treatment with antiviral therapy and the urgent need for integrated approaches to care. Osher et al[14] assessed human immunodeficiency virus (HIV), HCV, and HBV status, risk factors, demographics, and substance abuse patterns in 668 persons with serious mental illness. Eighteen percent of the sample was HCV positive, and 8% of this group had both HBV and HCV, 2% had HBV, HCV, and HIV, and 1% was co-infected with HCV and HIV. Twenty percent of the participants indicated lifetime intravenous drug use, and 14% engaged in needle sharing. Fifty-seven percent had used cocaine, and 39% had smoked crack. Needle sharing and crack cocaine usage were most strongly correlated with an increase in HCV infection.[14] A lack of medical care compounds these high rates of infection. A study of 777 adults with serious mental illness and HCV found that this cohort was less than 50% as likely as HCV-negative persons to have a regular source of health care. African Americans and those living in communities with a high incidence of violence had the lowest rate of health care.[15]

Examination of the 1997 and 2002 National Institutes of Health Consensus Development Conference Statements on the Management of Hepatitis highlights an expansion of the categories of patients considered appropriate for antiviral medications.[16,17] The 1997 recommendation that major depression and active drug use be considered contraindications to HCV treatment has been modified in the face of growing evidence that these populations can be effectively treated when psychiatric and addiction disorders are consistently monitored and vigorously addressed. The 2002 Statement recommends "that treatment of injection drug use be considered on a case-by-case basis, and that active drug use in and of itself not be used to exclude such patients from antiviral therapy."[17] In recognition of the paucity of programs designed to manage patients with co-occurring HCV, psychiatric and addictive disorders, the National Institute on Drug Abuse recently convened a panel of experts to develop such integrated models of care.[18] However, research suggests that physicians in many practice settings are not able to implement these recommendations because of lack of available consultation with psychiatrists and addiction professionals and inadequate social services for many patients with comorbidity.[14]

An article in the *Annals of Internal Medicine* reviewed the medical records of HCV patients referred to a county teaching hospital liver clinic in 1998–1999. Of the 293 patients considered for antiviral therapy, 72% were not offered treatment. Thirty-four percent were not treated because of severe medical or psychiatric problems, and 13% were rejected because of ongoing alcohol or drug abuse.[19] Cawthorne et al[7] retrospectively evaluated clinic show rates, eligibility, and antiviral response in a Veterans Affairs HCV clinic and concluded that only a minority of veterans who underwent a comprehensive evaluation met the treatment eligibility criteria. A study of the eligibility for treatment of chronic HCV patients at another Veterans Affairs hospital found that of 100 patients, only 32 met the criteria for antiviral therapy. Forty-four percent had hazardous alcohol consumption and psychiatric disorders that required multidisciplinary treatment.[20] Analysis of the clinical literature on HCV treatment discloses 5 interrelated justifications for limiting availability of antiviral therapies for HCV: risk/benefit balance, justice, compliance, cost-effectiveness, and discrimination. This article will summarize the clinically relevant research pertaining to each of these justifications as the basis for discussion of the ethical valence of the limitations.[11,21,22]

Table 1 presents brief definitions of the chief ethical concepts to be discussed in this article and their relevance to HCV care.

Risks and Benefits of HCV Treatment

The complications of HCV infection can lead to considerable morbidity and mortality. Between 65% and 85% of acute infections with HCV become chronic. Studies have suggested that from 3%–20% of patients with chronic infection will develop cirrhosis during a 20-year period, and these patients are at risk for hepatocellular carcinoma.[17,23]

The effectiveness of antiviral treatment for HCV has steadily improved since its inception in 1990, providing a stronger clinical and ethical imperative to treat even patients with conditions that might diminish positive outcome.[5] Potential benefits of treatment include clearance of the virus, improved liver histology, improved quality of life, reduced infectivity, and a reduced risk of hepatocellular carcinoma. Combined HCV therapy with interferon and ribavirin can cause serious medical and psychiatric side effects, and between 10%–14% of patients in large randomized trials discontinue therapy because of adverse effects.[17,24–29]

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