

Ethical Challenges in the Care of Persons With Hepatitis C Infection: A Pilot Study to Enhance Informed Consent With Veterans

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Psychiatric and addictive disorders are often considered contraindications to hepatitis C virus (HCV) treatment. In this pilot study, the ability of 30 veterans to provide informed consent for combined antiviral HCV therapy was examined with a mental health assessment protocol specifically geared to evaluate capacity in this area. The results showed that subjects lacked essential knowledge regarding the course of the disease and the nature of antiviral treatment despite receiving prior counseling. Informed consent assessments of candidates for HCV treatment may identify deficits that are responsive to intervention, thereby allowing patients with comorbid psychiatric and addictive disorders to receive effective HCV treatment.

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Hepatitis C virus (HCV) is the most common blood-borne infection in the United States, affecting an estimated 4 million individuals. More than 2.7 million people have chronic symptomatic HCV infection, which can have serious health consequences; the complications of HCV infection result in 8,000–10,000 deaths annually in the United States.^{1,2} Attempts to stem the spread of HCV among high-risk populations have been only modestly effective.³ Although the incidence of infection is predicted to decrease, prevalence and complications of HCV are expected to increase, with from 16% to 32% of untreated cohorts developing cirrhosis by the year 2020.⁴ Beyond the great human cost of suffering, illness burden, and lost productivity, the direct health care costs associated with this

HCV epidemic for the period 2010–2019 are expected to total \$10.7 billion.⁵ HCV thus represents a major contemporary public health problem that will only become more severe in the coming decade.⁶

The current standard of care for HCV infection is a very complex therapy with pegylated interferon (alfa 2a and alfa 2b) and ribavirin, a combination that achieves a sustained viral response (SVR) in more than one-half of treated patients.² Patients must adhere to a complex regimen of auto-injections once a week, daily oral medication, laboratory monitoring, reproductive precautions, and clinic appointments.⁷ The benefits of HCV treatment include possible clearance of the virus, improved liver histology, reduced infectivity, and a decline in the risk of hepatocellular carcinoma. The duration of treatment depends on the genotype of the virus with which the patient is infected. For HCV genotype 1, 48 weeks of treatment are recommended, compared with 24 weeks for other genotypes.⁷ Side effects of combined therapy with interferon and ribavirin include leukopenia, thrombocytopenia, anemia, nausea, flu-like symptoms, fatigue, insomnia, and malaise. Depression is

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the most common psychiatric symptom resulting from combined HCV therapy, although cases of psychosis, post-traumatic stress disorder (PTSD), mania, and both attempted and completed suicide have also been reported.⁸⁻¹³ Between 10% and 14% of HCV-infected patients in large randomized trials discontinue therapy because of its adverse effects.² Treatment rigor, comorbidities, and psychosocial factors may thus make adherence to combined therapy especially difficult for persons with HCV. The complicated nature and demands of the HCV treatment regimen and serious potential risks along with uncertain benefit highlight the need for rigorous informed consent procedures for all candidates for combined HCV therapy.

Informed consent is the cornerstone of ethical treatment, and yet, for several reasons, it is especially difficult to fulfill this important professional care standard in the context of HCV infection.¹⁴ Informed consent is the embodiment of central bioethical principles such as autonomy, respect for persons, veracity, beneficence, and justice; it is a dynamic process taking place in a relationship between a clinician and patient. The patient's ability to give informed consent is, in turn, based on his or her capacity to make balanced, well-founded decisions and on his or her capacity for voluntarism. Decisional capacity comprises four elements: the ability to communicate a treatment preference; the capacity to understand the nature of the condition, the treatment, and its risks and benefits; the ability to deliberate about the choices and consequences of treatment; and the capacity to appreciate the impact of treatment on life circumstances and values. Voluntarism, which is the

ability to make an authentic decision free from excessive internal or external coercion, is dependent on developmental factors, symptom and illness-related considerations, psychological and social issues, and contextual factors.¹⁴⁻¹⁶

The challenges to informed consent for HCV care are many, as noted in Table 1. First, the uncertainty of prognostic factors in HCV infection makes it difficult to predict the course of liver disease in an individual patient. Consequently, information pertaining to HCV treatment response and relapse rates is stated in probabilities and technical terms that may be difficult for clinicians to frame accurately and for patients to comprehend fully.¹⁷ Studies have found deficiencies in attention, speed of psychomotor processing, and learning/working memory in untreated HCV patients, as well as signs of frontal lobe dysfunction critical to executive function.¹⁸⁻²⁰ Second, neuropsychological impairments resulting from both the virus and treatment with interferon or other agents may negatively affect the cognitive dimensions of informed consent. The patient's mental faculties are critical to comprehending the complex medical information related to HCV. Furthermore, the experience of living with HCV can impair quality of life and be a source of psychological disturbance that can in turn compromise decisional capacity and voluntarism.²¹ These impairments are greater in patients with the comorbid medical and psychiatric conditions so often found in HCV patients.²²

Third, HCV is associated with stigmatizing conditions such as substance use and psychiatric comorbidity, which may also adversely affect the patient's ability to give in-

TABLE 1. Characteristics Associated With Hepatitis C Virus (HCV) Infection That Create Challenges for Informed Consent for HCV Treatment

Elements of Informed Consent	Relevance for HCV Infection
Capacity to communicate a choice	<ul style="list-style-type: none"> • Neuropsychiatric impairments resulting from HCV affect capacity • Neuropsychiatric side effects of interferon, chiefly depression affect capacity
Capacity to understand risks and benefits	<ul style="list-style-type: none"> • Statistical nature of treatment response and relapse rates complicates explanation of risks and benefits • Use of genotype, viral load, and liver fibrosis stage to predict treatment response rate complicates explanation of risks and benefits • Negative neuropsychiatric effects of both HCV and interferon treatment affect capacity
Capacity to deliberate and decide	<ul style="list-style-type: none"> • Individual variation in disease course and treatment response affect capacity • Scientific uncertainty regarding progression of disease, treatment response, and relapse rates complicates explanation of options
Capacity to appreciate implications of consent or refusal for life and values	<ul style="list-style-type: none"> • Psychiatric symptoms, such as anxiety, posttraumatic stress disorder symptoms, depression, affect capacity • Medical symptoms, such as fatigue and insomnia, and overall impairment in quality of life from effects of both HCV and interferon treatment affect capacity
Capacity for voluntarism	<ul style="list-style-type: none"> • Stigma of HCV infection complicates capacity • Associated vulnerabilities, such as drug use and homelessness, affect capacity • Psychosocial risks for individual patients and their families complicate capacity

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formed consent for care. The rate of psychiatric disease among HCV-positive persons is higher than in the general population and is higher still among veterans. A 2002 study found that 80% of 206 veterans eligible for HCV treatment had a history of alcohol abuse or dependence.²³ Sixty percent of this group had a psychiatric illness, most commonly depression or PTSD, for a total of 89% of patients with a documented addictive or psychiatric disorder, many of whom had dual diagnoses. Another study conducted in 2002 reviewed the medical records of 33,824 HCV-infected patients and found that 86.4% had a record of a past or present psychiatric or addictive disorder and that 31% had been hospitalized in a psychiatric or substance abuse unit.²⁴ Because of the high prevalence of psychiatric and addictive disorders in chronic HCV patients, psychiatrists are increasingly being enlisted to perform assessments of patients who are considering combined HCV treatment and to conduct ongoing monitoring and management of patients once they begin a course of interferon and ribavirin. The diagnosis of HCV infection has resulted in discrimination in employment and housing.²⁵ The association of HCV infection with high-risk sexual activity, intravenous drug use, homelessness, and incarceration may lead to emotional distress and conflict in marriages and families. High-risk sexual activity is defined by current Department of Veterans Affairs (VA) provider guidelines to be more than 10 sexual partners in a lifetime or as unprotected sex with a partner known to have tested positive for HIV or hepatitis B virus.²⁶ These psychosocial risks may influence the patient's ability to provide informed consent free from internal or external coercion.^{27,28}

Because of these factors, care of persons with HCV infection poses distinct ethical challenges and represents an important undertaking for the health of affected persons and for our society as a whole. In this article, we characterize qualitatively distinct clinical and ethical aspects of the informed consent process for HCV treatment and present preliminary findings of a project to identify and constructively address these factors in a distinct population of veterans in New Mexico. Extensive work has been performed in the area of informed consent, but no published work has yet focused on special issues related to HCV infection.²⁹⁻³² Thus, we know very little about patients' understanding and appreciation of the risks and benefits of treatment with interferon alfa and ribavirin, even though the 2002 National Institutes of Health Consensus Development Conference and VA have recommended expansion of treatment even to previously excluded populations.^{2,7} It is important to note that research on informed consent in

other areas has already shown that the patient's ability to provide informed consent can be improved through educational and therapeutic approaches.³³ In the pilot project presented here, we used a specially developed HCV informed consent assessment process to improve informed consent for HCV treatment in a group of veterans with complex psychiatric comorbidity whose care involves ethical challenges.

METHOD

Patients

Thirty veterans (27 men and three women) ranging in age from 44 to 64 years were sent to the New Mexico Veterans Affairs Health Care System behavioral medicine program by the gastroenterology service of the hospital between January 1 and December 1, 2002. The patients were initially evaluated in the hepatitis C clinic and identified as having current or past psychiatric symptoms on the basis of an interview, review of medical records, and/or a current Center for Epidemiologic Studies Depression Scale (CES-D) score of 16 or higher. The CES-D is a brief questionnaire that has been shown to be a useful indicator of current depression and anxiety symptoms.³⁴ The Human Research and Review Committee of the University of New Mexico and the Human Research and Development Committee of the New Mexico Veterans Affairs Health Care System approved the study. The informed consent requirement was waived because the assessment was conducted as part of patient care and no identifying patient information was reported.

Procedure

Patients underwent a detailed history and physical examination when they were initially evaluated by the medical team in the hepatitis C clinic. After this evaluation and before the psychiatric assessment, the patients completed a 30-minute educational session that included slides on the risks of acquiring HCV, the natural history of the infection, the success rate of combined therapy, and the major side effects of the treatment. The Veterans Health Administration also has extensive printed and electronic patient education resources on hepatitis C that were made available at the educational session. Patients were further encouraged to participate in a weekly hepatitis C support group offered through the behavioral medicine program. At the time these patients were in treatment, the program did not provide a family education session per se, but family members were encouraged to attend the patient's educational ses-

sion, support group meetings, and clinic visits. Several family members regularly attended the support group and often also attended the educational session and clinic visits.

HCV Informed Consent Assessment

When the behavioral medicine service at the New Mexico Veterans Affairs Health Care System was first asked to perform psychiatric screenings of HCV patients in January 2001, a standard mental health assessment was utilized. Several difficult cases pointed out the inadequacy of this standard evaluation in identifying problems with informed consent pertinent to HCV patients. In response to these concerning cases, the authors developed the HCV Informed Consent Assessment (HCVICA), an expanded mental health assessment that included a brief series of questions specifically geared to evaluate capacity for informed consent to HCV combined therapy. The assessment was developed by using four main sources: 1) an extensive review of the literature on hepatitis C, with emphasis on the neuropsychiatric and psychosocial dimensions; 2) the clinical experience of the hepatitis C clinic team with the assessments; 3) the primary author's knowledge of informed consent literature and prior research experience in this area;^{15,35} and 4) an analysis of well-validated decisional capacity instruments such as the MacArthur Competence Assessment Tool–Treatment³⁶ and instruments developed by Laura Roberts and the Empirical Ethics Group.³⁷

A psychologist or psychiatrist with experience in psychosomatic medicine administered all of the psychiatric assessments contained in the HCVICA protocol, which took less than an hour to complete. The HCVICA questionnaire contained open-ended questions covering the patient's reaction to receiving a diagnosis of HCV, current effects of HCV on the patient's health and life, the patient's reasons for wanting HCV treatment, and the patient's knowledge and attitudes toward the natural history of HCV infection, response and relapse rates of combined therapy, and side effects and strategies for managing them (See Appendix 1). The instrument was verbally administered, and the clinician recorded the patient's answers in writing. This process enabled the clinician, who had already obtained information on the patient's educational and occupational attainment and who had achieved an overall sense of the patient's cognitive functioning, to adjust the phrasing and explanation of the HCVICA questions to a level appropriate for a given patient to improve the patient's comprehension. Listed answers to each question enabled the clinician to provide standardized education to the patient after the

responses were collected. Results from the assessment were entered into the patient's medical chart and served as the basis of this review. The assessment resulted in one of three possible conclusions: 1) authorization to treat without conditions, 2) authorization to treat with conditions (such as attendance at a support group or after the initiation of or change in psychiatric medication), or 3) recommendation against HCV treatment at the current time. The adequacy of the patient's ability to give informed consent before, during, and after the interview was noted, and any recommendations for addressing ongoing deficits in decisional capacity and/or voluntarism were recorded.

Data Analysis

A retrospective chart review was performed. Demographic data, disease-specific variables, and psychiatric diagnoses and medications were summarized with descriptive statistics. These statistics are not intended to represent a quantitative analysis but to contextualize the qualitative analysis presented. Patients' responses to the open-ended HCVICA questions were compared and categorized by frequency. The responses were overall surprisingly similar. By using the three most frequent answers for each question and an "other" category, three or four categorical responses were developed for questions about 1) the patient's reaction to the diagnosis of HCV infection (including phrases such as "I thought I would die" and "I was devastated" and additional categories of no reaction and other), 2) the effect of HCV on the patient's quality of life now (including fatigue, pain, and other), and 3) why the patient wants HCV treatment (including to improve overall health, to follow doctors' instructions, and other). For questions on patients' knowledge of HCV and available treatments, the number of correct facts provided by the patient was tallied. Simple descriptive statistics were used to summarize the findings.

RESULTS

The subjects' HCV viral load ranged from 14,600 to 4,470,000 copies/ml. The majority of subjects were found to have HCV genotype 1 (17% had genotype 1; 26%, genotype 1a; 4%, genotype 1a/1b; and 35%, genotype 1b). Nine percent had genotype 2b, and another 9% had genotype 3a.

Sixty-four percent of the subjects were identified as having a depressive disorder; 43%, an anxiety disorder; 36%, a current substance use disorder; and 61%, a history of substance use disorder. Fifty-seven percent of the sub-

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jects were using antidepressants; 21%, anxiolytics; 32%, sleep medications; and 21%, antipsychotics. Subjects' CES-D scores ranged from 7 to 42, with a mean of 19 (a CES-D score of 16 or higher indicates some current depression).

Reaction to Diagnosis

Only 14% of the participants stated that they were indifferent to learning they were HCV-positive. Eighteen percent reported they were "devastated," another 18% stated that they were "scared," and 14% thought they would die without immediate treatment (Figure 1). The notion that they would die without HCV treatment resulted in an enormous sense of urgency for treatment that was usually not warranted.

Reasons for Treatment

Most participants reported fatigue (46%) and pain (14%) as current HCV symptoms. Ten percent listed "other" current HCV symptoms, such as pain in the liver or muscle aches. Fifty-seven percent reported the desire for improved health as their primary reason for seeking antiviral medications. Eleven percent indicated they were following their doctors' orders. About 25% listed other reasons for wanting treatment (Figure 2).

Although patients' views about the side effects of

HCV treatment were not measured by the HCVICA, it appeared that most patients with a history of serious psychiatric conditions were apprehensive about the neuropsychiatric side effects of HCV medication and their ability to cope with increased depression, insomnia, or irritability. Two patients volunteered that they were so depressed that they did not care if they lived or died and so were not interested in treatment; two other patients indicated that they were currently using substances (alcohol and, in one case, heroin) and that their need for substance abuse treatment was paramount.

Knowledge of HCV and Treatment

Perhaps the most striking finding of this preliminary study was the subjects' lack of knowledge regarding HCV, combined antiviral treatment, and possible side effects of treatment, despite having attended a 30-minute HCV education and counseling session and having received written take-home materials.

Subjects ranged from knowing no facts to three facts (of 13 facts listed under questions 4, 6, 8, and 9 of the HCVICA) about HCV (mean = 1.26) and no details to six details (of the nine details listed under question 1 of the HCVICA) of treatment side effects/risks (mean = 2.55). No patient understood the possibility of relapse after early viral response. The majority of patients could not accurately re-

FIGURE 1. Patients' Responses to the Hepatitis C Virus (HCV) Informed Consent Assessment Question, "What Was Your Reaction to Learning You Were HCV-Positive?"

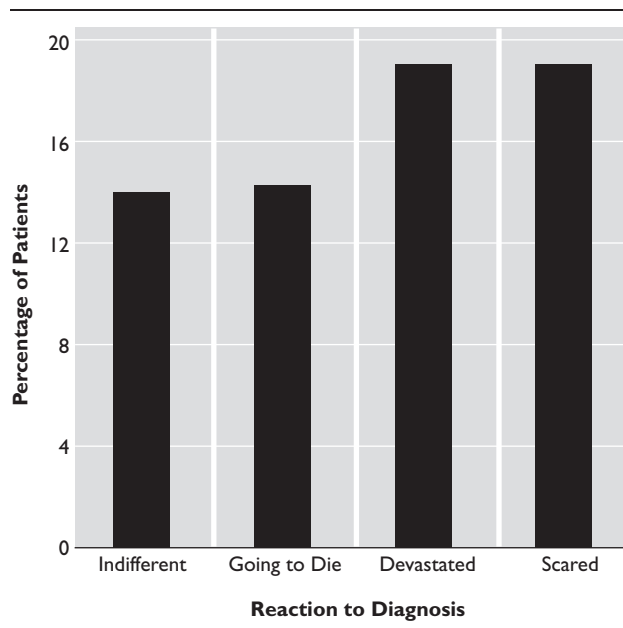
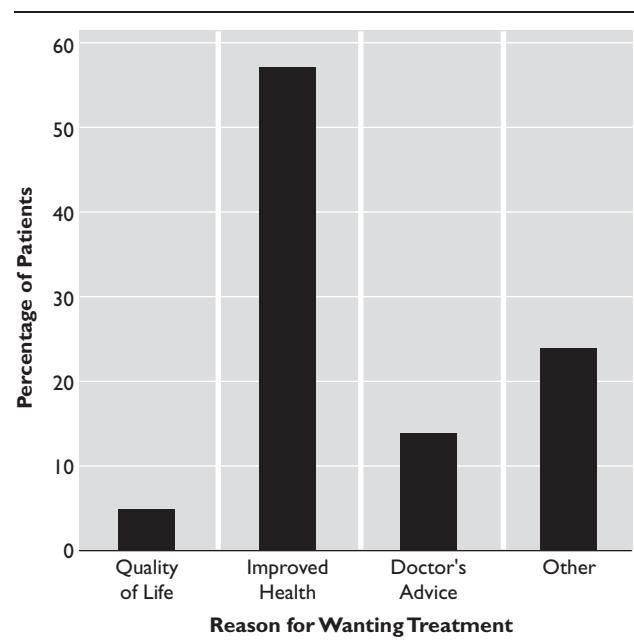


FIGURE 2. Patients' Responses to the Hepatitis C Virus Informed Consent Assessment Question, "Why Do You Want Interferon Treatment?"



call the general figure for SVR. Patients often knew their genotype and that it was either better or worse for treatment, but they could not explain the nature of a genotype. When we discussed genotype, we provided a simple description such as “a different kind of the hepatitis virus” and highlighted the clinical significance of the various genotypes. Every patient could list a few side effects of combined HCV therapy, usually sleep disturbances, flu-like symptoms, nausea, or fatigue. Hematological problems were seldom mentioned. Only depression was mentioned as a psychiatric side effect; no veteran was aware that combined HCV therapy can and has triggered mania, PTSD, and irritability and has led to suicide attempts and completed suicide. Few patients were aware of how disabling the treatment could be or of the need for social support. Misunderstandings of the treatment protocol were common. For example, one patient reported that it consisted of a single injection. Patients also were almost always unsure of how long they would be treated. Table 2 provides a sample of patient responses to the HCVICA questions and illustrates the clinical and dialogic nature of the interview.

DISCUSSION

In this retrospective chart review of the use of an informed consent assessment (HCVICA) with 30 veterans who were

candidates for antiviral treatment, most of whom had psychiatric comorbidity, we found several ethical and clinical problems that could potentially affect access to and efficacy of HCV treatment.

Our early and general impressions from interviews using the HCVICA support prior research showing that patients have difficulty comprehending the meaning of statistical probabilities for disease and treatment outcomes and that the ways in which the clinician frames such probabilities as either more or less positive has a major influence on patients' decision making.^{17,38} Primary care providers who initially made the diagnosis of HCV in these patients may have provided them with inaccurate, inadequate, or anxiety-provoking information before specialist referral. The patients' difficulty in understanding treatments and potential outcomes may also be an artifact of patients' misunderstanding or misinterpretation of interactions with clinicians, which nevertheless merits correction and explanation. Our analysis also underscored the role of stigma as the most common and complex aspect of HCV infection, an aspect that is often overlooked in the clinical literature. Stigma may dissuade some patients from seeking treatment and, conversely, may generate pressure from families and clinicians to obtain treatment, sometimes to the detriment of patients' voluntarism. It is interesting to note that none of the patients mentioned the risk of dis-

TABLE 2. Sample Patient Responses to Questions in the Hepatitis C Virus (HCV) Informed Consent Assessment

Question	Sample responses
How long have you known of your HCV-positive status?	<p>“I found out 2 years ago by blood test; no intravenous drug use. I found out when turned down for health insurance.”</p> <p>“My wife found a lab printout with an abnormal value the doctor did not mention.”</p>
What was your reaction to the diagnosis of HCV?	<p>“I thought I would die. I went on a trip by myself for 4 years. I kept calling my wife, came back for short trips, left again. I was in bad shape.”</p> <p>“I felt dirty like I could not be with anyone. You can't tell someone about this. It isn't just sexual.”</p> <p>“I felt that I would die within the next year. Diagnosis helped me to appreciate life, to not procrastinate, but also led to a lot of disappointment that I was not more careful in younger years.”</p>
What is the effect of HCV on your quality of life now?	<p>“I feel like I have no idea how long I will be around. I am always tired.”</p> <p>“[It is] causing a lingering dark cloud over my shoulder; [it affects] personal contact with kids, sex, not allowing others to use razors.”</p>
Why do you want combined HCV treatment?	<p>“To prolong my life.”</p> <p>“Now I have liver pain. I used to be fatalistic, but now I want to get better for my little ones. They are dependent on me. Now is not my time.”</p> <p>“I wanted HCV cured and assumed that would prolong my life.”</p>
What is your understanding about the course of HCV infection without treatment?	<p>“I felt I would die without treatment. My wife and family were concerned from reading articles in the newspaper that I would have liver failure.”</p> <p>“Fatigue is the major sign I'm looking for. Otherwise I feel ignorant about the disease.”</p> <p>“If you have it, you die from it.”</p>
What is your understanding of the side effects, risks, and benefits of combined HCV treatment?	<p>“You get sick, can't eat, depression, aches, everything bothers you.”</p> <p>“Fatigue and depression are common side effects. Otherwise I did not understand the side effects.”</p> <p>“I hear it is like chemotherapy; you give yourself an injection once a week; it makes you deathly ill with nausea, vomiting, headache, fatigue, depression.”</p>

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crimination, perhaps because their health care, insurance, and often pensions were part of their benefits as veterans and, in most cases, the VA health care system encouraged them to be treated.

Use of the HCVICA enabled us to identify several specific barriers to treatment that were not apparent in a review of records or psychiatric interviews and that would not have been identified with a standard mental health assessment. Our clinical experience and the reports of a number of researchers have demonstrated that much of the depression and mood lability that constitute the common adverse reactions to interferon can be treated with prudent dose reductions, antidepressant medications, and psychosocial support, allowing patients to safely continue in treatment.^{39,40} However, combined HCV treatment requires early identification of potential problems, ideally before therapy begins.

We believe an expanded HCV informed consent assessment process can assist clinicians in recognizing neuropsychiatric problems that may negatively influence treatment selection, adherence, and outcome. HCV treatment itself can strengthen decisional capacity and restore voluntarism by improving quality of life.⁴¹ The potential benefits of treatment and the availability of methods for reducing risk to patients generate an ethical mandate to use the informed consent process both to maximize the opportunity for all patients who merit HCV treatment on clinical grounds to receive this treatment and to improve the chances of maximal benefit from such treatment. The assessment also enables identification of those few individuals for whom treatment should be postponed because the current risks of antiviral therapy in the context of psychiatric or psychosocial instability outweigh the benefits. Resources can then be mobilized to address these areas of concern, and the patient can be reevaluated 6 months or a year later, with the first assessment as a baseline, to measure improvement. This approach enables the clinician to safeguard the welfare of patients, protect their ethical right to treatment, and honor the professional duty to not discriminate in provision of care.

Although only two clinicians have routinely utilized the HCVICA, we believe the assessment enabled us to develop educational and therapeutic strategies that assisted patients in successfully completing therapy that might otherwise not have been approved or might have been discontinued. The gastroenterologists we worked with were able to more confidently treat patients or refuse treatment when the psychiatric risks outweighed the medical benefits. In their own screening of patients, they began to use the re-

sults of the psychiatric and informed consent assessments, in addition to information on the patient's liver disease status, to make recommendations that treatment was either strongly needed or watchful waiting could be instituted. All members of the treatment team reviewed the assessments, and follow-up plans, which included the timing of reevaluation for many patients, were generated, which greatly improved the quality and continuity of care. Mental health clinicians reported that use of the HCVICA allowed a sense of standing on stronger ground when they made particular recommendations for or against treatment. They also felt better able to offer pharmacological and psychotherapeutic treatment interventions to address the barriers that were identified. We are currently teaching psychology interns and psychiatric residents to use the HCVICA to increase their literacy regarding the psychiatric complications of HCV treatment and to enhance their sensitivity to the nuances of informed consent. Our future plan is to become even more rigorous and systematic in our administration of the HCVICA protocol and our evaluation of its psychometric qualities to improve both the assessment of patients and communication with other health care professionals. Finally, several patients expressed appreciation for the opportunity to discuss their decision with a health care provider, and many felt relief that they were not forced to choose between what they perceived as imminent and inevitable death from HCV infection or intolerable side effects of combined therapy.

Limitations

First, because only a small number of patients and providers used the informed consent assessment in one VA hospital, any conclusions are tentative. Second, the results presented here are qualitative and descriptive and do not represent the level of validity and reliability of a quantitative statistical analysis. Third, this study took place in a rural state in a veteran population that is socioeconomically disadvantaged and known to have a high prevalence of comorbidity of psychiatric and substance use disorders. The barriers to informed consent identified here may not be found in civilian populations with fewer medical and social confounding factors. Fourth, the HCVICA is not a rigorously constructed and evaluated psychometric instrument but rather a clinically based assessment tool derived from our own experience and informed by the relevant literature in ethics and HCV treatment. Finally, the HCVICA has no global cutoff score that renders a patient capable or incapable of informed consent or that dictates the level or

type of intervention required for a patient to participate safely and ethically in treatment. Experience has informed our ability to make clinical judgments regarding adequacy of consent and to refine our consistency in informed consent assessments. However, realizing the weakness of this method, we are endeavoring to develop a quantitative version of the HCVICA tool that could be standardized and more readily evaluated for efficacy, reliability, and various forms of validity.

Strengths

The flexibility of the HCVICA protocol has allowed a variety of clinicians, including psychology interns and psychiatry residents, to perform HCV treatment assessments competently after instruction and supervision. Because of the relative ease of use and brevity of the assessment, it could be adapted to rural or urban treatment settings that are underserved and yet have a high HCV prevalence, including prisons and public health and rural clinics. HCVICA results could be used through telemedicine or other forms of consultation to expand the network of candidates for HCV combined therapy, particularly in areas without on-site psychiatric expertise. The HCVICA protocol we developed and the results of the pilot study reported here are preliminary at best. We offer them with an invitation to other scholars and clinicians to build on both

the instrument and our findings to expand access to high-quality and appropriate psychiatric and medical care for patients with HCV.

CONCLUSION

Four million Americans are currently infected with HCV. The high response rate to combined antiviral therapy for HCV suggests that this treatment is both cost-effective and clinically beneficial. The patients with the strongest clinical indications for treatment with interferon and ribavirin are most often those who possess addictive and psychiatric disorders that are potential barriers to successful treatment. The ability of these patients to provide informed consent for treatment is thus essential if they are to take advantage of scientific and institutional progress in the area of HCV therapy. Our early work with an HCV informed consent assessment process designed to identify clinician-, patient-, disease-, and treatment-specific factors influencing informed consent can provide the basis for educational and therapeutic interventions to maximize patients' decisional capacity to enter into and complete combined HCV therapy.

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APPENDIX 1. Hepatitis C Virus (HCV) Informed Consent Assessment Form Excerpt

- 1) Can you tell me when, how, and what you learned about having a positive hepatitis C test?
- 2) How did you feel when you were told you had a positive hepatitis C test?
- 3) How is hepatitis C affecting your health and life now?
 - a) Fatigue, depression, anxiety, gastrointestinal symptoms
- 4) What do you understand about how hepatitis C may affect your health and life in the future?
 - a) Disease course is slow, with the majority of subjects showing few signs or symptoms during the first 20 years of infection.
 - b) 10%–20% of subjects with chronic hepatitis C infection will develop cirrhosis over the course of 20–30 years.
 - c) The rate of liver cancer in cirrhotic subjects is 1%–4% per year.
 - d) Patients who contracted the virus when they were age 40 years or older, who drink alcohol excessively, are male, or are co-infected with HIV may have a faster rate of disease progression.
- 5) What and how did you learn about interferon treatment for hepatitis C?
- 6) What do you think are the benefits of interferon treatment for hepatitis C for your health and life?
 - a) Clearing of viral HCV RNA
 - b) Normalization of liver enzymes
 - c) Slowing or stopping the progression of liver damage
- 7) What do you think are the risks of interferon treatment of hepatitis C for your health and life?
 - a) Depression, anxiety
 - b) Fatigue, malaise
 - c) Rashes
 - d) Headaches
 - e) Nausea and vomiting
 - f) Decreased white blood cells
 - g) Decreased red blood cells
- 8) What are the alternatives to taking the interferon treatment?
 - a) Watchful waiting with medical monitoring for mild disease
 - b) Improvement in lifestyle, such as stopping alcohol consumption, eating well, getting adequate exercise and sleep and good nutrition
- 9) Facts about treatment response:
 - a) Approximately 50% of patients will never achieve a sustained benefit from therapy for HCV regardless of dose or duration of treatment.
 - b) In view of the lack of uniform benefit, treatment should ideally be provided to those at greatest risk of progressive liver disease whose quality of life is reduced.
 - c) Patients with certain genotypes (e.g., type 1) have a poorer treatment response.
 - d) If at 24 weeks there is still detectable virus, patients are not likely to respond from continued therapy.
- 10) Why do you want interferon treatment for hepatitis C?
- 11) What are you concerned may happen if you are not accepted for interferon treatment or cannot tolerate the treatment?