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From the Editor

## Hepatitis C: A Stakeholder Analysis

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## From the Editor

# Hepatitis C: A Stakeholder Analysis

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Imagine the following clinical scenario. A robust 45-year old female executive goes to her family doctor for an annual screening physical exam. She has been well her entire life and has been responsible for coordinating the health care of her husband and their adolescent children. Several days after her primary care doctor visit, she receives a telephone call alerting her to the fact that her liver enzymes (the test used to gauge liver function) are slightly elevated.<sup>1</sup> After an additional follow-up visit, she is diagnosed with a chronic viral infection of her liver that could slowly destroy this vital organ and, indeed, kill her in the next decade. This is the clinical face of infection with the hepatitis-C virus (HCV).

HCV is now the most common cause of viral-related cirrhosis in the United States and is currently the leading indication for liver transplantation. Nearly four million Americans, about 2% of the adult population, are infected with the hepatitis-C virus – most of them without knowing it. The numbers are undeniable. Nine thousand people die each year in the U. S. from complications of HCV (a number that is expected to triple by 2010).<sup>2</sup> Once infected, only 15% of patients are able to clear the virus. The other 85% suffer chronic infection<sup>3</sup>; of these, about 20% will suffer from progressive liver disease.

Where did this silent killer come from, and is any effective therapy currently available? Clinicians know that diagnosis of infection with different hepatitis viruses has been an important part of primary care practice for decades. Dr. Baruch Blumberg received the Nobel Prize for identifying the hepatitis-B virus in the mid 1960s, which paved the way for researchers to develop reliable blood tests for the virus. When new tests for hepatitis-A and B became available in the 1970s, researchers soon found that a substantial portion of cases of post-transfusion hepatitis were caused by neither of these two viruses.<sup>2</sup> This was labeled so-called non-A non-B hepatitis. It took another 15 years for researchers to identify many of these cases as hepatitis-C related.

Risk factors for hepatitis-C virus infection<sup>3</sup> include intravenous drug use (even if only once), transfusion of blood or blood products before 1992, intranasal cocaine use, history of multiple sexual partners, hemodialysis, needle stick injuries, history of sexually transmitted diseases, extensive body piercing, tattoos, and a history of having been in prison; resulting in tens of millions of Americans who are at risk.

While this is not the appropriate setting to evaluate all of the clinical trials for the therapy of HCV, it is appropriate to summarize the current treatment options as follows. After clinical evaluation, which may include a liver biopsy and an assessment of viral load, clinicians can offer patients therapy, which may include interferon alfa 2b alone or in combination with ribavirin.<sup>3</sup> When used at the recommended dosages, interferon alfa normalizes liver enzyme levels in 40 to 50% of patients and HCV becomes undetectable in 30 to 40% of patients during treatment. Yet, overall, only 10 to 15% of patients treated achieve long-term viral eradication.<sup>4</sup> Combination of interferon plus ribavirin increases long term eradication to 35-40% only.

Certainly, many important clinical challenges remain about the most effective therapy for HCV infection. I would like now to turn to a stakeholder analysis and review the impact of this silent epidemic on providers, patients, payers, and employers. This stakeholder analysis will focus on the future challenge for successful HCV therapy from each of the unique perspectives.

For providers, the key clinical mission may be to eradicate HCV in all patients for whom it is possible to do so and to stem the progression of liver disease.<sup>5</sup> As always, providers should seek to maximize the underlying health status of the individuals, prevent disability wherever possible, and maintain a reasonable quality of life. All of this must be done, of course, within the context of minimizing cost to the health care system. Collectively, it is a formidable challenge for the provider stakeholders.

In addition, from the provider perspective, we need to implement wide-spread physician education programs to help providers recognize the risk factors for HCV infection, to specifically motivate them to ask their patients about these risk factors, and to design appropriate referral tools to help primary care providers send select patients on to subspecialists for definitive care. Our collective track record as providers in implementing best practices and coordinating care across multiple caregivers could certainly be improved. HCV presents a "double whammy" to providers in terms of the complexities of disease screening and the uneven evidence about disease treatment.<sup>5</sup>

A case-in-point is, for providers who graduated from medical school as late as 1981, this disease was never taught in the classroom!

For patients, HCV presents comparable sociologic and economic challenges. What are the best methods for educating those patients who have tested positive for HCV? If one believes that the patient's role in the doctor-patient relationship is changing, especially with the advent of medical consumerism, how then can we take advantage of some of the new tools and techniques to engage patients in their own care? Once patients are diagnosed with HCV, how can we work together to improve their access to care and determine where a patient may be relative to their "readiness to change" index? What can we learn from studies demonstrating low patient compliance with the therapy for other chronic illnesses such as hypertension and hyperlipidemia? All levels of the industry must encourage patient adherence to appropriate therapeutic regimens.

Because HCV affects nearly 2% of the U.S. population, all payers should be concerned about reducing future expenses. No managed care organization can escape the burden of HCV! As a result, these stakeholders need to harness the tools of disease management and demand management to assess a population at risk for HCV and to deliver targeted services for them. Once patients are identified, new technologies linked to case management programs may be called for. Perhaps payers can facilitate appropriate physician network development to handle the "connections" needed among primary care doctors, patients, and subspecialists. How can we help to hold payers responsible and accountable for their care of persons with HCV? What rate-based measures of quality might apply to this population such as percentage of eligible patients who were successfully screened, or who completed a particular therapeutic regimen? Given the rapid turnover of patients enrolled in any single managed care plan and the uneven economic incentives to practice primary prevention; no single payer can be held responsible for society's obligation to treat HCV. In short, the public health dimensions of the HCV challenge transcend all

payers. In our diversified health care economy, this could be a particularly vexing problem in the near future.

HCV infection has a major impact on employers, the last of our four stakeholders. Some analysts believe that HCV contributes to an 8% drop in productivity in a typical work month in the United States due to absenteeism and related causes<sup>6</sup>. Employers, after all, bear much of the economic risk for both the direct and indirect costs of disability for persons infected with HCV. In certain job categories, especially many of those in the health care sector, employees are at a higher risk exposure level to get HCV in the first place. Employers will need to seek out innovative pharmaceutical coverage programs for those stricken with HCV. They will need to design worker's compensation plans appropriate to the risk that their employees may face both on and off the job site. Employers will have to interpret performance information provided by managed care plans for example, and share this with their employees. Perhaps one could envision a day when a particular plan's performance with regard to the care and therapy of persons with HCV far exceeds another plan, resulting in a shift of employees from one plan to another stimulated by data provided by the employer itself. Maybe employers should be actively involved in efforts to educate employees about HCV and to provide confidential screening at the workplace.<sup>6</sup>

HCV infection is a major public health problem affecting all the stakeholders in our system. No one can hide. What is your organization doing about this challenge? As always, I am interested in your views and you can contact me at [david.nash@mail.tju.edu](mailto:david.nash@mail.tju.edu).

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**Postscript:** The Centers for Disease Control (CDC) posted on its World-Wide Web site an interactive web-based training program titled: "Hepatitis C: What Clinicians and Other Health Professionals Need to Know." The Program is at <http://www.cdc.gov/hepatitis>.

This program provides users with up-to-date information on the epidemiology, diagnosis, and management of hepatitis C virus (HCV) infection and HCV-related

chronic disease. Users also can test their knowledge of the material through study questions at the end of each section and case studies at the end of the program. Continuing medical and nursing education credits are available free from the CDC on completion of the training. The American Academy of Family Physicians also will grant the academy's education credits on completion of training and filing with the academy.