Hepatitis C Treatment in the Real World: Hope Surrounded by Barriers

With numerous obstacles preventing widespread treatment of the U.S. hepatitis C population, how can the health care system successfully make use of recent treatment advances?

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The treatment outlook for hepatitis C virus (HCV) keeps looking brighter. First came the two protease inhibitors, Incivek (telaprevir) and Victrelis (boceprevir), each of which the U.S. Food and Drug Administration (FDA) approved in May 2011 as a combination therapy for use with pegylated interferon and ribavirin. Clinical trials showed that the drugs boast dramatically improved sustained virologic response rates (SVR, considered a cure) over treatment with interferon and ribavirin alone, with the chance of a cure ranging between about 50 and 80 percent.

Then, at the American Association for the Study of Liver Diseases annual conference in October 2012, a veritable avalanche of promising new data arrived, much of it from Phase II studies, showing that numerous new classes of direct acting antivirals (DAAs) are barreling their way through the pipeline with SVR rates soaring above 90 percent for all-oral, interferon-free combination therapies with much shorter durations.

Adding to that, a recent study, which focused on the expected annual health care costs associated with hepatitis C in the United States (projected to peak at an estimated $9.1 billion in 2024), made optimistic predictions about how quickly the virus could actually approach eradication in this country. The investigators speculated that if the current yearly figure of Americans treated for hep C could double to 126,000 through 2030 and the average SVR is increased to 70 percent, the total cases of HCV would plummet from the estimate of today’s cases, which is between 2.5 million and 4 million, to less than 100,000.

Putting aside the fact that investigators whitewash many of the early studies by only including patients who are more likely to achieve an SVR, there is another major factor drawing into question how applicable such hopeful statistics are to the hepatitis C population as whole.

They call it the real world.

“These treatments got designed and approved in almost these ivory tower specialist contexts,” says Daniel Raymond, policy director of the Harm Reduction Coalition in New York City, “and the work to do the translation as to how to make them viable in the real world for broader populations has really been an afterthought."

A major literature review recently published online in General Hospital Psychiatry highlights how the myriad challenges facing hep C patients chip away at the impressive SVR rates found in those tightly controlled clinical trials.

Researchers analyzed 25 studies looking at both the course of treatment and the treatment barriers in patients with hep C who were not included in a clinical trial. They found that the health care providers of the patients in this cohort considered a mere 19 percent of those with HCV and 16 percent of those coinfected with HIV and HCV eligible for treatment. Worse than that, only a respective 13 and 11 percent of the patients completed treatment, while a dismal 3 and 6 percent achieved an SVR, respectively.

These percentages do not represent projections about the U.S. hepatitis C population as a whole; rather, they reflect proportions of patients in the study. But accounting for the fact that up to 75 percent of Americans with hep C are unaware of their infection, projections about how effectively new therapies can actually reduce the overall burden of the disease in this country look grim.

The study found that barriers to treatment include a panoply of psychiatric and medical ineligibilities. Health care providers will frequently decide that patients are not prepared for the potential difficulties of interferon's notorious flu-like side effects, or that they are not able to properly adhere to their medications. Then there are the matters of substance abuse, mental illness or co-occurring medical problems such as anemia, HIV (there has been insufficient research on treating the coinfected population that can guide care) or the fact that their liver disease is too benign or advanced to warrant treatment.

Personal barriers to treatment also run the gamut. For example, people with hepatitis C might refuse treatment because they fear side effects, they doubt the treatment's potential success, they prefer to continue using drugs and alcohol instead of beginning treatment, or they fear losing their jobs in case the treatment's potential side effects take a toll on their performance.

"The first order of business is to get people tested and identified to begin with," says John Ward, MD, director of the division of viral hepatitis at the Centers for Disease Control and Prevention (CDC), which is currently running a national HCV awareness campaign called "Know More Hepatitis."

After that task is achieved, "Probably the number one reason why people don't get treated is cost," according to Martha Saly, executive director of the National Viral Hepatitis Roundtable in the San Francisco Bay area, who cites "tremendous barriers" toward receiving reimbursement from Medicaid for the expensive therapies.

"Maybe there will be something magic that happens when the Affordable Care Act really kicks in and is implemented," she says, referring to the national health care law that will greatly expand health coverage to most Americans in 2014. She says her team is currently trying to take a cue from HIV advocacy groups, which have been lobbying heavily in Washington, DC, to ensure that ACA policies will favor the needs of the HIV community.

“There are also barriers from the patients where they don’t recognize that this is a treatable disease,” says Mamta K. Jain, MD, MPH, an Infectious Disease specialist in the Department of Internal Medicine at the University of Texas Southwestern Medical Center in Dallas and one of the General Hospital Psychiatry study’s coauthors. “They don’t feel anything—so why do anything? Until it’s too late. When they start having complications from their hepatitis C, they’re at end stage liver disease.”

Jain laments the disease’s lack of visibility and, along with her colleagues in the paper, calls for much greater awareness and understanding about hep C. Indeed, there is a paucity of funds available for public awareness campaigns, and the hep C activist community is tiny and scattered to the point of near-invisibility.

The CDC, for example, spends a mere $20 million a year on all strains of viral hepatitis and has no standardized national surveillance system to track the disease and help guide the agency’s efforts, relying instead on a patchwork of available data. Only the rare municipal or state public health budget, such as those in New York City and State, appropriates money toward fighting the disease. Without interest from major public health players like the Kaiser Family Foundation or the Bill & Melinda Gates Foundation, pharmaceutical companies remain one of the only other major players when it comes to investing in public education.

Psychological issues also cast a wide shadow over the hope for successful treatment, which is why Jain and with her colleagues strongly advocate greater psychosocial support for people with HCV.

Thomas Witthöft, MD, an internist from Stade, Germany, who conducted a study on the non-virus-related factors key to successful hep C treatment, says health care professionals should coach both the patient and his or her family members about the disease. This, he says, “is a type of psychological helping.” Patients need not see a physician at every visit, he says, but can consult with others in the staff either by phone or in person. He suggests that physicians may prescribe light antidepressants to help some patients, and that they may refer to a psychiatrist or psychologist those with more pressing psychological needs.

Another study calls into question biases physicians may harbor against treating drug users, as many care providers remain concerned that drug use poses an obsticle to treatment and that users run the risk of reinfection through needle sharing after achieving an SVR. This literature review, published in Clinical Infectious Diseases, found a treatment completion rate of 83 percent and a robust overall SVR rate of 55 percent among treated drug users. The researchers concluded that addiction treatment, as well as a multidisciplinary approach to care, along with support services, are associated with treatment success.

One of the paper’s authors, Andrew H. Talal, MD, a hepatologist at State Univerity of New York at

Buffalo, also cites several studies that have followed drug users for up to three or four years after they achieved an SVR, finding that the rate of reinfection is low.

“Even if they do continue to use,” Talal says of hep C-cured drug users, “they’re less likely to reuse needles and to exchange in practices that would potentially expose them to the risk of reinfection.”

Whether facing medical, sociocultural or behavioral obstacles to fighting the disease, the fractured hep C health care and advocacy community clearly has its work cut out for it. Education, it seems, is the most important foundation on which to build the future model of care.

“It’s going to require providers talking more about hepatitis C as well as patients becoming more cognizant about their disease,” says Mamta K. Jain. She points to “educational programs geared toward patients, support groups, things like that, which we’ve done with HIV very effectively.” Unfortunately, she adds, “I don’t think we’ve been able to effectively [accomplish that] with hepatitis C.”