Yes, Nonspecialists Can Treat People With Hepatitis C Very Effectively

So why do insurers often still restrict approval for hep C drugs to those receiving treatment from specialists?

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The modern crop of highly effective direct-acting antivirals (DAAs) to treat hepatitis C virus (HCV) have been on the market for almost four years now. Gone are the days of onerous, lengthy and relatively ineffective treatments for the virus. Today's wide variety of DAAs boast cure rates in the high 90 percent range for most subgroups of the hep C population, are highly tolerable and require as little as eight to 12 weeks of use to achieve a cure.

From a physician's perspective, prescribing such medications for most people with hep C has become relatively simple, requiring only limited knowledge about the proper protocols. So why, then, do many insurers still allow only hepatologists, gastroenterologists and infectious disease clinicians to prescribe DAAs?

There are an estimated 2.7 million U.S. residents living with hep C, of whom 46 percent have been diagnosed; of those diagnosed, about one in six have received DAA treatment. And yet there are only 20,000 specialists across the nation working in the three aforementioned fields, a figure far too small to meet the high demand for HCV treatment.

According to Elana Rosenthal, MD, an assistant professor at the Division of Infectious Diseases at the University of Maryland, restricting reimbursement approval only to specialists "means that certain populations are disproportionately impacted or limited from receiving care, such as people who are living in more rural areas or people who have more limited insurance."

It's certainly easy to presume that insurers, mindful of the steep price of treating hep C, seek to restrict reimbursement in an attempt to control overall costs. But it's certainly possible a more legitimate reason drives such a policy. Perhaps general practitioners or nurse practitioners fare worse than specialists in shepherding their hep C patients through treatment, leading to lower cure rates.

To test whether this is the case, Rosenthal and a team of other researchers conducted a study in 2015 that sought to re-create as real-world a scenario as possible for comparing the success of DAA treatment for patients with hep C when administered by specialists versus nonspecialists.

Called ASCEND, the study ran in 13 urban federally qualified health centers (FQHCs) in Washington, DC. Six hundred people with genotype 1 of hep C (the most common genotype in the United States) were enrolled between January and November 2015. Ninety-six percent were Black, 69 percent were male, 82 percent were being treated for the virus for the first time, 20 percent had cirrhosis, 72 percent had genotype 1a of HCV and 23 percent were coinfected with HIV. Sixteen percent had advanced fibrosis (scarring) of the liver, and 20 percent had compensated cirrhosis (the milder form of the advanced liver disease). The study population primarily had public insurance.

The study excluded those who were pregnant or breast-feeding, who had hepatocellular carcinoma (HCC, the most common form of liver cancer) or reduced kidney function, or were taking medications that cannot be combined with Harvoni.

The participants were assigned to receive treatment with Harvoni (ledipasvir/sofosbuvir) from one of 16 medical providers in an existing medical network who fell into three categories: a nurse practitioner, a primary care physician (board-certified in family or internal medicine) or a specialist (an internist specializing in infectious disease or gastroenterology-hepatology).

The participants were all existing patients at their respective clinics during the previous five years and were connected to the study through their specialist physician. About half of the study members were selected by their referring physicians to remain in treatment with them for the study. The others were assigned to nurse practitioners and primary care physicians according to the following priorities: existing relationships with such clinicians, proximity of the participant's home to the clinician's office and the need to balance out participants among medical providers, including spreading those coinfected with HIV as evenly as possible among providers.

All the providers, including the specialists, were given a three-hour training course on treating hep C before prescribing DAAs to any of the participants. When treating patients, the providers scheduled monthly follow-up appointments. In a major departure from real-world practice, participants picked up all their medication at their own clinic (even if they missed a follow-up appointment), and the clinicians did not have to seek reimbursement for the treatment through an insurance company.

A respective 4 percent, 90 percent and 6 percent of the participants received 8, 12 and 24 weeks of Harvoni treatment.

Overall, 86 percent of the study population achieved a sustained virologic response 12 weeks after completing therapy (SVR12, considered a cure). Of the 84 people who were not established as having been cured, 45 (54 percent) were lost to follow-up, 35 (42 percent) saw their hep C relapse and 4 (4 percent) died. (None of the deaths were judged related to Harvoni, and most of those lost to follow-up dropped out of care after having completed treatment.) Broken down by provider type, the cure rates were 89.3 percent among the nurse practitioners, 86.9 percent among the primary care physicians and 83.8 percent among the specialists.

After adjusting the data to account for differences regarding age, sex, race, HIV status and

cirrhosis status between the three groups of participants and to account for the way that study members were clustered according to specific medical providers, the researchers found that the overall cure rate was 87.1 percent. The cure rates were 90.4 percent among those treated by nurse practitioners, 87.6 percent among those treated by primary care physicians and 84.8 percent among those treated by specialists.

The study authors concluded that there was no significant difference between the three cure rates and that people with hep C do just as well receiving treatment through nonspecialists as through specialists. Additionally, cure rates remained high even among those with HIV, cirrhosis or who had previously been treated for HCV with interferon, and none of these characteristics were associated with differences in cure rates based on whether individuals saw a specialist or nonspecialist for HCV treatment.

The 600 participants attended their treatment visits only 62.2 percent of the time. Looking just at the 539 people who were given 12 weeks of Harvoni, the study investigators found that people's attendance at their clinic visits declined over time, from a rate of 76.4 percent at week four to 61.6 percent at week eight to 50.5 percent at week 12. Those who were cured were more likely to have made their appointments.

Interestingly, those who saw a specialist were less likely to attend their clinic visits than those who saw a nonspecialist. Musing on this particular finding, Rosenthal said, "One of the things that we can definitely say is that having a relationship with the patient and having the patient's trust is an incredibly important component for care of any chronic illness. And I think that's probably more important than what kind of specialization they have."

Of particular note, 56.8 percent of those who were prescribed 12 weeks of Harvoni would have qualified for just eight weeks of treatment based on the regimen's prescribing label. The study authors concluded that additional training about prescribing eight weeks of the regimen—which cuts the cost of treatment by a third—might be needed in the future.

Asked whether the study's model was easily exportable to other health practices around the country, Rosenthal replied with a strong affirmative.

"I hope that this study demonstrates to [nonspecialists] that they can have confidence in themselves that with a limited amount of instruction they can really effectively treat their patients themselves and don't have to feel shackled to the concept of referring to specialist care."

But for nonspecialists, the looming hurdle of reimbursement by insurance companies remains. Obtaining the necessary preauthorization can be lengthy and arduous. And although many insurers that restrict nonspecialists from prescribing DAAs allow them to partner with a specialist to receive reimbursement for their patients, the administrative hassle is likely to keep certain people with hep C from receiving treatment.

In an ideal world, the findings of this study would sway insurers to broaden their criteria about who can prescribe DAAs.