Hep C Treatment Transformation

New drugs will offer people with hard-to-treat hepatitis C genotype 1 a second chance to clear their virus.

March 28, 2011 By Tim Murphy

Leslie Williams, 53, is a pretty confident guy. Diagnosed with HIV in 1993, this Brooklyn husband, father and grocery store dairy manager knows his HIV is undetectable and that his last CD4 cell count was about 388. He spends his leisure time at home with his wife Andrea (also HIV positive) and their 14-year-old daughter, playing with their cat Barney and watching classic TV sitcoms like *Seinfeld* and *Martin*. “I like old shows because I’m an old-timer,” he says, adding, “But if you saw me you wouldn’t think I’m over 40.”

There’s one area of his life where Williams is less certain—what to do about his hepatitis C, which was diagnosed in 1989, the year “non-A, non-B” hepatitis was named “C.” Williams is one of up to a third of all HIV-positive people in the United States who know they also have hepatitis C, or some 350,000 people. (If you don’t know whether you have C, consider getting tested—it’s a simple blood test, not unlike the HIV antibody test.) Unlike HIV, hep C is curable, but only for some—and least of all for those with genotype 1 virus, the strain overwhelmingly predominant in the United States.

The treatment, which involves weekly injections of pegylated interferon plus daily doses of oral ribavirin, stretches for months (as much as a year for some people who also have HIV) and can cause hard-to-take side effects including severe flu-like symptoms, fatigue and depression. To decide whether you’re a candidate for treatment, you and your doctor need to know how advanced your hepatitis C is and whether you have liver damage—and how far advanced that damage is. It takes a combination of blood tests and a needle biopsy to determine all this. At press time, Williams was awaiting results of tests assessing his liver damage.

While he waits, he has new cause for optimism, as do countless people who have hep C alone or both hep C and HIV (the combination can accelerate hepatitis and make HIV treatment more complicated, especially if either virus is poorly monitored and controlled). As early as mid-2011, a new hep C drug, Vertex’s telaprevir, might get FDA approval. A similar agent, Merck’s boceprevir, is not far behind. They’re the first of a whole new class of hepatitis C drugs—protease inhibitors, which, like the ones that revolutionized HIV treatment 15 years ago, work by blocking a crucial step in viral replication. Both drugs have performed well in studies of people monoinfected with hepatitis C, including those with the

stubborn genotype 1 variety.

When either drug was added to the current standard interferon/ribavirin treatment, rates of people who "cleared," or cured, their hep C rose notably. Seventy-five percent of people who took telaprevir plus the current treatment cleared hepatitis C, versus 44 percent of those who took the current treatment alone; clear rates in the boceprevir trial were up to 66 percent versus 38 percent for standard treatment only.

In both trials, clear rates were higher in people undergoing hep C treatment for the first time than in repeaters. But those re-treating with either of the new drugs added still did much better than with the standard treatment.

"It's a very good time to have hep C," jokes Doug Dieterich, MD, of New York's Mount Sinai Medical Center, who's been treating people with hep C (many co-infected with HIV) for years and has enrolled patients in the telaprevir trials. In addition to the two on-deck medications, he notes, 33 forthcoming hep C drugs were presented at a major conference last fall—so many that Dieterich predicts we'll be curing hep C without interferon as early as 2013 or 2014.

The cheerful news also applies to people coinfected with HIV, Dieterich says. "As long as your HIV is controlled, treating your hep C should be only a little more complicated." The complication? The body processes these new hep C drugs through pathways used by several HIV drugs, including Kaletra and Sustiva. Doses of those HIV meds will have to be adjusted for use alongside the hep C protease inhibitors.

Tracy Swan, who focuses on hep C at the New York City–based HIV-advocacy organization Treatment Action Group, raises some concerns about the new drugs. Boceprevir, she points out, appeared to cause anemia—already a possible side effect of standard hep C treatment—in half the people in those trials; they required Epogen (epoetin alfa) injections to counteract it. But, Swan notes happily, "Drug companies have been willing to open trials in HIV/hep C–coinfected people much sooner than ever before."

Indeed, Vertex just finished enrolling a trial of telaprevir plus standard treatment in people with both HIV and hep C, with the results possible by midyear. Merck's similar trial for boceprevir is still enrolling (for more information, search NCT00959699 at clinicaltrials.gov) and could release results in mid-2012.

If you're coinfected, whether or not you've tried hepatitis C treatment before, you'll need to work with your HIV doctor, and possibly a GI (gastrointestinal) or liver (hepatology) specialist, to create your plan of action. How advanced your hep C is will help indicate whether you should consider treatment with one of the two new drugs (Dieterich generally recommends treatment for anyone with stage 3 liver fibrosis or beyond), or whether you can afford to await more options (see sidebar at right). "If you can, wait until there are even better regimens," advises veteran HIV/hep C advocate Jules Levin, who kicked hep C years ago.

Studies of telaprevir and boceprevir show that unless they are paired with interferon and ribavirin, resistance to them can quickly develop, negating their potency. So waiting longer for more resistance-proof hep C drugs, possibly some that won't rely on being paired with interferon, might make sense—if your liver gives you the choice.

But can Williams really afford to wait? His liver test results will soon let this old-timer determine his options for becoming a man of the future.

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