Is Directly Observed Hepatitis C Treatment the Answer for People Who Inject Drugs?

Research suggests that individuals receiving opioid replacement therapy have a better chance of beating hep C through this method.

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For people with a history of injection drug use, following a daily regimen of direct-acting antiviral (DAA) drugs to treat hepatitis C virus (HCV) may prove a challenge. That's why researchers and clinicians have experimented with directly observed therapy (DOT)—in which a provider doles out daily medication and watches as an individual takes it—among this population.

Opioid substitution therapy (OST) programs, which involve daily contact between people who inject drugs (PWID) and the clinic staff who provide them with drugs such as methadone or buprenorphine, provide an ideal opportunity for the introduction of DOT. That said, the authors of a new systematic review and meta-analysis of research on the efficacy of DOT for HCV treatment advocate for expanding the realm of who can provide PWID with DOT to include others, such as pharmacists.

Publishing their findings in the Journal of Virus Education, a research team based at the University of Washington and the Fred Hutchinson Cancer Research Center in Seattle scoured the medical literature for studies comparing DOT with standard-of-care hep C treatment among PWID.

The need for hep C treatment is great among PWID, an estimated 60 percent of whom are living with hep C. Depending on local epidemic patterns, subpopulations of PWID may have infection rates as low as 25 percent or as high as 90 percent. In addition to providing many health benefits, successful HCV treatment can also prevent active injection drug users from transmitting hep C within their drug-using networks. However, reinfection following successful DAA treatment remains a pressing concern. To dramatically reduce new infection rates among PWID—and keep those rates down—members of specific drug-use networks ought to be treated en masse.

"Treatment as prevention is a promising strategy, but, frankly, given the price of these therapies, until they drop significantly, I can't see that being a feasible option for most insurers or most health care providers," says the new paper's lead author, Cara McDermott, PharmD, PhD, MSc, of the Cambia Palliative Care Center of Excellence at the University of Washington's School of

Medicine.

In the paper, McDermott and her coauthors note that some clinicians may be reluctant to prescribe DAA treatment to HCV-positive PWID for fear that these patients will not adhere well to regimens that today typically require eight or 12 weeks of daily pills. DOT could potentially assuage this reluctance.

The DOT model was initially created for tuberculosis and eventually adapted for use in providing antiretroviral therapy for HIV. In the HCV arena, studies have shown promising results for DOT's use in prisons, primary care clinics, drug treatment facilities and health care systems offering multidisciplinary care.

To assess DOT's efficacy, the new study's authors analyzed the pooled findings of six studies including a cumulative 407 PWID. Four of the studies, including 215 people, were randomized trials, in which participants either received DOT or standard-of-care HCV treatment; these studies were factored into the new paper's meta-analysis.

The participants were all adults receiving OST or actively injecting illicit drugs, such as heroin. Four of the studies were conducted in the United States, one in Canada and another in Italy.

The only studies that fit the purposes of the new paper's authors involved HCV treatment with injectable interferon plus oral ribavirin. Interferon treatment, once a mainstay of hep C therapy, is now obsolete thanks to the much more effective and well-tolerated DAAs that have been on the market for about the past five years. So the findings of the review and meta-analysis may not apply directly to contemporary HCV treatment. However, because success on DAAs remains reliant on good adherence to the daily drugs, methods that encourage individuals to stick to a regimen, including DOT, remain an important way to improve cure rates.

In a recent study conducted in Austria and published in the Journal of Viral Hepatology, 40 PWID who were deemed at risk of not adhering to daily DAAs were given DOT hep C treatment along with OST for eight weeks of Harvoni (ledipasvir/sofosbuvir) treatment. All of them were cured of the virus.

The new review and meta-analysis defined DOT as "treatment receipt during which time the patient was observed to consume an oral medication and/or receive an injection while in the presence of nursing, community health worker or other trained staff."

Excluded from consideration were studies performed in institutional settings or prisons, since the study authors' goal was to determine how well DOT works in outpatient settings.

A total of 242 of the study partcipants received DOT while 165 received standard non-observed treatment. A respective 124 and 91 people included in the meta-analysis received DOT and the standard of care.

Fifty-eight percent of those who received DOT achieved a sustained virologic response 12 weeks

after completing therapy (SVR12, considered a cure), compared with 39 percent of those receiving treatment as usual. This led the researchers to conclude that DOT was associated with a doubled likelihood of attaining a cure in this population.

According to McDermott, DOT offers not only more than just a promise of better hep C cure rates but also an opportunity for a vulnerable population to have more beneficial contacts

with the overall system that is in place to help them better their lives.

“What’s really important is to consider DOT in a larger framework of supportive care for people living with hepatitis C,” says McDermott, “and to holistically deliver care to patients to meet whatever social and other health needs they have.”

The new paper is limited by the fact that McDermott and her coauthors, lacking sufficient data, were not able to control for factors outside of the use of DOT that may have affected cure rates.

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