For Those With HIV, Hep C Drug Trials Don’t Offer Enough Real-World Data

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The major clinical trials of hepatitis C virus (HCV) drugs among those coinfected with HIV had such restrictive eligibility requirements, their findings’ generalizability is questionable. Publishing their findings in Clinical Infectious Diseases, researchers looked at 541 HIV/HCV-coinfected members of the Canadian Coinfection Cohort with genotypes 1 through 4 and compared them to the eligibility criteria for five major hep C drug trials: NCT01479868 (evaluating Olysio (simeprevir); PHOTON-1 (Sovaldi (sofosbuvir)); TURQUOISE-I (Viekira Pak (ombitasvir/paritaprevir/ritonavir; dasabuvir)); ION-4 (Harvoni (ledipasvir/sofosbuvir)); and ALLY-2 (Daklinza (daclatasvir) and Sovaldi).

First the researchers divided the group by genotype—a respective 410, 26, 94 and 11 had genotypes 1, 2, 3 and 4, which were the genotypes evaluated in the five major trials—and then deduced what percentage of those who were eligible for a trial according to genotype would have been eligible according to other criteria.

A total of 5.9 percent (24 of 410) would have been eligible for NCT0147968, as would 9.8 percent (52 of 530) for PHOTON-1, 6.3 percent (26 of 410) for TURQUOISE-I, 8.1 percent for (34 of 421) for ION-4, and 43 percent (233 of 541) for ALLY-2.

Putting aside the ALLY-2 trial, the eligibility exclusion that would eliminate the largest proportion of participants was a restriction based on HIV medications (63 to 79 percent of the cohort would be excluded), followed by active illicit drug use (53 to 55 percent).

The researchers concluded that because these trials largely excluded individuals who might be at risk of poor adherence to hep C treatment regimens—namely active drug abusers—their effectiveness ratings are poorly generalizable to the hep C population as a whole. More real-world data, the study’s authors write, “is urgently needed.”

To read the study abstract, click here.

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