

REAL WORLD DIRECT ACTING ANTIVIRAL (DAA) OUTCOMES AMONG PEOPLE WHO INJECT DRUGS: HEPATITIS C REAL OPTIONS (HERO)

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Background:

Well-designed, adequately-powered studies that compare the effectiveness of models for successful delivery of HCV therapy among people who inject drugs (PWID) are needed. HERO is an ongoing U.S.-based research study involving 8 states with geographic and policy diversity.

Approach:

HERO is enrolling 750 PWID (injecting within past 3 months) for a treatment uptake goal of 600 PWID for 12-weeks of sofosbuvir/velpatasvir (SOF/VEL). Participants, including those on and not on opioid agonist therapy, are treated at either community health centers (CHC) or methadone programs. Participants (DAA-naïve, any genotype, any HIV status) are randomized to modified directly observed therapy (mDOT) or patient navigation (PN). Those randomized to mDOT at methadone clinics receive SOF/VEL with daily methadone; those at CHC settings video-record themselves taking SOF/VEL daily using an 'app' (emocha). Participants randomized to PN receive a standardized intervention. Primary outcome is sustained virologic response (SVR) compared between mDOT and PN arms; secondary outcomes include treatment initiation, adherence, completion, resistance, and reinfection after treatment completion. HERO also includes a nested implementation study. The study benefits from guidance from a broad range of stakeholders.

Outcome:

As of 4/18/18, 1664 were screened, 826 (49.6%) were eligible, 663 (80.3%) were enrolled/randomized; 522 of 590 treatment-eligible initiated SOF/VEL (90%). Median age is 41; 28% are female; 64% have high school education or less. Race/ethnicity: 14% Black, 3% Native American, 58% White, 22% Other; 26% Latina/o. Enrollment is higher at CHC (n=377) than methadone settings (n=273). 12-week treatment initiation ranges from 73% to 94%, and is 83% overall.

Conclusion:

HERO has enrolled a diverse population across all sites. High enrollment of CHC-based participants shows the feasibility of extending HCV treatment to PWID beyond methadone clinics. Treatment initiation rates are high given project's parameters (12-weeks). Results suggest high feasibility of HCV treatment for active PWID in multiple settings.