Real World Direct-Acting Antiviral (DAA) Outcomes Among People Who Inject Drugs (PWID) in the United States: Hepatitis C Real Options (HERO)

#319

Lynn E. Taylor[1], Feinberg J[2], Kim AY[3], Lum PL[4], Mehta SH[5], Norton BL[6], Page KA[7], Tsui JI[8], Litwin AH[9]

[1]University of Rhode Island, [2]West Virginia University, [3]Harvard University, [4]University of California, San Francisco, [5]Johns Hopkins Bloomberg School of Public Health, [6]Montefiore Medical Center, [7]University of New Mexico, [8]Universtiy of Washington, [9]Greenville Health System, [9]Clemson University, [9]University of South Carolina School of Medicine

Contact: Alain H. Litwin
ALitwin@ghs.org
Greenville Memorial Hospital
Department of Medicine
701 Grove Road
Greenville, SC 29605 USA
864-430-0911

Background

- Well-designed, adequately-powered studies that compare effectiveness of hepatitis C virus (HCV) treatment delivery models among PWID are needed.
- HERO is an ongoing U.S.-based research study involving 8 states with geographic/ policy diversity.

Methods

- Enrolled 750 PWID (injecting within past 3 months) for treatment uptake goal of 600 PWID
- 12 weeks sofosbuvir/velpatasvir (SOF/VEL)
- Participants (on and not on opioid agonist therapy) are treated at community health centers (CHC) or methadone maintenance programs (MMPs) and are randomized to modified directly observed therapy (mDOT) or patient navigation (PN, standardized intervention). Those randomized to mDOT at MMPs receive SOF/VEL with daily methadone; those at CHC settings video-record themselves taking SOF/VEL daily using an 'app' (emocha).
- HERO involves broad range stakeholders: national advocacy & medical organizations (HRC, NVHR, AATOD, NATAP), government (CDC), clinicians, patients, industry.

Outcomes

Primary:
- Sustained virologic response (SVR) compared between mDOT and PN arms

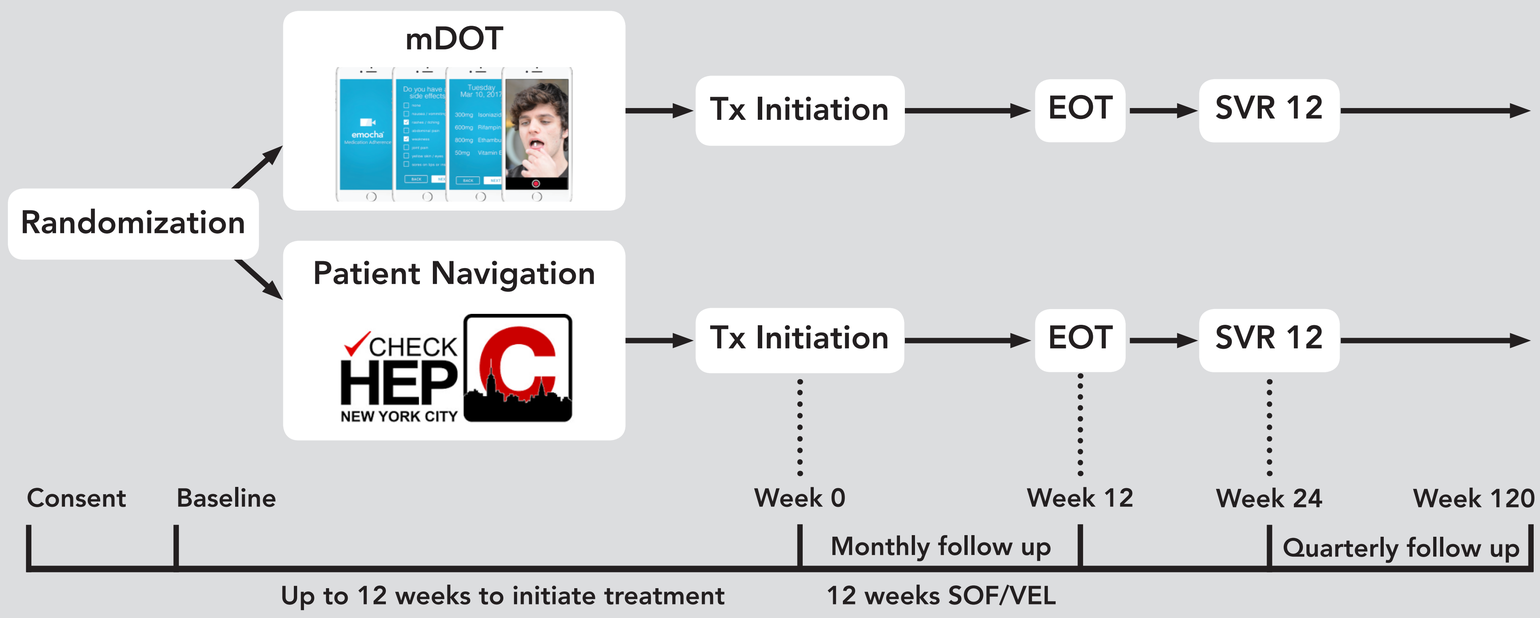
Secondary:
- Treatment initiation, adherence, completion, resistance, reinfection over 2 years

Nested Implementation Study:
- Assess study implementation
- Examine implementation barriers and facilitators using social-ecological framework
- Data analysis (mixed methods approach)

Study Design

Patient population: DAA-treatment naïve
Any genotype
+/- HIV

Arm A: 1) MMP, N=150; 2) CHC, N=150
Arm B: 1) MMP, N=150; 2) CHC, N=150



Results (August 10, 2018)

Total	N (%)*
Screened	1889
Enrolled	955 (50.5)
Enrolled & randomized	751 (78.6)
• Eligible for treatment	651 (86.7)
• Treatment initiation	601 (92.3)

*Percents (%) reflect the proportion of patients from previous stage; N and % of patients is not adjusted for time or losses.

	Median (IQR) (N%)
Age	40.0 (18.0)
Gender indentity	
Female	211 (29)
Male	512 (70)
Transgender	4 (<1)
Other	4 (<1)
Education	
<High school	167 (23)
High school/GED	292 (40)
Some college/associate degree	231 (32)
≥College degree	35 (5)
	N (%)
Race	
Asian	1 (<1)
Black	100 (14)
Native American	20 (3)
White	448 (62)
Multi-race	24 (3)
Other	135 (18)
Ethnicity	
Hispanic/Latino	175 (24)
Non-Hispanic/Non-Latino	554 (76)

Enrollment higher at CHC (n=438) than methadone settings (n=313). 12-week treatment initiation 80%.

Study Sites

Conclusions

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

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