A COMMUNITY-BASED TRIAL OF HEPATITIS C TREATMENT AT POINT OF DIAGNOSIS FOR MARGINALIZED POPULATIONS: PRELIMINARY RESULTS FROM THE NO ONE WAITS (NOW) STUDY

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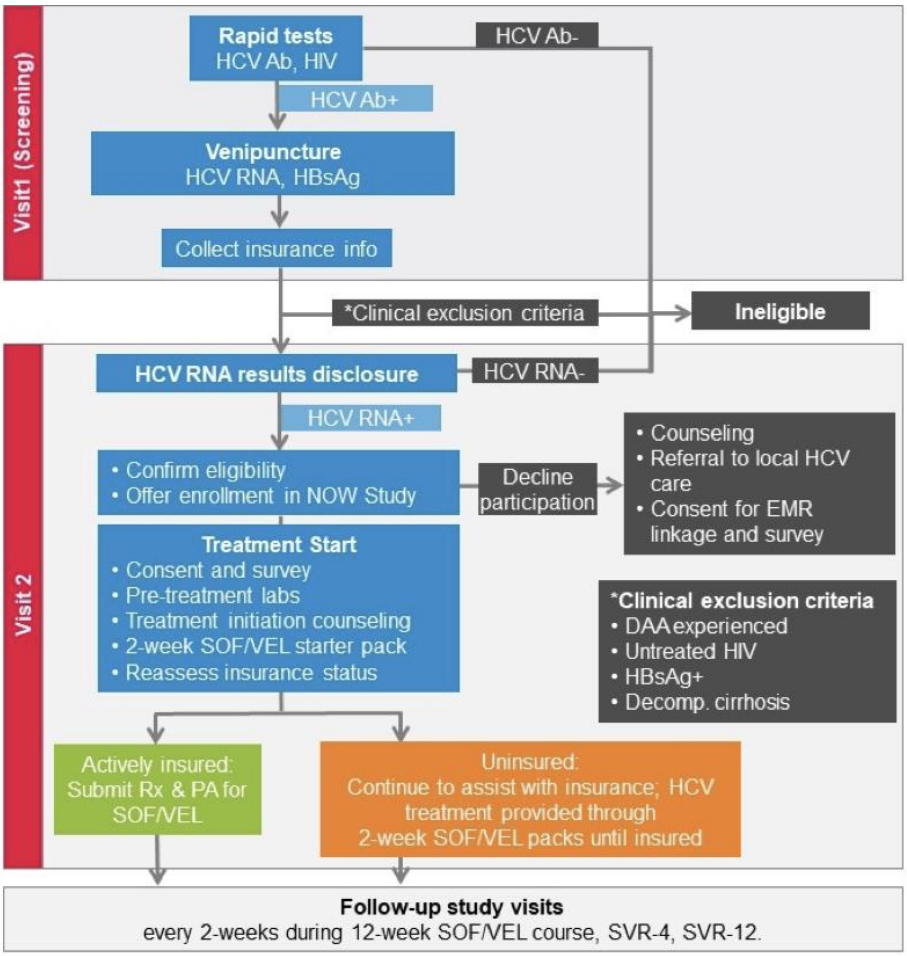
Background:
A principal barrier to hepatitis C virus (HCV) treatment is linkage-to-care upon diagnosis, particularly for marginalized populations. Pairing community-based HCV testing services with low-threshold treatment eliminates medical system navigation.

Methods:
We conducted a single-arm trial in an urban US community setting to assess the acceptability, feasibility, and effectiveness of delivering HCV treatment at the point of HCV RNA positive diagnosis disclosure. Street-outreach recruitment targeted people experiencing homelessness and injecting drugs for rapid HCV antibody (anti-HCV) testing followed by confirmatory HCV RNA testing if positive (Figure). At HCV RNA result disclosure, enrolled participants were given 2-weeks of study-provided SOF/VEL and transitioned to insurance-provided SOF/VEL upon authorization. Based on enrollment to date, we estimated (i) time from HCV RNA disclosure to treatment initiation, (ii) proportion who completed treatment, and (iii) proportion who attained SVR-12.

Results:
Between July 2020 and October 2021, 500 individuals were screened; 102 (20%) have tested anti-HCV positive and RNA negative and 121 (24%) anti-HCV and HCV RNA positive. Eighty-eight (73%) of the 121 HCV RNA positive returned for diagnosis disclosure and were eligible to enroll. Two people declined enrollment and, 86 (98%) initiated treatment upon diagnosis disclosure (median age: 49 years [IQR: 38, 59]). Sixty-three (73%) injected drugs in the past 3-months, 43 (50%) were unhoused, and 40 (47%) had a primary care provider. To date, 65 (75%) have completed SOF/VEL treatment, 88% (57/65) of whom had undetectable HCV RNA upon completion. To date, lost to follow-up occurred for 14 people and treatment termination due to low medication adherence occurred for two. Follow-up is currently underway, to date, 87% (53/61) have attained SVR-4 and 84% (41/49) have attained SVR-12.

Conclusion:
Preliminary results from our trial of people experiencing homelessness and currently injecting drugs indicate that initiation at the time of diagnosis is acceptable, feasible, and results in high treatment completion and SVR.

Figure1: Study flow diagram



Disclosure of Interest Statement: ***See example below:***

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