

OUTCOMES FROM THE KENTUCKY VIRAL HEPATITIS TREATMENT (KeY TREAT) TRIAL: A MODEL OF CARE FOR THE TREATMENT OF THE HEPATITIS C VIRUS IN A RURAL APPALACHIAN COUNTY IN THE U.S.

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Background: Multiple models of care will need to be employed to achieve elimination of the hepatitis C virus (HCV) in the United States. Implemented in 2019, KeY Treat sought to remove barriers to accessing HCV care in a rural county in the U.S. severely impacted by the opioid/HCV syndemic.

Methods: The Xpert HCV VL Fingerstick assay was utilized to streamline enrollment for those age $\geq$ 18 with detectable HCV RNA. Most (85%) participants were initiated on sofosbuvir/velpatasvir (SOF/VEL) at the first visit. The analytic sample includes 380 participants who were eligible and consented to study enrollment and per-protocol (PP) and intent-to-treat (ITT) sustained virologic response (SVR-12) rates are reported. A generalized linear model was used to estimate the relative risk (RR) of PP SVR-12.

Results: The majority of participants were male (58.5%), White (96.6%), and the median age was 41.8 years (IQR: 35.4, 48.7) One-third of participants injected drugs (mostly methamphetamine [92.3%]) in the past 30 days. Approximately 15% of participants were lost to follow-up. Per protocol SVR-12 rates were 92.7% and intent-to-treat SVR-12 78.1%. The RR of SVR-12 was significantly greater among females and older participants. Those reporting recent drug injection were 11% less likely to achieve SVR-12 versus those without recent injection (adjusted RR: 0.89, 95% Confidence Interval [CI]: 0.83, 0.97).

Conclusions: Results suggest that KeY Treat is a viable model of care, especially in those rural areas impacted by the opioid/HCV syndemic. SVR-12 was achievable for most participants. Even though people injecting drugs were less likely to achieve SVR, cure rate were still upwards of 85% in this population. Efforts to optimize outcomes among those who are actively injecting drugs should be a priority to facilitate elimination efforts. This, however, may be particularly challenging in rural regions of the U.S. with little to no access to harm reduction.

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