

# EFFICACY AND SAFETY OF SOFOSBUVIR/VELPATASVIR IN PEOPLE WITH CHRONIC HEPATITIS C VIRUS INFECTION AND RECENT INJECTING DRUG USE: THE SIMPLIFY STUDY

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## Introduction:

Interferon-free direct-acting antiviral therapy (DAA) is safe and effective in people with hepatitis C virus (HCV) receiving stable opioid substitution therapy (OST), but there are little data among recent people who inject drugs (PWID). Improved evidence of DAA outcomes among recent PWID is crucial for elimination efforts, given the potential impact of HCV treatment as prevention. The aim of this study was to evaluate the efficacy and safety of sofosbuvir/velpatasvir for chronic HCV among recent PWID.

## Methods:

SIMPLIFY is an international open-label study that recruited participants with recent injecting drug use (previous six months) and chronic HCV genotype (G) 1-6 infection between March and October, 2016 in seven countries (19 sites). Participants received sofosbuvir/velpatasvir daily administered in a one-week electronic blister pack (records the time and date of each dose) for 12 weeks. The primary endpoint was sustained virological response at 12 weeks (SVR) after the end of therapy.

## Results:

Of 103 participants who initiated treatment (mean age 47 years; 72% male; 9% cirrhosis), 35% had HCV G1, 5% G2, 58% G3, and 2% G4. At screening, 57% were receiving OST, with 74% injecting in the past month, 48% at least once a week. Overall, 96% (99/103) completed treatment. There were four discontinuations (loss to follow-up, n=3; overdose death, n=1). End of treatment response (ETR) was 96% (99/103). Overall, two participants with an ETR did not have SVR12 [loss to follow-up, n=1; virological relapse/reinfection, n=1 (undergoing sequencing to confirm)]. In intent-to-treat analyses among all participants, SVR12 was 94% (97/103).

## Conclusion:

In this study of once-daily sofosbuvir/velpatasvir among people with recent injecting drug use and chronic HCV, high treatment completion, and SVR were observed, with no cases of

virological failure and one case of virological relapse/reinfection. This supports DAA therapy in recent PWID, a key population for HCV elimination strategies.