

ADHERENCE TO SOFOSBUVIR AND VELPATASVIR AMONG PEOPLE WITH CHRONIC HCV INFECTION AND RECENT INJECTION DRUG USE: THE SIMPLIFY STUDY

Evan B. Cunningham¹, Janaki Amin^{1,2}, Jordan J Feld³, Julie Bruneau⁴, Olav Dalgard^{5,6}, Jeff Powis⁷, Margaret Hellard^{8,9}, Curtis Cooper¹⁰, Phillip Read^{1,11}, Brian Conway¹², Adrian J Dunlop^{13,14}, Briana Norton¹⁵, Alain H. Litwin¹⁵, Behzad Hajarizadeh¹, Maria Christine Thurnheer¹⁶, John F Dillon¹⁷, Martin Weltman¹⁸, David Shaw¹⁹, Philip Bruggmann²⁰, Edward Gane²¹, Chris Fraser²², Philippa Marks¹, Tanya L Applegate¹, Sophie Quiene¹, Sharmila Siriragavan¹, Gail V. Matthews^{1,23}, Gregory J Dore^{1,23} and Jason Grebely¹

¹The Kirby Institute, UNSW Sydney, Sydney, Australia, ²Faculty of Medicine and Health Sciences, Macquarie University, Sydney, Australia, ³Toronto General Hospital, Toronto, ⁴Centre Hospitalier de l'Université de Montréal, Canada, ⁵Akershus University Hospital, Oslo, Norway, ⁶ Institute of Clinical Medicine, University of Oslo, Oslo, ⁷South Riverdale Community Health Centre, Toronto, Canada, ⁸The Burnet Institute, Melbourne, Australia, ⁹Department of Infectious Disease, The Alfred Hospital, Melbourne, Australia, ¹⁰Ottawa Hospital Research Institute, Ottawa, Canada, ¹¹Kirketon Road Centre, Sydney, Australia, ¹²Vancouver Infectious Diseases Center, Vancouver, Canada, ¹³Drug & Alcohol Clinical Services, Hunter New England Local Health District, ¹⁴Centre for Translational Neuroscience and Mental Health, Hunter Medical Research Institute & University of Newcastle, ¹⁵Montefiore Medical Centre, New York, United States and Albert Einstein College of Medicine, New York, United States, ¹⁶Department of Infectious Diseases, Bern University Hospital, ¹⁷Ninewells Hospital and Medical School, University of Dundee, Dundee, United Kingdom, ¹⁸Nepean Hospital, Penrith, Australia, ¹⁹Royal Adelaide Hospital, Adelaide, Australia, ²⁰Arud Centres for Addiction Medicine, Zurich, Switzerland, ²¹Auckland City Hospital, Auckland, New Zealand, ²²Coolaid Community Health Centre, Victoria, Canada, ²³St Vincent's Hospital, Sydney Australia.

Background: Treatment adherence has been a concern regarding the scale up of HCV DAA therapy in people who inject drugs. This study investigated treatment adherence among people with recent injecting drug use in a study of sofosbuvir/velpatasvir therapy for HCV infection.

Methods: SIMPLIFY is an international open-label, single-arm multicentre 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 once-daily for 12 weeks administered in a one-week electronic blister pack (records the time and date of each dose) for 12 weeks. We evaluated non-adherence (<90% adherent) as measured by electronic blister-pack assessed using logistic regression and generalised estimating equations (continuous) with detailed analyses of dosing dynamics.

Results: Among 103 participants, 97% (n=100) completed treatment. Median adherence to therapy was 94%. Overall, 32% (n=33) were considered non-adherent (<90% adherence). Adherence significantly decreased over the course of therapy. Recent stimulant injecting (cocaine and/or amphetamines) at treatment initiation and

during treatment was independently associated with non-adherence. Inconsistent dose timing (standard deviation of daily dose timing of ≥ 240 minutes) was also independently associated with non-adherence to therapy. Factors associated with inconsistent dose timing included lower levels of education and recent stimulant injecting. SVR was similar among adherent and non-adherent populations (94% vs. 94%, $P=0.944$).

Conclusion: This study demonstrated high adherence to once-daily sofosbuvir/velpatasvir therapy among a population of people with recent injecting drug use. Recent stimulant injecting prior to and during DAA therapy and inconsistent dose-timing during treatment was associated with non-adherence. However, there was no impact of non-adherence on response to therapy, suggesting that adherence is not a significant barrier to successful DAA therapy in people with recent injecting drug use.

Disclosure of Interest Statement:

The conference collaborators recognise the considerable contribution that industry partners make to professional and research activities. We also recognise the need for transparency of disclosure of potential conflicts of interest by acknowledging these relationships in publications and presentations.