Preliminary Data from the Prime Study: a Randomised Controlled Trial of Community vs Hospital Direct Acting Antiviral Therapy

Wade AJ[1,2], Doyle JS[1,3,5], Thompson AJ[4,5], Hellard ME[1,2,3] on behalf of the Prime Study Group

[1]Centre for Population Health, Burnet Institute, [2]School of Population Health and Preventive Medicine, Monash University, [3]Department of Infectious Diseases, The Alfred, [4]Department of Medicine, University of Melbourne, [5]Department of Gastroenterology, St Vincent's Hospital Melbourne, Melbourne, Australia

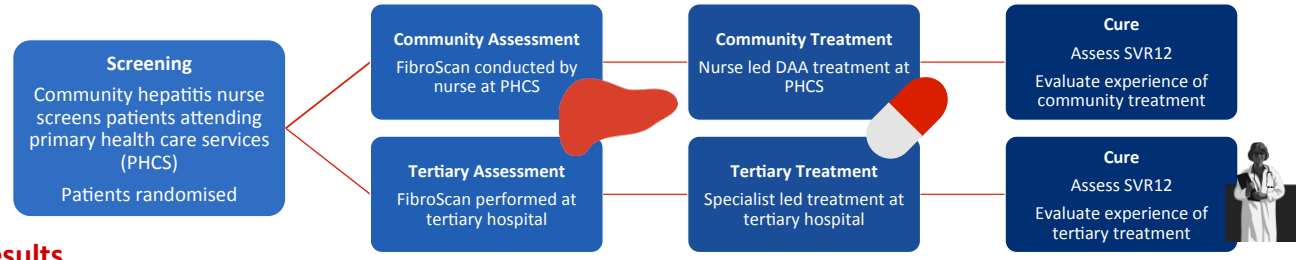
Background

- The Prime Study is the first real-world, randomised, model of care study comparing direct acting antiviral (DAA) hepatitis C treatment uptake and outcomes in the community with a tertiary hospital.
- A high proportion of Primary Health Care Services (PHCS) clients have a history of injecting drug use and traditionally have been harder to engage in hospital-led care.
- Community based care has the potential to substantially increase treatment uptake in this population.
- We describe the baseline characteristics of the first 61 participants recruited at PHCS by community hepatitis nurses.

Recruitment timeline

- First patient first visit - November 2015; last patient first visit - June2017; last patient last visit - December 2017.

Figure 1: Participant journey from screening to cure



Results

Recruitment

- 61 G1 participants have been screened and randomised

Baseline demographics

- Median age was 45 years (range 33 – 65 years)
- Majority were male (n = 45, 74%)
- Majority (n= 54, 89%) had completed high school
- Almost one third (n=17, 28%) were employed or studying
- Only a small proportion (n= 7, 11%) had unstable housing

Baseline HCV characteristics

- Only 5 participants (8%) had previously received treatment for HCV
- Almost all (n = 59, 97%) participants reported a history of injecting drug use
- Approximately half (n= 26, 43%) had injected in the last 6 months
- Over half (n = 36, 59%) were on opioid substitution therapy
- Of 61, 25 participants had FibroScan results reported; median result = 6.8 kPa (range 3.1 – 17.8)

Methods

- The Prime Study is a randomised controlled trial comparing DAA uptake and outcomes in community care with tertiary hospital care.
- Patients are randomised to undergo a FibroScan and receive DAA therapy at their community PHCS (intervention arm) or the local tertiary hospital (standard of care arm).
- 380 patients will be randomised 1:1 to PHCS vs tertiary care. This provides 80% power to detect a minimum 15% difference in treatment uptake and cure between the two arms.

Eligibility

- Part 1: Individuals with genotype 1 (G1) hepatitis C virus (HCV) mono-infection, who were not known to be cirrhotic and did not have concomitant medication interactions with ombitasvir, dasabuvir, paritaprevir/ritonavir and ribavirin
- Part 2: Recruitment expanded to include individuals with genotype 3 and genotype 4 HCV, July 2016
- Patient found to have advanced fibrosis were ineligible.

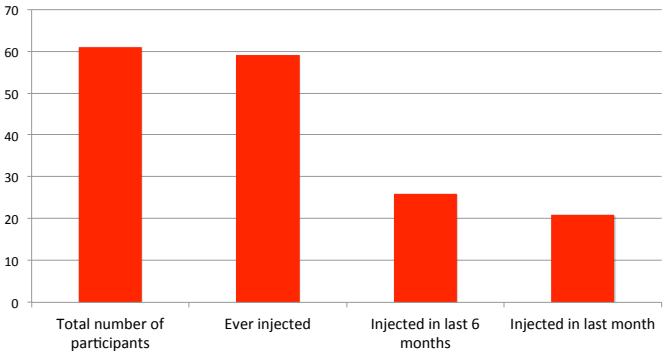


Figure 2: Baseline injecting frequency

Conclusions

- Treatment of people who inject drugs (PWID) has the dual benefit of curing their HCV and reducing ongoing HCV transmission
- Key will be to increase the number of PWID undergoing HCV treatment
- Community based care is likely to increase HCV treatment accessibility and uptake in this priority population

Disclosure of interest statement & Acknowledgements

The Prime Study is an investigator driven study sponsored by AbbVie. The investigators recognise the need for transparency of disclosure of potential conflicts of interest and acknowledging these relationships in publications and presentations.

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For enquiries, contact Dr. Amanda Wade, amanda.wade@burnet.edu.au