Eliminating hepatitis C transmission by enhancing care and treatment among HIV co-infected individuals: The co-EC Study rationale and overview

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Background

- Hepatitis C virus (HCV) infection is a significant health issue among individuals with HIV infection, causing more rapid progression to liver disease & increased risk of liver cancer.
- In Australia, the highest prevalence of HCV/HIV co-infection is in gay and bisexual men (GBM).
- New direct-acting antivirals (DAA) are available for treating HCV and provide a unique opportunity to increase the number of people accessing HCV treatment.
  - ✓ Australian Government-subsidised for affordable access
  - ✓ Can be administered in the Primary Health Care setting
  - ✓ No disease-stage restrictions on who can be treated
- This abstract presents the study design of the co-EC (Eliminate Hepatitis C) Study
- The Co-EC Study aims to offer proof of concept that scaling up treatment could lead to elimination of HCV/HIV co-infection in GBM in Victoria, Australia.

Methods

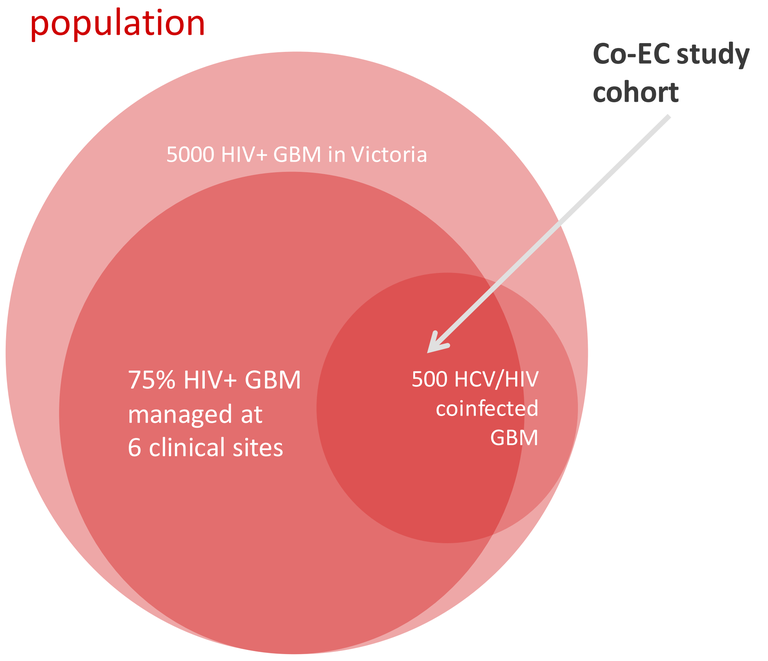
Study design

- The co-EC Study is a clinician-directed-nurse managed non-randomised trial of DAA treatment among people with HCV/HIV co-infection.
- Testing, liver assessment (including transient elastography) and treatment is delivered by trained nurses at primary care or tertiary sites in Melbourne under clinician supervision **(figure 1)**.
- Treatment is with any licensed and subsidised DAA, following standard-of-care practice with 8-24 weeks of treatment.
- The study will follow participants for up to 80 weeks in total comprising screening, treatment, and follow-up at weeks 12, 24 and 48 post-treatment.
- co-EC Study aims to recruit up to 375 participants aged 18+ years (see assumptions)
- An enhanced statewide surveillance system linking clinical and laboratory data will be used to monitor HCV epidemiology in the greater population.

Primary endpoints

- SVR12
- Community HCV viral load
- HCV prevalence, incidence and reinfection incidence

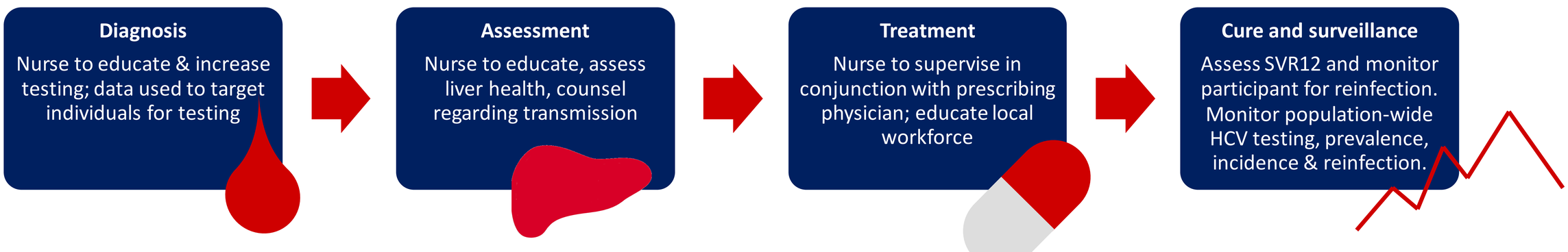
Figure 2: Study cohort in relation to local population



Preliminary results

- Fifty participants have been recruited in two months since study commencement.
- All participants are male (median age 51 years)
- At screening, 66% reported any male-to-male sexual activity in the past six months, of whom 91% had casual partners, 32% engaged in group sex, and 10% consistently used condoms during sexual activity.
- Injecting drug use was reported by 64% ever, 58% injected in the past six months, and 26% injected in the past month (all amphetamines).

Figure 1: Participant journey and role of study nurse from diagnosis to cure



Study aims

Primary objectives are:

1) Achieving HCV sustained virological response (SVR12) among HIV co-infected participants in a real-world primary care or hospital clinic settings; and
2) Measuring the impact of treating HCV among HIV-infected individuals on HCV prevalence, incidence, and reinfection incidence GBM in Victoria.

Statistical assumptions and sample size

It is estimated that there are 500 HCV/HIV coinfected GBM in Victoria. 75% of HIV-positive GBM are managed at 6 clinical sites participating in the co-EC Study. Subsequently, the co-EC study is targeting a cohort of estimated 375 HIV/HCV positive GBM managed at these sites **(figure 2).**

Treating 90% of our cohort may reduce statewide prevalence of HCV from 10% to 3.4%.

Treating 50% of our cohort may reduce statewide prevalence of HCV from 10% to 5.5%.

Conclusion

This study will provide proof of concept that scaling-up treatment could lead to elimination of HCV/HIV co-infection in GBM by treating prevalent infection thereby reducing new primary infections and re-infection.

It will inform the implementation of treatment as prevention strategies among HCV/HIV co-infected GBM in jurisdictions with similar epidemics.

Acknowledgements

The authors declare investigator initiated research funding support from Bristol-Myers Squibb for the co-EC study.

The authors kindly than the participants and support from nurses and recruiting sites at: the Alfred Hospital, Prahran Market Clinic, Centre Clinic, Northside Clinic, Melbourne Sexual Health and Royal Melbourne Hospital.

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