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Hepatitis C elimination in HIV/HCV coinfection through treatment in primary care is feasible and effective

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Disclosures

- The co-EC Study is funded by an investigator-initiated research grant from Bristol Myers Squibb
- MH and JD's institutions have received investigator-initiated research funding from Gilead Sciences, Abbvie, Merck
- MH and JD's institutions have received honoraria from Gilead Sciences, Merck, Bristol Myers Squibb

HIV/HCV co-infection in Australia

- 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)
- Among approximately 5,000 diagnosed HIV-positive GBM in Victoria
  - 10% are co-infected with HCV
  - 1-2% incidence HCV infection
  - Sexual transmission of HCV is a major driver of transmission
  - In general, frequently tested population (tested 1.4 times per year)
- Need for targeted HCV testing, prevention and treatment strategies among HIV positive GBM

Background

- New direct-acting antivirals 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

- HIV positive GBM are well engaged in care, HCV infection could be promptly diagnosed and treated with a systematic approach

- Offering treatment in the primary health care setting will improve treatment capacity and accessibility, whilst potentially reducing treatment costs

co-EC Study objectives

The co-EC Study

- Eliminating hepatitis C transmission by enhancing care and treatment among HIV co-infected individuals
- co-EC aims to offer proof of concept that scaling up treatment could lead to elimination of HCV/HIV co-infection in GBM in Victoria, Australia.

Primary objectives:

- Achieve HCV sustained virological response (SVR12) among HIV co-infected participants in a real-world primary care or hospital clinic setting.
- Measure the impact of treating HCV in HIV infected individuals on primary HCV and reinfection incidence and HCV prevalence in gay and bisexual men in Victoria.

Study endpoints

Primary endpoints:

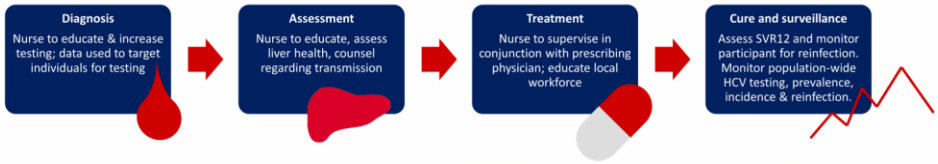
- Proportion of people who commence hepatitis C treatment and have a sustained virological response 12 weeks after treatment (SVR12)
- HCV prevalence, primary HCV incidence, HCV reinfection incidence 2-3 years after implementation

Secondary endpoints:

- HCV testing among individuals with HIV infection engaged in care
- Among HIV/HCV co-infected individuals:
  - Treatment uptake in primary or hospital clinics;
  - **Referred to specialist care;**
  - **High-risk sexual and injecting behaviour**

Methods: Study design

- 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
- Treatment is with any licensed and subsidised DAA, following standard-of-care practice with 8-24 weeks of treatment
- coEC follows participants for up to 80 weeks in total comprising screening, treatment, and follow-up at weeks 12, 24 and 48 post-treatment



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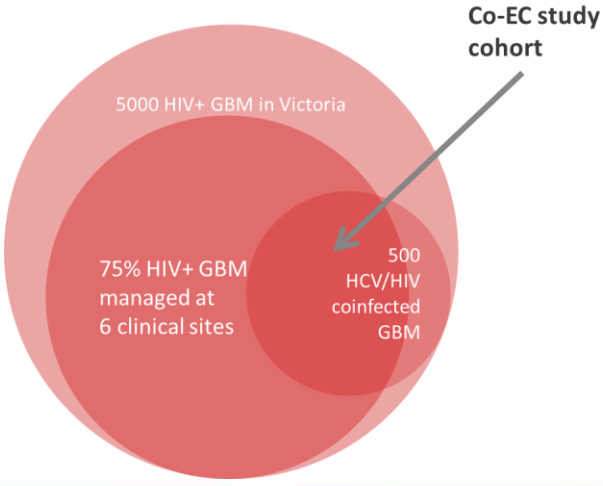
Methods: Study cohort

- co-EC Study aims to recruit up to 375 participants aged 18+ years at tertiary (n=2) and primary care (n=4) sites in Melbourne, Victoria



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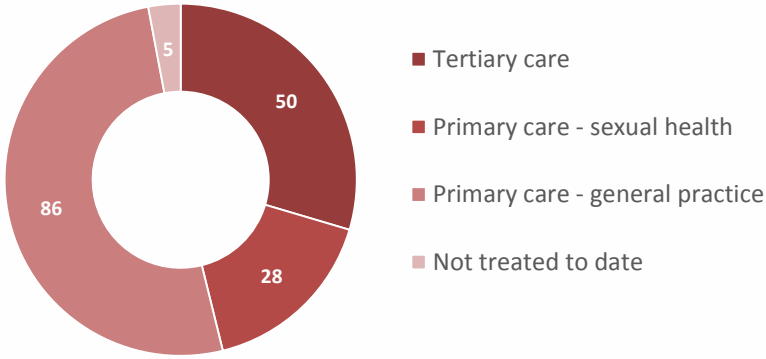
Results: enrolment

- First year enrolment from March 2016 – March 2017
- 169 individuals enrolled
- Treatment location:



Results: Cohort characteristics

At enrolment	n (%)
Male Gender	162 (96%)
Age, median	47 year (IQR 42-56)
HCV genotype	Genotype 1: 114 (67%) Genotype 2: 4 (3%) Genotype 3: 42 (25%)
Liver stiffness, median using transient elastography	5.5 kPa (IQR 4.7 – 7.1)
HCV Treatment history	Treatment naïve: 127 (82%) Experienced: 31 (18%)
Reasons for retreatment	Reinfection: 8 (28%) Treatment failure: 23 (72%)
HIV antiviral therapy	163 (97%)
HIV suppressed	155 (92%)

Results: Cohort characteristics

At enrolment	n (%)
HCV acquisition	
Sex with men as only risk factor	110 (65%)
Injecting drug use, ever	50 (30%)
Incarcerated, ever	16 (12%)
Other/Unknown/unreported risk	9 (5%)
Social demographic	
Australian born	108 (72%)
Higher education undertaken	88 (60%)
Regular employment (part or full time)	68 (45%)
Low income (< AU$1000 per week)	81 (59%)

1. Risk behaviour prior to treatment

Behaviour data available pre-treatment on 150/169 participants

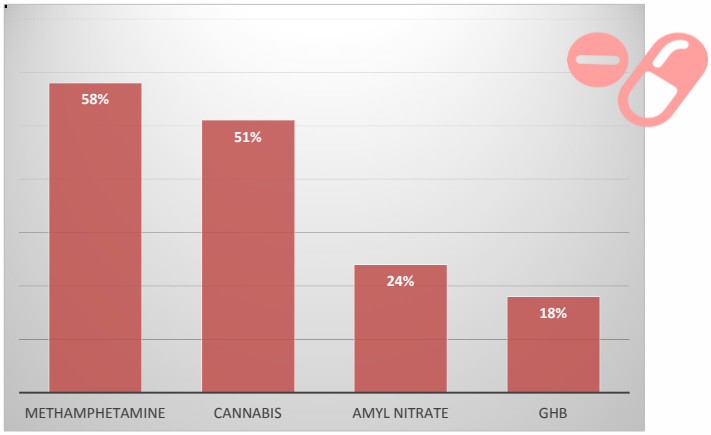
Sexual risk behaviour

- In previous 6 months, 87 (66%) male participants reported sex with men
- Of these sexually active men:
  - 69 (86%) reported casual sex partners
  - 54 (75%) reported inconsistent condom use with casual partners
  - 41 (47%) reported group sex
  - 42 (48%) reported substance use (non-alcohol) with sex

1. Risk behaviour prior to treatment

Illicit drug use

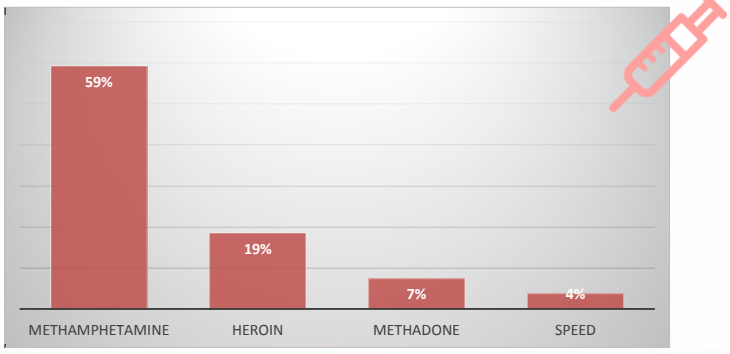
- 71 (51%) participants reported recreational drug use in the previous month



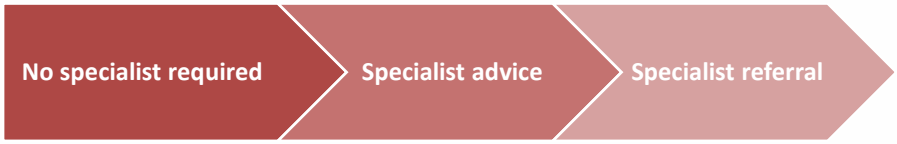
1. Risk behaviour prior to treatment

Illicit drug use

- 93 (65%) participants reported ever injecting drugs
- 33/93 (40%) reported ever using a needle/syringe that had been used by someone else
- 27/93 (29%) reporting injecting in the previous month

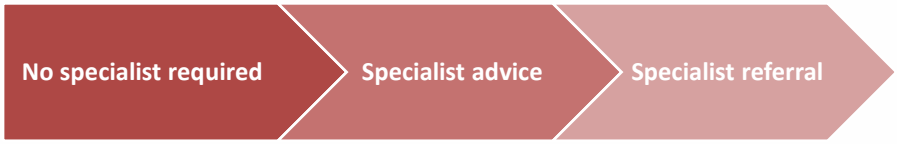


2. Suitability of treatment in primary care



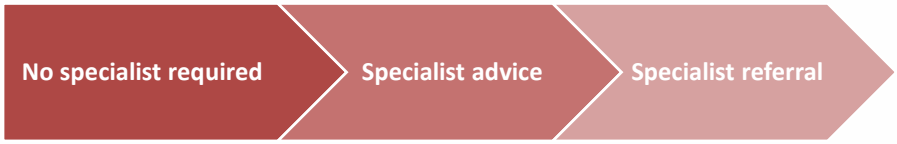
- **No specialist input required** -> participant treated by general practitioner/sexual health expert with nurse support
- **Specialist advice** required some form of communication (telephone or electronic communication)
- **Specialist referral** required direct consultation by specialist with the participant

2. Suitability of treatment in primary care



- Parameters prompting **specialist advice**:
  - platelets <150,000/uL
  - AST:Platelet Ratio Index (APRI) >1.0
  - total bilirubin >1.5x upper limit of normal

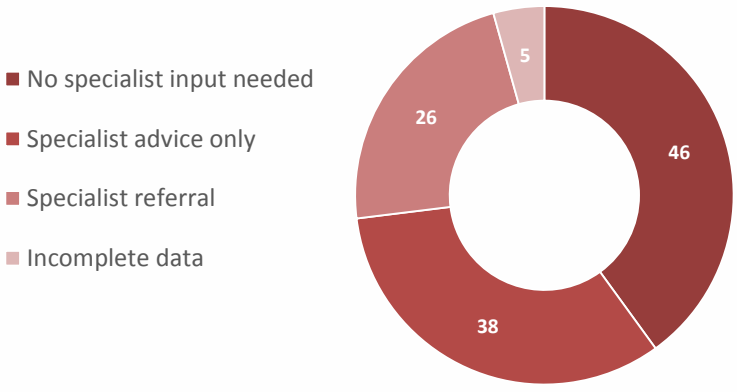
2. Suitability of treatment in primary care



- Parameters prompting **specialist referral**:
  - known cirrhosis
  - liver stiffness (FibroScan) >12.5kPa
  - hepatitis B coinfection
  - previous interferon-free DAA therapy
  - or drug allergy, organ transplant, malignancy within 5 years, or chronic renal or cardiac disease

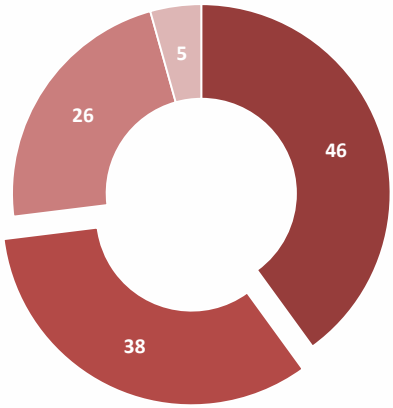
Specialist input

- Among patients screened outside tertiary care (n=114):



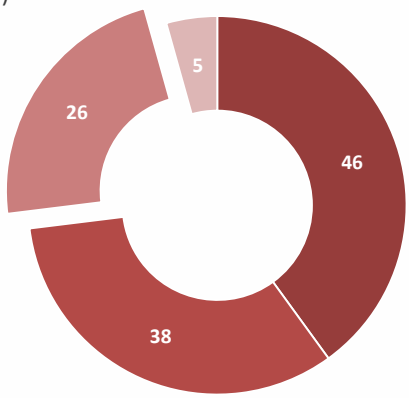
Specialist input

- Among patients screened outside tertiary care (n=114):
- Specialist advice required (n=38)
  - 49% APRI >1.0
  - 15% low platelet count
  - 10% elevated bilirubin



Specialist input

- Among patients screened outside tertiary care (n=114):
- Specialist referral required (n=26)
  - 27% renal or cardiac disease
  - 20% known cirrhosis
  - 15% elevated liver stiffness
  - 15% recent malignancy



Conclusions

- The co-EC Study has recruited HIV/HCV coinfected men with high-risk sexual and drug use behaviour, including concurrent injecting drug use
- These behaviours may put participants at risk of HCV reinfection, and ongoing transmission of HCV
- Education and tailored interventions for mitigating risks of reinfection will be critical for this cohort
- It will be important to follow this cohort to assess behaviour change, HCV cure and HCV reinfection rates

Conclusions

- Despite HIV/HCV coinfection traditionally requiring specialist management, a majority of people can receive HCV treatment in primary care settings without referral
- Mechanisms to facilitate specialist advice and referral are needed to enhance care and rapidly scale-up treatment
- Strategies to achieve and sustain HCV elimination targets will require enhanced HCV care and treatment in primary care settings in most jurisdictions in Australia

Acknowledgements

- Dr Anna Bowring, Dr Rebecca Winter, Dr Julia Cutts
- Janine Roney
- Alfred Health Clinical Research Unit
- Study participants
- Bristol Myers Squibb
- NHMRC fellowship support
- Victorian Operational Infrastructure Fund