



Burnet Institute
Medical Research. Practical Action.

**RECRUITMENT AND FOLLOW-UP
OF PEOPLE WHO INJECT DRUGS
INTO A NURSE-LED HCV
TREATMENT TRIAL**

Sally von Bibra

Disclosures

- The TAP study is an investigator initiated study supported by a research grant from Gilead Science



Background

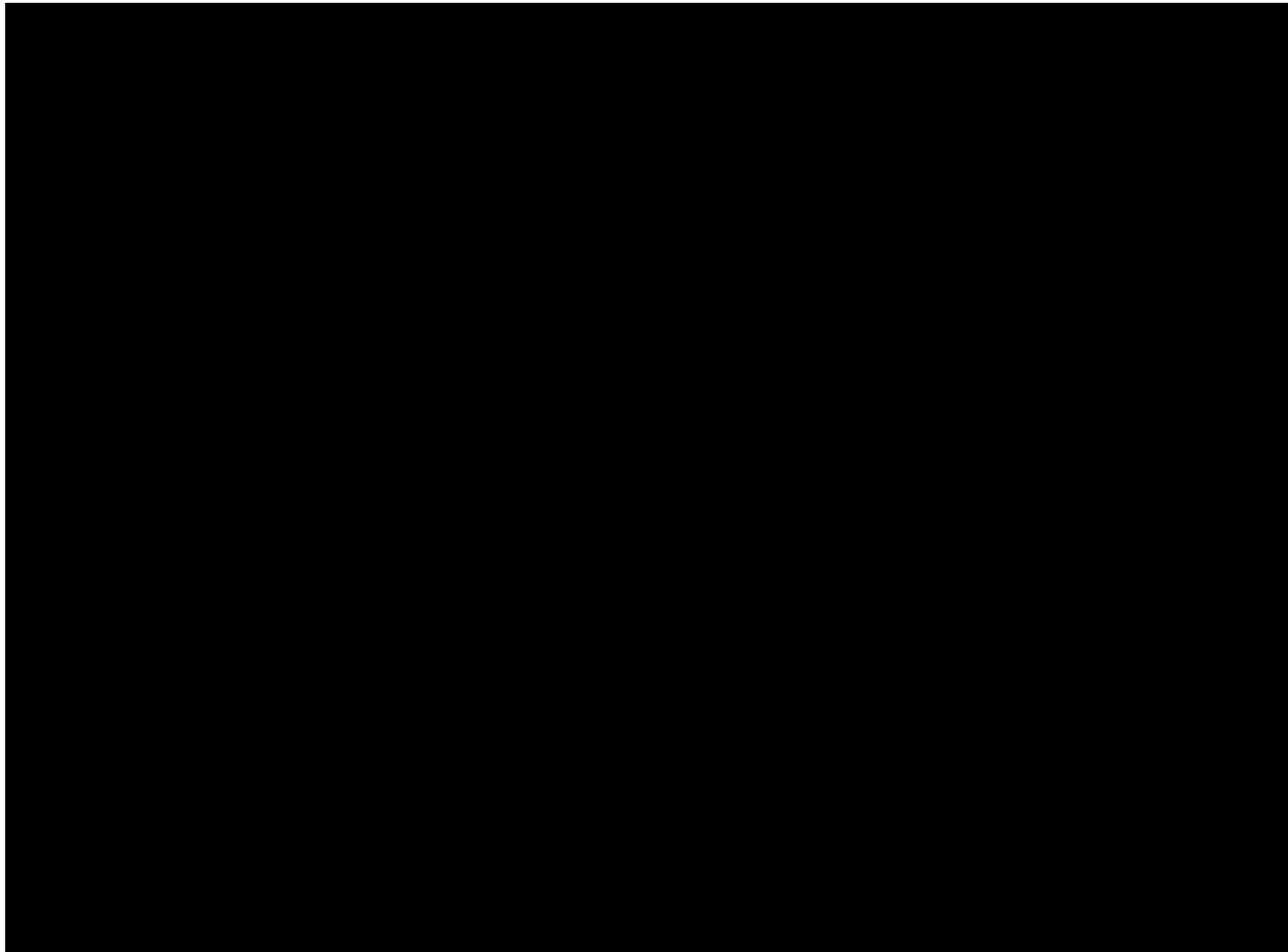
- The Hepatitis C Treatment and Prevention (TAP) Study is the first real-world community-based trial to explore a network-based approach to treat people who inject drugs (PWID) and their partners, and measure its impact on HCV prevalence and incidence. The TAP Study uses a nurse-led model of care that has potential to substantially increase treatment uptake among people at high-risk of transmitting HCV.



Methods

- **RECRUITMENT** :The Tap Study recruits active PWID with their injecting partners from outreach sites throughout Melbourne.
- **TREATMENT GROUPS** :Participants are randomly allocated to sofosbuvir/Velpatasvir(Epclusa) treatment alone or concurrent with their injecting partners.
- **DATA COLLECTION** :Study nurses perform pre-treatment assessment (including Fibro Scan),manage therapy and follow-up participants using a mobile clinic van and outreach clinics.
- **PRIMARY OUTCOME**: Feasibility of delivering care using a nurse-led care.





Recruitment

- SMX cohort
- Outreach Clinics
- Local GP Clinics (OST providers)
- Self referral
- Path cohort



Recruitment Challenges

- Early challenges identified in the community outreach aspect of the project included:
- limited understanding of new HCV therapies among PWID as many were sceptical of previous treatments success, and many where less interest in HCV treatment than anticipated.
- Feelings of stigmatisation and marginalisation among participants, due to experiences with previous service providers this impacted on early engagement in care .
- Unstable housing, contact with the justice system, and inadequate income support have affected participation
- Some participants are at risk of homelessness, social isolation and change contact information frequently.
- Study eligibility, protocol constraints, secondary reluctance and distrust
- Mental Health Issues



Strategies to improve recruitment

These challenges are being overcome by delivery of treatment:

- mobile sites (van), outreach clinics, home visits
- Sites close to NSP, GP and OST providers
- flexible scheduling of visits
- experienced non-medical fieldworkers and peer support
- Education
- Support throughout the project by nurses
- One stop shop
- Non judgemental service that values and respects participants
- Time

A recently implemented state-wide hepatitis treatment program in prisons will also in managing participants who become incarcerated



Burnet Institute

Participant Characteristics

This cohort would be traditionally difficult to engage in clinical care

- More than 241 individuals have been screened and 142 participants recruited to date
- Median age of participants is 36 years (range 24- 58)
- 71% are male
- Participants report a median of two injecting partners (IQR1-2)
- Median duration of injecting of 20 years (IQR 15-27)
- Current opiate substitution therapy use among 39%
- 89% are unemployed
- 24% have unstable accommodation or are homeless;
- 52% have been incarcerated
- 13% completed secondary education



Participants comments about the nurse led model of care.

- No Dr, no hospitals, no waiting, amazing, overwhelming. Its the best
- No delays, easy ,great service
- Awesome chicks in a van, F.....king brilliant
- Treatments changed my life ,never could have done this one my own, the nurses in the van are great
- Real good and I get paid to come
- I would never have got treatment any other way its awesome
- The nurses care, Dr don't ,its great
- The nurse kept me on track with texts, calls kept on my case, they cared



Conclusion

- The TAP study is a novel design utilising nurses in the management and treatment of HCV
- A flexible nurse-led model of care is able to overcome some of the barriers associated with engaging PWID in care and treatment
- Since HCV transmission is driven by PWID in many settings, a nurse-led care is an important strategy in the drive to eliminate HCV

With the continuous enthusiasm of MH and her idea of a fun project, the support and medical expertise of JD and the tenacity of the outreach team that continuously express a sense of humour ,patience and persistence the nurse led model is feasible and eventually we are having FUN !!!



Acknowledgements

Gilead Science
Professor Margaret Hellard
Dr Joseph Doyle
Amy Kirwan

Nurses

Kate Allardice
Nigel Pratt

Outreach workers

Arthur Truong
Emma Woods
Daniel O'Keefe
DeArne Quelch
Peter Higgs
Michael Curtis



Burnet Institute



Burnet Institute