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

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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 sofobuvir/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
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 (IQR 1-2)
• 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. It's 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

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