Point-of-care HCV RNA testing with peer-led and nurse-based support to enhance HCV treatment among people with recent injecting drug use at a community-led needle and syringe program: the TEMPO pilot study

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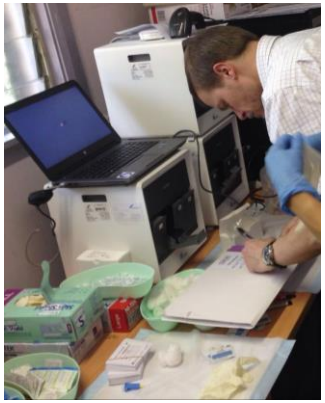
NUAA NSW USERS AND AIDS ASSOCIATION
AIVL
ashm Supporting the HIV, Viral Hepatitis and Sexual Health Workforce
ST VINCENT'S CENTRE FOR APPLIED MEDICAL RESEARCH

Background/rationale

- Simple, tolerable HCV DAA therapies with cure >95% is one of the greatest medical advances in decades
- Testing, diagnosis and linkage to care is a major barrier to HCV elimination
- Xpert® HCV Viral Load Fingerstick assay brings us one step closer to single-visit test and treat
- Needle and syringe programs offer one potential setting to expand access to testing and treatment

Finger-stick testing for HCV RNA detection

60 mins

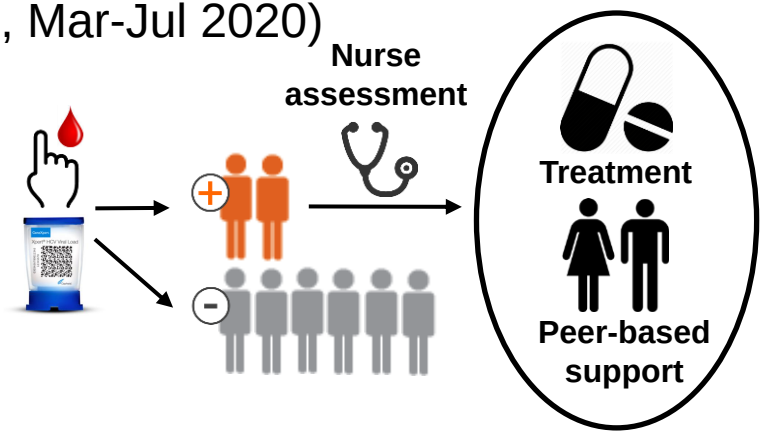


- Relatively easy-to-use point-of-care HCV RNA test – GeneXpert in many LMIC
- Real-world performance for HCV RNA quantification very good
  - Venepuncture HCV Viral Load – Sensitivity – 99%, Specificity 96%[1]
  - Modified finger-stick assay – Sensitivity – 98%, Specificity 99%[2]
  - Xpert® HCV Viral Load Fingerstick - Sensitivity – 100%, Specificity 100%[3]
- One step closer to a single-visit diagnosis

McHugh J Clin Micro 2017, Grebely Lancet Gastro Hep 2017, Lamoury Journal of Infectious Diseases 2018

Study Design

- Investigator initiated, Kirby/UNSW sponsored, single-center open label trial
- Recruitment at one needle and syringe program in Sydney (NUAA)
- Participants were recruited as people were accessing NSP services with the support of a dedicated peer-support worker
- Participants enrolled between September 2019 and April 2021 (recruitment halted during COVID-19, Mar-Jul 2020)



Single-visit

Study design and participant eligibility

- >18 years of age
- Recent injecting drug use (previous month)
- For HCV RNA positive participants commencing treatment:
    - Eligible to initiate therapy with the prescribed DAA treatment medication (sofosbuvir/velpatasvir or glecaprevir/pibrentasvir)
    - Suitable for NSP-based DAA treatment delivery (opinion of the Investigator)
    - Participants with Fibroscan score >12.5 Kpa were excluded

Procedures

1. Study Enrolment
Informed consent

2. Finger stick - dried blood spot and GeneXpert only

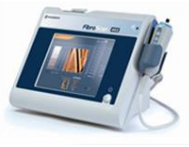
HCV antibody and RNA analysis

3. Pre-Assessment Survey

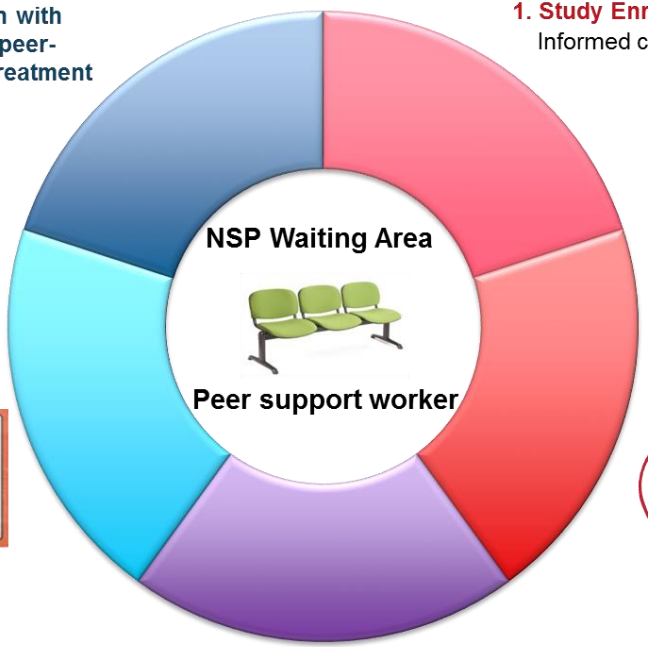
Self-Administered Survey

- Demographics
- Injecting history
- Treatment history
- NSP utilisation

4. Fibroscan



5. Physician Consultation with nurse via telephone and peer-based support through treatment



Model for initiation of DAA therapy

- Fibroscan-based liver disease assessment
- Point-of-care testing for HIV infection (Alere HIV Combo assay) and HBV infection (HBsAg – Alere Determine HBsAg assay)
- Arrangements with local pharmacy in place for DAA dispensing
- Phone call to physician at KRC to arrange a script
- Email the pharmacy for dispensing (hard copy delivered the next day)
- Medication co-payment covered through the study

Peer supported engagement/delivery of testing/treatment

- A dedicated peer-based support worker provided peer-led education and engagement
- This peer-worker facilitated health promotion and led engagement in testing as people were accessing the NSP service
- Provided a bridge between participants and clinical staff at the service
- Provided expertise and support for the completion of research survey
- Provided ongoing support for participants who initiated treatment through weekly communication and follow-up (most often via telephone)

Study endpoints and statistical analysis

- Primary endpoint
  - HCV treatment uptake among people who were HCV RNA positive

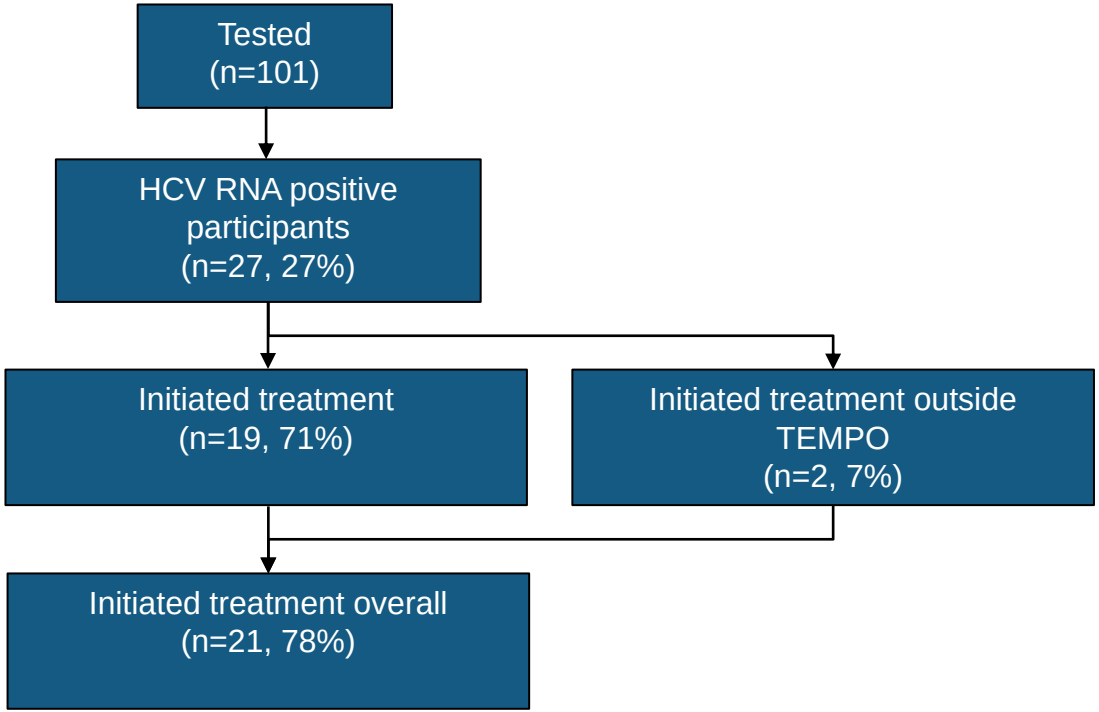
- HCV RNA levels measured using the Xpert HCV Viral Load Finger-Stick Assay (Cepheid; lower limit of detection 40 IU/mL, lower limit of quantification of 100 IU/mL)

- Participants completed a self-administered questionnaire to collect information on demographics, drug and alcohol use, and injecting risk behaviours

Participant characteristics

Characteristic	Enrolled N = 101
Female, n (%)	31 (31%)
Age, median years	44
Any injecting drug use (last 30 days), n (%)	101 (100%)
Heroin	56 (56%)
Methamphetamines	80 (80%)
Other opioids	11 (11%)
Cocaine	13 (13%)
≥Daily injecting drug use (last 30 days), n (%)	18 (18%)
Current opioid substitution therapy, n (%)	27 (27%)
Methadone	18 (67%)
Buprenorphine ± naloxone	9 (33%)

Participant disposition



Results – Participants who initiated treatment

- Among the 19 participants who initiated treatment through TEMPO
  - Mean age 44 years
  - 58% male
  - 100% with recent injecting

- Sofosbuvir/velpatasvir, n=7; glecaprevir/pibrentasvir, n=12

- Treatment initiation
  - Same-visit (53%, n=10)
  - Next-day (37%, n=7)
  - >Next-day (11%, n=2)

- Median time to treatment initiation = 1 day (range, 0-3)

Results – Reasons for not initiating treatment

- Eight participants did not initiate treatment
  - Loss to follow-up (n=2)
  - No Medicare for reimbursement (n=2)
  - Previous DAA treatment
  - Inability to obtain accurate medical history
  - Not suitable for treatment (mental health concerns)
  - Inability to perform liver disease assessment

Conclusions

- Overall, a high uptake of treatment (78%) was observed following an intervention including fingerstick point-of-care HCV RNA testing, offer of same-visit treatment, and peer-led and nurse-based support

- The majority of participants (53%) initiated treatment on the same day

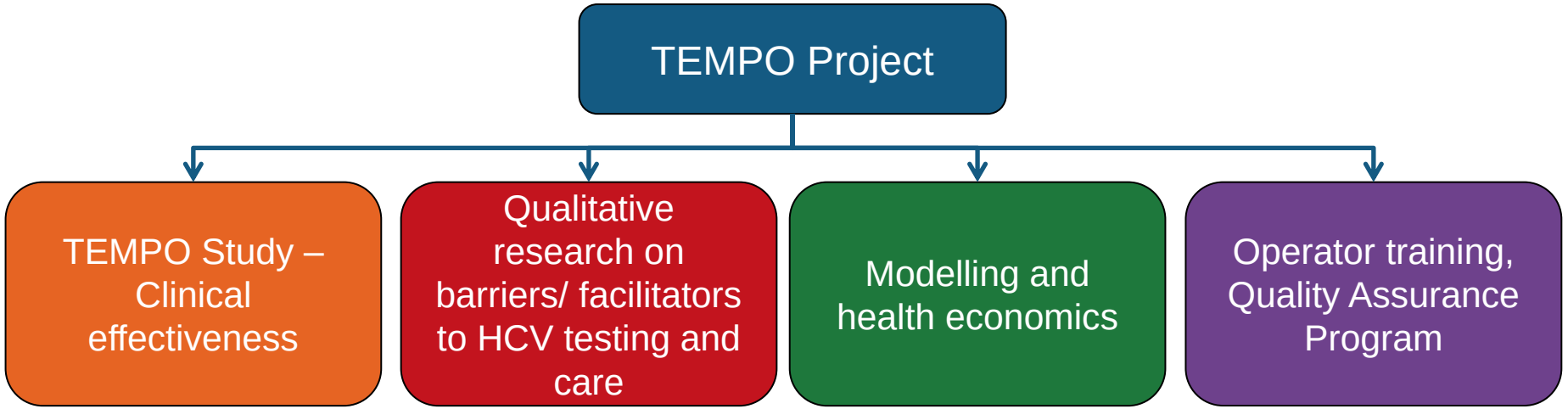
- Peer-based support provided a critical component to lower barriers and simplify pathways for testing and treatment
  - Endorsement and engagement from a peer facilitated improved trust and reduced stigma and discrimination
  - Peer-based model was embedded within a clinic-based model of testing/treatment

- Next steps will include an evaluation of the response to therapy in TEMPO Pilot and the implementation of a randomized controlled trial

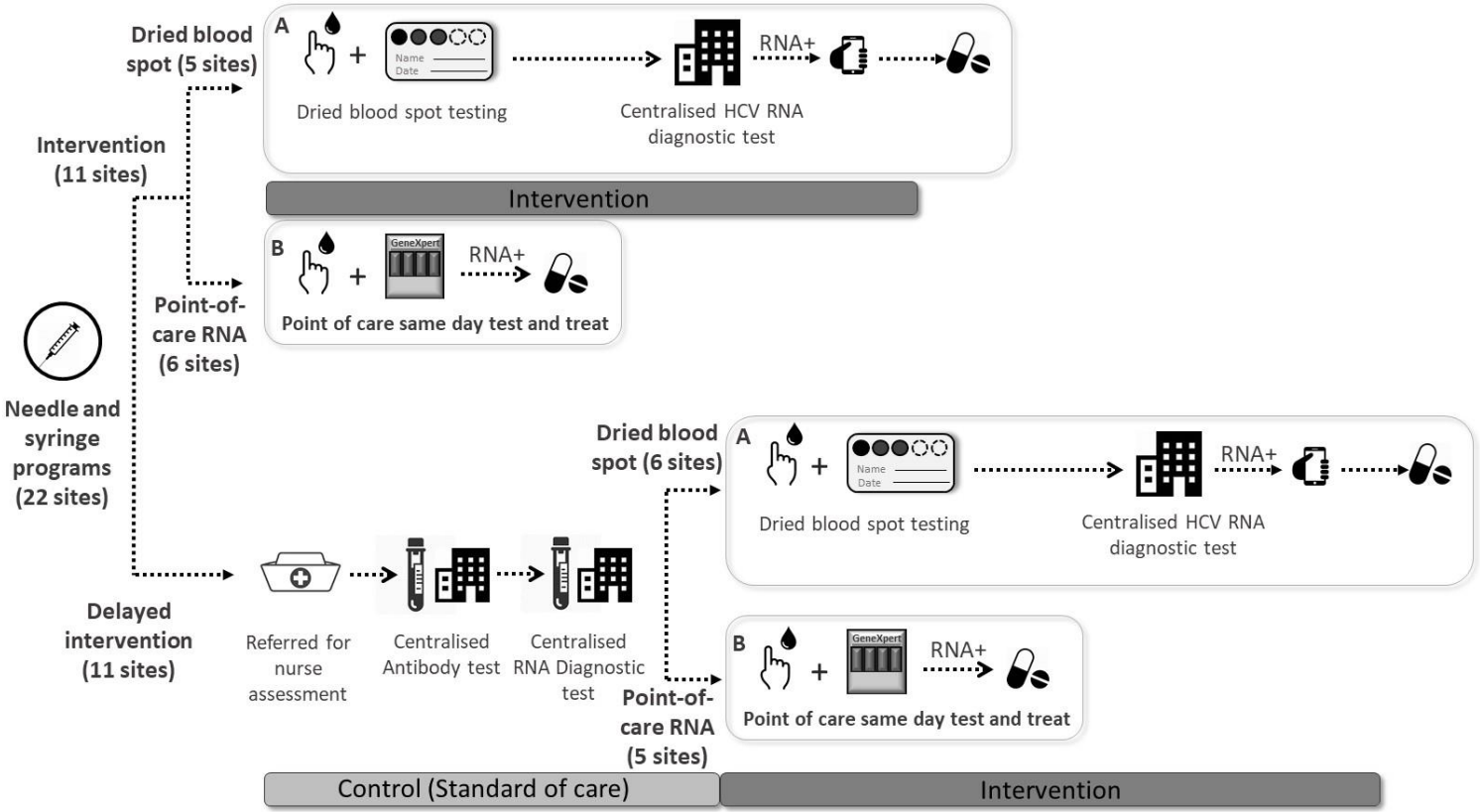
TEMPO NHMRC Partnership Project

Overall goals:

- To enhance HCV testing in primary needle-syringe programs
- To develop a translational framework for subsequent scale-up of HCV dried-blood-spot and point-of-care HCV RNA testing



TEMPO Study Design



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