Rationale

- Treatment in PWID in various AOD settings are encouraging, *however* these represent only a selected group already engaged with health care services.
- Up to 75% of people admitted to hospital with an injecting related infectious disease (IRID) eg cellulitis, endocarditis, osteomyelitis, are HCV positive. Many of these IRID require inpatient management with prolonged IV therapy (2-6 weeks).
- The period of hospitalisation for IRID, particularly when prolonged, may represent an ideal opportunity to engage HCV-infected PWID. Current models of care in which DAA therapy is delayed to be dealt with as an outpatient after discharge are failing.

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TOPIC study design

An ***inpatient HCV initiation*** study for PWID admitted with IRID facilitated by two strategic interventions:

- Point-of-care RNA testing on site
- Short course DAA regimens

Treatment strategy of two sequential treatment cohorts:
Cohort A: Dual regimen: G/P for 8 weeks (standard therapy), n=30
Cohort B: Triple regimen: SOF/G/P for 4 weeks (short therapy), n=30

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Hypotheses

Will enhance:

1. Acceptability/feasability/follow-up

2. Efficacy

3. Time to treatment intitaion

4. Engagement

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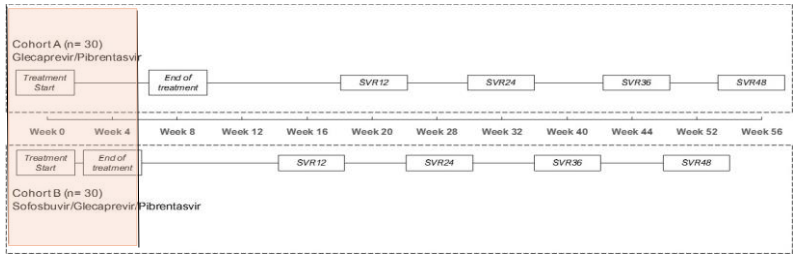
Study design

A Phase IV open-label single-arm multicenter pilot study consisting of two sequential cohorts: Cohort A (8 weeks G/P) and Cohort B (4 weeks of SOF/G/P).

Admission | Discharge



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Eligibility

Specific Inclusion criteria

- Injected drugs within the last 6 months
- Hospitalized with an IRI with an anticipated inpatient stay of > 1 weeks [1]
- Documented non-cirrhotic at enrolment with a qualifying liver FibroScan ≤ 9.5 kpA or an APRI <1.5

Specific Exclusion criteria

- Inability or unwillingness to provide informed consent or abide by requirements of study
- Actively intoxicated.

1 Patients without an IRI but who fulfil all other criteria and are admitted with an expected duration of stay > 1 week may also be included at discretion of study team

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Endpoints

Primary endpoint

- Confirmed SVR12

Secondary endpoints

- DAA adherence and completion
- Viral Hepatitis outpatient attendance post discharge
- Attending at SVR12 assessment
- Discharge against medical advice
- Frequency and type of IDU (inpatient stay and SVR12)
- Changes in quality of life (EQ-5D-5L)
- Engagement with D&A services post discharge
- Reinfection rates and recall over 12 months of follow-up
- Attitudes and barriers towards health service engagement in PWID

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Study sites

Adelaide
RAH (Shaw)

Sydney based sites:
St Vincent's (Matthews/Dore)
Blacktown (Martinello)
Liverpool (Malley)
POW (Post)

Melbourne
St Vincent's (Thompson)
Alfred (Doyle)

<u>Funding</u>
Triple III/Sphere: gain pilot data
Potential to move to NHMRC submission 2010

<u>Challenges and opportunities</u>
Pharmacy engagement?
Community?
Use of peer workers?

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