HCV Treatment as Prevention in the Prison Setting: The SToP-C Project

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Background

- Hepatitis C virus (HCV) infection is common among prisoners due to high rates of incarceration of people who inject drugs (PWID) and ongoing risk behaviours during incarceration.
- Among inmates who report injecting drug use, 70% are incarcerated for drug-related crimes. Overall HCV prevalence is 30% and more than 50% in inmates who inject drugs.
- A combination of harm reduction strategies such as needle syringe programs (NSPs) and opioid substitution treatment (OST) is needed to prevent HCV transmission in the community. Currently, NSPs are not available in Australian prisons and access to OST is limited.
- Antiretroviral therapy has been used as a "Treatment as Prevention" strategy for HIV.
- Similarly, highly effective, simple and tolerable interferon-free direct acting antiviral (DAA) regimens may offer an additional strategy to prevent HCV transmission.
- Multiple barriers to HCV testing, assessment and treatment exist in prisons.
- In NSW, an established nurse-led model of care and a decade of HCV incidence monitoring through the HITS study provide the foundation for a HCV treatment as prevention evaluation in prisons.

Objectives

The Surveillance and Treatment of Prisoners with Hepatitis C (SToP-C) partnership project aims to evaluate Treatment as Prevention (TasP) for hepatitis C in the prison setting.

The objectives are:

- To evaluate the impact of a rapid scale-up of DAA treatment for HCV on the incidence and prevalence of HCV infection in the prison setting.
- To evaluate patient and provider attitudes and barriers towards DAA therapy for HCV TasP in the prison setting.
- To mathematically model the epidemiological impact, cost-effectiveness and budget impact of scaled-up DAA treatment in NSW prisons and in the community.
- To develop a translational framework and toolkit for subsequent establishment of TasP programs in the prison sector across NSW and nationally.

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Methods

A project partnership led by the University of New South Wales will conduct the project. Partners include: Justice Health & Forensic Mental Health Network, Corrective Services NSW, NSW Health, Hepatitis NSW , NSW Users and AIDS Association and Gilead Sciences Inc.

The project is planned over two phases *(Figure 1):*

Phase I will be conducted at two maximum security correctional centres and is funded by Gilead Sciences Inc. It is intended to provide 'proof-of-principle' evidence for TasP (*Figure 2).*

In **Phase II** the project will be expanded to a more transient population in medium-security prisons. An application has been submitted under the NHMRC Partnership Project Scheme.

Treatment regimen will be an all oral sofosbuvir-based regimen with activity against all HCV genotypes (probable 12 week duration, depending on phase III trial evaluation data available early 2015).

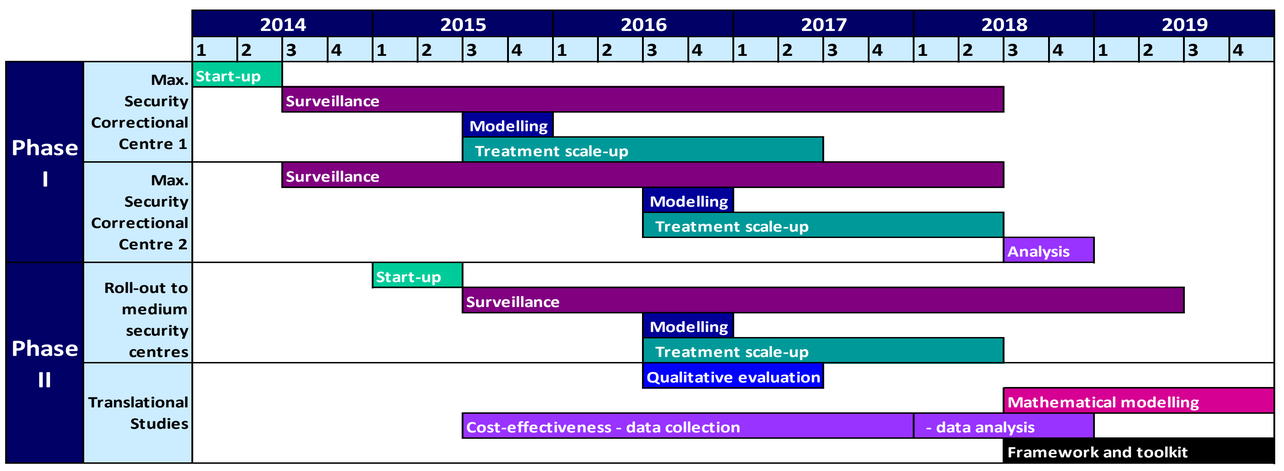

Figure 1 – Phase I and Phase II timeline. Each phase includes Surveillance, Modelling and Treatment Scale-up Stages. Data collected during the Surveillance Stage will be used to model the number of patients which need to be treated to demonstrate significant reduction in HCV incidence in each phase. This includes HCV incidence and prevalence data, and movements from each prison. Phase II translational studies include: qualitative research to identify barriers to treatment at the patient, provider and systems level; mathematical modelling of epidemiological impact, cost-effectiveness and budget impact of scale-up; and development of a toolkit for roll-out including guidance on implementation planning, stakeholder consultation, mobilising policy makers, and monitoring and evaluation systems.

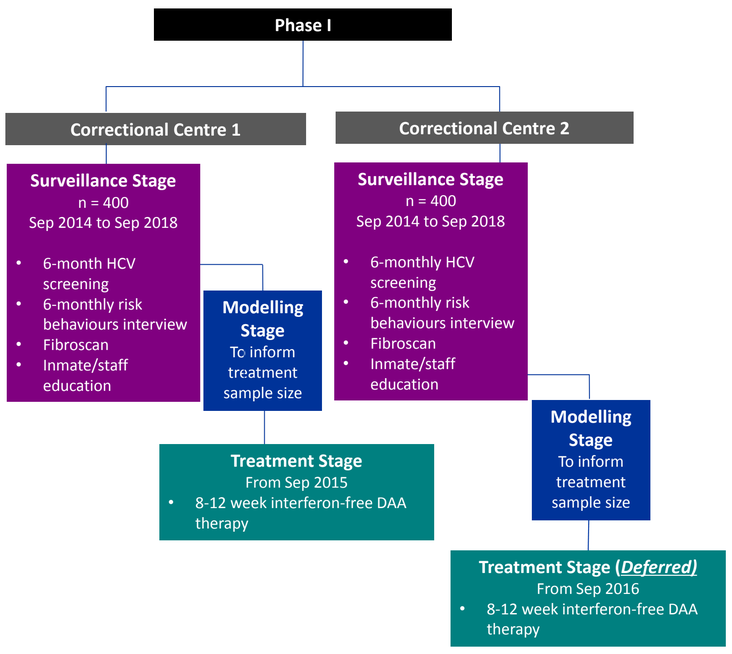

Figure 2. Phase I Study Schema. Surveillance stage data will provide baseline incidence and prevalence data and inform Treatment Stage sample size. Treatment scale-up at Correctional Centre 2 will be delayed by 12 months to evaluate the impact of the intervention at the "active" prison (Correctional Centre 1).

Results

- Phase I Surveillance will commence patient recruitment in September 2014 (*Figure 1 and Figure 2)*.
- A Protocol Steering Committee has been established as the overarching governing body and includes representatives from all partners and key stakeholders (*Figure 3)*.
- The 2nd Annual SToP-C Stakeholder Workshop will be held in December 2014.
- Educational resources for inmates, health and custodial staff are in development.

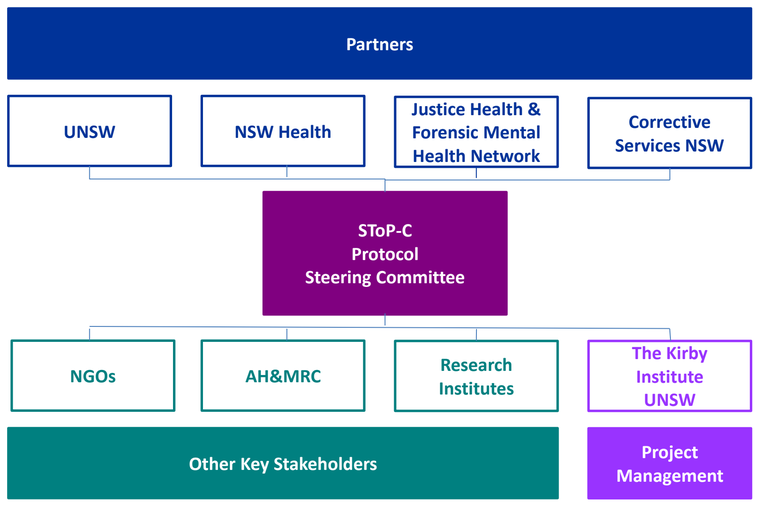

Figure 3. A partnership has been established to oversee the project. The Protocol Steering Committee is the central governing body and will guide the project over its lifetime. Sub-Committees will be formed to advise on various aspects as appropriate.

Conclusion

- SToP-C is the first study internationally to evaluate TasP for HCV in the prison setting.
- Evaluation will include translational components to inform subsequent public health policy for HCV treatment in NSW prisons and provide the framework for implementation across the prison sector nationally.

Challenges include:

- project delivery and evaluation within the NSW prison system's complex organisational structure and stakeholder landscape;
- high levels of transfer (release, and within prisons) of prisoners, particularly within medium security prisons;
- ensuring TasP is considered alongside other harm reduction strategies as a multi-pronged approach;
- the potential impact of vastly improved HCV treatment on risk behaviour and HCV reinfection rates (monitored throughout the project).

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