

SToP-C clinical trial to help eliminate hep C in NSW prisons

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JH&FMHN is part of an innovative world-first project aiming to eliminate hepatitis C virus (HCV) infection in NSW correctional centres. The Surveillance and Treatment of Prisoners with Hepatitis C (SToP-C) study is a NHMRC Partnership Project developed by University of New South Wales (UNSW) researchers in collaboration with JH&FMHN, Corrective Services NSW, NSW Health, the pharmaceutical company Gilead Sciences, and hep C community organisations.

The burden of hep C in prison is substantial. *“Approximately 28% of men and 45% of women in custody in NSW have been exposed to HCV. The SToP-C trial presents an excellent opportunity to provide our patients with access to new treatment that has the potential to greatly improve their health and wellbeing”*, says JH&FMHN CE Julie Babineau.

The annual HCV transmission rate in the prison system among people with a history of inject drug use is 10-20%, despite existing prevention strategies. JH&FMHN provides a targeted screening program and opioid substitution therapy, whilst Corrective Services provides Fincol to clean used syringes. However, there is evidence that even a combination of such interventions has only modest effect on reducing transmission.

The SToP-C study applies the principle of treatment-as-prevention, which has proven effective in HIV. By reducing the circulating virus in the population, both staff and other prisoners are protected from exposure and potential infection. This is now possible in hep C for two reasons: the development of simple, well-tolerated and high effective directly acting antiviral (DAA) therapy; and JH&FMHN’s existing infrastructure. NSW is uniquely placed to conduct the study because of its nurse-led model of HCV treatment and care, developed by study co-lead Professor Andrew Lloyd of UNSW.

The study has commenced enrolment of prisoners at Goulburn and Lithgow Correctional Centres, and will be expanded to several additional centres in late 2015. Participants complete 6-monthly HCV screening and risk-behaviour interviews. Patients with chronic HCV infection will then be offered DAA therapy, commencing in 2016. The treatment regimen is one pill once daily for 12 weeks, has minimal side effects, and a cure rate of over 90%. This has the potential to dramatically simplify HCV clinical management, reducing required resources and allowing many more patients to be treated.

Reductions in HCV incidence and prevalence will be evaluated, and these data used to mathematically model the epidemiological impact and cost-effectiveness of scaled-up DAA treatment in NSW prisons and the community at large. Rates of re-infection and impact on risk behaviour will be monitored. Other components of the project include development of hep C educational resources and qualitative interviews

to evaluate patient and provider attitudes and barriers towards DAA therapy for hep C treatment-as-prevention in the prison setting. This will assist development of an implementation framework for scale-up of the intervention nationally.

The SToP-C project offers considerable opportunities to halt the transmission of HCV in prisons through delivery of simple, effective new therapies and significantly impact public health policy in this area. This model represents a potential strategy to reduce the burden of liver disease and improve the safety of the prison population and staff. Proposals for additional value-add research and activities by JH&FMHN are welcomed.

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