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New research supports the removal of drug use as a restriction to hepatitis C treatment

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New, highly curative hepatitis C therapy is both safe and effective as a treatment option for people who inject drugs receiving opioid substitution therapy according to the results of a world-first clinical trial led by Professor Gregory Dore at the Kirby Institute at UNSW Australia and published today in the *Annals of Internal Medicine*.

In Australia, more than 230,000 people are living with hepatitis C. People who inject drugs are the major population affected by the virus, however clinical trials for direct acting antiviral hepatitis C treatment have to date excluded people who were actively injecting drugs based on concerns around adherence to medication and risk of reinfection. People who are receiving regular opioid substitution therapy have also been excluded from clinical trials if they demonstrate ongoing illicit drug use.

In this world-first clinical trial, participants were drawn from a population currently on opioid substitution therapy, which included a majority of participants who had ongoing illicit drug use.

"The results of this trial show that illicit drug use prior to and during hepatitis C therapy had no impact on the effectiveness of the therapy, and that reinfection was low, at 4 per cent," said lead investigator, Professor Gregory Dore who is also a physician at St Vincent's Hospital in Sydney. "The results also show excellent treatment adherence. At greater than 95 per cent, this is comparable to results in hepatitis C populations that exclude people who use drugs."

In some countries, including the United States, people who have not ceased injecting drug use or people who are receiving opioid substitution therapy are ineligible or not considered suitable by general practitioners to receive new treatments.

Professor Dore believes that the results of this trial provide important data to support the removal of drug use as a restriction to access interferon-free hepatitis C treatment.

"In Australia, thanks to advocacy, research and government support we are realistically talking about ending hepatitis C by 2026," said Professor Dore. "The availability and accessibility of treatment has been vital to Australia being in this exciting position. I am optimistic that the results from this study will help to reduce stigma associated with drug use and hepatitis C infection and really open up access to hepatitis C treatment globally."

This clinical trial is called C-EDGE CO-STAR and was funded and conducted by MSD, the tradename of Merck & Co., Inc., Kenilworth, N.J., USA. Professor Gregory Dore was the lead investigator. Patients for the trial were recruited from a large international network of sites that included St Vincent's Hospital, Sydney.

"We welcome the findings of this trial conducted by Professor Dore and colleagues. It affirms what we at AIVL, as a peer based drug user organisation, have always known. That is, given equitable access to appropriate healthcare we are likely to see very positive outcomes in the community of people who use drugs. People who use drugs are just as invested in their well-being as the rest of the population. Assumptions based on misinformation and stereotypes about drug users often function to restrict access to treatment often with grave, life-threatening outcomes.

"In this era of new effective treatments for hepatitis C it is important that such assumptions are actively challenged and this trial does just that. People who use drugs have the same health and human rights as the rest of the community, we are no less deserving of high quality health care than anybody else. We hope that the findings of this trial will be used to challenge the remaining restrictions that exist around the world on access to hepatitis C treatment for people who use drugs including those not currently enrolled in opioid treatment programs." - Dr Angella Duvnjak, CEO, AIVL

"MSD is pleased to partner with scientific and community leaders in exploring the potential of chronic hepatitis C therapy in underserved and undertreated patient populations, including those who continue to use drugs of potential abuse.

"The findings of the C-EDGE CO-STAR clinical trial provide evidence to support the treatment of patients infected with chronic hepatitis C who are on opioid agonist therapy." -Dr. Heather Platt, Principal Scientist, infectious diseases, Merck Research Laboratories, a U.S.-based division of Merck & Co., Inc., Kenilworth, N.J., USA.

Provided by University of New South Wales