Protocol Synopsis

Title of Study	LiveRx: Eradicating Hepatitis C in Alberta – Test and Treat Intervention
Lead Investigators	Dr. Mark Swain
Study Sponsor	Alberta Innovates, Partnership for Research and Innovation in the Health System (PRIHS), Alberta Health Services, EPICORE
Background	Hepatitis C (HCV) is a virus that infects up to 1 in 100 Albertans leading to serious liver complications including cirrhosis and liver cancer. New, widely available treatments can cure over 95% of HCV-infected people using a well-tolerated eight-to-twelve-week regimen of once-daily medication. However, equitable access to HCV cure is not available to many Albertans, as current specialist referral-based HCV care in Alberta disproportionately fails priority populations, including those experiencing homelessness, people who inject drugs, incarcerated or previously incarcerated individuals, individuals identifying as Indigenous, or those living in rural areas. With an expanded scope of practice and the potential to act as the most accessible health care professional, Alberta pharmacists are well positioned to provide comprehensive HCV care to patients with chronic uncomplicated HCV infection. While novel, pharmacist-led HCV care has successfully reduced HCV burden in other jurisdictions, community-based HCV outreach by pharmacists is a new and largely untapped practice in Alberta.
Study Purpose	Design and implement a pharmacist led, collaborative, community-based, wrap-around shared care model for HCV, implementing novel interventions that support HCV case finding and retention in care to increase HCV cure rates for priority populations in Alberta.
Study Hypothesis	Through the collaboration of community based organizations and pharmacies, the LiveRx study will demonstrate that Pharmacists are well positioned to provide curative HCV treatment to Alberta priority populations.
Study Objectives	<u>Primary objective:</u> Evaluate the effect of a community pharmacy-based case finding and intervention program on cure rates in patients living with Hepatitis C, assessed using a negative HCV PCR 12 weeks, a sustained virologic response (SVR), after completing 8 to 12 weeks of DAA therapy <u>Secondary objectives:</u> 1. To understand patient-reported quality of life and satisfaction with pharmacist-led Hepatitis C care 2. To assess patient treatment adherence, treatment dose (duration, coverage), required intervention complexity, component activation, and workflow integration
Study Design	Multi-centre, mixed methods, before-after hybrid implementation study.
Study Setting	Up to 100 community pharmacies across Alberta
Study Population	Focus on priority populations including those experiencing homelessness, people who inject drugs, incarcerated or previously incarcerated individuals, individuals identifying as Indigenous, or those living in rural areas.

Study Duration	Participants eligible for treatment will complete 8 to 12 weeks of drug therapy and 12 weeks after completion will undergo laboratory investigation to assess HCV cure. Total study duration for participants will be 20-24 weeks based on treatment selected.
Sample Size	Enrolled in study: 879 participants Initiate treatment: 451 participants Complete treatment: 435 participants Cured: 413 participants
Inclusion Criteria	Participants are eligible for inclusion if they meet the following: 1. ≥18 years of age 2. Positive for chronic HCV infection
Exclusion Criteria	Participants will be excluded from the LiveRx study if any of the following are present: 1. HCV treatment experienced 2. Decompensated cirrhosis 3. Hepatitis B surface antigen positive 4. Human immunodeficiency virus (HIV) positive 5. Pregnant, planning to become pregnant, or breastfeeding 6. <18 years of age 7. Unwilling to participate/sign consent form 8. Unwilling or unable to participate in regular follow-ups
Screening	Potential participants with risk factors for HCV will be identified via case finding approaches at community pharmacies or through referral from community based organizations, local clinics, or peers.
Intervention	1. Education on harm reduction measures 2. Prescribing HCV curative therapy 3. Laboratory monitoring
Enrollment and Follow-up	Eligible and consenting participants will be enrolled at community pharmacies for the treatment of chronic HCV infection. All patients will be followed throughout their HCV treatment through collaborative efforts of the pharmacy and community based organizations to ensure adequate supports are in place for HCV cure. Final follow-up will occur through laboratory monitoring to assess HCV viral load via sustained virologic response (SVR) at 12 weeks post therapy completion.