Exploring hepatitis C virus testing and treatment engagement over time in Melbourne, Australia: a study protocol for a longitudinal cohort study (EC-Experience Cohort study)

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ABSTRACT

Introduction The advent of direct acting antiviral therapy for hepatitis C virus (HCV) means the elimination of HCV is possible but requires sustained effort to achieve. Between 2016 and 2019, 44% of those living with HCV were treated in Australia. However, treatment uptake has declined significantly. In Australia, people who inject drugs (PWID) are the population most at risk of HCV acquisition. Eliminating HCV in Australia will require nuanced understanding of the barriers to HCV treatment experienced by PWID and tailored interventions to address these barriers. The EC-Experience Cohort study aims to explore the barriers and enablers reported by PWID to engagement in HCV care.

Methods and analysis The EC-Experience Cohort study is a prospective cohort of PWID, established in Melbourne, Australia in 2018. Participants are assigned into three study groups: (1) those not currently engaged in HCV testing; (2) those diagnosed with HCV but not currently engaged in treatment and (3) those completed treatment. Participants complete a total of four interviews every 6 months across an 18-month study period. Predictors of experience of key outcome events along the HCV care cascade will be explored over time.

Ethics and dissemination Ethical approval for the EC-Experience Cohort study was obtained by the Alfred Hospital Ethics Committee in Melbourne, Australia (Project Number: HREC/16/Alfred/164). All eligible participants are assessed for capacity to consent and partake in a thorough informed consent process. Results from the EC-Experience Cohort study will be disseminated via national and international scientific and public health conferences and peer-reviewed journal publications. Data from the EC-Experience Cohort study will improve the current understanding of the barriers to HCV care for PWID and guide the tailoring of service provision for specific subgroups. Understanding the barriers and how to increase engagement in care of PWID is critical to achieve HCV elimination goals.

INTRODUCTION

Hepatitis C virus (HCV) infection causes significant morbidity and mortality globally.1 Approximately 120000 Australians were living with chronic HCV at the end of 2019 and, as is the case in much of the world, people who inject drugs (PWID) are the priority population for HCV prevention efforts.2 Australia is a signatory to global 2030 HCV elimination targets set by the WHO.3,4 Direct acting antivirals (DAAs) for HCV treatment are highly efficacious, with a short regimen, low toxicity and cure rates of over 95%, providing an opportunity to eliminate HCV as a global public health threat.5 However, to realise the potential of DAAs, it is essential to understand factors that contribute to or hinder DAA treatment uptake among PWID.
to better enable strategies to increase HCV testing and treatment.

In 2016, DAAs were included in Australia’s list of approved subsidised medicines, the Pharmaceutical Benefits Scheme (PBS), significantly reducing the cost to consumers. Access is essentially universal with no restrictions on current injecting status, stage of liver disease, whether diagnosis is a primary infection or re-infection. Moreover, general practitioners and nurse practitioners (nurses qualified to prescribe medication) are permitted to prescribe treatment to patients without severe liver disease, thereby removing barriers associated with tertiary level care. By the end of 2019, an estimated 82 000 people had been treated with DAAs under these policies. However, treatment uptake has recently declined; 11 580 people were treated in 2019, compared with 32 650 in 2016. Mathematical modelling suggests that at least 4700 PWID need to be treated annually to achieve elimination targets. While Australia is only one of nine countries (from 45 analysed) currently on track to achieve the WHO targets, maintaining adequate treatment numbers will require a concerted effort at all levels of the health and community sector to ensure people with different health and social care needs are supported to access testing and are linked to treatment to achieve cure. Razavi et al identified commonalities among the nine countries on track to elimination: (1) sufficient political will, (2) a financed national elimination programme, (3) properly implemented harm reduction programmes, (4) expanding treatment beyond specialists, (5) removal of treatment restrictions, (6) monitoring and evaluation, (7) awareness and screening programmes, (8) linkage-to-care programmes.

From diagnosis to treatment access, maintenance and completion, multiple barriers are well documented along the HCV care cascade. Centralised testing and treatment within tertiary services, onerous and lengthy testing procedures, and copayments represent structural barriers to receiving HCV care. Lack of awareness of HCV status or available services, low perceived risk, or fear of HCV-related stigma and discrimination deter people from seeking HCV care, while time constraints and lack of specific HCV knowledge prevent providers from offering HCV care. Madden et al previously categorised reported barriers to HCV treatment as broadly based on personal, provider and system-level barriers. An individual may be disinclined to access HCV treatment due to being asymptomatic (personal barrier), while also unable to receive treatment from their usual doctor (provider barrier) and further worried about experiencing stigma from a new provider (system-level barrier). Recent declines in testing and treatment numbers indicate that existing care models may not be meeting the needs of all PWID, particularly compared with populations already treated. Along with disproportionate levels of unemployment, poverty, homelessness and criminalisation, PWID also experience compounded structural barriers to HCV care, including difficulties navigating health systems, and the experience of discrimination when accessing health services. Taken together, the multiple and complex barriers to HCV care experienced by PWID can impede the initiation of, and retention in, HCV care. Methods to address the above barriers and better enable access to HCV testing and treatment for PWID have been implemented, such as community-based primary care services that provide a targeted, lower threshold access point for healthcare, which have resulted in higher rates of treatment uptake and viral cure, both among the general and PWID populations. Still, many PWID living with HCV remain disengaged from HCV care. Understanding the multifaceted and complex barriers to HCV care experienced by PWID, and the subsequent methods to enable better access, are vital to achieving the WHO's elimination goals.

The EC (Eliminate HCV) Victoria Partnership is a programme led by the Burnet Institute to support community services to increase HCV testing and treatment uptake through nurse-led models of care. As part of the EC Victoria Partnership, the EC-Experience Cohort study was implemented across a subset of community service sites participating in the EC Victoria Partnership. The EC-Experience Cohort study is a prospective cohort of PWID or people who have a history of injecting drug use who are engaged in primary health services, that aims to explore trajectories of HCV care over time, with a focus on the associated barriers and enablers to HCV testing and treatment. Findings from the EC-Experience Cohort study will help guide the development of tailored services to meet the needs of former and current PWID to ultimately improve access, engagement and retention across the HCV care cascade.

The EC-Experience Cohort study has the following aims.

**Primary aims**
- To better understand patient utilisation and experience of HCV testing and treatment in primary care settings.
- To understand how health service utilisation influences engagement in HCV testing and treatment.
- To understand the impact of barriers and enablers to accessing HCV testing and treatment.

**Secondary aims**
- To assess level of knowledge of HCV infection, testing, and treatment among the cohort.
- To assess experiences of stigma and discrimination among the cohort.
- To assess level of health literacy among the cohort.
- To assess exposure to HCV health promotion resources.
- To assess patient reported experiences and outcomes of HCV care.
- To explore changes to individual health and wellbeing during and post HCV treatment.
METHODS AND ANALYSIS

Study setting
The EC-Experience Cohort study is being conducted in Melbourne, Australia. In Australia, annual HCV testing (HCV-antibody screening test followed by confirmatory RNA testing) is recommended for all PWID. Annual HCV testing is subsidised by Australia’s universal healthcare system, Medicare and in many settings, requires no patient copayment. People living with HCV who are over 18 years and hold a current Medicare Card are eligible for subsidised access to primary care and subacute specialist care according to the Medicare Benefits Schedule (MBS) and subsidised pharmaceuticals under the PBS.

Like other international settings, HCV treatment in Australia was traditionally prescribed by clinical specialists, being gastroenterologists, hepatologists or infectious disease physicians in tertiary settings. In 2016, the PBS expanded prescribing authority to include general practitioners, and later nurse practitioners (as of 2020), to increase patient access. General practitioners not experienced in providing HCV treatment can work in consultation with a specialist until they achieve competence and may then prescribe independently. Patients with complex presentations (liver cirrhosis, comorbidities or other types of liver disease), or those who have previously failed first line DAA treatment, will be referred to specialist care.

Following the expansion of treatment providers, between 2016 and 2018, 51% of national HCV treatment initiations were prescribed by non-specialists, such as general practitioners.

Study sites
The EC Victoria Partnership is implemented in collaboration with eight clinical sites with a high caseload of PWID: four private primary care and four community-based services. These sites offer services specifically targeting PWID, with colocated needle and syringe programmes, welfare support services and on-site opioid agonist therapy (OAT) prescription. While the EC-Experience Cohort study originally intended to recruit from all eight EC Victoria Partnership sites, ultimately recruitment was initiated at only four study sites (with a fifth site added later in the study). Original recruitment sites include three primary healthcare services targeting PWID, and one private primary care clinic with a high caseload of OAT clients. The four recruitment sites are all situated within metropolitan Melbourne and have at least one OAT prescribing general practitioner on site who also prescribes DAA treatment.

Sample size calculations
Cohort sample size calculation was determined to allow for the detection of key outcome events (ie, engagement in HCV testing and treatment over time). Further, calculations were performed to permit multivariable modelling that would test associations with engagement in HCV care adjusted for site as a random effect and inclusion of five other exposure variables. The following assumptions informed sample size calculation:

- A loss to follow-up rate of 40% over the study period based on experience from other Burnet Institute-led cohort studies recruiting PWID.
- That 66% of those currently unengaged in HCV testing would receive HCV antibody (exposure) testing during the follow-up period. This was based on data from the 2016/2017 Australian Needle and Syringe Programme Survey (ANSPS—a national, annual survey of NSP attendees which includes HCV testing), where 55% of participants reported being tested for HCV antibody within the year prior to interview. Support at EC Victoria Partnership sites aimed to increase HCV testing in our sample, leading us to increase our assumed percentage.
- That 33% of all participants would test HCV RNA positive, based on 2016/2017 ANSPS data.
- That 25% of people newly diagnosed with HCV would take up HCV treatment during the follow-up period, based on treatment data from ANSPS (36% treated in 2017, 22% in 2016).

Based on these assumptions, a sample size was calculated to allow for at least 10 cases and 10 non-cases per predictor in multiple regression analysis. To this end, the calculation estimated the inclusion of at least 300 participants classified as not recently tested and 360 participants classified as diagnosed with HCV but not yet treated. In addition, 10 participants who had completed DAA treatment would be recruited at each site for comparative purposes.

At study screening, participants are assigned to one of three baseline study groups prior to initiating the study interview based on their current engagement with HCV testing and treatment (study group assignment determines questions asked during the interview; see table 1):

- Those not currently engaged in HCV testing (never tested, tested but do not know the result, or not tested for at least 12 months prior to recruitment).
- Those diagnosed as HCV-positive but not currently engaged in HCV treatment.
- Those who have completed DAA treatment.

Site-specific recruitment quotas for each of the above groups included: 30 participants not currently engaged in HCV testing, defined as having never tested or have not tested in at least 12 months (Study Group 1), 30 participants diagnosed as HCV-positive but not currently engaged in HCV treatment (Study Group 2) and 10 participants recently completed DAA treatment (Study Group 3). Baseline study group assignment was hierarchical, so that an individual who had completed HCV treatment but had not been re-tested in 12 months was assigned to Study Group 3. However, over their respective study period, participants could change study group membership depending on progression through the HCV care cascade. This study methodology is described in more detail (Data collection section).
Eligibility and recruitment

Participant recruitment initiated in September 2018 at four participating services in Victoria, Australia. A fifth recruitment site was added in October 2020. Recruitment occurs at sites sequentially after the target of ~70 participants enrolled per site is reached. Participants are recruited using convenience sampling by service staff who initially identify interested clients meeting study eligibility criteria and conduct screening to determine HCV testing and treatment history (figure 1). These individuals are then referred to EC-Experience study researchers for more complete eligibility assessment.

Individuals eligible to participate in the EC-Experience Cohort study are:

► Aged ≥18 years.
► Report current or lifetime history of injecting drug use.
► Are actively engaged with the recruitment site (as verbally confirmed by participants) during the recruitment period; defined as accessing one or more of the following services over the previous 12 months: HCV care, OAT prescribing, general healthcare and/or sterile needle and syringe procurement.
► Have not been diagnosed as HCV-negative within the 12 months prior to interview.
► Are not currently receiving DAA treatment at the time of baseline recruitment.
► Are willing and able to provide informed consent to participate in the study.

Following screening of potential participants, EC-Experience researchers obtain written informed consent. Study methodology includes data linkage to external data sources (see the Data sources section), which participants can opt-out of.

To facilitate study follow-up, participants are asked to provide comprehensive contact information, including home address, phone numbers, email addresses, social media accounts and secondary contact information (eg,
family, friends and healthcare providers). All contact information is strictly confidential and stored separately from questionnaire data. Study data collection is tentatively scheduled to end December 2021, with the possibility of extension depending on ongoing follow-up rates.

**Data collection**

Following study enrolment and baseline interview, participants complete three follow-up interviews every 6 months over an approximate 18-month follow-up period (figure 2). Baseline questionnaires take approximately 45–60 min to complete and follow-up questionnaires approximately 20–30 min to complete. Participants are reimbursed $A40 for their time and associated expenses at baseline interview and $A20 at subsequent interviews.

**Impact of COVID-19 on recruitment and follow-up**

EC-Experience research activities have been impacted by COVID-19 pandemic response which includes multiple and protracted city-wide restrictions on movement and association in Melbourne. EC-Experience research activities were put on hold between March and August 2020. These study challenges meant that intended follow-up timelines were not maintained, and some participants did not complete first follow-up until approximately 12 months after their baseline interview. Initially, baseline interviews were conducted face-to-face and follow-up interviews were conducted via phone/internet calling service. Due to COVID-19 restrictions, all ongoing baseline and follow-up interviews were moved to phone/internet methods. COVID-19 restrictions also required change in study practice to allow for verbal consent to be obtained over the phone/internet calling service for newly recruited participants.

**Patient and public involvement**

Extensive consultation was performed with Harm Reduction Victoria, a peer-run advocacy organisation for PWID in Melbourne, Australia. Harm Reduction Victoria provided invaluable expert input regarding questionnaire design, such as identification of common barriers and enablers to HCV care among PWID.

**Data sources: interviewer administered questionnaires**

EC-Experience interviewer administered questionnaires are designed to capture data on participants’ experience and engagement with HCV testing and treatment over time. To better identify predictors beyond simple demographics and individual level factors, we purposely included additional variables and scales in the questionnaires that have not traditionally been used in HCV research but reflect broader social stability and support indicators that may help to identify new motivators or enablers to HCV care among PWID.
Figure 2 Participant prospective interview schedule.

group assignment. We note that if the time between interviews is protracted (ie, a participant is lost to follow-up for a period of time), participants may ‘skip’ certain study groups. For example, a participant who has not been HCV tested in over 12 months at baseline, may report having completed HCV treatment at first follow-up, if the events have occurred and sufficient time has elapsed between interviews. All interview data is collected using the online Research Electronic Data Capture platform.35

Baseline questionnaire
At baseline, all participants provide data on demographics, HCV transmission risk, HCV testing and treatment knowledge and history, current alcohol and other drug use, injecting risk behaviours, health service utilisation, experience of stigma and discrimination due to injecting drug use (IDU)/HCV-status, incarceration history, health literacy and awareness of health promotion resources (table 1). Participants in Study Groups 1 and 2 also complete questions on barriers, enablers and preferences for HCV testing and treatment. Participants in Study Group 3 complete questions on enablers to starting HCV treatment and subsequent Patient Reported Outcome Measures (PROMs),36 a validated survey instrument that measures the impact of a therapeutic intervention on a person’s physical health, mental well-being and quality of life regarding completion of DAA treatment.

Follow-up questionnaire
Follow-up questionnaires include: demographics, HCV testing/treatment knowledge, HCV transmission risk, HCV testing and treatment history, alcohol and other use, opioid treatment, incarceration history, experience of stigma and discrimination using a validated tool,37 health service utilisation, knowledge of peer experience with HCV care, the Health Literacy Questionnaire38 and the Brief Resilience Scale (BRS)39 (see table 1).

For participants classified as not engaged with HCV testing or treatment at follow-up (Study Groups 1 and 2), questionnaires include items on barriers to HCV testing (Study Group 1) and HCV treatment (Study Group 2). Hypothetical enablers to HCV testing (eg, provision of rapid HCV testing) and HCV treatment (eg, financial reimbursement for receiving HCV treatment) are also explored.

Participants who initiate DAA treatment during the study period complete the Patient Reported Experience Measure, a validated questionnaire that aims to understand patient experience of provided health services.36 Participants reporting treatment completion complete the PROMs instrument.

Australian Collaboration for Coordinated Enhanced Sentinel Surveillance of Blood Borne Viruses and Sexually Transmitted Infections surveillance system
All EC Experience Cohort study sites contribute data to the Australian Collaboration for Coordinated Enhanced Sentinel Surveillance of Blood Borne Viruses and Sexually Transmitted Infections (ACCESS). ACCESS automatically extracts de-identified HIV, HCV and STI test information from clinic patient management systems through the GRANITE data extraction software. ACCESS is capable of linking individuals within a single clinic and across
all clinics in the ACCESS network. Consent ing participants’ clinical attendance at their study site and HCV testing and treatment data will be extracted and linked to survey responses.

**MBS and PBS linkage**

MBS and/or PBS data linkage will assess health service use and medications prescribed. MBS and PBS data will be collected for a 4-year period from the date of enrolment and will include data on MBS-ordered HCV testing and PBS medications dispensed during this time.

**Analyses**

The study’s primary aims will be evaluated via the primary study outcome, being progression through the HCV care cascade, as indicated by the experience of key outcome events; (1) HCV testing uptake and (2) HCV treatment uptake/completion.

**Outcomes events**

- HCV testing uptake: defined as any observed HCV testing event during the follow-up period.
- HCV treatment uptake/completion: defined as any observed initiation onto HCV treatment or reported completion of HCV treatment during the follow-up period.

**Potential co-variates**

- Demographics: age, gender, employment and accommodation status.
- Health service utilisation: utilisation of different health service types (eg, community health service, hospital, pharmacy, etc) within the past 12 months (at baseline) and between interviews.
- Barriers/enablers to testing (eg, distance to HCV testing provider, reticence towards HCV testing).
- Barriers/enablers to treatment (eg, distance to HCV treatment provider, concern about HCV reinfection).
- Drug use: drug of choice, recent injecting drug use (past 6 months, past month).
- Incarceration history: historic (at baseline) and recent (between interview) experience of incarceration.
- Experience of stigma and discrimination: measured by a stigma indicator developed by Broady et al.
- Health literacy: measured by the Health Literacy Questionnaire.
- Resilience: measured by the BRS.

Outcome data will be obtained from questionnaires and MBS/PBS linkage. To answer the primary study aims we will conduct generalised linear modelling to determine covariates associated with progression through the HCV care cascade with adjustment for clustering at the individual level. To answer the secondary aims we will describe baseline survey findings and assess changes over time using linked follow-up survey data, stratified by status in the HCV care cascade and recruitment site type (private or community-based service).

**ETHICS AND DISSEMINATION**

**Ethical approval**

Ethical approval for the EC-Experience Cohort study was included within the broader EC-Victoria submission for ethical consideration and approved by the Alfred Hospital Ethics Committee (Project Number: HREC/16/Alfred/164). All eligible participants were assessed for capacity to consent. All participants have the purposes and methods of the study thoroughly explained to them, including their right to withdraw from the study at any time without consequence to access of services (including HCV treatment). All participants are asked if they have any questions regarding the study. The EC-Experience Cohort Study does not include an intervention arm.

**Dissemination of results**

Results from the EC-Experience cohort will be disseminated via national and international scientific and public health conferences, and peer-reviewed journal publications. Further, dissemination of results may occur at local community presentations. EC-Experience data may form the basis of student (honours, masters or PhD) study. In all instances, data will only be accessed by ethically approved individuals and presented as aggregated, anonymous statistics.

**Study summary**

Many countries, including Australia, have capitalised on the introduction and subsequent improvements of DAA treatment by vastly enhancing the accessibility of these life-saving drugs. However, substantial numbers of people either at risk of HCV infection, or those chronically infected, remain disengaged from HCV care. In their paper ‘The phases of hepatitis C elimination’, Pedrana et al (2021) recently described people considering HCV treatment as falling into one of four phases or categories: (1) willing and waiting, (2) motivated but needing support, (3) hesitant and needing social encouragement and (4) doubtful, uncertain and unaware. Reaching affected populations with different motivations, capabilities and/or awareness regarding HCV care, founded on varied reasonings and perspectives, requires novel strategies tailored to the broad needs and opportunities of individuals. Would-be patients need to be empowered by the information received and clinical pathways that are patient-centred. The EC-Experience Cohort study aims to improve the current understanding of the barriers and enablers to HCV care for PWID and guide the tailoring of innovative services, designed to address the specific needs of population subgroups. Such innovations will be necessary if HCV elimination goals are to be reached.

**Potential limitations**

The EC-Experience Cohort study is predicated on observing sufficient key events over the study period to allow identification of factors associated with change in HCV care engagement. Insufficient follow-up interviews (ie, participants lost to follow-up) will reduce statistical
power and effect planned analyses. Further, COVID-19 associated restrictions in Melbourne were particularly severe and comprehensive (including curfews and limited radius of movement from a person’s home). These restrictions meant many services had to drastically amend their methods of service provision, and for a 6-month period, the EC-Experience cohort was put on hold, potentially increasing loss to follow-up.

Study interviews are only conducted in English. Limited English-speaking ability may be an important barrier to accessing HCV care, which could not be captured by this study.

Participant recruitment occurs in community health services, targeting clients/patients of these services, including those who only used the NSP component of the service. Findings may not therefore be extrapolated to individuals disengaged from health services. Further, by virtue of their involvement in the EC-Experience Cohort and consequent discussion about HCV testing and treatment with study researchers, some participants may be more inclined to access HCV care than they may otherwise would if not recruited into the cohort.

Within the EC-Experience questionnaires, participants must select from a preconstructed set of barriers and enablers, determined via literature searching, service provider/service user consultation and researcher knowledge. We decided to use preconstructed lists to better prompt recall about the experience of barriers and enablers. Even so, there may be other barriers or enablers not captured in the list, and so we included a free-text ‘other’ response category within such questions.

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