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Initial outcomes of integrated community-based hepatitis C treatment for people who inject drugs: Findings from the Queensland Injectors' Health Network

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ABSTRACT

Background: Integrated treatment and harm reduction services provide a unique opportunity to facilitate direct-acting antiviral (DAA) therapy for hepatitis C virus (HCV)-infected people who inject drugs (PWID). We examine outcomes of community-based delivery of DAA therapy for PWID.
Methods: The Queensland Injectors' Health Network (QuIHN) is a community-based agency providing harm reduction and treatment services. Data (including current injecting, involvement in opioid substitution therapy and other treatment, level of case management support) for participants initiating DAA therapy were collected. The primary endpoint was sustained virological response at 12 weeks (SVR) after the end of therapy.
Results: By the end of February 2017, 127 treatment clients who consented for research had completed therapy and were due for post-treatment sustained virological response (SVR) testing. In an intent-to-treat analysis, 96% completed their course of prescribed treatment, 80% had confirmed SVR and 92% adhered to treatment. There were no confirmed cases of treatment non-response. The clients without confirmed SVR (20%) had not attended their post-treatment test. No client characteristics, including involvement in less-than-daily (odds ratio (OR) 0.27, 95% confidence interval (CI): 0.06–1.17) or daily injecting drug use (OR 0.65, 95% CI: 0.17–2.43) were associated with non-attendance at the SVR test.
Conclusion: PWID can be effectively treated for HCV and comply with DAA therapy in an integrated community-based service. However, strategies are required to support client retention until SVR is confirmed.

Introduction

Hepatitis C virus (HCV) infection is a global health concern, with approximately 71 million people infected with chronic hepatitis C and the full burden of HCV-related liver disease still to be realised (Blach et al., 2017; Razavi et al., 2014). This burden disproportionately affects people who inject drugs (PWID), with 50% having chronic HCV infection (Nelson et al., 2011). However, HCV treatment uptake rates among PWID have historically been low (1–2%) (Iversen & Maher, 2015).

Until recently, low treatment uptake was largely attributable to interferon-based treatment regimens, which were long-duration, of limited efficacy and caused severe side effects in many patients (Mehta et al., 2008). The introduction of highly efficacious and tolerable interferon-free all-oral direct-acting antiviral (DAA) therapies has removed many treatment-based barriers. Clinical trials of DAA treatment among people receiving opioid substitution therapy (OST) have reported sustained virological response (SVR) among 90%–97% of participants (Dore et al., 2016; Grebely, Dore et al., 2016; Grebely, Mauss et al., 2016; Lalezari et al., 2015). However, most of these trials excluded individuals with clinically significant drug use. Dore et al. (2016) found that drug use at

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baseline and during treatment did not affect SVR or treatment compliance (Dore et al., 2016). While these trials provide promising evidence for successfully treating PWID, there is currently a lack of evidence for treating PWID with DAAs in 'real-world' community settings.

This study examines treatment response among PWID presenting for HCV treatment through Queensland Injectors' Health Network (QuIHN), a community-based agency providing integrated services comprising harm reduction (including needle and syringe programs [NSPs]), drug and alcohol counselling, and medical care.

Methods

Study design and setting

This observational study evaluated HCV treatment among clients of QuIHN's Hepatitis C Treatment and Management Program (TMP). QuIHN is a not-for-profit alcohol and other drug (AOD) health service delivering clinical programs including the Better Access Medical Clinic (BAMC; primary health care service) and the TMP, and ancillary programs (NSPs, case management, outpatient therapeutic programs and counselling, and peer education). QuIHN's TMP operates in Brisbane, the Gold Coast, the Sunshine Coast, and Townsville (Queensland, Australia). All four sites are included in the study. The TMP uses a case manager support framework, employing Health Education Officers to perform case management. In Brisbane and the Gold Coast, the TMP is supported on-site by the BAMC teams, comprising medical practitioners, registered nurses and a nurse practitioner specialising in hepatology. At these sites, the NSP is collocated with the BAMC. In Townsville and the Sunshine Coast, case managers work closely with external hepatology specialists or general practitioners who have a shared care agreement with QuIHN. The TMP was piloted in 2014 with interferon treatments and has been out of pilot since July 2015. DAAs became widely available in Australia March 2016 and represents the start date of the study. However a small number of participants were able to access DAA treatment through compassionate access from the pharmaceutical companies and their data have been included. Data was extracted at the end of February 2017.

Individuals are eligible for the TMP if they are any of the following: (1) a current injecting drug user (injected last 12 months); (2) receiving OST; (3) receiving drug counselling; (4) a community rehabilitation client. Participants complete an initial screen with a case manager and are allocated a support level (1 = minimal, 2 = moderate or 3 = intensive) based on housing situation, social supports, financial or legal issues, alcohol and drug use, and mental health. Level 1 support consists of the case manager providing assistance to access the treatment clinic (if necessary), a phone call in the first week of treatment, and further reminder phone calls for the four-week blood test, to collect the next treatment script, for the end of treatment blood test and for the 12-week post-treatment SVR blood test. Level 2 support builds on Level 1 support and also provides the participant with weekly phone calls or face-to-face contact, monthly reviews of the case management plan, and referral support where required. In addition to the support provided in Level 2, Level 3 support provides crisis or intensive intervention through referral and face-to-face support as often as required. Clinically complex presentations are referred to a specialist for treatment and monitoring. These cases are identified by cirrhotic liver, advanced liver disease (evidence of cirrhosis or decompensation in combination with biochemical markers [Fibrosis-4 calculations and Aspartate aminotransferase to Platelet Ratio Index calculations]), and co-morbid health factors (Human Immunodeficiency Virus co-infection, Hepatitis B co-infection, complex drug-to-drug interactions).

Ethical approval was provided by Bellberry Human Research Ethics Committee (approval number: 2016-05-363), for the University of Queensland. Clients provided informed consent to allow their data to be used for research.

Participants

Participants were included if they were prescribed DAAs and commenced treatment early enough to be eligible for 12-week post-treatment SVR testing within the study period (i.e. began 8-, 12-, or 24-week DAA treatment on or before September 29th, September 2nd, or June 8th, 2016 respectively).

Measures

The TMP initial screen collected information on participants' age, gender, Aboriginal and Torres Strait Islander (ATSI) status, referral source, previous HCV treatment, current injecting (no injecting, less-than-daily, or daily injecting), and engagement in OST or other outpatient drug treatment (counselling or rehabilitation).

Data were collected regarding participants' HCV genotype (genotype 1, 2 or 3), length of prescribed therapy (8-, 12-, or 24-week), treatment regimen prescribed, attendance at and results of end of treatment and 12-week post-treatment SVR blood tests (SVR12). The treatment regimens prescribed included ledipasvir and sofosbuvir, sofosbuvir and daclatasvir with and without ribavirin, and ombitasvir, paritaprevir, and ritonavir with and without ribavirin.

Study outcomes

The outcome variables were treatment completion, treatment response and treatment adherence. The primary endpoint was sustained virologic response (SVR), or undetectable HCV RNA at twelve weeks post-treatment. The secondary endpoint was end of treatment response (ETR), or undetectable HCV RNA at end of treatment. In a small number of cases (n = 9), difficult to reach participants were opportunistically SVR tested when they presented at QuIHN before the 12-week post-treatment date. Tests at least 8 weeks post-treatment were included as SVR. Case managers recorded treatment adherence based on participant self-report, with adherence defined as taking at least 90% of doses ($\geq$90% adherence).

Data analysis

Intent-to-treat (ITT) analysis was used to evaluate treatment response, including the proportion of TMP participants who completed and adhered to treatment, and the proportion with an ETR and SVR. A modified ITT (mITT) SVR proportion was also calculated, excluding participants with an ETR who had not attended SVR testing. Age, gender, ATSI status, injecting frequency, OST engagement, other drug treatment, level of case manager support, on-site (QuIHN's BAMC) or off-site (external provider) treatment, and treatment regimen prescribed were included as predictors of a lack of confirmed SVR. Treatment adherence was not included due to the small proportion who were non-adherent.

Penalised maximum likelihood logistic regression was used for unadjusted analyses and for the full model adjusted for all variables. Seven cases were removed due to missing data. All analyses were performed using Stata version 14.0 (StataCorp., 2015), with statistical significance assessed at $p < 0.05$.