Outcomes of Treatment for Hepatitis C in Primary Care, Compared to Hospital-based Care: A Randomized, Controlled Trial in People Who Inject Drugs

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Background. To achieve the World Health Organization hepatitis C virus (HCV) elimination targets, it is essential to increase access to direct-acting antivirals (DAAs), especially among people who inject drugs (PWID). We aimed to determine the effectiveness of providing DAAs in primary care, compared with hospital-based specialist care.

Methods. We randomized PWID with HCV attending primary care sites in Australia or New Zealand to receive DAAs at their primary care site or local hospital (standard of care [SOC]). The primary outcome was to determine whether people treated in primary care had a noninferior rate of sustained virologic response at Week 12 (SVR12), compared to historical controls (consistent with DAA trials at the time of the study design); secondary outcomes included comparisons of treatment initiation, SVR12 rates, and the care cascade by study arm.

Results. We recruited 140 participants and randomized 136: 70 to the primary care arm and 66 to the SOC arm. The SVR12 rate (100%, 95% confidence interval [CI] 87.7–100) of people treated in primary care was noninferior when compared to historical controls (85% assumed). An intention-to-treat analysis revealed that the proportion of participants commencing treatment in the primary care arm (75%, 43/57) was significantly higher than in the SOC arm (34%, 18/53; P = .002; relative risk [RR] 2.19, 95% CI 1.54–3.95), and the proportion of participants with SVR12 was significantly higher in the primary care arm, compared to in the SOC arm (49% [28/57] and 30% [16/53], respectively; P = .043; RR 1.63, 95% CI 1.0–2.65).

Conclusions. Providing HCV treatment in primary care increases treatment uptake and cure rates. Approaches that increase treatment uptake among PWID will accelerate elimination strategies.

Clinical Trials Registration. NCT02555475.

Keywords. hepatitis C; primary care; people who inject drugs; randomized controlled trial; cascade of care.

Globally, approximately 71 million people have hepatitis C virus (HCV); each year, an estimated 400 000 people die from HCV-related liver disease [1]. In high-income countries, the epidemic is driven by transmission associated with injecting drug use [2, 3]. Until recently, in Australia, New Zealand, and most other countries, HCV treatment was pegylated-interferon (PEG)-based, had poor efficacy and significant morbidity, and could only be accessed from specialist physicians, usually located in hospital clinics. Overall, treatment rates were low, with high resultant morbidity and mortality from the HCV [4].

The introduction of safe, effective direct-acting antivirals (DAAs) for HCV has revolutionized the treatment landscape [5, 6]. In 2016, the World Health Organization set HCV elimination targets for 2030 at 80% reduction in new cases and 65% reduction in mortality [1]. For this to be achieved, it is essential that there is increased access and uptake of DAAs. This is highlighted in the first Global Hepatitis Health Sector Strategy [7].

Worldwide, the availability of DAAs is variable due to their cost and patient- and provider-based restrictions [8, 9]. The availability of DAAs in primary care is poor, limiting access to treatment [8, 10, 11]. Moreover, people with HCV commonly report experiencing stigma and discrimination in healthcare settings, which creates an additional barrier to treatment [12].

The primary outcome of the Prime Study was to determine whether people with HCV and a history of injecting drug use who were treated in primary care had a noninferior rate of sustained virologic response at Week 12 (SVR12) when compared to historical controls; secondary outcomes were to compare...
DAA initiation, SVR12 rate, and the care cascade in primary care against hospital-based specialist care. The care cascade describes the proportion of people with HCV who have completed the following: diagnosis, assessment, treatment initiation, and cure. Our hypothesis was that the provision of DAAs in primary care would increase treatment uptake, cure rates, and retention in the care cascade.

Our study was undertaken from 2015 to 2018, during a period of unprecedented change in HCV treatment policy in Australia and New Zealand. In 2015, DAAs were not available outside of clinical trials. In 2016, any medical practitioner could prescribe government-subsidized DAAs. The implications of these policy changes on our study are discussed throughout, as well as in our protocol paper, Wade et al [13].

**METHODS**

The Prime Study was a randomized, controlled study that compared DAA uptake and treatment outcomes in primary care against hospital-based specialist care in people who inject drugs (PWID).

**Study Sites**

The study was performed at 13 primary care sites in Australia (Melbourne and Geelong) and New Zealand (Christchurch and Auckland) between November 2015 and June 2018 (recruitment ceased in December 2017). Hospitals employed community hepatitis nurses to provide HCV education, assessments, linkage to treatment, and support whilst patients were in treatment at the primary care clinics. All primary care study sites were staffed by general practitioners who provided opioid substitution therapy (OST). In Australia and New Zealand, OST is not provided from hospital-based HCV services: people requiring OST continue to attend their OST provider in primary care. An infectious diseases physician conducted a viral hepatitis clinic every 2 weeks at 2 of the primary care study sites in Melbourne.

**Patients**

Patients eligible for enrollment were adults with HCV and no known cirrhosis who were treatment-naive or PEG/ribavirin-experienced and attending a primary care study site. Recruitment initially included only people with Genotype 1 at Australian sites. However, as the Prime Study treatment for Genotype 1a included ribavirin, when ribavirin-free, government-subsidized DAAs became available in 2016, in order to facilitate recruitment the study was amended to include people with Genotype 3. The study also expanded to include people with Genotype 1 in New Zealand, where government-funded DAAs for Genotype 1a included ribavirin. Normal laboratory indices (other than aminotransferase levels) were required. People with a human immunodeficiency virus (HIV) or hepatitis B coinfection were ineligible.

**Study Design and Conduct**

The Prime Study was an open label, nonblinded, noninferiority, randomized, controlled effectiveness and implementation study of noncirrhotic PWID with HCV. The assessment of liver fibrosis is a key part of the care cascade, and the treatment of people with cirrhosis in primary care is not currently recommended in Australasia [14]. As we were investigating the care cascade, we randomized participants before they had had an assessment of liver fibrosis. Therefore, liver fibrosis was managed as follows:

1. People known to have cirrhosis were not eligible for study enrollment; and
2. Participants with newly identified cirrhosis were not eligible for study treatment, and were referred for hospital-based specialist management.

The first study visit was at the primary care clinic and included consent, a questionnaire, and clinical screening. Participants were issued a pathology request for HCV viral load and genotype, HIV and hepatitis B serology, full blood count, liver function tests, renal function, and, if female, a pregnancy test. At all sites bar 1, participants were randomized at the end of the first study visit to receive transient elastography, an eligibility assessment, and treatment at either their primary care clinic (primary care arm) or at their local hospital specialist clinic (standard of care [SOC] arm). In Christchurch, transient elastography was available as a routine service in the primary care clinic and was performed as part of the first study visit.

We randomized participants using a block randomization approach. Randomization occurred at the primary care level. Random sequences of permuted blocks were generated, with each block allocating 6 participants in a balanced fashion across study arms. Randomization was programmed using Stata version 13.0 and provided to the community hepatitis nurses in sealed envelopes (Australia) or via the REDCap database (New Zealand).

Participants were eligible for study treatment if their liver stiffness was less than 12.5 kPa and they fulfilled the eligibility criteria as outlined above (the liver stiffness threshold was adjusted from less than 9.5 kPa to 12.5 kPa to align with newly published Australian consensus guidelines [14]). Eligible participants were offered DAAs at the site to which they were randomized and were reviewed according to national guidelines in their country [13]. There were no relevant differences in national guidelines. Participants could exit the study at any time, meaning they declined to have further appointments scheduled, were withdrawn from the study by their medical practitioner on clinical grounds, or were lost to follow-up (LTFU) by failing to attend appointments during the study period.
This study received ethics approval from the St Vincent’s Hospital (Melbourne) Human Research Ethics Committee (HREC-D 080/15).

Study Medications
Participants with Genotype 1 were treated with coformulated paritaprevir at 75 mg, ritonavir at 50 mg, and ombitasvir at 12.5 mg in 2 tablets daily and with dasabuvir at 250 mg in 1 tablet twice daily. For Genotype 1a, weight-based ribavirin was added: participants ≤75 kg received 1000 mg daily in 2 divided doses and participants ≥75 kg received 1200 mg daily in 2 divided doses. Participants with Genotype 3 were treated with sofosbuvir at 400 mg in 1 tablet daily and with daclatasvir at 60 mg in 1 tablet daily. The treatment duration was 12 weeks for all regimens. Government-funded DAA therapy became available on 1 March 2016 in Australia and 1 October 2016 in New Zealand.

Study Outcomes

Primary Outcome
In order to calculate the sample size, in keeping with DAA trials at the time of the study design, the SVR12 rate in our intervention arm (primary care) was compared with an historical control rate of 85% (based on SVR12 among patients with Genotype 1 who were treated with PEG, ribavirin, and simprevir) [6, 15, 16]. A required sample size of 380 participants was estimated, based on the assumption that 50% of people offered treatment in primary care and 30% of people offered treatment in the SOC would commence DAA. It was attributed most of this difference to LTFUs after referrals from primary care to the hospital. We anticipated that 90% of people that started treatment would be cured. The sample size was estimated to give a minimum of 90% power to show noninferiority in those receiving DAA in primary care using a historical SVR12 response comparator of 85% with a 10% margin (1-sided, 2.5% significance).

Secondary Outcomes
Secondary study outcomes and minimum detectable differences (80% power, 5% significance) included:

1. The proportion of participants commencing DAAs (16% absolute minimum difference) in the primary care arm, compared to the SOC arm;
2. The proportion of participants obtaining a recorded SVR12 (15.3% absolute minimum difference) in the primary care arm, compared to the SOC arm; and
3. Calculation of the care cascade by study arm. We measured the care cascade by the proportion of participants who (1) completed transient elastography and blood tests (liver assessment); (2) started treatment (prescription written); and (3) obtained SVR12 (defined as a negative HCV RNA blood test 12 weeks or more after DAAs were completed or ceased).

Secondary Study Outcomes and Minimum Detectable Differences

Statistical Analysis

Primary Outcome
A Clopper-Pearson exact 1-sided binomial 95% confidence interval (CI) was estimated to determine noninferiority of DAA treatment in primary care in terms of SVR12 [17].

Secondary Outcomes
Given the individual-level randomized nature of the study, we used Pearson chi-square tests of independence and risk ratios with 95% CIs to compare differences in DAA treatment initiations and SVR12 responses across the 2 study arms.

Treatment uptake and SVR12 rates by study arm were calculated using intention to treat (ITT) analyses and excluded ineligible participants:

Treatment uptake rate = Participants that commenced DAAs/
Participants randomized – ineligible participants

In ITT analyses of SVR12 responses between study arms of randomized participants (excluding ineligible participants), participants who were LTFU and did not provide an SVR12 test result were considered not to have achieved SVR12. Logistic regression analyses were used to identify both factors of treatment uptake and SVR12. Potential factors included age (>40 vs ≤40 years), sex, injecting within 6 months prescreening, and receipt of OST at screening. The multivariate logit model for both factors associated with treatment uptake and SVR12 explored factors that were significant at the 0.10 level in univariate analyses in a backwards stepwise model. Data were entered into REDCap software and analyzed with STATA statistical analysis package version 14.2 [18, 19].

RESULTS
There were 140 participants who consented to treatment. We randomized 136 participants; their characteristics are listed in Table 1. Over 70% of study participants were unemployed; nearly all had a history of injecting drugs. The characteristics of the participants were similar in the 2 study arms. Of the 4 participants not randomized, 3 were LTFU and 1 was ineligible (Genotypes 1 and 6). We randomized 70 participants to the primary care arm and 66 to the SOC arm.

Care Cascade
Of the 70 participants randomized to primary care, 48 were eligible for study treatment and 13 were ineligible due to fibrosis level (8), thrombocytopenia (3), drug-drug interactions prohibiting available DAAs (1), and anemia (1). The other 9 did not complete their liver assessment and exited the study (see Figure 1).

Of the 66 participants randomized to the SOC arm, 29 were eligible for study treatment and 13 were ineligible due to fibrosis level (8), thrombocytopenia (1), drug-drug interactions prohibiting available DAAs (3), and not being infected with HCV (1).
The other 24 did not complete their liver assessment and exited the study (see Figure 1). No HIV or hepatitis B coinfections were detected on screening. Available liver/hepatitis characteristics for randomized patients are presented in Table 2.

Of 48 participants eligible for study treatment in primary care, 43 commenced DAAs and 5 did not: 2 were LTFU, 1 patient withdrew, and 2 were clinically withdrawn (both had uncontrolled diabetes mellitus; see Figure 1). Of the 43 participants who commenced DAAs, 28 obtained SVR12 and 3 obtained SVR 4+ then exited the study. Of the other 12 participants, 2 ceased DAAs within 48 hours of commencing (1 because of nausea and 1 because of alanine aminotransferase (ALT) flare >500 IU/L in the context of excess alcohol consumption) and 10 were LTFU. The last study attendance data for participants that commenced DAA and were LTFU are described in Table 3.

Of 29 participants eligible for study treatment in the SOC arm, 18 commenced DAAs and 11 did not: 5 were LTFU, 5 withdrew from the study, and 1 was clinically withdrawn (unable to identify sub type of Genotype 1). Of the 18 participants who commenced DAAs, 16 obtained SVR12. The last study attendance data for participants that commenced DAA and were LTFU are described in Table 3. The participant that last attended at Week 8 reported missing 5–7 tablets per month (was on a regimen of 5 tablets a day). No treatment failure was documented in either study arm. Figure 2 summarizes the Prime Study cascade of care.

Primary Outcome
Using a per protocol analysis of participants treated in primary care for whom an SVR12 outcome was known, we found that the participant SVR12 rate of 100% was noninferior (n = 28, exact 1-sided 95% CI 87.7–100) when compared to a historical SVR12 comparator of 85% (PEG, ribavirin, and simeprevir), applying a noninferiority margin of 10%.

Secondary Outcomes
Using an ITT approach, the proportion of participants commencing treatment in the primary care arm (excluding ineligible participants; 75%, 43/57) was significantly higher than the proportion in the SOC arm (34%, 18/53; χ²[1] = 19.1; P < .001, relative risk [RR] 2.48, 95% CI 1.54–3.95). A subanalysis of eligible participants who completed their liver assessment showed similar results (primary care 90% [43/48] vs SOC 62% [18/29]; χ²[1] = 8.3, P = .004; RR 2.26, 95% CI 1.07–4.75).

Using an ITT approach (excluding ineligible participants), participants in the primary care arm showed significantly higher SVR12 responses (49%, 28/57) than those in the SOC arm (30%, 16/53; χ²[1] = 4.10; P = .043; RR 1.63, 95% CI 1.0–2.65). Logistic regression was undertaken to investigate whether the following variables were associated with either commencing DAAs or obtaining SVR12: age (>40 years old compared to ≤40 years old), sex, injecting in past 6 months, and use of OST at screening. Univariate analyses showed that participants aged over 40 years were more likely to achieve SVR12 (odds ratio 4.43, 95% CI 1.21–16.16; P = .024). Multivariate analyses were not undertaken, as no other factors were significant at the 0.10 level.

DISCUSSION
The Prime Study is the first randomized trial comparing DAA initiation and outcomes in primary care with specialist-based hospital care in PWID. Our results demonstrate significantly
higher treatment uptake and cure rates in primary care. At the time of writing, only 20% of European countries offer HCV treatment in nonhospital settings and two-thirds of the United States restricts DAA prescribing based on prescriber type: this study investigated how such restrictions impact the elimination of HCV [8, 20]. Importantly, our study population represents the current “real-world” population: people with HCV who have not yet been linked to care. In our study, 83% of participants were on OST, 50% reported injecting in the last 6 months, and over 70% were unemployed.

A key step in the care cascade is a liver assessment. In the SOC arm, 36% (24/66) of participants did not complete a liver assessment and were LTFU, compared to 13% (9/70) in the primary care arm, which highlights the importance of providing on-site liver assessments in primary care. Using the aspartate aminotransferase to platelet ratio index (or other serum-based markers of liver fibrosis) as a tool to triage those that require transient elastography has been successfully utilized in regional Australia [21].

Table 2. Liver/Hepatitis Characteristics by Study Arm

<table>
<thead>
<tr>
<th>Variable</th>
<th>Primary Care (n = 70)</th>
<th>SOC (n = 66)</th>
</tr>
</thead>
<tbody>
<tr>
<td>HCV viral load (n = 111)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>HCV viral load &gt;400 000 IU/mL</td>
<td>53 (83)</td>
<td>24 (51)</td>
</tr>
<tr>
<td>HCV viral load &lt;400 000 IU/mL</td>
<td>11 (17)</td>
<td>22 (47)</td>
</tr>
<tr>
<td>HCV viral load undetectable</td>
<td>0</td>
<td>1 (2)</td>
</tr>
<tr>
<td>HCV genotype (n = 112)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>HCV Genotype 1</td>
<td>51 (80)</td>
<td>44 (92)</td>
</tr>
<tr>
<td>Subtype 1a</td>
<td>45</td>
<td>38</td>
</tr>
<tr>
<td>Subtype 1b</td>
<td>5</td>
<td>5</td>
</tr>
<tr>
<td>Subtype 1 unspecified</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>HCV Genotype 3</td>
<td>13 (20)</td>
<td>4 (8)</td>
</tr>
<tr>
<td>Transient elastography</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Test completed</td>
<td>55 (79)</td>
<td>41 (62)</td>
</tr>
<tr>
<td>Mean liver stiffness, kPa, n (SD)</td>
<td>7.2 (3.0)</td>
<td>7.3 (5.2)</td>
</tr>
<tr>
<td>APRI (n = 102)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>APRI ≥ 1.0</td>
<td>14 (23)</td>
<td>6 (14)</td>
</tr>
<tr>
<td>APRI &lt; 1.0</td>
<td>46 (77)</td>
<td>36 (86)</td>
</tr>
</tbody>
</table>

Data are given as n (%) unless otherwise indicated.
Abbreviations: APRI, aspartate aminotransferase to platelet ratio index; HCV, hepatitis C virus; SD, standard deviation; SOC, standard of care.

Table 3. Last Study Attendance for Participants That Commenced Direct-acting Antivirals and Were Lost to Follow-up

<table>
<thead>
<tr>
<th>Last Study Attendance</th>
<th>Primary Care (n = 15)</th>
<th>SOC (n = 2)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Obtained SVR 4+</td>
<td>3</td>
<td>...</td>
</tr>
<tr>
<td>Attended ETR, adherent</td>
<td>3</td>
<td>...</td>
</tr>
<tr>
<td>Attended Week 8, adherent</td>
<td>5</td>
<td>...</td>
</tr>
<tr>
<td>Attended Week 8, incomplete adherence</td>
<td>...</td>
<td>1</td>
</tr>
<tr>
<td>Attended Week 4</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Attended baseline</td>
<td>1</td>
<td>...</td>
</tr>
<tr>
<td>Ceased DAA within 48 hours</td>
<td>2</td>
<td>...</td>
</tr>
</tbody>
</table>

Abbreviations: DAA, direct-acting antivirals; ETR, end-of-treatment review; SOC, standard of care; SVR 4+, sustained virologic response at between Weeks 4–12 post treatment.
This study significantly advances the previous evidence available on HCV treatment in primary care. Prior cohort studies and 1 small, randomized trial conducted in the era of PEG treatment suggested that community-based treatment resulted in high uptake and similar SVR12 outcomes compared to hospital-based treatment [22]. A cohort study demonstrated that DAAs provided by primary care physicians, nurse practitioners, or specialists were equally efficacious [23]. Primary care practitioners have demonstrated successful management of other medical treatments previously considered to be in the specialist realm, such as preexposure prophylaxis for HIV [24].

To attain the World Health Organization HCV elimination target of an 80% decrease in incident HCV, it is critical to increase the treatment uptake in PWID [1]. Treatment capacity and service delivery are key drivers of treatment uptake. The Australian government policy in 2016 that enabled universal access to DAAs in primary care corresponded with a dramatic rise in respondents in the Australian Needle and Syringe Program Survey who reported a lifetime history of HCV treatment: from 11% in 2015 to 29% in 2016 and 45% in 2017 [25]. These cohort data are consistent with the findings of our study: that providing treatment in primary care is an essential component in engaging PWID in HCV treatment.

In Australia, recruitment was hampered as the Prime Study treatment for Genotype 1a included ribavirin, whereas ribavirin-free, government-subsidized DAAs for Genotype 1a only became available in 2016 in standard clinical practice. Therefore, we did not achieve our target sample size: nonetheless, statistically significant findings support our study hypotheses, as SVR12 responses and intervention effects were of sufficient magnitude [13]. Limitations of our study include the lack of SVR12 data in participants that exited the study. Our analysis assumed these participants did not obtain SVR12. However, of the 15 participants in primary care that exited after commencing treatment, 3 obtained SVR 4+ and 9 exited after attending their Week 8 or end-of-treatment appointment. As a complete treatment course had been dispensed by this time, and many reported high adherence, it is likely that a number obtained SVR12. This would enhance our finding that people in primary care are more likely to be cured than those in the SOC.

Future research should evaluate the factors related to why some people do not have SVR12 tests and whether a test of cure is clinically required. LTFU at the SVR12 time point has been observed in numerous studies [23, 26–28]. Potential explanations include relocation to another healthcare service, avoidance of tests due to complications of venesection, or a presumption of cure given the high treatment efficacy.

CONCLUSION

Providing DAAs in primary care increases treatment uptake and cures in PWID, compared to hospital-based specialist care. Broadening access to DAAs beyond hospital-based services must occur if their benefits are to be fully realized. Strategies that engage priority populations, such as PWID, are key to achieving HCV elimination.

Notes

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