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Outcomes of a nurse-led model of care for hepatitis C assessment and treatment with direct-acting antivirals in the custodial setting

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ABSTRACT

Background: People in prison have been identified as an important population to prioritise for hepatitis C virus (HCV) treatment to achieve HCV elimination goals. We evaluated the efficacy of the New South Wales Justice Health and Forensic Mental Health Network Hepatitis Nurse Led Model of Care during the 12 months following the widespread availability of HCV direct acting antivirals (DAAs) in Australia.

Methods: A retrospective cohort study was conducted of a network of 36 correctional centres across NSW from April 2016 to March 2017, with approximately 13 000 full time inmates. Population Health Nurses conducted initial clinical assessments and confirmatory testing. Patients were referred to a Hepatitis Clinical Nurse Consultant (CNC) for protocol-driven assessment, including transient elastography to assess hepatic fibrosis. The CNC then discussed the case with an Infectious Diseases physician and DAA therapies were prescribed. The total number of patients who commenced and completed treatment, and sustained virological response 12 weeks post treatment completion (SVR 12) were recorded.

Results: During the first 12 months of DAA treatment 698 patients were commenced on HCV treatment. Of those who were tested at the 12-week post treatment completion timepoint the per-protocol SVR12 (cure) rate was 92% (396/430), with 34 patients having a detectable viral load. 52 (7%) patients were released to freedom before completing treatment and a further 211 (30%) were released prior to SVR12 assessment. These outcomes indicate an intention-to-treat SVR 12 cure rate of 57% (396/698). There were no differences in demographic or treatment characteristics between those who underwent SVR12 testing and those released prior.

Conclusions: Treatment for HCV can be delivered safely, efficiently and in high numbers in the prison setting using a nurse-led model of care. This will be an important component of the strategy to eliminate HCV infection as a public health concern by 2030.

Introduction

Hepatitis C virus (HCV) infection is a major public health issue with an estimated 80 million people infected worldwide (Gower, Estes, Blach, Razavi-Shearer, & Razavi, 2014). At the end of 2015 there were an estimated 227 306 people living with HCV infection in Australia, including 16 000 Indigenous Australians (Australian Government Department of Health, 2014; The Kirby Institute, 2017a). Transmission of HCV occurs through exposure to contaminated blood, predominantly via injecting drug use (IDU) with over 10 000 new cases occurring annually in Australia (The Kirby Institute, 2017a). Antiviral treatment rates worldwide have been low due to the arduous nature of the traditional IFN-based treatments and the largely marginalised patient population (Gidding et al., 2009; Grebely, Oser, Taylor, Dor, & 2013). Hence, the population living with chronic infection had been steadily increasing (Australian Government Department of Health, 2014; Gidding et al., 2009). In the absence of dramatic improvements in treatment rates, over the next 20–40 years approximately 20% of those with untreated chronic HCV will progress to liver cirrhosis (Freeman et al., 2001), and thereafter approximately 3% per year will die as a result of liver failure or hepatocellular carcinoma (Westbrook & Dusheiko, 2014).

Persons in prison are a population in which HCV infection is concentrated due to the association between injecting drug use and

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incarceration (Butler & Simpson, 2017). The Fourth Australian National Hepatitis C Strategy 2014–2017 and the World Health Organisation hepatitis C 2018 guidelines identified people in prison as a priority population for HCV treatment (Australian Government Department of Health, 2014; *Guidelines for the care and treatment of persons diagnosed with chronic hepatitis C virus infection*, 2018). Around 30 000 individuals are held in Australian prisons at any one time with over 50,000 cycling through the prison system annually (Mina, Herawati, Butler, Lloyd, & 2016). The most recent serosurvey of Australian prison entrants found 31% to be seropositive for HCV (ranging from 3% in the Northern Territory to 52% in Queensland), with higher rates among those who report IDU (58%) (Butler & Simpson, 2017). This is comparable to globally reported rates of 26% and 64% respectively (Larney et al., 2013). Despite the large numbers this population has not typically been well engaged with specialist care, highlighting the need to develop new models of care for HCV treatment.

In New South Wales (NSW), the Justice Health and Forensic Mental Health Network Hepatitis Service has been in place for more than two decades. It is coordinated state-wide across 36 custodial centres through a speciality health network independent of the custodial authority; and features well developed assessment and treatment infrastructure. An innovative nurse-led model of hepatitis care built on a central premise of task-transfer to skilled nurses with highly protocol-driven nursing assessments, telemedicine and a portable fibro-elastography service is utilised to facilitate decentralised access to care (Lloyd et al., 2013). The service provides equitable access to Indigenous patients (Post, Lloyd, & Monkley, 2013).

From March 2016, the subsidised supply of the direct acting antivirals (DAAs) via the Australian government funded Pharmaceutical Benefits Scheme (PBS) offers improved cure rates to better than 90% for all genotypes (Dabbouseh & Jensen, 2013; Kim, Ahn, & Han, 2014). There is limited data on the outcomes of HCV DAA treatment in prisons (Aspinall et al., 2016; Bartlett et al., 2018; Hochstatter et al., 2017; Morey et al., 2018; Papaluca et al., 2019; Pontali et al., 2018). As the PBS listing of the DAAs made specific arrangements to ensure access for prison inmates, the nurse-led model of care protocols were updated for the DAA era and implemented. This study aimed to evaluate a nurse-led model of care for HCV assessment and treatment of people in prison in the DAA era.

Methods

Design and study period

A retrospective cohort study including all patients treated during the first 12 months (April 2016 – March 2017) after HCV DAA therapy availability in the NSW prison system was conducted. During the study period there were approximately 30 000 admissions, and approximately 13 000 prison inmates in full-time custody at any time (92.5% male) in 36 correctional centres across the state. There were approximately 150 000 movements of these inmates between centres annually (Corben, 2017). Of full time custody prison inmates in NSW in 2016 32.9% were unsentenced, 25.3% had a sentence length of less than 2 years and 41.8% had longer sentences or were forensic patients (Corben, 2017). Each correctional facility had access to Population Health Nurse(s) and during the study period there were two Hepatitis Clinic Nurse Consultants (CNC) that travelled to each facility. The CNCs had specific training and experience in the clinical assessment of people with HCV and were accredited in the use of transient elastography.

Ethics approval

The study design and access to clinical data was approved by the Justice Health and Forensic Mental Health Network Human Research Ethics Committee (HREC) reference number G235/17, and by the Aboriginal Health and Medical Research Council HREC reference number 1293/17.

Clinical pathway

All at risk prison inmates and those who request testing were offered screening for viral hepatitis (Hepatitis B and HCV serology) after prison admission assessment. HCV antibody positive patients were referred for assessment by a Population Health Nurse at their local prison. Population Health Nurses conducted initial clinical assessments and confirmatory testing including screening for human immunodeficiency virus (HIV) and hepatitis B virus (HBV) co-infection; assessment of liver function tests, platelet count, and internationalised normalised ratio; as well as HCV genotype and viral load. Patients were then referred to a Hepatitis Clinical Nurse Consultant (CNC) who travel around to all the correctional facilities performing protocol-driven assessments. During the study period this included a hepatitis and injection drug use focused history, physical examination, and liver stiffness measurement using portable transient elastography (FibroScan™) for all patients, followed by further investigations if cirrhosis was identified. Following these assessments, the CNC discussed the case in-person with a specialist Infectious Diseases physician and DAA therapies were prescribed based on the protocol-driven assessments. Patients assessed by the CNC to have decompensated cirrhosis or complex comorbidities were reviewed face-to-face or via telemedicine by the Infectious Diseases physician prior to DAA prescription as described previously (Lloyd et al., 2013). After treatment prescription by the specialist, suitable patients received 28-day medication packs, for self-administration, until therapy was completed or via daily nurse administered treatment if not deemed suitable for self-administration. Patients were followed up as recommended in the Australian recommendations for the management of HCV (Hepatitis C Virus Infection Consensus Statement Working Group, 2016) including to assess for SVR12. During the study period there was access to opioid substitution therapy and disinfectant was available in the prison accommodation blocks.

Data collection

All patients who were prescribed DAA treatment from April 2016 to March 2017 were included. Each patient's electronic medical record (eMR) and completed nurse-led model of care protocol driven assessment forms were reviewed. Data collected included: age at the time of treatment initiation, sex, Indigenous status, country of birth, HCV genotype, cirrhosis status, treatment type and duration, and prison at commencement of treatment.

Outcomes and statistical analysis

The primary outcome of the study was the proportion of patients who achieved SVR 12 (absence of detectable HCV ribonucleic acid (RNA) 12 weeks after completing treatment). This was analysed per-protocol and in an intention-to-treat (ITT) analysis. The per-protocol analysis included those who completed treatment and follow-up according to the protocol and excluded those lost to follow-up (mainly via release to freedom). The ITT analysis assessed the proportion of people who started treatment and achieved SVR12 and included all subjects lost to follow-up in the analysis. Data was entered into Microsoft Excel which was used to calculate median and interquartile ranges (IQR). Comparisons between groups were made using chi-square statistical test for categorical variables and the Mann-Whitney test for non-categorical variables. Vassar stats (Lowry, 2019) was used to perform the statistical analysis.

Results

During the first 12 months of DAA availability, 698 patients were commenced on HCV treatment. Patient clinical characteristics are

Table 1
Demographic characteristics of patients who were commenced on DAA treatment (N = 698).

Characteristics	No. patients (%)
Sex	
Male	633 (90.7)
Female	65 (9.3)
Age (years)	
Median	38
IQR	32–45
Aboriginal or Torres Strait Islander	214 (30.7)
Overseas born	64 (9.3)
Cirrhotic	113 (16.2)
Genotype	
1	373 (53.4)
3	290 (41.5)
Other	35 (5.1)
Treatment	
Sofosbuvir/ledipasvir	348 (49.9)
Sofosbuvir/daclastasvir	308 (44.1)
Other	42 (6.0)

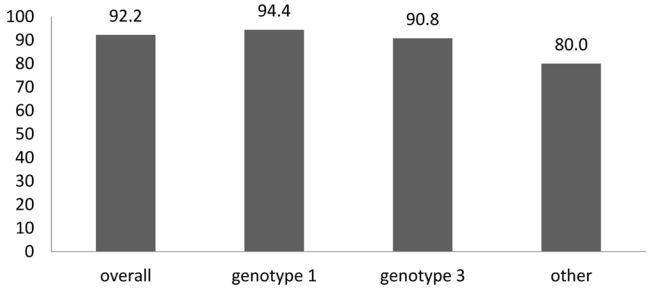

Fig. 1. Percentage of subjects who achieved SVR 12 by genotype (per protocol analysis).

summarised in Table 1. The most common HCV genotypes were genotype 1 (53.4%) and genotype 3 (41.5%). 113 (16.2%) patients had cirrhosis as determined by a FibroScan™ reading of greater than 12.5 kPa. The majority of the patients (634, 90.8%) were treated after assessment only with the nurses through the nurse-led model of care, whereas 64 (9.2%) patients had an assessment with a specialist either through telehealth or face-to-face review. Sofosbuvir/ledipasvir was the most commonly prescribed regimen (49.9%) followed by sofosbuvir/daclastasvir (44.1%) and only 6% of patients received an alternate regimen (Table 1). Of those who completed treatment and had SVR12 assessed whilst in prison, the cure rate was 92% (396/430), with 34 patients having a detectable viral load indicating either treatment failure or reinfection. Fig. 1 displays the per-protocol SVR12 rates by genotype. Genotypes other than 1 and 3 had lower SVR12 rates ($\chi^2 = 11.16$, $p = 0.004$). Of the 34 non-responders five had decompensated cirrhosis, 16 reported ongoing injecting drug use, including seven who had documented reinfection with a different genotype. There were 52 patients (7.4%) who were released to freedom before completing treatment. Of these 52 people there were 9, 28 and 15 patients receiving 8, 12 and 24 weeks of treatment respectively. Two patients failed to complete treatment due to mental health issues resulting in treatment refusal. A further 211 (30.2%) patients were released prior to SVR12 data collection; one patient died from an unrelated cause during the follow-up period, and two patients refused SVR12 blood testing (Fig. 2). These outcomes indicate an ITT SVR12 cure rate of 57% (396/698). There were no differences in key demographic or treatment variables between subjects who remained in prison for assessment at the SVR12 timepoint and those who were not able to be assessed (Table 2).

Discussion

This paper demonstrates the feasibility, safety and efficiency of a nurse-led, telemedicine assisted and specialist-supported protocol driven HCV care pathway in correctional settings. This is the largest evaluation of a treatment program for chronic HCV in the correctional environment since the wide spread availability of DAAs. The program is novel in that the majority of patients (90.8%) underwent assessment and treatment without face-to-face or telehealth interaction with a specialist physician. The service provided efficient assessment and treatment of HCV for several population groups with poor health care access, including Indigenous Australians (30.7%) and IDUs. The high treatment rate amongst Indigenous patients is of particular importance given that the overall rate of HCV diagnoses has increased in the Indigenous population to fourfold the rate in non-Indigenous populations over the past decade (The Kirby Institute, 2017a).

Despite remarkable advances in HCV treatment, chronic HCV infection remains a major public health problem. An estimated 80 million people are infected worldwide (Gower et al., 2014), and almost a quarter of a million in Australia alone, with the overwhelming majority infected via injecting drug use (Australian Government Department of Health, 2014). As there is a close relationship between imprisonment, injecting drug use, and HCV, in any given year at least 15, 000 of those infected in Australia spend time in prison (Butler & Simpson, 2017). Of the estimated 10·2 million people incarcerated worldwide on any given day, it is estimated that 1 546 500 (15·1%) have HCV (Dolan et al., 2016). This group are likely to constitute one of the most marginalised patient groups affected by HCV who are unlikely to access health services in any other setting. In addition, this group features high rates of on ongoing HCV transmission both in prison and in the community (Hunt & Saab, 2009). In combination, these attributes argue for high priority to be placed on antiviral treatment for prison inmates. Other smaller studies of prison-based HCV treatment with DAAs have reported equivalent outcomes in assessable subjects (Aspinall et al., 2016; Hochstatter et al., 2017; Morey et al., 2018; Papaluca et al., 2019; Pontali et al., 2018). There is also some evidence of substantial reduction in HCV prevalence within prisons with "micro-elimination" (Bartlett et al., 2018; Blogg, Wood, McGrath, & Lobo, 2018; Cuadrado et al., 2018).

Delivery of health services in the prison context is challenging, as prisons feature complex bureaucratic structures, overcrowding, frequent movements, high rates of mental illness, and exposure to violence and illicit drugs (Boonwaat, Haber, Levy, & Lloyd, 2010; Post, Arain, & Lloyd, 2013). Despite these challenges 644/698 (92%) patients completed treatment within the custodial setting. Although follow up data is not available for the 52 patients who were released to freedom whilst on treatment these individuals were given the remaining supply of medications and prescriptions were transferred to a pharmacy of their choice for ongoing dispensing. No patients in this study period failed to complete treatment due to side effects or safety concerns.

The high SVR12 rate within the per-protocol population (92%) is clear evidence of high efficacy within this study population. The absence of detectable HCV RNA at SVR 12 is also evidence of the lack of early post-treatment HCV reinfection in the vast majority of patients. Seven patients (1%) with detectable HCV RNA had a different genotype to their pre-treatment assessment indicative of likely reinfection. The lower SVR12 rate within the intention to treat analysis (57%) was predominately attributable to the large number of patients (211; 30%) released to freedom during post-treatment follow-up, but all had completed treatment with a negative end of treatment HCV RNA test. It is to be expected that more than 90% of this population were also successfully treated (*"EASL Recommendations on Treatment of Hepatitis C, 2018," 2018*; *"Hepatitis C guidance: AASLD-IDSA recommendations for testing, managing, and treating adults infected with hepatitis C virus," 2015*). All patients who were released to freedom either whilst on treatment or after completing treatment where given discharge letters

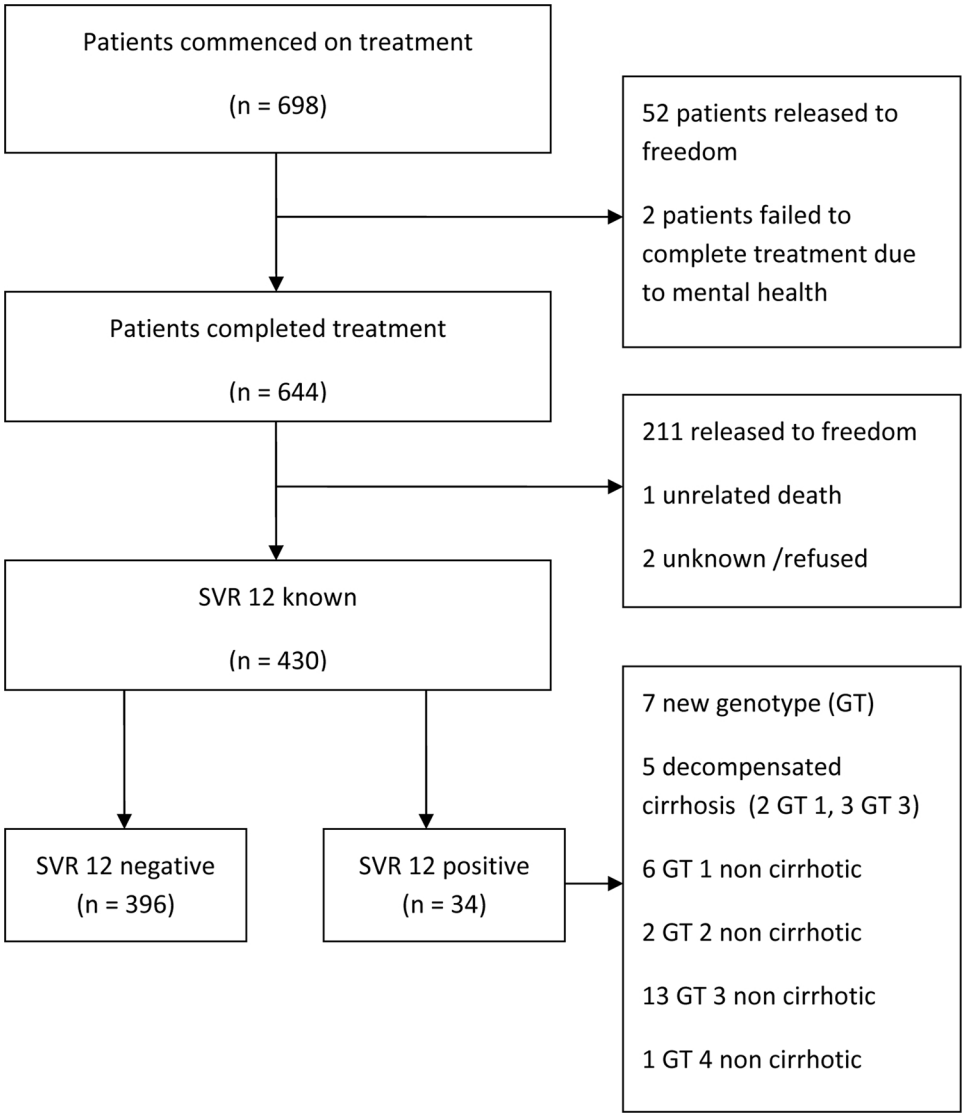

Fig. 2. Outcome of patients treated for HCV infection in custody.

and referred back to their primary care physician for SVR 12 assessment, the outcome of which we do not know. However, it is worth noting imprisonment has been reported as a risk factor for not attending for SVR12 assessment in other Australian cohorts (Haridy et al., 2018).

In Australia, an estimated 58 280 individuals initiated DAA treatment for HCV infection between March 2016 and March 2018, equating to 26% of the people living with chronic HCV infection nationally (The Kirby Institute, 2018). This large initial uptake may represent successful treatment of the easy to access patients or the 'low-hanging fruit' of the HCV epidemic: patients already connected with tertiary clinics awaiting treatment (van Driel, Lim, & Clark, 2017). This is supported by data from 2016 that identified that 62% of individuals were prescribed DAA treatment by specialists, while 19% of individuals were prescribed DAA treatment by general practitioners (GPs) (The Kirby Institute, 2017b). If Australia is to capitalise on the opportunity of universal access to DAA therapy, it will require a shift from predominately tertiary specialist treatment to community-based treatment. To assist this, it will be important to consider shifts to more efficient assessment of people in the community and prison for HCV treatment as afforded by non-invasive algorithms to exclude cirrhosis (Kelly, Riordan, Bopage, Lloyd, Post, & 2018). This paper demonstrates how a prison-based nurse-led model of care can successfully diagnose, treat and follow up patients in a non-hospital setting, whilst remaining safe and effective with minimal direct specialist involvement. This is consistent with other data supporting task transfer to nurses in the non-correctional setting (Kattakuzhy et al., 2017). Given the proven safety of the currently available DAA therapies such nurse-led models would likely be feasible and cost-effective in many settings.

Australia is positioned to achieve HCV elimination as there is universal access to DAAs, including for people in prison. The lack of widespread access to due to cost has limited the implementation of prison treatment programs worldwide (Rich, Allen, & Williams, 2014) and often where treatment is available to people in custody, it has often been restricted (Spaulding et al., 2013). However, were access to DAA treatments to become more widely available this study along with others (Kattakuzhy et al., 2017; Papaluca et al., 2019), supports the introduction of nurse-led models of care as feasible and potentially cost-effective in many settings. With great potential to impact on health systems, clinical guidelines and policies in other countries globally.

Limitations of the study include the large proportion of patients who were lost to follow up, most of whom were released from prison between the end of treatment and assessment for SVR12. However, the study aims to evaluate a nurse-led model of care, rather than to assess DAA effectiveness, which is already established (*"EASL Recommendations on Treatment of Hepatitis C*, 2018," 2018; *"Hepatitis C guidance: AASLD-IDSA recommendations for testing, managing, and*

Table 2
Comparison of subjects who completed assessment as per protocol and those lost to follow-up.

Characteristics	Per-protocol No. (%)	Lost to follow up No. (%)	P value
Sex			0.49
Male	393 (91.4)	240 (89.6)	
Female	37 (8.6)	28 (10.4)	
Age (years, median)	38	38.3	0.15
Indigenous			0.46
Yes	127 (29.5)	87 (32.5)	
No / Unknown	303 (70.5)	181 (67.5)	
Overseas born			0.25
Yes	44 (19.1)	20 (7.5)	
No / Unknown	386 (80.9)	248 (92.5)	
Cirrhotic			0.38
Yes	65 (15.1)	48 (17.9)	
No	365 (84.9)	220 (82.1)	
Genotype			0.71
1	235 (54.7)	138 (51.5)	
3	174 (40.4)	116 (43.3)	
Other	21 (4.9)	14 (5.2)	
Treatment			0.94
Sofosbuvir/ledipasvir	216 (50.2)	132 (49.3)	
Sofosbuvir/daclastasvir	189 (44.0)	119 (44.4)	
Other	25 (5.8)	17 (6.3)	
Treatment duration			0.12
8 weeks	126 (29.3)	67 (25.0)	
12 weeks	265 (61.6)	166 (61.9)	
16 weeks	2 (0.5)	0 (0.0)	
24 weeks	37 (8.6)	35 (13.1)	

treating adults infected with hepatitis C virus," 2015). Due to the retrospective nature of the study upstream data from the care cascade on the number who were screened, but unable to receive confirmatory testing is not available. The retrospective nature of the study limited the scope of data collection that could be informative for others wishing to replicate the program outlined here. Although this study did not assess the potential effects of upstream factors such as novel testing approaches (such as point of care testing), linkage to care systems, and the utility of shorter treatment courses in this population these are important aspects to be considered in the expansion of HCV treatment programs in prisons (Kronfli et al., 2018; Vroling et al., 2018).

Conclusion

Treatment for HCV can be delivered safely, efficiently and in high numbers in the prison setting using a nurse-led model of care. The prison setting provides an excellent opportunity to engage and treat high risk individuals. Given the high prevalence of chronic HCV in custodial settings and the turnover of inmates back into the community, the successful outcomes argue for infrastructure investment in such programs to improve the previously low treatment rates. Elimination of HCV as public health threat by 2030 will not be possible without a major focus on DAA access and optimised outcomes within the marginalised prison population.

Conflict of interest

The Authors have no conflicts of interest related to this article to declare. This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

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