Establishment of a successful assessment and treatment service for Australian prison inmates with chronic hepatitis C

Leng Boonwaat, Paul S Haber, Michael H Levy and Andrew R Lloyd

ABSTRACT

Objective: To evaluate the assessment and treatment outcomes of a prison hepatitis service.

Design and setting: A retrospective, observational cohort study of prison inmates who attended hepatitis clinics from 1996 to 2005 at correctional centres in New South Wales.

Patients: Inmates who attended the clinics, including a nested case–control series of patients who received antiviral treatment and age- and sex-matched patients who did not receive treatment.

Main outcome measures: Demographic and clinical characteristics of patients who attended the service; correlates of selection for antiviral treatment; and clinical and virological outcomes of treatment.

Results: Of the 1043 inmates who attended the clinics, 851 were men (82%) and 994 (95%) were referred for HCV infection; the mean age for this group was 33 years (range, 18–74 years). In the case–control series (185 treated and 186 untreated patients), selection for treatment was not biased by culturally and linguistically diverse background, current methadone treatment or psychiatric status. In the treated group, 76 of 138 genotyped patients had a genotype that is predictive of favourable treatment response, and a small minority of those with available liver biopsy results had established cirrhosis (7/119 patients). Of treated patients for whom complete follow-up data were available, 55% achieved sustained virological response and 100% adhered to therapy. In addition, treatment episodes were not especially complicated.

Conclusion: Although the prison population has high rates of injecting drug use and poor mental health, imprisonment offers an opportunity for assessment and treatment of chronic HCV infection.

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About 2.2% of the world's population is infected with hepatitis C virus (HCV),[1] including 260 000 Australians.[2] After primary infection, persistent viraemia and chronic hepatitis occurs in 50%–80% of patients. For each decade of infection, patients with chronic hepatitis C face an increasing risk of cirrhosis, liver failure and hepatocellular carcinoma.[3] The morbidity, mortality and economic impact associated with chronic hepatitis C are substantive.[4] The dominant mode of HCV transmission is parenteral exposure to infected blood, with most cases of HCV infection occurring in injecting drug users (IDUs).[2] Seroprevalence estimates in Australia range from 0.2% in blood donors,[5] to 75% among clients of opioid substitution programs.[6]

IDUs have high rates of imprisonment, predominantly due to illicit drug use and funding of drug dependence through crime. Almost half of all Australian prison inmates report intravenous drug use at some time in their life, and up to 70% are incarcerated for drug-related crimes.[7] HCV infection is common among Australian inmates with an overall prevalence of 30%, and 56% among those who reported intravenous drug use at some time in their life.[8] Transmission of HCV within prisons is known to occur via sharing of injecting apparatus, tattooing, and possibly other blood-to-blood contact such as barbering and fighting.[9,10] The challenge of managing HCV infection is amplified among prison inmates, as about one-third of the female and half of the male inmate population report drinking alcohol in the "hazardous" or "harmful" range according to the Alcohol Use Disorders Identification Test prior to imprisonment.[7] In addition, 54% of women and 39% of men have previously been diagnosed with a psychiatric disorder, and current major depression is evident in 23% of women and 38% of men.[7]

Antiviral treatment for chronic hepatitis C currently involves combination therapy with pegylated interferon-α (IFN-α) and ribavirin (RBV). Under optimal conditions, this treatment achieves a 45% sustained virological response (SVR) in genotype 1 and 4 infections, and an 85% SVR in genotype 2 and 3 infections.[11] Such treatments are cost-effective.[12]

The large pool of inmates with chronic hepatitis C therefore presents a challenge and an opportunity for treatment. Health care provision is challenging in prisons because: the primary concern is secure incarceration rather than health care; the demand on resources is vast as chronic psychiatric and medical illnesses are prevalent; and inmates are distributed across multiple centres and moved frequently (eg, during the financial year 2005–06, about 150 000 movements of full-time inmates were recorded in New South Wales[13]). However, prisons are also likely to be an ideal setting for delivery of complex treatment interventions to this traditionally hard-to-reach population. Successful delivery of HCV treatment has been established in few prison jurisdictions worldwide.[14-16] Many questions regarding such services remain, including questions about indications, contraindications and appropriate models of care for this patient group and setting.[17]

Here, we describe the establishment of a statewide network of hepatitis clinics operating in several of the 30 prisons in NSW, which house approximately 9000 full-time inmates, and the evaluation of the assessment and treatment outcomes of this service. The Hepatitis Service was developed by Justice Health, which is responsible for providing health care to inmates, and is independent of Corrective Services NSW, which is responsible for custody of inmates.

METHODS

Design and setting

We conducted a retrospective, observational cohort study of prison inmates who attended hepatitis clinics between 1996 and 2005 at correctional centres in NSW.

A hepatitis clinical service was initiated in 1995 with a monthly clinic held at one correctional centre with one visiting specialist. Liver biopsies were conducted in the prison hospital, and antiviral treatment (IFN-α monotherapy) was offered to highly selected patients (particularly those who were no longer injecting drugs, and

1 Demographic and clinical characteristics of treated and untreated prison inmates with chronic hepatitis C

	Number (%) of patients		
	Treated patients (n = 185)	Untreated patients (n = 186)	P
Mean age in years (SD)	34 (8.4)	34 (8.8)	0.89
Male	143 (77%)	140 (75%)	0.65
Indigenous Australian background	27 (15%)	23 (12%)	0.52
Culturally and linguistically diverse background	26 (14%)	15 (8%)	0.07
Injecting drug use (ever)*			
In the community	99/143 (69%)	131/178 (74%)	0.01
In prison	41/143 (29%)	48/178 (27%)	0.74
Tattooed (ever)*			
In the community	30/142 (21%)	50/179 (28%)	0.16
In prison	23/143 (16%)	28/178 (16%)	0.93
Methadone treatment (current)	56 (30%)	43 (23%)	0.09
Psychiatric diagnosis			
Previous	26 (14%)	31 (17%)	0.54
Current	29 (16%)	31 (17%)	0.87
HIV co-infection	12 (6%)	6 (3%)	0.14
Hepatitis B virus co-infection	6 (3%)	24 (13%)	0.001

* Denominators are indicated for these variables as patients with no data recorded in the medical record were excluded from this comparison. ◆

2 Reasons for deciding not to treat

	Number (%) of untreated patients (n = 186)
Imminent release from prison	111 (60%)
Not eligible for treatment*	38 (20%)
Free of hepatitis C viraemia on follow-up	24 (13%)
Declined treatment	7 (4%)
Not specified	6 (3%)

* The Pharmaceutical Benefits Scheme provides subsidised antiviral therapy for eligible patients with chronic hepatitis C under section 100 of the National Health Act. ◆

had long prison sentences). By 2005, 12 additional clinics had been established, with liver biopsies being performed in prison facilities at two sites and in nearby hospital clinics at three sites. The clinics were supported by public health nurses, who were the major referral source following voluntary screening for blood-borne viruses and provided post-test counselling. Protocols were established for nurse-led investigation, to triage those most suitable for further assessment and antiviral treatment. Combination therapy with IFN-α and RBV was initiated in 2002, and replaced by pegylated IFN-α combined with RBV in 2004. Inmates administered their own injections and disposed of needles and syringes appropriately under close supervision.

Data collection and analysis

A list of clinic attendances was collated and cross-checked against other sources, including pathology records for liver biopsy specimens sent to various diagnostic pathology services from Justice Health, and pharmacy dispensing records. Demographic data were obtained from the Offender Information Management System held by Corrective Services NSW.

To examine the factors influencing the decision to treat, inmates who received antiviral treatment were identified and matched by age (within 5 years) and sex to inmates who had attended the service but did not receive treatment. Medical records of these patients were systematically examined and data regarding factors likely to influence the treatment decision were extracted, including demographics, behavioural risk characteristics, comorbidities, and laboratory results. Adverse events for those on treatment were categorised according to the toxicity grading scales of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use *Guideline for good clinical practice*.[18]

Statistical analysis was conducted using SPSS v16.0 for Windows (SPSS Inc, Chicago, Ill, USA). Associations between categorical outcome variables were analysed using the χ^2 test (or the Fisher exact test when cell numbers were less than five). The means of continuous variables were compared using unpaired two-tailed Student t tests.

RESULTS

During the study period, 1043 patients attended the hepatitis clinics (851 men [82%] and 192 women), with a mean age of 33 years (range, 18–74 years). The group included 182 Indigenous Australians (17%) and 154 patients from culturally and linguistically diverse backgrounds (15%). Most of the referrals were for evaluation of HCV infection (n = 994; 95%); the remainder (n = 49) were for hepatitis B (HBV) infection. Fifty-two patients (5%) were HIV-infected, of whom 15 were co-infected with HCV, one with HBV, and two had no viral hepatitis.

Demographic and clinical characteristics of a nested case–control series of 371 patients — 185 treated (case) patients and 186 age- and sex-matched untreated (control) patients — are summarised in Box 1. Of those in whom the likely mode of HCV transmission was recorded (n = 242; 65%), 230 (95%) were thought to have acquired HCV through intravenous drug use. Tattooing (n = 5; 2%), fights (n = 2; 1%) and other factors (blood transfusion, or born in a country with high prevalence of HCV infection; n = 4; 2%) were the likely modes of transmission for the remainder. No significant bias was apparent in the selection of patients for treatment in terms of Indigenous Australian or culturally and linguistically diverse background, current methadone treatment or psychiatric status (Box 1). The major psychiatric disorders that were evident during the hepatitis clinic visits in the 185 patients who received antiviral treatment, included major depression (n = 14; 8%) and schizophrenia (n = 10; 5%).

3 Laboratory characteristics of treated and untreated prison inmates with chronic hepatitis C

	Number (%) of treated patients ($n = 185$)	Number (%) of untreated patients ($n = 186$)	P
Liver biopsy			
Performed	182 (98%)	42 (23%)	< 0.001
Results available	119 (64%)	33 (18%)	0.09
Fibrosis score*			0.31
0 or 1	66/119 (55%)	21/33 (64%)	
2 or 3	47/119 (39%)	12/33 (36%)	
4	7/119 (6%)	0/33	
HCV genotyping†			< 0.001
Results available	138 (75%)	73 (39%)	
Results not available	47 (25%)	113 (61%)	
HCV genotype†			< 0.001
1 or 4	62/138 (45%)	34/73 (47%)	
2 or 3	76/138 (55%)	37/73 (51%)	
Untypeable	0/138	2/73 (3%)	

HCV = hepatitis C virus. * Possible range: 0 (no fibrosis) to 4 (cirrhosis). † HCV genotyping was not available in clinical practice in Australia until 1999. ◆

4 Outcomes of antiviral treatment in prison inmates*

	IFN-α monotherapy ($n = 13$)	IFN-α combined with ribavirin ($n = 81$)	Pegylated IFN-α combined with ribavirin ($n = 91$)	Total ($n = 185$)
Complete follow-up (n = 115)				
Sustained virological response	1	22	28	51
Non-responder	9	32	23	64
Incomplete follow-up ($n = 70$)				
Early virological response	2	11	18	31
Virological outcome unknown†	1	16	22	39

IFN-α = interferon-α. * Data are number of patients. † Released from prison before completing 12 weeks of antiviral therapy, follow-up unknown. ◆

The major reason identified in the decision not to treat was the likelihood of imminent release from prison, and therefore the potential for interruption to antiviral treatment (Box 2). In addition, there were 24 patients who were free of HCV viraemia on follow-up and were considered to have naturally cleared their infection. There were also 38 patients who were considered ineligible for treatment under the Pharmaceutical Benefits Scheme, which provides subsidised antiviral therapy for patients with chronic hepatitis C under section 100 (s100) of the National Health Act. The eligibility criteria for s100 access varied during the study period, with an initial stipulation (1995–1998) that individuals have a fibrosis score of at least 1 and that current IDUs were ineligible. In May 2001, the exclusion of individuals on the basis of active injecting drug use was removed.

HCV genotyping became generally available in 1999. Genotyping results were therefore available for 138 of the 185 treated patients (75%), of whom 76 (55%) had genotypes predictive of a more favourable treatment response (genotypes 2 and 3) (Box 3). A liver biopsy was performed on 182 of the treated patients (98%), in comparison to 42 of the untreated patients (23%). Biopsy results were available for 119 patients in the treated group and 33 in the untreated group. Of patients with a biopsy result available, a small minority of those who went on to treatment ($n = 7$; 6%) had established cirrhosis (ie, a fibrosis score of 4) and the majority of those who were not treated had early stage disease ($n = 21$; 64%) (fibrosis scores of 0 or 1).

Of the 185 patients who received treatment, complete follow-up after treatment to assess for an SVR was available for 115 patients (62%) (Box 4). Of this group, SVR was documented in 51 patients (44%; or 28% on an intention-to-treat analysis). The remainder were released from prison either after an early virological response was confirmed at 12 weeks ($n = 31$; 17%) or before 12 weeks with no further follow-up data available ($n = 39$; 21%). The SVR rate for those receiving the current standard of care (pegylated IFN-α combined with RBV) was 55% (28/51).

Despite substantive comorbidity in the inmate population, treatment episodes were relatively uncomplicated. Two patients (1%) experienced grade 3 toxicities — one with severe headaches requiring narcotic analgesia, and one with severe depression requiring antidepressant medication — but both continued on antiviral therapy. Four patients (2%) experienced grade 2 toxicities, including one patient with each of the following: moderate depression, thrombocytopenia (50 000–75 000 × 10^9/L), nausea with reduced oral intake, and diffuse maculopapular rash. Seventy-four patients (40%) reported grade 1 toxicities, including 21 patients (11%) with mood disturbance.

Adherence to therapy for the 115 patients with complete follow-up data available was 100%. If the remaining 70 patients without complete follow-up data available are assumed to have been non-adherent, the overall adherence rate may be estimated to be 62%.

DISCUSSION

This is the first report of a decentralised model of care for chronic hepatitis C in an Australian prison population. The service provided effective assessment and treatment of chronic hepatitis C for several population groups who are typically hard to reach in the community setting, including Indigenous Australians, IDUs and those with significant psychiatric comorbidities. Our findings add to a growing body of literature which confirms that chronic HCV may be successfully treated in prison,[14,15,19] including a preliminary report from one centre of the statewide service.[20]

Recently adopted federal and state policies have recommended doubling the numbers of patients who receive antiviral treatment for chronic hepatitis C, with a long-term goal of reducing the burden of advanced liver disease in Australia.[21,22] As prison hepatitis services are essentially absent in most states and territories, the prison jurisdiction offers significant potential for service development with a view to meeting antiviral treatment targets.[23] In addition, given the high rates of HCV and imprisonment among IDUs, treatment of IDUs in the prison setting offers an opportunity to achieve high levels of treatment adherence and successful treatment outcomes, despite common adverse effects and high rates of psychiatric co-morbidity. It may be reasonable to initially restrict such treatment to individuals with a sufficient period of incarceration to complete treatment while in prison, although this should be coupled with development of improved post-release health care programs to ensure continuity of care. As the efficacy of antiviral therapy for chronic hepatitis C continues to improve and treatment duration shortens, the rationale for delivery of such treatment in the prison setting will strengthen further.[24]

Over the study period (1996–2005), the average full-time adult prison population in NSW expanded from 6288 to 8796 individuals, of whom 93% were males, 17% were Indigenous Australians, 18% were from a culturally and linguistically diverse background and 48% had a maximum sentence of more than 2 years.[7,25] Patients attending the Hepatitis Service and those receiving treatment for chronic hepatitis C had similar demographic characteristics.

Nevertheless, referral of patients to the Hepatitis Service appeared to be subject to strong selection biases. About 187 000 individuals were placed in full-time custody in NSW during this period;[25] about 40% of this population (74 800 individuals) were likely to be HCV antibody positive, of whom 70% (52 360 individuals) were likely to be chronically infected with HCV.[3] Assuming that 40% of chronically infected patients (ie, the proportion who were in custody for ≥ 6 months) were possible candidates for assessment at the Hepatitis Service, about 20 944 individuals could have been referred. Thus, the 1043 individuals who attended the service represent about 5% of those notionally eligible, and the 185 who received treatment represent about 0.9% of those notionally eligible. These biases are likely to include a lack of awareness of the service among both inmates and health care providers in the early years; and reluctance of those with chronic hepatitis C to undergo an arduous treatment with significant adverse effects. In addition, as the rates of current psychiatric diagnoses were lower in those attending the service (60/371; 16%) than are reported for the prison population as a whole,[7] it is likely there was also a bias against referral of inmates with current psychiatric diagnoses.

Also, although information regarding the current injecting behaviour of those attending the service was not available, it is highly likely that active IDUs were less likely to be referred. In contrast, no underrepresentation of minority groups, including Indigenous Australians and individuals of culturally and linguistically diverse backgrounds, was apparent, as representation of these groups closely matched the prison population as a whole.[7] Furthermore, women constituted 18% of attendees, although women represent only 7% of the inmate population, which is likely to reflect the significantly higher prevalence of HCV in female inmates.[7]

In the case–control patient comparison in our study, no substantive differences in clinical or demographic characteristics were detected between treated and untreated patients, with the exception that HBV co-infection was more prevalent in those who were not treated. Not unsurprisingly, the proportion of the untreated group who had a liver biopsy performed was lower than for the treated group, as biopsy was stipulated by the s100 scheme for the provision of antiviral therapy throughout the study period. The majority of biopsy results identified early stage disease; this is consistent with the mean age being 34 years and the most common likely mode of acquiring HCV infection being intravenous drug use (likely to have commenced in late teenage years), indicating an estimated mean duration of HCV infection of about 15 years. These data are consistent with disease progression estimates which suggest that 4%–22% of patients will develop cirrhosis over 20 years.[3] There was also a trend for those treated to be more likely to be receiving methadone, consistent with the eligibility requirements of the s100 scheme, which stipulated exclusion of active IDUs until 2001.

Clinical trials of antiviral therapy which have specifically focused on treatment of current or recent IDUs suggest outcomes comparable to the general community.[26] The 44% SVR reported here in those with complete follow-up data (and 28% on an intention-to-treat analysis) is consistent with the community standard. This outcome is somewhat lower than in previous international reports of the prison setting, which have recorded SVR rates of 28%–44% on intention-to-treat analyses.[14,15,19] The key issue highlighted by these retrospective studies is the need for systematic and prospective follow-up. In particular, the residual concern about the incidence of re-infection in this high-risk population, which may undermine the argument for treatment, needs to be addressed.

In conclusion, prison inmates who attended hepatitis clinics during the study period — as well as those who received treatment — were representative of the prison inmate population, including minority groups. However, these individuals constituted a very small proportion of inmates with chronic hepatitis C. Treatment outcomes, including virological response and adverse event rates, were comparable to those achieved in community settings. We therefore argue that hepatitis assessment and treatment services in the prison setting are both feasible and worthwhile.

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COMPETING INTERESTS

None identified.

AUTHOR DETAILS

Leng Boonwaat, RN, MPH, Clinical Nurse Consultant and Manager[1]
Paul S Haber, BSc, MD, FRACP, Gastroenterologist and Director,[2] and Visiting Medical Officer[3]
Michael H Levy, MB BS, MPH, FAFPHM, Public Health Physician and Director[4]

Andrew R Lloyd, MB BS, MD, FRACP, Infectious Diseases Physician and Director,[5] and Visiting Medical Officer [3]

1 Blood Borne Viruses and Sexual Assault Services, Population Health, Justice Health, Sydney, NSW.
2 Drug Health Services, Royal Prince Alfred Hospital, Sydney, NSW.
3 Hepatitis Service, Justice Health, New South Wales Department of Health, Sydney, NSW.
4 Corrections Health, Canberra, ACT.
5 Centre for Infection and Inflammation Research, School of Medical Sciences, University of New South Wales, Sydney, NSW.

Correspondence: a.lloyd@unsw.edu.au

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