MAJOR ARTICLE

Safety and Effectiveness of a Nurse-Led Outreach Program for Assessment and Treatment of Chronic Hepatitis C in the Custodial Setting

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Background. The global burden of disease attributable to chronic hepatitis C virus (HCV) is very large, yet the uptake of curative antiviral therapies remains very low, reflecting the marginalized patient population and the arduous nature of current treatments.

Methods. The safety and effectiveness of a nurse-led model of care of inmates with chronic HCV was evaluated in 3 Australian correctional centers. The model featured protocol-driven assessment, triage, and management of antiviral therapy by specifically trained nurses, with specialist physician support utilizing telemedicine. Outcomes were evaluated qualitatively with key informant interviews, and quantitatively with patient numbers completing key clinical milestones and adverse events.

Results. A total of 391 patients with chronic HCV infection were enrolled, of whom 141 (36%) completed the clinical and laboratory evaluations for eligibility for antiviral therapy over 24 months. Treatment was initiated in 108 patients (28%), including 85 (79%) triaged for specialist review conducted by telemedicine only. The demographic and clinical characteristics of the patients who entered the model and completed workup and those who initiated treatment featured a high prevalence of individuals of indigenous background, injection drug users, and those with psychiatric disorder. Serious adverse events occurred in 13 of 108 treated patients (12%) with discontinuation in 8 (7%). The sustained virologic response rate among those with complete follow-up data (n = 68) was 69%, and by intention-to treat analysis was 44%.

Conclusions. This nurse-led and specialist-supported assessment and treatment model for inmates with chronic HCV offers potential to substantively increase treatment uptake and reduce the burden of disease.

Keywords. hepatitis C; treatment; correctional centers; nursing; telemedicine.

It is estimated that 170 million people worldwide are infected with the hepatitis C virus (HCV) [1]. The dominant mode of HCV transmission is via parenteral exposure to infected blood, with most cases in the Western world documented in injection drug users (IDUs) [2–4]. Following primary HCV infection, persistent viremia and chronic hepatitis occur in 50%–80% of patients [5]. Chronic infection is associated with a steadily increasing risk of cirrhosis, liver failure, and hepatocellular carcinoma [6]. It is these late-stage complications that confer the major morbidity, mortality, and economic impact [7]. Until recently, the standard of care in treatment for chronic HCV with pegylated interferon-α and ribavirin for 24–48 weeks

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offered a 40%–80% sustained virologic response (SVR) rate, according to viral genotype [8]. This response provides long-term viral eradication, reduced risk of liver failure, and improved survival [9]; therefore, treatment is cost-effective [7, 10]. In addition, modeling data suggest that despite concerns of reinfection, even modest treatment rates among active IDUs could effectively reduce transmission. These benefits are likely to be amplified with the advent of direct-acting antivirals, which offer significantly higher cure rates [11].

Very close relationships exist between illicit drug use, HCV infection, and incarceration. IDUs have high rates of incarceration, predominantly because of the illegal nature of drug use and the imperative to fund drug dependence through crime. Almost half of Australian inmates report a lifetime history of injection drug use, and more than half are incarcerated for drug-related crimes [12], with similar rates in the United States [13]. Given this nexus, HCV infection is very common among Australian inmates, with an overall prevalence of 30% and up to 80% among IDUs [14], with comparable rates in the United States and United Kingdom [15–17].

Establishing effective disease prevention and treatment programs in the custodial setting is challenging, as correctional centers are unique in physical structure and inmates form a distinct microsociety with their own rules and regulations [18]. The environment features overcrowding, exposure to violence and illicit drugs, lack of purposeful activity, separation from family networks, and emotional deprivation [18]. By contrast, for some inmates with chaotic lifestyles, incarceration provides a unique opportunity for therapeutic intervention owing to the relative stability with housing, diet, and access to healthcare. However, antiviral treatment for chronic HCV in the custodial population is complex as inmates also have high rates of comorbidities that affect treatment, including psychiatric disorders and ongoing substance abuse [15, 16]. Furthermore, the logistic challenges are substantial, as security rather than healthcare is paramount, and most inmates are incarcerated for months only and are transferred frequently between centers [15, 16].

Nevertheless, successful delivery of HCV treatment has been established in several custodial jurisdictions worldwide, with outcomes equivalent to those in community settings [17, 19–28]. However, these reports all describe retrospective reviews of physician-led clinics, with assessment and treatment often completed via transfer of inmates to hospital centers. We recently reported successful outcomes of such a service in New South Wales, Australia [27]. However, we estimated that <1% of those potentially eligible actually received treatment.

Accordingly, many questions remain, including the indications, contraindications, and appropriate models of care [15, 16]. This report describes investigation of the effectiveness and safety of a nurse-led model of care for inmates with chronic HCV in 3 Australian correctional centers. The model featured protocol-driven assessment and management of antiviral therapy by trained nurses, with arm's-length involvement of specialist physicians utilizing telemedicine.

METHODS

Protocol and Training

A protocol was developed by experienced nursing staff, specialist physicians, and administrators, including detailed guidelines and proformas for clinical and laboratory assessments, and for management of antiviral therapy. Paper-based case records were developed to capture the clinical assessments, and treatment-related adverse events were categorized according to standard toxicity grading scales [29]. The outcomes of the clinical pathway through treatment and follow-up, including dates and reasons for discontinuation, were recorded. The protocol was approved by the institutional review boards of Justice Health and Corrective Services.

Three nurses with substantial experience in clinical support for the existing Hepatitis Service were appointed to fractional positions (each 0.6 full-time equivalent) at the clinical nurse consultant level (described as "a registered nurse … who has at least 5 years of full-time equivalent post registration experience and in addition who has approved postregistration nursing qualifications" [30]) in 1 metropolitan and 2 rural correctional centers. These nurses completed a 2-day HCV-focused training program, including structured coursework and assessment, and 3 half-day sessions of practical training with the specialists focused on recognition of clinical signs and interpretation of laboratory tests.

Setting

During the project (2009–2010), there were approximately annual 15 000 receptions, and 10 000 inmates at any time in full-time custody (92.5% male; 25% on remand [ie, unsentenced]) in 34 correctional centers across the state. There were approximately 150 000 movements of these inmates between centers annually. Approximately 50% of inmates were incarcerated for <2 years, including 30% who stayed <6 months. The prevalence of HCV antibody positivity in male inmates in 2009 was 28% [31].

Three centers were selected: Long Bay in metropolitan Sydney, which housed 679 maximum-security male inmates and was attended by the 2 specialist physicians (A.R.L., J.J.P.); and 2 rural facilities: Goulburn Correctional Centre, which housed 542 male inmates (424 maximum security, 118 minimum security), and Lithgow Correctional Centre, which housed 318 maximum-security male inmates [32].

Clinical Pathway

Enrolments included consecutive patients who were receiving posttest counseling after a diagnosis of chronic HCV. Those who were willing undertook further nurse-initiated investigations with a view to antiviral treatment, including screening for human immunodeficiency virus and hepatitis B virus infections; assessment of hepatic synthetic function with liver function tests, platelet count, and prothrombin time; HCV genotype and viral load; and testing for other causes of liver disease via antinuclear and anti–smooth muscle antibody screening, as well as iron and copper studies. An upper abdominal ultrasound was arranged. The nurses then undertook a structured, hepatitis- and injection drug use–focused history and physical examination, followed by further investigations if necessary, such as a fasting blood sugar level if diabetes mellitus was suspected. A conservative designation of likely advanced liver disease was made by the nurses if any of the following were detected: thrombocytopenia, hypoalbuminemia, coagulopathy, clinical signs of liver failure (eg, ascites), or splenomegaly on ultrasound examination.

Following these assessments, the nurse independently triaged each patient in relation to comorbidities, motivation, and psychosocial supports, as well as the likely the risk of adverse events on treatment (Supplementary Data): category A: suitable for treatment after discussion between the specialist physician and nurse only; category B: suitable for treatment, but a teleconference with the specialist physician required; or category C: needing face-to-face assessment by the specialist physician before the decision to treat could be resolved.

After treatment prescription by the specialist, patients were commenced on antiviral therapy by the nurses, including protocol-driven patient education, clinical follow-up, and laboratory monitoring for the 24 or 48 weeks of treatment, and 24 weeks of follow-up to designate SVR. Adverse events were monitored by the nurses who sought specialist input via teleconference if severe (ie, category 3 or 4 indicating a "marked or extreme limitation in function, medical intervention/therapy required").

Evaluation

Qualitative data were sought after 12 months via semistructured interviews conducted among (1) a selection of relevant staff (n = 20 from each of the 3 correctional centers), including primary healthcare medical and nursing staff as well as custodial staff; and (2) a consecutive series of patients (n = 10 newly enrolled inmates in each of the 3 centers). The interview covered knowledge of HCV and its treatment; attitudes to treatment for chronic HCV; and awareness of, and attitudes toward, the Hepatitis Service. Responses were recorded manually prior to thematic analysis of the dataset by all members of the research team.

Quantitative data included recording of the numbers of enrollments, diagnostic workup completions, treatments initiated, posttreatment follow-ups completed, discontinuations and their reasons, and adverse events and their outcomes.

Statistical Analysis

Descriptive statistics were applied to the demographic and clinical datasets. Rates of SVR were calculated for those with complete data to 6 months of follow-up, including discontinuations due to nonresponse or adverse events; and for the intention-to treat group (ie, all patients who commenced treatment). Logistic regression analysis was used to examine factors associated with treatment initiation (SPPS version 18.0).

RESULTS

Patients

Over 24 months, 391 consecutive patients were enrolled, including 385 men (98%) and 6 women (2%), enrolled via Long Bay (n = 256 [66%]), Lithgow (n = 53 [14%]), and Goulburn (n = 79 [20%]) Correctional Centers. These prisons are male custodial centers; hence, the females enrolled were referrals from women's centers for specialized medical assessment in relation to complex comorbidities. The mean age was 35 years (SD, 8.5 years). The ethnic background was diverse with 64% white, 23% indigenous descent (Aboriginal or Torres Strait Islander), and 13% of other culturally and linguistically diverse backgrounds.

The number of patients who completed the key milestones in the clinical pathway and the reasons for discontinuation are summarized in Figure 1. After enrollment, there was a generally high level of retention, with discontinuations before treatment (n = 254 [65%]) being largely attributable to those released to freedom (n = 95 [24%]) and those not interested in treatment (n = 89 [23%]). At study closure, 44 patients (11%) were still in progress toward initiation, or completion of treatment and follow-up.

The timelines for completion of each clinical milestone varied widely with a mean of 58 days from enrollment to workup completion (95% confidence interval [CI], 44–72 days); a mean of 67 days from workup completion to specialist review (95% CI, 51–84 days); and a mean of 54 days from specialist review to treatment initiation (95% CI, 42–65 days).

Two hundred seventeen individuals completed the nurse-led assessments (Table 1). They were predominantly male (n = 215 [99%]), many with an indigenous background (n = 43 [20%]). As expected, the group reported very high rates of risk factors for HCV infection, including injection drug use as well as tattooing in prison. The group also featured high rates of medical comorbidities associated with accelerated liver disease,

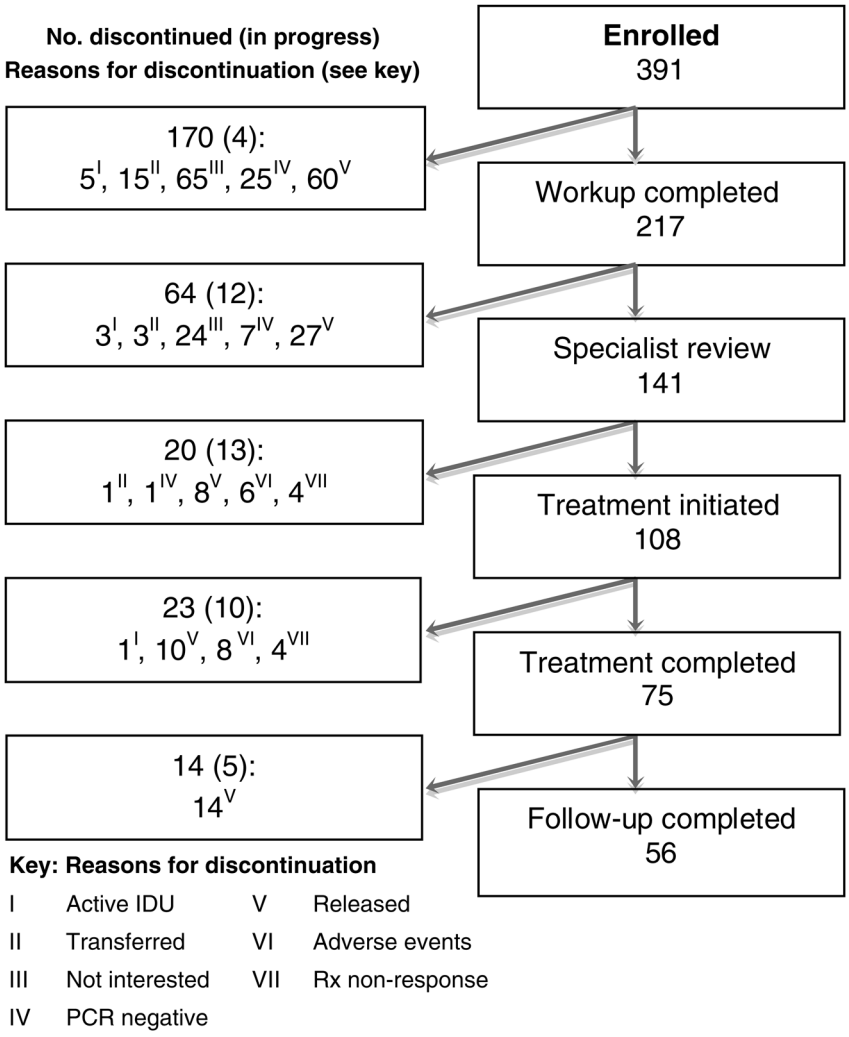

Figure 1. Number of patients who completed each milestone in the clinical pathway and reasons for discontinuation. Abbreviations: IDU, injection drug user; PCR, polymerase chain reaction; Rx, antiviral treatment.

such as alcohol abuse in 62 (29%); and psychiatric comorbidities that complicate antiviral treatment, such as a history of mood disorder or psychosis in 135 (62%) and current mood disorder or psychosis in 38 (18%). Of these individuals, the nurses triaged 70 (32%) as category A; 101 (47%) as category B; and 31 (14%) as category C; 15 (7%) had no status recorded.

Of the 217 individuals who completed workup, 141 also completed the specialist physician review, which resulted in the recommendation for antiviral treatment in 108 (77%; including 47 of 53 in category A [87%], 48 of 69 in category B [70%], and 13 of 19 in category C [68%]); deferral was pending further investigation in 25 (12%; including 5/53 [9%], 15/69 [22%], and 5/19 [26%] in categories A, B, and C, respectively) and 9 (7%; including 1/53 [2%], 6/69 [95], and 2/19 [11%] in categories A, B, and C, respectively) who were deemed not suitable as they were scheduled for release or were no longer interested in treatment. Of 25 patients who were initially deferred, 24 were subsequently rereviewed, and 14 were recommended for treatment.

Antiviral Treatment

The 108 patients who commenced treatment (28% of the total) included 107 men with a mean age of 35 years (SD, 8.0 years), and 23 (21%) of indigenous background. These patients had been triaged as (1) category A (n = 47) and were largely free of comorbidities, although 7 were current IDUs and 3 had current major depression; (2) category B (n = 48), of whom 7 had histories of autoimmune disorder including thyroid disease (n = 1), psoriasis (n = 4), and diabetes mellitus (n = 2), 5 reported ongoing injection drug use, and 12 reported current major depression; and (3) category C (n = 13), who all had advanced liver disease and of whom 2 also had

Table 1. Demographic and Clinical Characteristics of the Patients Who Completed Assessments for Treatment (N = 217)

Variable	No. (%)[a]
Age, y, median (SD)	36 (8)
Male sex	215 (99)
Born in Australia	184 (85)
Aboriginal or Torres Strait Islander	43 (20)
Remand	37 (17)
Risk factors for hepatitis C virus infection	
Lifetime injection drug use	186 (86)
Lifetime tattooing	187 (86)
Current injection drug use	177 (82)
Current methadone/buprenorphine	84 (39)
Comorbidities	
History of excessive daily alcohol use	61 (28)
History of excessive binge alcohol use	62 (29)
History of major depression	103 (47)
History of anxiety disorder	43 (20)
History of psychosis	81 (37)
Current mood disorder or psychosis	38 (18)

Abbreviation: SD, standard deviation.

[a] Percentages vary slightly with missing data (10% or less only).

Table 2. Adverse Events Recorded Among 108 Patients Receiving Antiviral Therapy

Variable	Grade 1	Grade 2	Grade 3	Grade 4	Total
Constitutional symptoms	154	131	7	0	292
Psychiatric disturbance	98	85	8	0	191
Gastrointestinal symptoms	43	12	0	0	55
Respiratory symptoms	4	4	3	0	11
Local reaction at injection site	9	2	0	0	11
Cardiovascular symptoms	4	0	0	0	4
Hematological disturbance	160	44	52	4	260
Thyroid function disturbance	8	0	0	0	8
Liver function disturbance	23	11	2	0	36

All data are numbers of events.

autoimmune disease (psoriasis, n = 1; diabetes, n = 1), 5 had current major depression, and 3 had current schizophrenia. Forty-two (39%) patients were receiving opiate pharmacotherapy. The HCV genotypes included 58 with 1a or 1b; 43 with 3; and 7 with other genotypes (2, 6, and indeterminate). None of these demographic or clinical factors were associated with initiation of treatment in logistic regression analysis.

Of those who commenced treatment (n = 108), 8 subsequently discontinued due to adverse effects; 4 were discontinued due to nonresponse (ie, persistent viremia at 12 weeks); 34 remained on treatment or in follow-up; and 14 were released to freedom before treatment was completed. Fifty-six patients had posttreatment outcomes recorded: 47 had an SVR, and 9 were aviremic at the end of treatment but viremic at 6 months' follow-up; an additional 14 had been released, and 5 remained in follow-up at study closure. These data indicate an SVR rate among those with complete follow-up data of 69% (denominator = 68, including discontinuations); and an intention-to treat response rate of 44%.

There were 868 adverse events recorded in 91 treated patients (84%), consistent with the frequent side effects of this therapy (Table 2). The most common were constitutional symptoms (headaches, fatigue, sleep disturbance, and rash), all of mild or moderate severity only. Psychiatric complaints (irritability, depression, anxiety) were also very common and were predominantly mild to moderate in severity. The 8 episodes of grade 3 psychiatric disturbance (all major depression) were managed without treatment interruption. Eight patients developed thyroid function disturbances, which were managed symptomatically. The most significant laboratory-confirmed adverse events (n = 260) were hematologic, particularly anemia and thrombocytopenia. Of these, 52 (6%) were grade 3 events, and 4 were grade 4 events. These serious adverse events occurred in a total of 13 patients, resulting in treatment discontinuation in 8 (7%) after telemedicine consultations with the specialist physician.

Qualitative Evaluation

Two key outcomes were identified. First, areas of limitations in knowledge among the stakeholders were identified as barriers to the service. For example, custodial officers generally expressed support for the service but were largely ignorant of chronic HCV, its sequelae, and treatment effectiveness, and many general nurses were unfamiliar with the side effects of treatment and their management. The inmates were uniformly supportive of the service and opportunities for access to care, but anxious about coping with the adverse effects of treatment while in custody. Second, organizational barriers to implementation of the model were identified, including the need for better delineation of the roles of general nurses in hepatitis care (eg, administration of antipyretics for fever), and difficulties regarding access to inmates to provide treatment due to custodial priorities.

On the basis of these data, targeted education programs for inmates, primary care nurses, and custodial staff were developed, and Justice Health agreed to better delineate the role(s) of general nurses in hepatitis care.

DISCUSSION

These data illustrate the feasibility, efficacy, and safety of nurse-led and specialist-supported assessment and treatment

of inmates with chronic HCV utilizing telemedicine. This is the first prospective evaluation of a treatment program for chronic HCV in the correctional environment. The program is novel in that program the majority of patients underwent assessment and treatment without face-to-face interaction with a specialist physician. Given the high prevalence of chronic HCV in custodial settings and the turnover of prisoners back into the community, the successful outcomes argue for infrastructure investment in such programs to improve the low treatment rates in many developed countries [33–35].

A growing evidence base suggests that antiviral treatment for chronic HCV can be provided in primary care. The recent report from the Extension for Community HealthCare Outcomes (ECHO) project utilized video-teleconferencing to link specialists with primary care providers for training, and to facilitate treatment [36]. The 21 primary care sites included 5 prisons, and reported comparable outcomes when compared to tertiary care. No details of the number, characteristics, or outcomes of the patients from the prison sites were provided. Similarly, a Canadian report of a model based on a public health nurse and physician partnership in rural and small urban centers reported outcomes comparable to community standards [37]. In combination with the data reported here, it is evident that after suitable training and with specialist support, skilled nurses can safely and effectively undertake independent assessment and treatment of inmates with chronic HCV. Indeed, the key informant interviews demonstrated clear support for this model of care from both patients and healthcare providers.

The triage process described here designated approximately one-third of patients as suitable for treatment with only a case discussion between the nurse and specialist, and another half who were found to be suitable after a teleconference between the specialist and patient. Provision of treatment after these evaluations was associated with the typical high prevalence of minor adverse events and a low frequency of serious adverse events and treatment discontinuations. These rates are comparable to those reported in the ECHO study [36].

We previously reported in a retrospective analysis that there were no demographic or clinical features associated with noncommencement of antiviral treatment in Australian correctional centers [27]; this was confirmed in the current study. Community-based studies in settings of universal healthcare have identified current drug and alcohol use as the major factors predicting treatment deferral [38, 39]. Given the stable environment and the fact that alcohol use is not pertinent in custody, this suggests that treatment opportunities are likely to be greater during incarceration.

In the dataset reported here, almost 1 in 3 of those enrolled commenced treatment. This rate is consistent with the wide range (1%–48%) reported in community-based clinics [38–41], reflecting differences in patient-, provider- and systems-level barriers to uptake. As almost a quarter of the subjects enrolled in the present study discontinued prior to treatment, it would be reasonable to consider limiting inclusion to those likely to remain incarcerated for at least 6 months (which was the mean interval from enrollment to commencement of treatment). In addition, establishment of better infrastructure to ensure continuity of care in those released to freedom remains a priority, as a significant minority of participants were lost to follow-up upon release.

Given the emerging prospects for shorter duration and more effective therapies for chronic HCV, this model of care has the potential to markedly increase the scope and uptake of treatment in the correctional setting, and thus impact on the future burden of disease in the community at large.

Supplementary Data

Supplementary materials are available at *Clinical Infectious Diseases* online (http://cid.oxfordjournals.org/). Supplementary materials consist of data provided by the author that are published to benefit the reader. The posted materials are not copyedited. The contents of all supplementary data are the sole responsibility of the authors. Questions or messages regarding errors should be addressed to the author.

Notes

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