

A survey of hepatitis C management by Victorian GPs after PBS-listing of direct-acting antiviral therapy

Amanda Wade, Bridget Draper, Joseph Doyle, Nicole Allard, Paul Grinzi, Alexander Thompson, Margaret Hellard

Background and objective

To increase access to hepatitis C virus (HCV) treatment, the Pharmaceutical Benefits Scheme (PBS) enabled general practitioners (GPs) to prescribe direct-acting antiviral (DAA) therapy. We conducted a survey to identify GPs' knowledge and management of HCV.

Methods

A questionnaire consisting of 20 items about HCV knowledge and management was sent to 1000 GPs.

Results

One hundred and ninety-one GPs (19.1%) responded; 74% answered correctly that antibody and RNA positivity is diagnostic of HCV. Only 12% could directly request transient elastography. Although 53% of respondents reported interest in prescribing DAAs, 72% continued to refer all patients to specialists. Fifty-five per cent were unsure if people who currently inject drugs were eligible for treatment.

Discussion

Most respondents were interested in prescribing DAAs, but education, access to transient elastography and clear consultation pathways are required to translate this interest into increased treatment availability. PBS eligibility of current injectors needs promotion.

Approximately 230,000 Australians are infected with the hepatitis C virus (HCV) but prior to 2016, less than 2% were treated and cured annually.^{1,2} Barriers to HCV treatment included prolonged and poorly tolerated pegylated interferon (PEG)-based treatment regimens, difficulty in accessing care from specialists, stigma experienced in healthcare services, and historical practices of excluding people who inject drugs from treatment.³⁻⁵ The availability of direct-acting antiviral (DAA) therapy for HCV infection has revolutionised the treatment landscape. DAA therapy is highly efficacious, well tolerated and usually involves taking a course of tablets for 12 or 24 weeks.⁶ DAA therapy can be provided by a variety of healthcare professionals to increase access to care.

On the 1 March 2016, the Australian government made the landmark decision to fund DAAs for every Australian infected with HCV via the Pharmaceutical Benefits Scheme (PBS).⁶ Broad treatment and healthcare access mean that Australia could reduce HCV transmission, prevent HCV-related deaths and eliminate HCV as a public health threat by 2030. Gastroenterologists, hepatologists and infectious diseases physicians experienced in the treatment of chronic HCV infection are eligible to directly prescribe DAA treatment, as with earlier PEG-based containing regimens.⁷ However, in order to increase access to DAAs, a novel new system of prescribing was developed,

whereby all medical practitioners, including general practitioners (GPs), were eligible to prescribe DAAs 'in consultation' with one of the aforementioned specialists. In October 2016, the prescribing criteria were adjusted so that consultation with a specialist was not required for GPs experienced in the treatment of chronic HCV infection. To date there has been no formal PBS definition of 'experienced in the treatment of chronic HCV infection'.

The PBS 'in-consultation' process required the prescribing medical practitioner to consult with a specialist; the patient did not have to attend a specialist appointment. Consultation was defined broadly to include telephone, mail, email or videoconference interaction prior to prescribing. To assist in establishing these novel treatment pathways, the Australian Liver Association developed a referral form for GPs to complete and send to specialists (Appendix 1; available online only). However, the HCV treatment pathway has since evolved in an ad hoc fashion, and the form has been modified by various institutions so that currently no universal consultation form or pathway exists.

The optimal model of care for community-based HCV DAA treatment in Australia is yet to be determined. PEG-based HCV treatment in the community has previously been shown to be as effective as treatment in tertiary services,⁸ and recent data from the US

suggest primary care physician prescription of DAA is highly effective.⁹ In Australia, research has shown that GPs have variable knowledge about HCV diagnostics^{10,11} and variable interest in prescribing PEG-based HCV treatment.¹² Liver stiffness measurement via transient elastography (eg FibroScan, Echosens), a tool routinely used by specialists to assess hepatic fibrosis, is not widely available to GPs. Given these barriers, and the rapid change in clinical practice, we conducted a survey to determine the willingness of Victorian GPs to prescribe DAA, and the structural barriers to DAA prescription. The primary objective

was to inform the development of tools to support GP DAA prescribers.

Methods

We surveyed GPs using a questionnaire (Appendix 2; available online only) developed by a steering committee that included two GPs, three infectious diseases physicians and a hepatologist.

The questionnaire consisted of 20 items regarding HCV knowledge and management, and interest in prescribing DAAs. Degree of interest in prescribing DAAs was assessed using a five-point Likert scale.

Factors potentially associated with participants' knowledge of HCV and prescription of DAAs, were determined from the literature and included geographic location, specialised opioid agonist therapy training, and HCV caseload.^{13,14} There is no agreed stratification for HCV patient caseload, but extrapolating from human immunodeficiency virus (HIV) care, low caseload was defined as fewer than 10 patients with HCV, and high caseload as 10 or more patients with HCV.^{15,16} Participants were asked to characterise their general practice clinics as private or community, and as metropolitan, regional or rural.

Table 1. Demographic characteristics of study participants

Variable (number of available data)	n (total = 191)	Proportion (%)
Age, median (IQR) (n = 188)		52 years (42, 61)
Male (n = 190)	105	56
Type of general practice (n = 187)		
Private	173	93
Community clinic	10	5
Other	4	2
Location (n = 191)		
Metropolitan	120	63
Regional	27	14
Rural	44	23
Co-location with specialised services (n=191)		
NSEP	6	3
Opioid agonist therapy prescriber	8	4
Opioid agonist therapy prescriber and community hepatitis nurse	1	0.5
NSEP, opiate agonist therapy prescriber and community hepatitis nurse	2	1
NSEP and opioid agonist therapy prescriber	2	1
Correctional facility	4	2
Nil	168	88
Previous highly specialised drug program (S100) training (n=190)		
Opioid agonist therapy training	30	16
No prior opioid agonist therapy training	160	84
Estimated number of patients with known HCV infection (n = 190)		
<10	148	78
10–50	29	15
5–100	2	1
>100	3	2
Unsure	8	4

HBV, hepatitis B virus; HCV, hepatitis C virus; HIV, human immunodeficiency virus; IQR, interquartile range; NSEP, needle syringe exchange program

All GPs practising in Victoria were eligible to participate. The questionnaire was posted to a random selection of 1000 Victorian GPs of 7072 listed in the Australasian Medical Publishing Company database, six weeks after community prescribing was introduced (mid-April 2016). GPs were given the option of completing the questionnaire online or on paper and returning it via a pre-paid envelope. GPs who did not respond at four

and eight weeks following the initial mail out were sent reminder letters.

Returned questionnaires were entered into REDCap software 6.12.0 (2016) and analysed with Stata13.1 (Statacorp). Descriptive statistics were used to report participant characteristics, HCV knowledge and HCV management. Logistic regression analyses were undertaken to investigate factors associated with participants'

knowledge of eligibility for DAA of people who inject drugs, and use of consultation pathways to prescribe DAAs.^{13,14,17} P values of <0.05 were regarded as statistically significant, and 95% confidence intervals (CI) were reported. The multivariate model for factors predictive of participants' HCV knowledge and management included age, gender, practice location, opioid substitution therapy training and HCV caseload.

Table 2. Summary of respondents knowledge of HCV

Variable (number of available data)	n	Proportion (%)
Correct HCV risk factor identification (n = 190):		
• Unsterile tattooing or body piercing	179	94
• Injecting drug use	190	100
• History of imprisonment	170	89
• Unprotected heterosexual intercourse, not a risk factor for HCV	111	58
• Unprotected male–male sexual intercourse without HIV, not a risk factor for HCV	45	24
• Unprotected male–male sexual intercourse, if infected with HIV, is a risk factor for HCV	170	89
Correctly identified hepatitis C serology as the screening test for HCV (n = 189)	184	97
Correctly identified HCV antibody positivity and RNA positivity as diagnostic of current infection (n = 188)	139	74
Correctly identified that BMI, fasting status and ALT could confound transient elastography results	1	0.5

ALT, alanine aminotransferase; BMI, body mass index; HCV, hepatitis C virus; HIV, human immunodeficiency virus

Table 3. Regression analyses comparing general practitioners' knowledge of HCV

Characteristic	Unaware PWID eligible, No (n = 117)	Aware PWID eligible, No (n = 68)	OR (95%CI)	P value	AOR (95%CI)	P value
Age						
≤40 years	26	15	1.0			
>40 years	88	53	1.0 (0.5, 2.1)	0.91	1.1 (0.5, 2.3)	0.87
Gender						
Male	68	34	1.0			
Female	48	34	1.42 (0.7, 2.6)	0.26	2.1 (1.0, 4.0)	0.04
Location						
Metropolitan	74	42	1.0			
Rural/regional	43	26	1.06 (0.6, 1.9)	0.84	1.19 (0.6, 2.3)	0.61
OST training						
No	102	52	1.0			
Yes	14	16	2.24 (1.0, 4.9)	0.05	1.78 (0.8, 4.2)	0.19
Caseload						
Low	104	46	1.0			
High	12	22	4.14 (1.9, 9.1)	<0.001	4.53 (1.9, 10.1)	0.001

AOR, adjusted odds ratio; HCV, hepatitis C virus; OST, opioid substitution therapy; PWID person who injects drugs

Human research ethics approval was granted by The Alfred Human Research Ethics Committee (reference number 134/16).

Results

Completed questionnaires were returned by 191 of 1000 GPs (19.1%). Eighty-five GPs returned the survey after the initial mail out, and 106 after reminder letters. Characteristics of the study participants are summarised in Table 1. Almost all participants worked in private general practice; nearly two-thirds were located in a metropolitan area; most reported no prior opioid agonist therapy training; and most reported managing fewer than 10 patients with HCV infection.

Data regarding HCV knowledge are summarised in Table 2. Almost all participants correctly identified all of the following risk factors as reasons to screen for HCV: a history of unsterile tattooing or body piercing, injecting drug use or imprisonment. However, many respondents overestimated the risk of acquiring HCV

sexually, and would screen individuals not considered at risk in current guidelines.¹⁸ Twenty-four participants (13%) correctly identified all risk factors that should prompt screening.

Almost all participants reported that they would order an anti-HCV antibody test to screen for HCV, and most correctly identified that positive anti-HCV antibody and RNA tests are diagnostic of current infection. However, 26 participants (14%) incorrectly identified anti-HCV antibody positivity alone as diagnostic of current infection. Of the 22 respondents (12%) who reported being able to directly order transient elastography through their local liver clinic, all had done so. Two-thirds reported being unsure of which factors confounded transient elastography results.

One hundred and two respondents (53%) indicated interest in prescribing DAAs, but 135 (72%) of 187 GPs reported they currently refer all their patients to a specialised service. One hundred and forty respondents (73%) were interested in reading guidelines from a peak body, 135

(70%) were interested in attending DAA education sessions, and 98 (51%) were interested in a DAA training program. Since 1 March 2016, 40 (21%) of the 191 GP respondents had tried to access specialists to gain approval to prescribe DAAs. Of these 40 GPs, 21 (52%) agreed there was a defined local consultation pathway, 22 (55%) thought the process was timely, 24 (60%) had found the consultation process satisfactory, and 25 (62%) believed clinical decision-making support was available.

One hundred and one (55%) of 185 respondents were unsure if people who inject drugs were eligible to receive DAA treatment, 14 (8%) thought they were ineligible and 68 (37%) thought DAA treatment decisions for people who inject drugs should be based on individualised evaluation.

Regression analyses are summarised in Tables 3 and 4. Univariate regression analysis showed that GPs who had undertaken specialised opioid agonist therapy training were more likely to have accessed specialists to gain approval to

Table 4. Regression analyses comparing general practitioners' management of HCV

Characteristic	Have not prescribed DAA, No (n = 150)	Accessed approval to prescribe DAA, No (n = 40)	OR (95% CI)	P value	AOR (95% CI)	P value
Age						
≤40 years	28	13	1.0			
>40 years	119	27	0.48 (0.2, 1.0)	0.07	0.47 (0.5, 2.2)	0.09
Gender						
Male	79	26	1.0			
Female	70	14	0.6 (0.3, 1.3)	0.18	0.95 (0.4, 2.1)	0.91
Location						
Metropolitan	95	24	1.0			
Rural/regional	55	16	1.15 (0.6, 2.4)	0.69	1.1 (0.5, 2.5)	0.78
OST training						
No	135	24	1.0			
Yes	15	15	5.6 (2.4, 12.9)	<0.001	3.9 (1.6, 9.8)	0.003
Caseload						
Low	132	23	1.0			
High	17	17	5.7 (2.6, 12.8)	<0.001	4.9 (2.0, 12.1)	<0.001

AOR, adjusted odds ratio; DAA, direct acting antiviral; HCV, hepatitis C virus; OR, odds ratio; OST, opioid substitution therapy; PWID, person who injects drugs

prescribe DAAs than GPs who had never undertaken such training, and this predictor remained significant in multivariate analysis after adjusting for age, gender and location (adjusted odds ratio [AOR]: 3.9; 95% CI: 1.6, 9.8; $P = 0.003$). Multivariate analyses also showed that GPs with a high caseload were more likely to report accessing specialists to gain approval to prescribe DAA (AOR: 4.9; 95% CI: 2.0, 12.1; $P < 0.001$) and know that people who inject drugs are eligible for DAAs (AOR: 4.53; 95% CI: 1.9, 10.1; $P = 0.001$) than those with a low caseload.

Discussion

In this study, most GP respondents reported an interest in prescribing DAAs for HCV and willingness to undertake educational activities to further their knowledge. Almost all respondents were aware of which test to use to screen for HCV. Seventy-four per cent of respondents correctly identified pathology results diagnostic of HCV infection, a higher proportion than reported in previous studies.^{10,11} However, 14% incorrectly identified anti-HCV antibody positivity alone as diagnostic of current infection, a misconception that could result in unnecessary DAA treatment or referral to specialist care. Most GPs do not have adequate access to transient elastography, which may be why 72% of participants continue to refer patients to specialist services for treatment.

Only 21% have used the 'in-consultation' process to prescribe DAAs; of the GPs who had used it, only 60% found the process satisfactory, demonstrating an opportunity for improvement. GPs with high HCV caseloads have the most knowledge of HCV and familiarity with prescribing, suggesting their patients will be offered DAA treatment. Conversely, our data suggest that GPs with low HCV caseloads could improve their understanding of HCV management and could benefit from the clinical support offered through the 'in-consultation' process, as a large cohort of people with chronic HCV infection is beginning to seek care for their HCV

infection, now that effective and well-tolerated treatment is available.¹⁹

Of concern is that over 60% of GPs were uncertain or did not think people who inject drugs were eligible for DAA treatment. In May 2016, the World Health Organization (WHO) announced global HCV elimination targets, aiming for an 80% reduction in new cases and 65% reduction in deaths by 2030.²⁰ In August 2016, the Victorian government announced an even more ambitious target of a 90% reduction in new cases.²¹ To achieve HCV elimination, it is critical to increase treatment uptake, especially among people who inject drugs.²⁰

In Melbourne, the annual HCV treatment rate in people who inject drugs prior to the introduction of DAAs was estimated to be three per 1000.²² Recent modelling data suggest that increasing treatment uptake to 59 per 1000 people who inject drugs annually could achieve the WHO incidence target.²³ For this to occur, treatment must be more accessible to people who inject drugs. Nurse-led HCV treatment in custodial settings has proven effective and DAAs are PBS-funded for Australian prisoners.²⁴ Previous studies have shown that people who inject drugs can be successfully treated in the community, and are more likely to undertake treatment if it is offered in the community instead of a tertiary hospital.^{17,25}

Australia is one of few countries in which HCV elimination is currently conceivable. In many countries, fibrosis stage and behaviour restrictions (such as injecting status) limit prescribing, whereas in Australia, DAAs have been funded for all people who are infected.^{26,27} Moreover, in contrast to other countries, the Australian government has negotiated a maximum cap on annual payment to pharmaceutical companies over the next five years, in exchange for providing DAAs, rather than a fixed payment per patient treated.²⁸ GP treatment of HCV with DAA should become the new norm, and the imminent availability of pangenotypic DAA regimens will further facilitate this. Specialist treatment should be reserved for people with cirrhosis or a second liver disease,

special populations (people with HIV or hepatitis B virus co-infection, renal failure or decompensated liver disease), or failure of first-line DAA therapy. Our findings support the development of working relationships between tertiary institutions, specialists and key community HCV care providers, with the view to developing user-friendly, 'in-consultation' pathways for GPs not experienced in the treatment of HCV, and improved access to transient elastography, to achieve treatment targets.

Our study has limitations. Our response rate of 19.1% is low; however, the response rate in other published surveys of GPs regarding management of viral hepatitis varies from 11.6% to 44%.^{11,12} This reflects the difficulty in conducting healthcare surveys, which are critical in informing service delivery.^{29,30} Participant bias cannot be excluded and, if present, may overestimate the degree of interest in DAA prescribing and knowledge about HCV infection. This study was conducted shortly after the PBS-listing of DAAs, and many services were adapting to the change; financial issues for community pharmacies dispensing DAA have now been addressed; it is possible that further development of 'in-consultation' pathways has occurred in recent months. In addition, the PBS prescribing criteria changed some months after this survey was administered, to enable GPs experienced in the management of HCV to prescribe DAA independently. Repeated surveys over time will be useful in mapping changing familiarity with DAA treatment and assist in workforce training.

Conclusion

Shortly after the PBS-listing of DAAs, most GPs reported interest in prescribing, but education, access to transient elastography and clear 'in-consultation' pathways for GPs not experienced in the treatment of HCV, are required to translate this interest into increased HCV treatment accessibility. Given the dynamic nature of the HCV-prescribing environment, it is critical to collect ongoing data regarding GP engagement in HCV management,

and tailor engagement interventions accordingly. GP education on the importance of treating people who inject drugs is vital as treatment of this priority population has multiple benefits of curing their HCV infections, preventing end-stage liver disease and liver cancer, and reducing ongoing transmission. The elimination of HCV as a public health threat in Australia will not be achieved without GPs engaging in HCV management for all people with chronic infection, including people who inject drugs.

Authors

Amanda Wade MBBS, FRACP, PhD student, Centre for Population Health, Burnet Institute and School of Population Health and Preventive Medicine, Monash University, Melbourne, Vic. amanda.wade@burnet.edu.au

Bridget Draper BA (Hons), Research Assistant, Centre for Population Health, Burnet Institute

Joseph Doyle MBBS, FRACP, PhD, Co-Head, Viral Hepatitis Research Program, Burnet Institute; Consultant Physician, Department of Infectious Diseases, the Alfred and Monash University, Melbourne, Vic

Nicole Allard MBBS, FRACGP, PhD student, Department of Medicine, University of Melbourne and WHO Collaborating Centre for Viral Hepatitis, Doherty Institute, Vic

Paul Grinzi MBBS, FRACGP, MMed, Consultant General Practitioner, the Royal Australian College of General Practitioners, Melbourne, Vic

Alexander Thompson MBBS (Hons), FRACP, PhD, Director, Department of Gastroenterology, St Vincent's Hospital, Melbourne; Professor, Department of Medicine, University of Melbourne, Vic

Margaret Hellard MBBS, FRACP, PhD, Director, Centre for Population Health, Burnet Institute; Consultant Physician, Department of Infectious Diseases, the Alfred and Monash University, Vic

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