ORIGINAL ARTICLE



Identifying barriers to treatment of HCV in the primary care setting

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Abstract

Objective To identify practice, attitudes, and potential barriers to treatment of Hepatitis C to primary care practitioners. **Design** A postal survey of general practitioners in New Zealand.

Setting Nationwide postal survey to all general practitioners in New Zealand.

Participants All general practitioners in New Zealand identified by their association with Primary Health Organizations. **Main outcomes** Identification barriers to treatment of Hepatitis C amenable to intervention by general practitioners in New Zealand.

Results 3817 general practitioners surveyed. 925 (24.2%) surveys returned. 187 (21%) currently prescribe Hepatitis C medications. 620 (70%) indicated that no general practitioner in their practice had interest in managing Hepatitis C therapy. Hepatitis C training was associated with increased prescribing activity—29% in those with training versus 10% in those without training. Confidence levels in initiating or continuing Hepatitis C therapy significantly rose from 23.8 and 47.8 to 50.2 and 67.7, respectively, with training. Inadequate reimbursement (44%), too few Hepatitis C patients (40%), and caseload with other patients (40%) were the most frequently identified barriers to treatment. Difficulty in obtaining transient elastography (35%) prior to treatment, lack of training (32%), and the perception that Hepatitis C therapy should be done by a specialist (30%) were also frequently reported barriers. General practitioners consistently underestimated the prevalence of Hepatitis C in their practice by a factor of 4.3 to 13.6 (based on an estimated prevalence of 1.9%).

Conclusion Although the most frequently cited barrier to general practitioner treatment of HCV was reimbursement, this is entwined with other purported barriers such as complexity of the patients, time commitment, caseload, and need for expertise. A lack of awareness of the prevalence of Hepatitis C in the general population is an important barrier. A comprehensive strategy to address multiple barriers, improve treatment regimens, and increase awareness of HCV is needed for ultimate success in the eradication of HCV in New Zealand and worldwide.

Keywords HCV · Hepatitis C · Barriers · General practitioners · Treatment · Primary care

Background

The World Health Organization has set an ambitious goal to eliminate viral hepatitis as a major public health threat by 2030 [1]. Worldwide, the prevalence of Hepatitis C viral (HCV) infection is estimated to be 2.35% or 160 million

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people infected [2]. Another estimate in 2014 reported adult anti-HCV antibody prevalence to be 1.6% globally and 1.9% in New Zealand. In the United States alone, 2.7 million persons have chronic HCV infection [3]. Worldwide, approximately 399,000 people die each year due to HCV, predominately due to cirrhosis and hepatocellular carcinoma [1].

New direct-acting antiviral agents have revolutionized HCV therapy. Efficacies for sustained virologic response (SVR) of more than 90%, coupled with minimal side effects, have increased demand for therapy and for the first time offer a high likelihood to eradicate this disease [4]. However, there are an inadequate number of gastroenterologists/hepatologists and infectious disease specialists worldwide to treat the substantial number of persons with



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HCV, thus necessitating a large portion of the patients to receive their care in the primary care setting [3, 5, 6]. Patients that achieve SVR have a reduction in liver-related mortality to one approaching the general population [7–9]. All-cause mortality is also reduced with achievement of SVR [10]. Despite the prevalence of HCV and increasing efficacy of treatment, relatively few patients are receiving treatment [11].

Treatment of HCV with interferon/ribavirin-based therapy in New Zealand has historically been restricted to the domain of specialists (infectious disease, gastroenterology, or hepatology). Prescribing these medications required special authority only granted to these specialists and any manipulation of these medications by GPs was actively discouraged. In Australia in 2008, GPs operated under a shared care model, where they could continue HCV treatment initiated by a specialist or, with accreditation, initiate treatment themselves. A survey in Queensland of GPs in this environment found 42% of GPs had interest in prescribing interferon-based HCV therapy, 35% were willing to maintain treatment initiated by others, and only 7.2% were confident to initiate treatment. However, 53% of the respondents expressed an interest in education about HCV therapy [12].

Attitudes and confidence of general practitioners (GPs) in prescribing HCV therapy have also been studied. A Canadian study in 2006 found that over 63% of the surveyed GPs held the belief that HCV care was not part of their practice and provided no ongoing HCV care [13]. Another study found that GPs felt that inadequate time was available in their clinic visits to discuss treatment and preferred this to be done by gastroenterologists [14].

Given the high HCV burden and limited specialist services, it is necessary that general practitioners be at the forefront in treating this disease. Unfortunately, there appears to be minimal uptake for treatment of HCV by GPs.

This study seeks to identify potential barriers to HCV treatment by GPs. In addition, this study explores attitudes and possible demographic differences that may affect primary care providers' willingness to treat HCV.

Methods

An anonymous postal survey (Supplement 1) inquiring into the practice and attitudes regarding HCV treatment was mailed to all identified GPs in New Zealand. GP practices are organized among 32 Primary Health Organizations (PHOs) in New Zealand. Using the online database of membership maintained by each PHO, each practice was searched to obtain mailing addresses of the individual GPs. Surveys returned as undeliverable was re-sent after further investigation to obtain a current address.

The survey requires demographics and practice characteristics, estimated practice size and number of patients with HCV in the practice. Confidence level to initiate or maintain treatment of HCV was assessed by having the participant mark on a linear 0–100-point scale. TeleForm (OpenText Corp., Canada; version 11.2) was used to read the surveys, followed by a manual check.

Statistical analysis

Means, standard deviations, medians, and interquartile ranges (IQR), as appropriate, were calculated to describe the study sample. A Chi-square test for independence was used to determine if there was any association between having been offered and having completed HCV training, and if there was any association between HCV training and the state of HCV management. Spearman correlation was performed between confidence to initiate and maintain treatment and the number of years in practice, number of GPs and patients in each practice. p values ≤ 0.05 were considered significant. Missing responses were omitted from descriptive statistic calculations from each factor. Data analysis was performed using R statistical computing language [15].

Results

Study sample

3817 GPs were identified. For comparison, the Royal New Zealand College of General Practitioners reported 3791 fellows in 2017 [16], while the New Zealand Medical Council reported 3561 doctors specifically registered in general practice that hold both a vocational scope of general practice and a current practicing certificate. In total, there are 5003 doctors with a current practicing certificate who have reported to the Council they are working in general practice (A. Cullen, Senior Information Systems Analyst, New Zealand Medical Council, personal communication, 16 March 2018).

925 of the contacted GPs completed surveys that were returned and used for analysis giving an overall response rate of 24.2%. Seven surveys were returned as undeliverable after the second attempt and not analyzed. 22 were returned indicating the doctor was no longer in practice.

Practice characteristics

894 GPs had a median (IQR) practice length of 23 (14–30 years), with a range of 0–50 years. The majority (63.3%) of



the physicians were in a group size of five or more, 13.7% were in a group of four, 11.3% were in a group of three, 7.0% were in a group of two, and 4.8% had solo practice.

Estimated HCV prevalence

We calculated the predicted number of HCV patients in the GP practices based on their estimated practice size and the estimated HCV prevalence of 1.9% in New Zealand (Table 1). Majority of the GPs (37.0%) reported the estimated size of the practice as less than 5000.

Interest, activity, and education in prescribing HCV therapy

20.5% GPs reported that they are currently prescribing HCV medications. 70% indicated that no GP in their practice has interest in managing HCV therapy.

54% of respondents have completed HCV-related educational activities (Fig. 1). Completion of HCV training by District Health Board ranged from a low of 29% in Wairarapa to 100% in West Coast (n=4) with the remainder being 38–74%. 65% have been offered education on HCV. GPs who were offered HCV educational activities were more likely to have completed HCV training (p < 2.2e-16).

There was also strong evidence that GPs with HCV training had a higher interest in managing HCV—38% versus 20% in those without training (p = 9.459e-09). History of HCV training was also associated with higher HCV medication prescribing activity (p = 1.292e-12): 29% in those with training versus 10% among those without training.

Confidence and training in managing HCV

The median confidence for initiating HCV treatment was 31.0% (IQR 11.0–61.0). For confidence in maintaining treatment, the number rose to 63.0 (IQR 38.0–81.0). For those having completed training, the mean confidence level initiating treatment was 50.2, and 67.7 for maintaining treatment (Fig. 2). Those without training had corresponding confidence levels of 23.8 and 47.9, respectively. Confidence levels varied substantially between the District Health Boards, but show a significant positive effect of education (p < 0.05).

There was a strong correlation between confidence to initiate and confidence to maintain HCV treatment (Spearman's rho = 0.67, p < 2.2e-16). There was no correlation between confidence to initiate and maintain treatment and (a) years of practice (rho values 0.060 and 0.10, respectively), (b) number of GPs in their practice (rho values -0.028 and -0.063, respectively), nor (c) the

Table 1 GP practice size and number of HCV patients by GP estimate and prediction based on HCV prevalence in New Zealand

Estimated practice size	Number of GPs (%)	GP estimate average	GP estimate median	IQR	Predicted number of HCV patients*
< 5000	291 (39.5)	14	8	4–13	< 95
5001-10,000	265 (36.0)	22	10	6–20	95-190
10,001-15,000	118 (16.0)	25	20	10-30	190-285
15,001-20,000	41 (5.6)	31	20	10-40	285-380
> 20,000	22 (3.0)	28	13	5–30	> 380

^{*}Based on HCV prevalence of 1.9% in New Zealand

Fig. 1 Interest, prescribing, and education



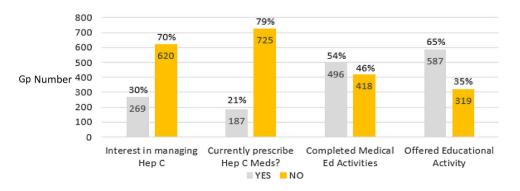
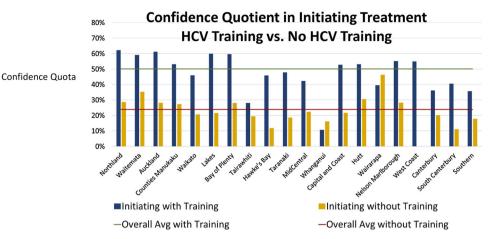




Fig. 2 GP confidence in treating HCV with and without training by region



number of patients in the practice (rho = -0.039 and -0.041, respectively).

There was no correlation between estimated number of HCV patients and confidence to initiate treatment (rho = 0.175, p value = 1.43e-06) but less so for confidence to maintain treatment (rho = 0.107, p value = 0.0034).

A median GP was 1.46 (IQR = 1.01–3.03) times more confident to maintain HCV treatment initiated by another doctor than initiate the treatment. Only 16.2% of the GPs were more confident initiating treatment than maintaining.

There was no correlation between the estimated HCV patients' population and confidence to initiate treatment (rho = 0.175, p = 1.453e-06).

Analysis by practice characteristics demonstrated no correlation between GP group size and estimated practice size, and their interest in managing HCV, prescribing HCV medicines, or completion of HCV education. Confidence in initiating or maintaining treatment of HCV did not correlate to group size or estimated patient population size. Though practice experience did not correlate with confidence in initiating treatment (rho = 0.060, p = 0.075), there was weak correlation with confidence to maintain HCV therapy (rho = 0.103, p = 0.0021).

Barriers

Practice/caseload

40% of GPs reported not treating HCV in their practice due to insufficient patient numbers. Though many acknowledged not knowing the prevalence of HCV in their practice, all estimates provided were much lower than would be predicted based on the estimated practice size (Table 1). Even using a conservative HCV prevalence in New Zealand of 1.9%, estimates were substantially lower than would be predicted. Only 1.4% of GPs reported identifying patients with HCV as a problem. 3.1% of GPs felt that

there was insufficient awareness of HCV among GPs and the public.

40% of GPs reported that their caseload with other patients is too high to engage in HCV treatment. The perception that this patient population will disproportionally demand time is reflected in the 26% that report the paperwork requirements were too high and there were too many steps to accomplish prior to initiating treatment. 9.4% reported on insufficient time in clinic appointments to adequately care for these patients. Table 2 summarizes the reported barriers.

Reflective comments "Expected to manage 3 other problems and hep C in 15-minute consult".

"The hardest thing is to make the diagnosis, i.e., testing people and who to test".

"The health pathway is extensive but it's not feasible in 15-minute appointments."

"Another burden in an increasingly complex GP environment."

Fibroscan® availability

Lack of access to Fibroscan® (Echosens, Paris, France) or shear wave Elastography was cited as a barrier by 35% of GPs. By region, there is great variability for this being a barrier, ranging from 8 to 67%. The comments were indicative of confusion as to GP access to Fibroscan®. Though not addressed in this study, the mechanism for GPs to order Fibroscans® likely varies among the various regions. Many GPs want the ability to order a Fibroscan® directly and to have it done in a timely manner.

Reflective comments: "Make Fibroscan available to GPs".

"Getting Fibroscans for long-term patients is difficult".

"I am still awaiting a Fibroscan result so I can get on and treat".



Table 2 Barriers

Reason	n	% of GPs
Inadequate reimbursement	404	44
Not enough HCV patients to make it worthwhile	366	40
Caseload with other patients too high	369	40
Liver Elastography not easily available	322	35
Lack of expertise/training	300	32
Consider this a specialist's area	273	30
Current guidelines too complex or not clear	259	28
Paperwork requirements	241	26
Too many steps prior to initiating treatment	240	26
Lack of access to specialists for advice	144	16
Too many drug interactions	73	8
Cost to patient	64	7
Lack of diagnosis/no routine testing/identifying patients	45	5
Patient compliance/motivation	41	4
Prescribing issues	24	3
Not enough HCV awareness among GPs and public	29	3
Staffing issues	12	1

Reimbursement

Inadequate reimbursement is the most frequently cited barrier with nearly half (44%) indicating this as an issue. The comment section of the survey heavily reflected this. Many expressed feeling the time commitment and complexity of these patients at the current level of funding to be non-viable from a business perspective.

- "Money is unfortunately the biggest barrier."
- "It is not financially viable for GPs".
- "Money is always good bait."

In four northern regions of New Zealand (Watemata, Auckland, Counties Manukau, and Northland) that provided a \$100–\$330 per patient incentive to treat HCV, 31% reported currently prescribing HCV therapy versus 16% averaged across the remainder of the country (p = 1.5e-07). These regions likewise had an interest in managing HCV of 40% versus 26% in the remainder of the country (p = 1.5e-07).

Training

The lack of adequate training or expertise in the management of those with HCV was a barrier to 32% of the GPs. HCV training offered to GPs in New Zealand has consisted of 1–2-h evening or afternoon seminars by gastroenterologists, hepatologists, or hepatology specialty nurses. The training is organized by the individual District Health Boards, so varies tremendously in availability. Treatment guidelines and protocols for treatment of HCV in New Zealand are available through bpac^{NZ}, an organization which works with multiple independent and government

stakeholders to promote best practice. [17] In addition, the New Zealand Society of Gastroenterology has a detailed online treatment guide for practitioners treating HCV [18]. Training for HCV has also been provided by presentations given by hepatologists at the National GP conference in 2017 in addition to available eLearning resources [19, 20].

The effect of training on confidence levels to treat HCV is significant (Fig. 2). Though over half of the respondents (54%) had completed some educational activity on HCV, lack of training remains one of the top barriers. Many expressed a desire for further training.

"Just keep educating...".

"Detailed education program. More than just an hour one evening which is all we had."

"At present, most of us are very time pressured, doing long days, and practice financial viability is a looming issue".

Attitudes

The perception that management of HCV should remain in the domain of the specialist is a powerful barrier with 30% of GPs responding as such. Early treatments of HCV with interferons and first-generation antivirals were complex and routinely obtained through gastroenterology or infectious disease services. The shifting of treatment of HCV to primary care is regarded as an additional burden in an already over-burdened practice.

Reflective comments "GPs do enough without having more secondary care responsibilities dumped on them".



Table 3 Suggestions by GPs to increase HCV therapy prescribing

Suggestion	n	% of GPs
Increased training and experience	288	31
Increase reimbursement to GPs	273	29
Provide clear/concise guidelines to follow	108	11
Have easy access to specialists for questions	105	11
Create specialized GPs or nurses	71	7.7
Reduce cost to patient	57	6.1
Have elastography easily available to GPs	41	4.4
Increase diagnosis/routine testing	40	4.3
Raise awareness of HCV to public	29	3.1
Provide more staffing (nurses or GPs)	8	0.9
Simpler prescription process	8	0.9
Reduce paperwork requirements	3	0.3
Fund meds covering all genotypes	2	0.2
Interactive prescribing support module	1	0.1

"Why would anyone put their hand up to undertake a complex treatment regimen?"

"I am sorry but I think specialist should start treatment".

Suggestions to increase GP treatment of HCV

Many suggestions are provided by the respondents to increase treatment rate of HCV by GPs. This roughly correlates with the barriers discussed and are summarized in Table 3.

Discussion

Important barriers are identified that fit into several underlying themes. First, inadequate reimbursement coupled with GPs already feeling over-burdened and unwilling to take on new responsibilities is a dominant obstacle. GPs are the subjects of increasing demands in the form of guidelines and mandates. Though many are open to treating HCV, they feel that the allocation of practice resources to HCV therapy is too great. 40% of GPs responded that their caseloads were already high and that they did not have the time to adequately treat potentially complex patients with HCV. These patients will not easily fit into the flow of a busy GP practice with time-limited slots. The perception of HCV treatment as being complex and time consuming might stem from experience when this indeed was the case.

Reimbursement adjustments to compensate the GP for the resource allocation in the initiation of HCV treatment would remain less expensive than referral to a specialist. An increase in reimbursement, if effective, as an incentive to HCV therapy by GPs would likely be a net savings by the prevention of cirrhosis and the attendant complications. Though increasing reimbursement to GPs in their treatment of HCV might seem to be an attractive option, this study suggests that in isolation, this approach is unlikely to be successful. The increased reimbursement to GPs in the northern regions did improve interest and prescribing rates, but they were still suboptimal with an average of 31%. Despite this increased reimbursement, 40% of the GPs within these areas reported reimbursement as a barrier. This would suggest that an increase in reimbursement has a positive effect, but by itself may not be effective and a more comprehensive strategy is required.

Second, a lack of awareness of prevalence and risk factors for HCV in a primary care practice is an important barrier. The perception that HCV is relatively uncommon in their individual practices is a consistent finding in this study. Though many acknowledge they do not know or may be underestimating the numbers of infected in their practice, the discordance of these GP estimates to population estimates of HCV prevalence in New Zealand is large. A conservative estimated prevalence of HCV in New Zealand of 1.9% would have these estimates off by a factor ranging from 4.3 to 13.6.

To identify the considerable number of persons with HCV both in New Zealand and worldwide will require increased awareness and testing by GPs. Means to facilitate testing should be explored. Formalized guidelines, screening, and reflex testing for those at risk should be promulgated. Point of care rapid HCV antibody tests that can be done with a finger prick or oral fluid would likely result in an increase in diagnosis and are currently available elsewhere [21].

The belief by nearly a third of respondents that HCV is in the specialist domain is a challenging barrier. Increased emphasis on HCV screening and treatment in training programs is a crucial step. Ongoing HCV education of GPs is clearly shown here to be linked to increasing treatment rates. Treatment of HCV in the past was complex and routinely managed by specialists, and indeed, HCV management by GPs in some areas was actively discouraged. The effect educational activity on the treatment rate would suggest that many are finding the treatment regimens to be less complex than thought. 35% of our total sample indicated that they had not been offered training in HCV management. This would indicate that there is a large group of GPs that have yet to be engaged in educational activities. As confidence in the management of HCV by GPs increases over time, the perception of this being a disease requiring a specialist will diminish. Interestingly, the most frequent suggestion by GPs to increase the treatment rate is to increase educational opportunities.

Though GPs demonstrate interest in the treatment of HCV as demonstrated by over half already having engaged in educational activity, there is a discordance in practice as



only 21% of surveyed GPs are currently prescribing therapy for HCV. Although 70% overall indicated no interest in managing HCV by GPs in their medical center, the fact that 54% have completed educational activity suggests a larger number may be amenable to prescribing in the future.

Lack of access to Fibroscan[®] or shear wave elastography is a prominent barrier. There are limited number of machines available, often with geographic constraints to availability. Even in areas with available services, there is often confusion as to who performs and how to order these. The published guidelines for GPs to follow include using APRI as an alternative to Fibroscan[®], where availability is limited [17]. Unfortunately, many GPs are unaware of this alternative. For those regions with limited access to Fibroscan[®], educating on alternative methods to stage the liver disease with physical exam and APRI is needed [22].

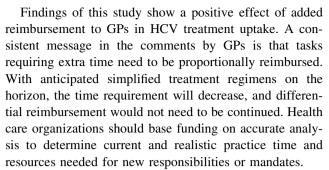
Confusing guidelines and the perception the paperwork requirements are too great are barriers to 28% and 26%, respectively. A flow analysis of HCV treatment steps within each region is needed to identify the specific barriers of these types.

Conclusion

Eradicating HCV from New Zealand and worldwide remains a challenge. With roughly half of HCV infections are yet to be identified, improvement in identifying the infected patients must become a priority or the other barriers to GP-based treatment remain irrelevant. An underlying perception that HCV is relatively rare must be addressed before considerable progress in addressing other identified barriers is likely to be effective.

Screening and subsequent testing for HCV is difficult to integrate into a busy GP practice. GPs are overwhelmed by mandates and guidelines coming from numerous professional societies and government agencies. Pressures to provide these time consuming and increasingly complicated services to their patient population have strained GPs' ability and willingness to take on new responsibilities. Despite this, many GPs have already engaged in HCV education and treating HCV.

Improving access to HCV education by GPs should be a national priority. HCV educational activity is clearly shown in this study to be critical in moving HCV therapy into primary care. The many GPs yet to undergo HCV training represent a very large untapped segment of the workforce that could make a profound difference in the number of persons identified and treated for HCV. HCV training that is efficient, convenient, and effective should be available to all GPs. A standardized training resource available nationwide should be developed.



A clear national HCV-screening strategy is much needed. The 2016 WHO guidelines for HCV recommend a public health approach with a strong recommendation to offer HCV testing on individuals identified to be in a highrisk population [4]. The difficulty lies in identifying those with a risk factor that are often unwilling to discuss this due to fear of stigmatization. Improving acceptability of testing with point of care, rapid HCV assays, and reflex testing would likely improve awareness and diagnosis rate and deserve further study.

Moving treatment of uncomplicated HCV into primary care is mandatory to ultimately achieve the WHO goal of HCV eradication. Complicated patients with viral coinfections, comorbidities, the presence of advanced fibrosis or cirrhosis, treatment failures, or drug resistant viruses will continue to require specialist treatment and expertise. Long-term follow-up of successfully treated persons with HCV who have residual advanced fibrosis or cirrhosis, and thus, an elevated risk of hepatocellular carcinoma will require a cooperative strategy between GPs and specialists. It is clear from this study that the ability of GPs to engage with specialists for support is critical to them becoming comfortable with and taking on the treatment of HCV. Ongoing dialogue and cooperation between generalists and specialists in the care of persons with HCV must be improved and needs to be considered an important component of the HCV national strategy.

Although the most frequently cited barrier to GP treatment of HCV was reimbursement, this is entwined with other purported barriers such as awareness of HCV, complexity of the patients, time commitment, caseload, and need for expertise. A comprehensive strategy to address multiple barriers, availability of improved treatment regimens, and an increased awareness is needed for ultimate success in the eradication of HCV in New Zealand and worldwide.

Compliance with ethical standards

Conflict of interest Steve Johnson, Kristina Aluzaite, Anna Taar, and Michael Schultz declare that they have no conflict of interest.



Ethical statement Ethical approval was obtained from the University of Otago Human Ethics Committee (reference number D16/400).

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