

**NSW/ACT HEPATITIS C COMMUNITY PRESCRIBING PILOT
EVALUATION REPORT**

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EXECUTIVE SUMMARY

The NSW/ACT Hepatitis C Community Prescribing Pilot was designed to increase access to drugs for the treatment of hepatitis C in the community. The pilot of accredited general practitioners as eligible prescribers of highly specialised drugs for the treatment of chronic hepatitis C within the administrative arrangements of the Highly Specialised Drugs Program involved:

- a pilot of accredited general practitioners as prescribers for ongoing treatment which has been initiated by a specialist associated with a hepatitis C treatment centre
- GPs undertaking a training and accreditation program to become authorised prescribers and being linked to a hepatitis C treatment centre
- GPs entering a shared care arrangement with a specialist at a hepatitis C treatment centre.

The evaluation of the pilot has been informed by a focus group with nurses from specialist centres, interviews or surveys with participating specialists, a focus group and survey of community prescribers, a survey and interview with pilot patients.

Overall, the pilot demonstrated that administrative arrangements can be put in place to train, accredit and support community prescribing of HCV s100 treatment.

Key findings:

- Thirty-eight prescribers enrolled 236 patients in the pilot. Of these; 40 patients have been treated and had scripts written by their community prescribers; 38 patients have not returned to their referring GP or clinic; 48 patients have been treated by the liver clinic (this number includes those known to be on clinical trials); 110 patients have yet to treat.
- The pilot had a significant impact on increasing the skills of medical practitioners in understanding hepatitis C treatment and in the management of patients with hepatitis C.
- Community prescribing was found to be acceptable to patients. Those patients who had not treated indicated that it would make little difference to their decision to treat if all their treatment was managed solely by the specialist.
- GPs involved in the pilot, while supportive of community prescribing, were critical of the restriction on their authority to initiate HCV treatment. Prescribers argued this hindered the development of an effective model of community prescribing.
- Community prescribing is supported by some specialists but not by other specialists. Those that supported the pilot believed it worked well. Those that did not support community prescribing believed the wrong model was adopted, were concerned about patient access to ancillary services, and/or believed hepatitis C required specialist care.
- The pilot initially failed to adequately engage with nurses working in liver clinics. This was rectified as the pilot proceeded. Any future community prescribing model needs to recognise the pivotal role nurses play in supporting patients, as well as the key role they can play in supporting community prescribers.
- The numbers of patients treated by community prescribers is lower than expected. However, the pilot's primary aim was to demonstrate that administrative arrangements could be implemented to enable community prescribing. A range of

factors were identified that hindered the uptake of treatments – a few of these factors may be addressed by changes to the community prescribing model adopted.

- In general the pilot was well administered. However, some of the systems could have been simplified to reduce the administrative workload.

Evaluation findings have been reported against three key aims of the pilot.

1. Whether the mechanism in place for the training, accreditation and ongoing support of HIV s100 prescribers could be appropriately transferred to the HCV setting.

Effective mechanisms for training, accreditation and support were implemented:

- Training curriculum was developed and implemented.
- A procedure to assess and accredit community prescribers was implemented.
- Medical practitioners demonstrated considerable interest in community prescribing with 140 individuals trained, and 88 community prescribers accredited.

2. Whether arrangements could be established between public hospital- based specialists and GPs to allow GPs to conduct the appropriate pre-tests necessary to precede biopsy.

Arrangements were established to enable community prescribers to conduct work-up:

- The pilot identified the importance of developing local protocols to reflect different requirements of collaborating specialist centres.
- Specialists reported that generally the protocols were well adhered to and that the work-up conducted by community prescribers was adequate, although some prescribers reported that the work-ups were repeated by the specialist.
- There were problems in communication between community prescribers and specialist centres, particularly in ensuring that pilot patients were identified and community prescribers kept informed of patient status.

3. In the case of patients going on to s100 therapy, provide the appropriate management to prescribe for, support and review them through their duration of therapy.

Generally, specialists reported favourably on the level of care provided by community prescribers. Patients reported that they felt well supported by their GP.

Based on the findings from this evaluation, and input from key stakeholders, any future community prescribing model should consider:

- continuing to provide a training and accreditation program, as developed during the pilot, by an appropriate training provider contracted by the appropriate jurisdictional health authority
- ensuring the training and accreditation program complies with nationally agreed education standards and competencies on prescribing hepatitis C treatment
- developing a continuing education program for accredited prescribers, including annual updates
- linking accredited prescribers to authorised hepatitis C treatment centres;
- recognising the key role nurses from hepatitis treatment centres play in linking with and supporting community prescribers
- enabling community prescribers to link to specialists working in public or private hospitals with appropriate hepatitis C specialist facilities

- ensuring patients of community prescribers are well supported and have full access to ancillary services provided by hepatitis C treatments centres and other community-based support services, as well as any other strategies that can increase the support available to patients in general practice
- supporting the training of practice nurses in hepatitis C management
- supporting accredited community prescribers initiating hepatitis C treatment.

1. INTRODUCTION

1.1 Background

The NSW/ACT Hepatitis C Community Prescribing Pilot was approved by the Highly Specialised Drugs Working Party (HSDWP) and funded by the NSW Department of Health and ACT Department of Health. The Australasian Society for HIV Medicine (AHSM) managed the pilot. The pilot allowed trained and accredited general practitioners in NSW and ACT to prescribe section 100 drugs for the treatment of people with chronic hepatitis C.

The rationale for the pilot project was to increase access to hepatitis C treatment to enable the health system to cope with an anticipated increase in demand for treatment. It was hoped that access to treatments could be improved by facilitating access in a general practice setting. This anticipated increase in demand is due to the numbers of patients infected with hepatitis C and the improved efficacy of treatment.

An independent evaluation of the pilot project commenced in November 2006.

1.2 Terms of reference

The evaluation of the pilot aims to:

- describe the strengths and weaknesses of the pilot in its current form
- evaluate to what extent access to treatment has been increased by community prescribers
- assess the quality of clinical and support services for patients of GP prescribers
- distinguish between the prescriber program and broader issues of access to treatment
- develop a future HCV prescribers program that incorporates the strengths of the pilot and improves on the weaknesses that have been identified by the evaluation.

1.3 Issues to be addressed

The terms of reference for the evaluation identified that the following issues had arisen during the pilot and should be investigated and reported on:

- the number of medical practitioners trained under the pilot, particularly in regards to any increase in the overall capacity of GPs trained under the pilot to provide appropriate care to people with hepatitis C
- reasons why half of the medical practitioners who were trained have not been participating in the pilot and in particular what the barriers to participation were, and whether those doctors may have increased their role in hepatitis C management despite not prescribing
- reasons why patients did not join the pilot (e.g. participation in clinical trials)
- acceptability of community prescribing to patients
- factors which contribute to a lengthy period of time elapsing between initial work-up of the patient and actual referral to specialist, and the implications this has had on pilot participation

- pilot uptake in rural areas, including comments on achievements and barriers, particularly why numbers have not been as high as expected and future strategies to strengthen community prescribing in rural areas
- strengths and limitations of the current model of community prescribing
- issues about dispensing s100 medication from hospital pharmacies
- the adequacy of psychological support services for patients in the pilot
- future feasibility and acceptability of community prescribing of hepatitis C treatment, if prescribing is feasible, to make recommendations about the model and infrastructure required to support it.

1.4 Methodology

The methodology included:

- focus group with eight nurses
- interview or survey of five participating specialists
- focus group with 14 participating community prescribers
- analysis of community prescribers survey (65 respondents)
- analysis of patient survey (41 respondents)
- interviews with key informants
- review of project patient data
- review of project documentation.

2. CONTEXT¹

Epidemiologyⁱ

By the end of 2005 an estimated 197,000 people were living in Australia with chronic hepatitis C infection, including 43,400 with moderate to severe liver disease. In 2005 there were 12,594 diagnoses of hepatitis C infection. It is estimated that there are 10,000 new infections every year.

In Australia, hepatitis C transmission predominantly occurs among people with a recent history of injecting drug use. Hepatitis C transmission continues to occur at the highest rate among adults aged less than 30 years.

The number of people with chronic hepatitis C infection undergoing liver transplantation is increasing significantly. Hepatitis C is currently the most common indicator for liver transplantation in Australia. In 2005, chronic hepatitis C infection was the underlying cause of liver disease in 37% of liver transplants.

Natural history

There are nine different genotypes of hepatitis C identified. The most common in Australia are genotypes 1 (55%) and 3 (30%). Genotype is a significant factor associated with the efficacy of antiviral treatment.

Most people with HCV develop a chronic infection. Between 20 and 30% who are exposed to HCV will clear the virus, however, they will demonstrate a persistent positive hepatitis C antibody. Those who don't clear the virus become chronically infected. Of those with chronic infection, 10 to 20% will develop cirrhosis over 20 to 40 years. Between 20 and 40% will have chronic hepatitis symptoms, and 40 to 70% will have minor liver problems.

Table 1: The outcome of exposure to HCV		
Of 100 infected patients		
20-30 will clear the virus with no evident ongoing problem anti-HCV positive for years	70-80 become chronically infected	
Of 100 chronically infected individuals		
10-20 will develop cirrhosis over 20-40 years; risk increased by alcohol, obesity, diabetes, HIV and/or HBV coinfection	20-40 will have chronic hepatitis symptoms; impaired health-related quality of life	40-70 will have minor liver problems; no risk of cirrhosis

Hepatitis C treatment

The aim of treatment is to decrease or prevent the chance that infection will result in progressive liver damage which can lead to cirrhosis, liver failure or liver cancer.ⁱⁱ Elimination of the virus, or cure, is defined as having attained a sustained virological response. Changes that have occurred during the planning and implementation of the

¹ Unless otherwise indicated, information has been sourced by an Hepatitis C Update article written by Professor Robert Batey published in the Medical Observer on 11 March 2005.

prescribing pilot have meant that the ability to manage antiviral therapy and achieve successful clinical outcomes has improved significantly.

At the commencement of the pilot project, interferon monotherapy or standard interferon plus ribavirin was the primary treatment available. It has a low efficacy and low sustained response, particularly for people with genotype 1, the dominant type in Australia.

Pegylated interferon plus ribavirin has become the standard treatment for hepatitis C in Australia. Pharmaceutical Benefits Scheme (PBS) listing of peginterferon alfa-2a/ribavirin (Pegasys RBV[®]) and peginterferon alfa-2b/ribavirin (Pegatron[®]) occurred in November 2003. The treatment involves injecting peginterferon once a week for either six or 12 months and taking ribavirin capsules daily. The course of treatment must be continuous and the length of treatment depends on early response to the treatment and genotype.

Combination therapy is successful in treating many people with hepatitis C. Sustained virological response of 40 to 50% for genotypes 1 and 4 (12 months therapy) and 70 to 90% for genotypes 2 and 3 (six months therapy) are expected.

Pegylated interferon monotherapy is available for people who cannot take ribavirin. This treatment involves taking pegylated interferon on its own. Pegylated interferon used alone achieves an overall end of treatment response of about 60%. However, the sustained virological response rate is only 30% (i.e. about 50% of those who responded to treatment relapse within six months of completion).ⁱⁱⁱ

People who achieve a sustained virological response to treatment have a significantly improved prognosis. Hepatic damage reverses and even cirrhosis has been shown to resolve in about 30% of successfully treated patients.

An estimated 2,079 people living with chronic hepatitis C infection were prescribed ribavirin and peginterferon combination treatment for hepatitis C infection in 2005. Annually only 1% of people living with hepatitis C are accessing treatment.^{iv} Since the removal of liver biopsy as a prerequisite for treatment, the number of people accessing hepatitis C treatments is believed to have increased significantly to over 3,000 per year.

Section 100 Highly Specialised Drugs Program

The Australian Government funds Pharmaceutical Benefits Schedule (PBS) subsidised hepatitis C drug treatment under the Highly Specialised Drugs (HSD) Program. PBS-subsidised drugs for the treatment of hepatitis C may only be prescribed by physicians associated with accredited hepatitis C treatment centres for outpatients who meet the specific indication and criteria for each drug listed on the HSD Program.

Since November 2003, peginterferon alfa-2a/ribavirin (Pegasys RBV[®]) and peginterferon alfa-2b/ribavirin (Pegatron[®]) combination therapy have become available under the section 100 HSD Program for patients who fit the specific indication and criteria for each individual drug.

Currently treatment under the program is available for patients, managed by an accredited treatment centre, with chronic hepatitis C in patients 18 years or older who have compensated liver disease and who have received no prior interferon alfa or peginterferon alfa treatment for hepatitis C and who satisfy all of the following criteria:

1. Documented chronic hepatitis C infection (repeatedly anti-HCV positive and HCV RNA positive)
2. Female patients of child-bearing age are not pregnant, not breast-feeding, and both patient and their partner are using effective forms of contraception (one for each

partner). Male patients and their partners are using effective forms of contraception (one for each partner). Female partners of male patients are not pregnant

For patients with genotype 2 or 3 hepatitis C without hepatic cirrhosis or bridging fibrosis, the treatment course is limited to 24 weeks. For hepatitis C patients with genotype 1, 4, 5 or 6 and those genotype 2 or 3 patients with hepatic cirrhosis or bridging fibrosis, the treatment course is limited to 48 weeks.

Patients with genotype 1, 4, 5 or 6 who are eligible for 48 weeks of treatment may only continue treatment after the first 12 weeks if the result of an HCV RNA quantitative assay (performed at the same laboratory using the same test) shows that the plasma HCV RNA has become undetectable or the viral load has decreased by at least a 2 log drop. (An HCV RNA assay at Week 12 is unnecessary for genotype 2 and 3 patients because of the high likelihood of early viral response by Week 12).

Patients with genotype 1, 4, 5 or 6 who are viral positive at week 12 but have attained at least a 2 log drop in viral load may only continue treatment after the first 24 weeks of treatment if plasma HCV RNA is not detectable by an HCV RNA qualitative assay at week 24.

Similarly, genotype 2 or 3 patients with hepatic cirrhosis or bridging fibrosis may only continue treatment after the first 24 weeks if plasma HCV RNA is not detectable by an HCV RNA qualitative assay at Week 24. An HCV RNA qualitative assay at Week 24 is unnecessary for those patients with genotype 1, 4, 5 or 6 who became viral negative at Week 12.

Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C: (a) a nurse educator/counsellor for patients; (b) 24 hour access by patients to medical advice; (c) an established liver clinic; and (d) facilities for safe liver biopsy.

People who inject drugs and/or use methadone and people co-infected with HIV are eligible for s100 combination therapy.

The requirement for a liver biopsy prior to treatment with hepatitis C drugs was removed from the criteria from 1 April 2006. As this is no longer required to access treatment, it is likely that more patients will consider treatment.

Side effects

Adverse side effects of combination therapy may include flu-like symptoms, such as fever, chills, muscle aches and headaches. These are usually experienced in the first few months of treatments. Other side effects may include becoming forgetful, short-tempered, tired or depressed. A small percentage of patients will develop serious side effects which include anaemia, thrombocytopenia, leucopenia, depression and psychosis.

Treatment is generally better tolerated and has a higher success rate when the person has not developed advanced liver disease or cirrhosis.

Treatment with pegylated interferon has been associated with depression and suicide in some patients. Patients with a history of suicide or depressive illness need to be warned of the risks. Psychiatric status during therapy needs to be monitored.

Side effects are common but do not usually require discontinuation of treatment. Fortunately most side effects disappear once treatment has stopped. Due to the range and potential seriousness of side effects it is important that patients are closely monitored during therapy.

3. THE PILOT PROJECT

3.1 Background

Highly Specialised Drugs Program

The Highly Specialised Drugs (HSD) Program was established through an initiative of the Australian Health Ministers' Advisory Council in 1991, as a result of concerns raised by the states and territories about the rapid growth in the use of high cost drugs provided through the public hospital system. It was decided that the Commonwealth would fund an agreed list of highly specialised drugs as Pharmaceutical Benefits under section 100 of the *National Health Act 1953*, for use by outpatients and those attending day services in a hospital, while hospitals would continue to fund inpatient use.

Highly specialised drugs are medicines for the treatment of chronic conditions which, because of their clinical or special features, are restricted in supply.

The Highly Specialised Drugs Working Party (HSDWP) is a non-statutory body established by the Australian Health Ministers' Advisory Council, also in 1991, to oversee the policy and administrative aspects of the HSD Program. The HSDWP consists of representatives from the Health Departments of each of the states and territories with the Commonwealth as Chair. The HSDWP makes recommendations to the Pharmaceutical Benefits Advisory Committee (PBAC) on the suitability of supplying drugs via hospital outpatient departments under section 100 of the *National Health Act 1953*. Drugs included in the HSD Program are prescribed by specialist hospital units or authorised prescribers and dispensed through hospital pharmacies.

Hepatitis C therapy is made available under the HSD Program. To gain access to this program, patients must meet the specified medical criteria and be an Australian resident in Australia (or other eligible person).

A condition of funding for highly specialised drugs in the treatment of hepatitis C is the requirement for states/territories to adhere to specific requirements for the selection of treatment centres. Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C: (a) a nurse educator/counsellor for patients; (b) 24 hour access by patients to medical advice; (c) an established liver clinic; and (d) facilities for safe liver biopsy.

In NSW, the NSW Department of Health administers the HSD Program in the public health system.

Administration of the program through private hospitals is administered by the Australian Government. For highly specialised drugs prescribed through private hospitals, claiming and approval of authority prescriptions is administered by Medicare. Medical practitioners must seek approval to prescribe these items. Prescriptions for highly specialised drugs can then be dispensed by the private hospital pharmacy or by a community pharmacy.

As outlined earlier, the scope of this pilot was restricted to the HSD Program administered through the public health system.

Rationale

Under the current HSD arrangements, only specialists associated with an authorised treatment centre can prescribe s100 drugs for hepatitis C treatment. The pilot allows trained and accredited NSW/ACT medical practitioners outside specialist centres to prescribe s100 drugs for the treatment of people with chronic hepatitis C in collaboration

with a specialist from an accredited hepatitis C treatment centre. The pilot was designed to increase access to drugs for the management of hepatitis C in the community. Initially it was thought that this would result in the pilot model allowing for initiation of treatment by trained and accredited GPs. However, this was not supported by some key project stakeholders and so did not proceed. The pilot model that was adopted is outlined below.

The rationale for commencing the pilot was in line with the *National Hepatitis C Strategy 1999-2000 to 2003-2004* which identified that it was necessary to explore options that support broad access to treatment and specialist advice. It was also in line with the *NSW Hepatitis C Strategy 2000-2003* which identified the importance of encouraging greater use of general practitioners in the treatment and management of people with hepatitis C, and increasing availability and accessibility to treatment by seeking changes in prescribing rights.

At the time the pilot was proposed PBS-subsidised hepatitis C drug treatment was less efficacious, but it was thought that treatment would improve with the advent of combination therapy and pegylated interferon. It was considered essential that access to treatment was increased, to enable the health system to cope with the anticipated increase in demand for treatment. A growing pool of patients with chronic disease and improved efficacy of treatment meant that it was considered more likely that people would seek treatment. GP prescribing was considered to have the potential to significantly address access to treatment and ease pressure on hospital services.

Pilot proposal

In September 2001, the NSW Ministerial Advisory Committee on Hepatitis supported the development of a training and accreditation program to allow accredited GPs to prescribe s100 drugs for the treatment of hepatitis C.

ASHM worked with the NSW Department of Health to develop a proposal and model for a training and accreditation program. ASHM was already running the NSW HIV s100 prescriber training and accreditation program, and it had already provided some basic hepatitis C education to GPs.

In 2002, NSW Health sought approval from the HSDWP to pilot a program of hepatitis C GP prescribing. The HSDWP and the Australian Government Department of Health and Ageing agreed that the pilot may be beneficial in determining the advantages and disadvantages of community-based medical practitioners prescribing highly specialised drugs for the treatment of people with chronic hepatitis. The Hepatitis C Community Prescribing Pilot was approved by the HSDWP and funded by the NSW Department of Health and the ACT Department of Health.

The proposal submitted to HSDWP in 2002 was for an 18-month administrative pilot. The initial series of training workshops of community prescribers took place from February to April 2003. However, the first community prescription did not occur until May 2004. The pilot was originally scheduled to end in November 2005. An 18-month extension to the pilot was approved, provided patients' perceptions of the pilot were sought, resulting in the pilot being scheduled to end in May 2007.

Pilot aim

The aim of the 18-month administrative pilot was to determine:

1. Whether the mechanism in place for the training, accreditation and ongoing support of HIV s100 prescribers could be appropriately transferred to the HCV setting.
2. Whether arrangements could be established between public hospital based specialists and GPs to allow GPs to conduct the appropriate pre-tests necessary to precede biopsy.
3. In the case of patients going on to s100 therapy, provide the appropriate management to prescribe for, support and review them through the duration of their therapy.

The pilot was initially implemented in NSW and ACT, and then Victoria. The Victorian pilot was funded by the Victorian Department of Human Services and is being evaluated separately.

3.2 Pilot model

The pilot of accredited general practitioners as eligible prescribers of highly specialised drugs for the treatment of chronic hepatitis C within the administrative arrangements of the Highly Specialised Drugs Program involved:

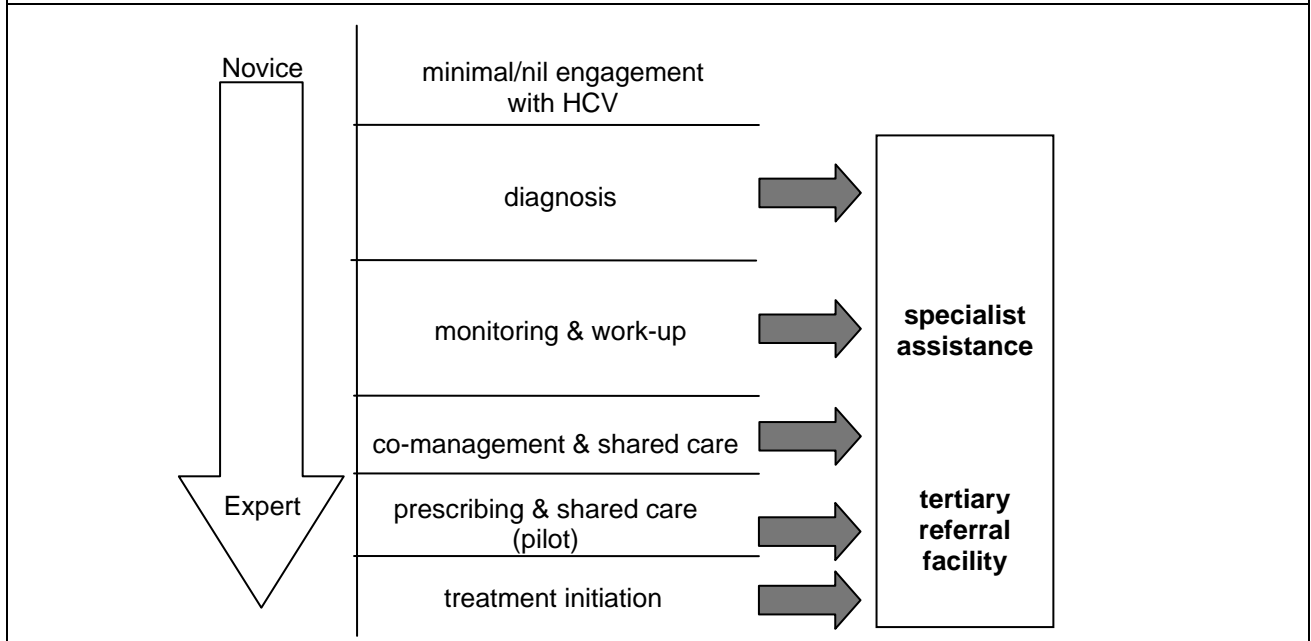
- a pilot of accredited general practitioners as prescribers for ongoing treatment which has been initiated by a specialist associated with a hepatitis C treatment centre
- GPs undertaking a training and accreditation program to become authorised prescribers and being linked to a hepatitis C treatment centre
- GPs entering a shared care arrangement with a specialist at a hepatitis C treatment centre.

Under the pilot model:

- GPs could not initiate treatment
- accredited GP prescribers had to nominate a link to a hepatitis C treatment centre authorised by NSW Health
- accredited GPs would have full access to services provided by liver clinics to their patients
- dispensing of highly specialised drugs would be from hospital pharmacies only
- ASHM would be responsible for running the training and accreditation program
- GPs would be accredited by the Chief Health Officer following advice from ASHM that they had successfully completed the training, nominated a link and accepted the Departments conditions
- the GP would manage the second supply of antiviral therapy and continued management of the patient on the therapy.

The model aimed to ensure that patients of GPs participating in the project would have the same access to services as provided by liver clinics to their patients, including mental health services. Importantly, their specialist could still offer patients that were referred under the pilot participation in clinical trials. Specialists would give the patient options as to how they wish to be treated.

It was anticipated that patients still in treatment at the end of the pilot period would be referred back to their specialist for treatment maintenance. GPs could continue to provide shared care but would not be authorised to prescribe treatments.

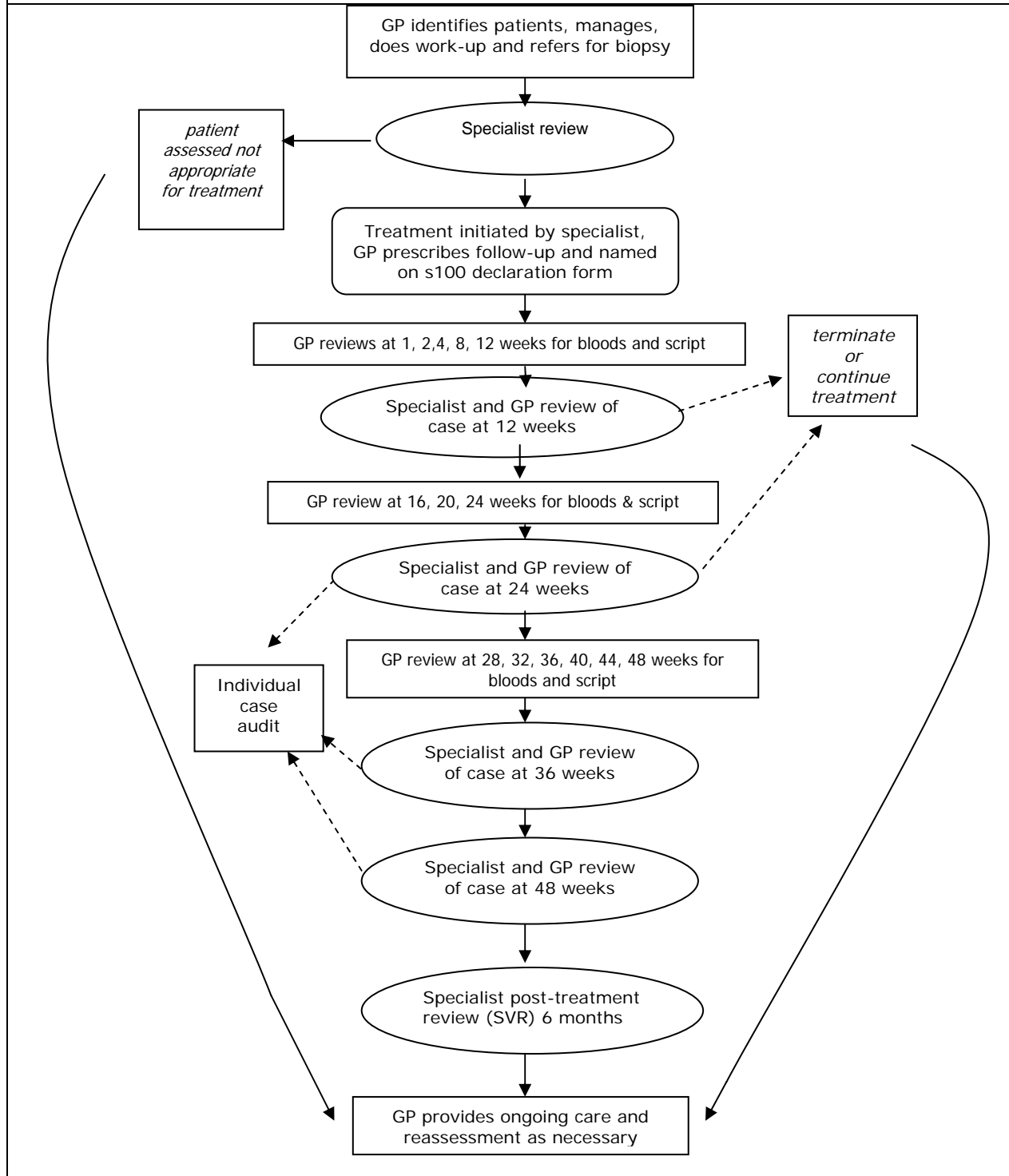
Figure 1: A model for GP prescribing

Participating general practitioners who successfully completed the training and associated assessment identified patients who were appropriate for therapy. The general practitioner undertook the initial work-up of the patient, performing all required diagnostic tests. Community prescribers were authorised to order diagnostic tests such as qualitative and quantitative genotype. Patients were then referred to a participating public tertiary facility where the co-operating specialist reviewed the patient.

The patient was then referred back to the general practitioner for follow-up. Treatment, where appropriate, was initiated by the specialist. The community prescriber wrote subsequent scripts for therapy.

Dispensing of highly specialised drugs for hepatitis C treatment was from public hospital pharmacies. The specialist and community prescriber were required to sign an s100 declaration form (which certifies the patients meets the criteria) and forward this to the hospital pharmacy. The pharmacist could only dispense and claim reimbursement for a prescription from a specialist associated with an accredited hepatitis C treatment centre or an accredited GP. The declaration form is a requirement for reimbursement through the HSD Program and the pharmacy is required to retain the declaration form for auditing purposes.

Under the pilot protocol, the general practitioner reviewed the patient regularly. Generally, the specialist reviewed the patient at 0, 12, 24, 36 and 48 weeks (depending on the duration of the therapy) or as indicated on the treatment protocol relevant to the specific liver clinic. In addition, the specialist could review the patient at any intervening time at the request of the patient, the community practitioner or as deemed necessary by the specialist.

Figure 2: Pilot treatment algorithm

ASHM, in collaboration with participating services, developed local protocols for participation in the pilot. Local protocols were developed in recognition that pathology requirements for each service may vary. The local protocols identified the actions, such as tests, physical exam, medical and psychosocial history, required at different time points in the treatment period. It also identified points for community prescriber review and specialist review. The protocols identified that community prescribers had to arrange for pathology to be available for each specialist review. Specialists were to ensure letters

were sent to community prescribers following each specialist review. The protocols also identified whether dose reduction needed to be discussed with clinic staff.

Case audits were required to be completed at the end of treatment for all patients managed under the pilot. The case audits were used to assess the standard of care provided to patients by community prescribers. The audit tool developed by ASHM for use by specialists and/or Clinical Nurse Consultants (CNCs) provided an opportunity for the specialist to assess the initial work-up done by the GP, and the ongoing management provided by the GP. This included assessing whether appropriate tests were completed and available to the specialists during specialist review visits. The audit form also identified whether specialists were consulted regarding abnormal results. The GP's role in adjusting dose reduction in an appropriate and timely manner was also assessed. The audit also provided for information to be reported on the nature of any referrals undertaken by the GP. Specialists were asked to provide an overall assessment on the adequacy of care provided for the patient, and whether patient care in the GP setting was different to that in the liver clinic.

3.3 Patient enrolment and referral

To enrol a patient in the pilot, the community prescriber was required to complete an enrolment form. The enrolment form required a referral date, name of the community prescriber and name of the specialist. A patient identification code was also required. The community prescriber then returned the form to ASHM and to the specialist. The patient referral letter was to be marked with a fluorescent green sticker to ensure the patient was clearly identified as a pilot referral. The patient referral letter and results of work-up investigations were then forwarded or sent with the patient to the specialist. The participating specialist assessed and, if appropriate, initiated therapy.

3.4 Participation of GPs, CNCs and specialists

GPs were informed of the pilot through a mail-out to methadone prescribers, GPs who had previously participated in an ASHM course and other lists of GPs that were deemed appropriate. It was determined that this was a more appropriate distribution strategy than, for example, promoting the pilot through mail-outs to the lists provided by Divisions of GPs. GPs working on HIV/AIDS and drug/alcohol issues were targeted, as it was believed they were likely to be already motivated and interested.

The terms of the pilot required that the shared care collaboration be between a specialist attached to a public hospital, and a community prescriber. To facilitate shared care between specialists and community prescribers, ASHM sent a letter to specialists informing them of the pilot and asking them to indicate if they would be willing to be a participating specialist. GPs notified ASHM of which specialist they wanted to work with for the pilot. ASHM then notified the specialist of the GPs who wanted to work with them on the pilot.

There were 35 collaborating specialists participating in the pilot, with a total of 19 tertiary facilities linked to the pilot, including:

- Bathurst Base Hospital
- Bigge Park Centre/Liverpool Hospital
- Campbelltown Hospital
- Canberra Hospital
- Coffs Harbour Hospital
- Concord Hospital
- Dubbo Base Hospital

- Gosford Hospital
- John Hunter Hospital
- Lismore Base Hospital/St Vincent's Specialist Centre
- Newcastle Mater Misericordiae Hospital
- Nepean Hospital
- Orange Base Hospital
- Prince of Wales
- Royal North Shore Hospital
- Royal Prince Alfred Hospital
- St George Hospital
- St Vincent's Hospital
- Westmead Hospital.

After the pilot had commenced, ASHM engaged with nursing staff from liver clinics. Meetings were held between ASHM and Clinical Nurse Consultants and/or Clinical Nurses Specialists. The meetings were used to facilitate the implementation of the pilot and address problems as they arose. This included examining strategies to enhance relationships between prescribers and referring clinics.

3.5 Training and accreditation

The ASHM HCV Clinical Sub-Committee set standards, reviewed course content, established assessment procedures and set criteria for maintenance of prescriber rights. The ASHM HCV Clinical Sub-Committee includes specialists, medical practitioners, community representative, CNCs, a representative from the Australian Liver Association, the NSW Department of Health and ASHM.

The training program included introductory and advanced levels. Prior learning was also recognised. Medical practitioners were eligible to receive Royal Australian College of General Practitioners Continuing Professional Development points for their participation in the course. Five points per hour could be earned, rather than two points, for the advanced training course if participants completed a pre-test and post test assessment. The assessment for prescribing for the pilot is the same assessment as for receiving RACGP CPD points.

The introductory course included:

- hepatitis C historical and current perspective
- issues with pre- and post-test counselling
- natural history, monitoring and treatment
- nutrition, self-help and complementary strategies
- living with hepatitis C
- monitoring and the role of the general practitioner.

The advanced course included:

- considerations before referring on for a liver biopsy
- the role of the specialists and the decision to treat
- psychological assessment, alcohol and other drugs, mental health
- practicalities of treatment
- complex aspects of treatment.

To become an accredited prescriber, participants had to attend the advanced course and pass the assessment exercise associated with it. The assessment comprised of completion of five cases studies. In order to pass the assessment, applicants had to get a clear pass in four out of five cases.

The assessment was graded by an independent marker. The procedure with assessments included re-submits and re-markers of case studies. Medical practitioners who passed were recommended to the Chief Health Officer for approval to prescribe hepatitis C treatment drugs listed on the s100 program.

Figure 3: Training and support flowchart

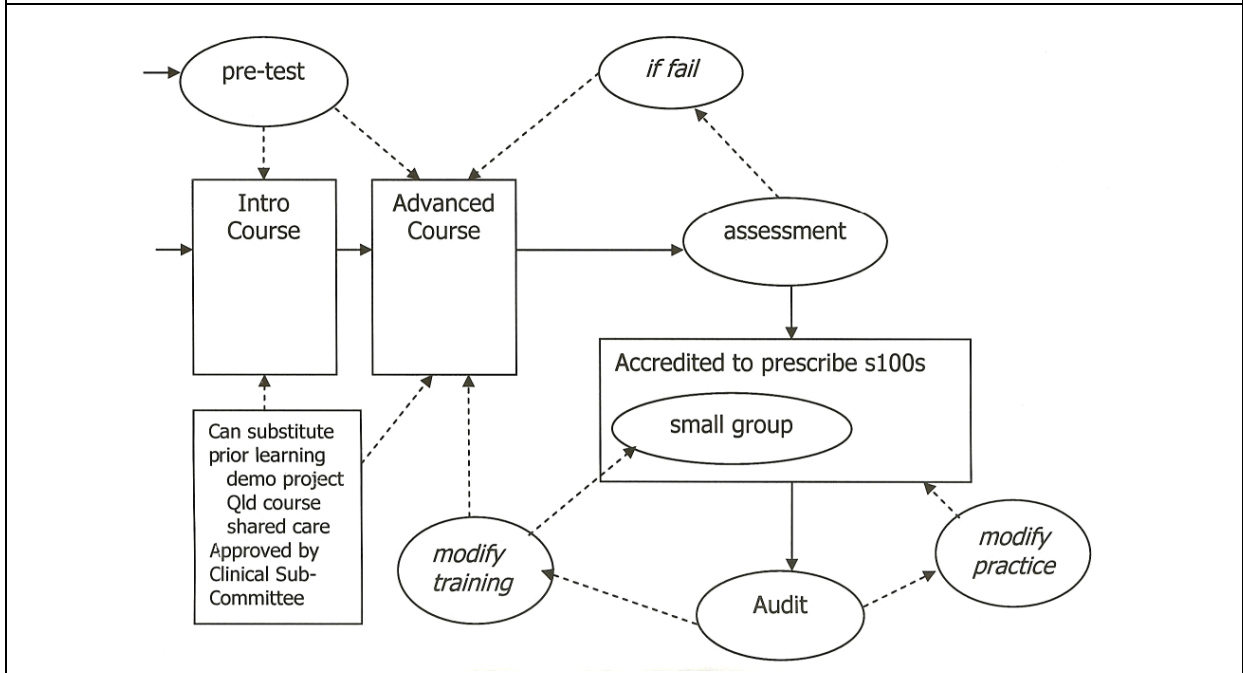
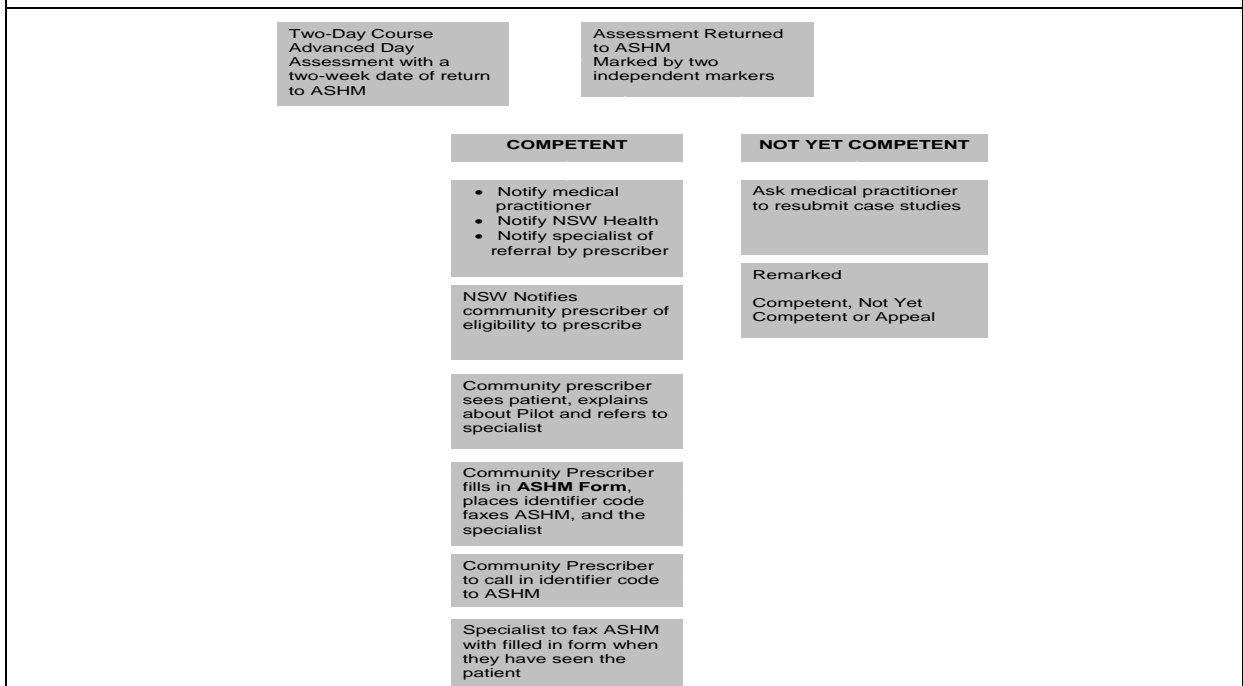


Figure 4: Procedure for assessment of prescribers



The initial training for the pilot was conducted in six locations throughout NSW and ACT in 2003. An additional course was conducted in October 2005. In total 114 participants completed the introductory course, and 140 participants completed the advanced course.

Location	Date	Introductory	Advanced
Surry Hills	Feb 2003	24	27
Surry Hills	Feb 2003	23	27
Hunter	Feb 2003	13	16
ACT	March 2003	16	15
Western Sydney	March 2003	19	24
Ballina	April 2003	19	18
Surry Hills	October 2005	-	13
Total		114	140

While the majority of participants were trained in Sydney, there was very good attendance in the regional and rural training conducted in NSW. In total there were 17 accredited community prescribers in rural/regional areas.

Total number trained in Sydney	91
Total number trained in rural NSW	34
Total number trained in ACT	15
Total number trained overall	140

A total of 98 medical practitioners returned assessment for accreditation. Of these, 88 completed assessment and indicated a preparedness to participate in hepatitis C management including prescribing. At the end of April 2007, there were 81 accredited GPs participating in the project (one prescriber had formally withdrawn from the pilot and six prescribers were overseas or on leave).

Total number completed assessments	98
Total number passed	88
Total number completed resubmits	22
Total number failed or failed to complete the assessment	10
Total number who chose not to submit the assignment (i.e. attended only)	42

During the training of community prescribers, participants were provided with patient education folders. The folders provided information on hepatitis C treatment and support services available for patients. Further resources could be requested from ASHM.

ASHM provided ongoing support and information to prescribers through the provision of regular information sheets that were emailed or faxed to prescribers, and by establishing an email group. In addition to the initial training that was provided, ASHM scheduled regular updates for participating GPs and other interested parties, such as practice nurses and pharmacists, throughout the pilot project. ASHM was also able to organise placements at liver clinics for interested parties.

In addition to training of community prescribers, ASHM also offered training to practice nurses of participating community prescribers in December 2004. The training included 14 participants. Nine participants were from the Sydney metropolitan area and five were from a drug and alcohol service.

4. PATIENT ENROLMENTS

4.1 Patient enrolment

As at 14 May 2007, 236 patients have enrolled in the pilot. Of these 236 patients:

- **40 patients have been treated and had scripts written by community prescribers**, and 22 of these have completed treatment
- **110 patients have not commenced treatment** for various reasons. Some of these patients may have had clinic appointments shortly
- **38 patients have been lost to follow-up** with prescribers and/or clinics (some of these may have ended up on clinical trials but could not be identified at the clinic and they have not returned to their GPs)
- **48 referred patients have been treated for HCV by the liver clinics**. A number of these patients are known to have entered clinical trials. Some patients may have also chosen to be treated by the clinic.

In the consultations conducted as part of the evaluation, a range of reasons has been put forward by patients, liver clinic nurses and community prescribers as to why many patients have not commenced treatment. These are synthesised in section 6.3.

There may be a range of reasons why 38 patients have been lost to follow-up. Some of the reasons include that the patient did not attend the liver clinic appointment or the patient was not correctly identified as a referral under the pilot project.

At the end of April 2007, there were 81 hepatitis C community prescribers still participating in the project. Of these, 38 had enrolled at least one patient.

Figures 5 and 6, below, highlight that most of the pilot patient referrals have been to hepatitis C treatment centres in Sydney, with St Vincent's Hospital and Royal Prince Alfred Hospital (RPAH) receiving the majority of those referrals.

Figure 5: Number (n=236) and geographical location of referrals to hepatitis C treatment centres

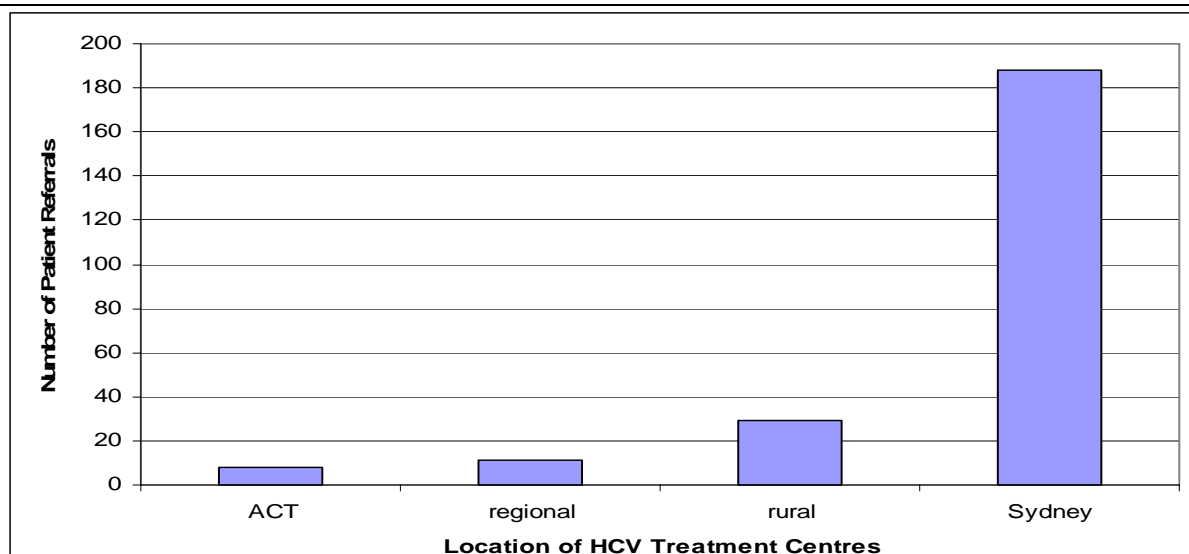
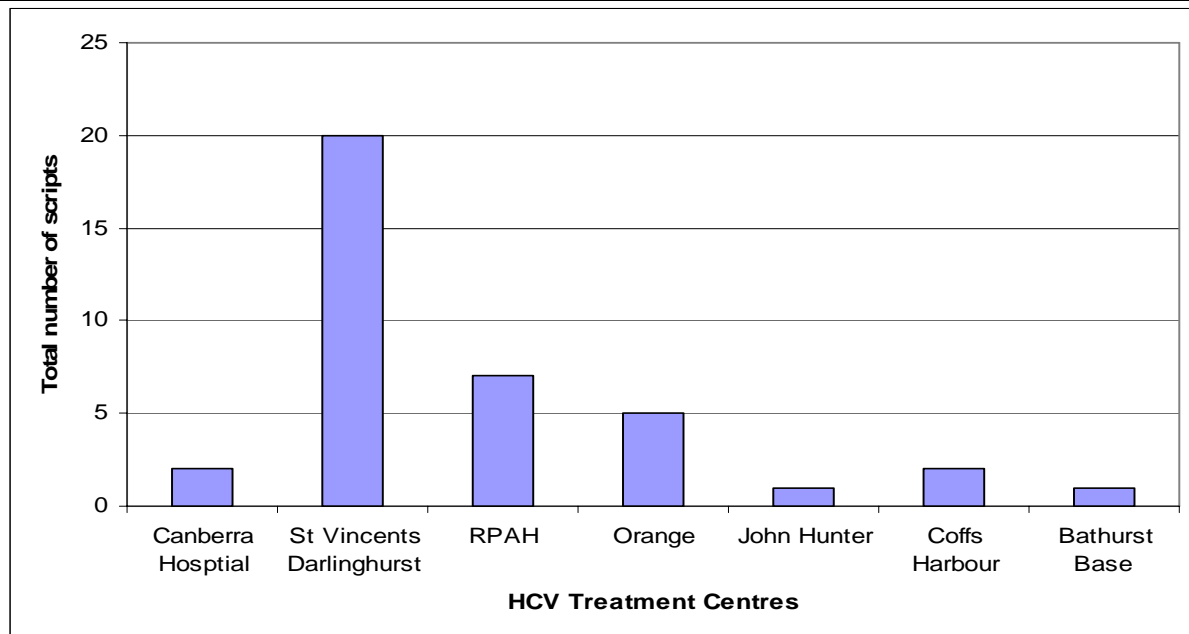


Figure 6: Total number of scripts (n=40) written by community prescribers linked to hepatitis C treatment centres



4.2 Review of case audits

Case audits were completed at the end of treatment by the collaborating specialist centre for each patient managed under the pilot. The case audits were used to assess the standard of care provided to patients by community prescribers.

As of 14 May 2007, 13 case audits had been completed. These audits were conducted at participating specialist centres at Coffs Harbour, John Hunter Hospital, Canberra Hospital, Orange Base Hospital, St Vincent's Hospital and Royal Prince Alfred Hospital.

As part of the evaluation, a review of case audits was undertaken. The review found that:

- Overall, specialists reported favourably on the level of care provided by GPs. In some cases clinics reported that community prescribers were in a position to provide more support to the patient.
- The pilot protocols were generally well adhered to by community prescribers. The shared care arrangements worked well with specialists reporting that community prescribers maintained close contact with themselves or clinic staff during patient treatment.
- The work-up conducted by community prescribers was adequate and, in general, community prescribers ensured test results were available to specialists as required.
- Where community prescribers identified that dose reduction was required, this occurred in consultation with liver clinic staff and dose reduction occurred in an appropriate and timely manner.
- Specialists reported that community prescribers handled additional visits and interventions appropriately.
- Specialists reported that community prescribers appropriately consulted clinic staff on abnormal tests results.
- Specialists reported community prescribers made appropriate referrals to other services, as required.

- In some cases, the pilot demonstrated how access to treatment could be increased particularly for those candidates who lived in rural areas where specialist services may not be in close proximity to their home.

5. STAKEHOLDER VIEWS AND EXPERIENCES

5.1 Patients

The experiences of patients participating in the pilot, particularly the care they received from community prescribers, were sought through a survey and one-on-one interviews.

5.1.1 Survey findings

Respondents

ASHM developed, in collaboration with the National Centre in HIV Social Research, a survey that was forwarded to patients who were enrolled in the pilot. The survey was distributed in March 2006 to 32 prescribers for distribution to the patients they had enrolled in the pilot. Completion of the survey by patients was voluntary. Surveys were accompanied by reply-paid envelopes to maximise response rates.

A total of 41 surveys were returned. Of these, 28 were surveys returned from patients of one community prescriber at a drug and alcohol practice. The other 13 respondents were attending various practice locations.

The large response rate from the patients of the drug and alcohol practice was due to these patients regularly attending the clinic for their pharmacotherapy maintenance and the practice actively encouraging the completion of the surveys while the patients were waiting to be seen. Where there are differences in the response from participants of the practice, these have been reported separately.

Of the 41 respondents, six were female, one was transgender and the rest were male. Twenty-one respondents were patients who had decided not to have treatment or were still considering treatment.

The age of respondents varied from 30 to 59. Most respondents were in their forties.

Respondents who were to commence, currently on or completed treatment (treatment managed by GP)

Twenty respondents were due to commence, currently on or completed treatment. Eight respondents reported that their hepatitis C treatment was managed by their GP.

All respondents generally reported favourably on the care provided by their GP. They reported that the GP provided them with the right information about hepatitis C treatment before they started and that the GP informed them about the possibility of severe side effects of treatment.

All respondents reported that their GP spent enough time with them when they went to see them during treatment. All respondents reported that they felt well supported by their GP during treatment and felt comfortable talking with their GP about any issues that bothered them during treatment. They also reported that their specialist had been kept up to date on the progress of their treatment.

No experience of discrimination from their GP or any other health care worker during treatment was reported by the respondents.

Four respondents reported that their GP discussed with them whom they should tell that they were on treatment. Two respondents didn't answer this question and two respondents indicated their GP did not tell them.

Five respondents reported that their GP discussed how treatment might affect their relationship with their partner and family. Two respondents didn't answer this question, the other respondent indicated that his GP did not tell him.

Six respondents reported that their GP provided them with information on support groups, one respondent did not answer and one indicated that his GP had not but his specialist had done so.

Seven reported they were able to contact their GP at anytime when they needed to. One reported he was not able to.

Patients were asked to rate their experience of hepatitis C treatment from their GP on a scale of 1 (poor) to 10 (good). Five respondents rated it as 10, another as 9, another as 7/8, and one patient rated it as one. The rating of 1 by one respondent does not correlate with answers to the other questions pertaining to the GP, which the respondent rated very positively, suggesting that the rating scale for this question might have been misunderstood.

Respondents who were to commence, currently on or completed treatment (treatment managed by specialist)

Twenty respondents were due to commence, currently on or completed treatment. Twelve respondents reported that their hepatitis C treatment was managed by their specialist.

Respondents were asked their reasons for deciding to continue their treatment with a specialist at the liver clinic. The most common response was that the respondent went on to a clinical trial. Other reasons nominated by respondents included:

- liver clinic offered more support
- preferred to access all treatment needs at one site
- proximity of liver clinic
- referred to specialist due to clinical status.

Patients were asked to rate their experience of hepatitis C treatment from their specialist on a scale of 1 (poor) to 10 (good). Seven respondents rated it as 10, another as 7, another as 6, another as 5 and another as 4 and one provided no rating.

All respondents reported that the specialist provided them with the right information about hepatitis C before treatment commenced, including about the possibility of severe side effects during treatment. Ten respondents reported that they were provided information about support groups, one respondent reported that he was not.

All respondents reported that the specialist spent enough time with them when they went to see him/her during treatment, and being well supported during treatment. Two respondents reported that they were able to contact their specialist any time they needed to, and one reported not feeling comfortable talking to their specialist about any issues that bothered them during treatment.

One respondent reported experiencing discrimination from their specialist during treatment. That same respondent rated their overall experience of treatment through the specialist at the liver clinic lower than other respondents. No other experience of

discrimination from a GP or any other health care worker during treatment was reported by the respondents.

Nine respondents reported that the specialists discussed with them disclosing to others, including discussing how treatment might affect their relationship with partners and/or family. Two respondents reported that they did not.

Respondents who were still considering treatment

Twenty-one respondents reported that they were not having treatment. Importantly, of these 21 respondents, 16 indicated in their response to the question that they were still considering treatment.

A range of factors influenced their decision not to treat at this point in time. Most commonly respondents reported that they were concerned about the impact it would have on family and friends, and the impact it would have on their work. Some of the other personal and social factors included:

- unmotivated or ambivalent about treatment
- wanting to have children in the near future and not finding contraception acceptable
- lack of supportive environment
- waiting for partner to complete treatment
- needing to reduce alcohol intake
- incompatibility of commencing treatment while still using illicit drugs
- other upcoming events impacting on ability to commence now (e.g. court appearance).

The most common treatment-related concern reported was about side effects of the treatment. Some of the other treatment-related concerns included:

- difficulties committing to long treatment program
- HIV coinfection
- can not meet requirements to stay on regimen
- fear of liver biopsy
- current liver status is good and feeling really well.

Patients were also asked if they would consider having hepatitis C treatment if the specialist did all of it. Seven respondents provided no answer. Eight respondents said it would make no difference. Two respondents said no, as they preferred the shared care model. Three patients said yes, and one replied maybe.

5.1.2 Interview findings

Interviews with patients, analysis of interview data and reporting of findings were undertaken by the National Centre in HIV Social Research. A summary of the key findings from the NCHSR report are outlined below.^v

Seventeen people participated in a telephone interview. Of these 17 people, 14 people had completed or were undergoing treatment. Of these, ten people had their hepatitis C treatment managed by GPs, the other four people were managed on treatment through the liver clinic. Three were still considering treatment.

The three people who were considering treatment expressed differing reasons for not yet taking up treatment including family issues, other health issues and ambivalence about liver biopsy and medical treatment in general. Two of them indicated that they would prefer to receive hepatitis C treatment from their GP.

Of the ten people who had their hepatitis C treatment managed by their GP, six people had recently finished treatment. Overall, people were very positive about having their GP involved in their hepatitis C treatment. They felt prepared for treatment and well-supported. They also reported that the advantage of GP prescribing was that they had long-standing, close and comfortable relationships with their GP (five of those who had completed treatment were also on methadone maintenance treatment), and that access to treatment via their GP 'streamlined' hospital procedures, thereby saving time. For one person living in a regional area, the GP was in closer proximity than the specialist.

However, there were some cases where people reported that their needs during treatment were not met. One person reported that he did not take up a referral to a mental health professional even though he needed emotional assistance. Another man felt he needed assistance with antidepressant medications but was not provided with this (this man was assessed for depression at the liver clinic by a specialist). One person reported significant dissatisfaction with his shared care arrangement; he felt that his GP was busy and difficult to access and that in a shared responsibility arrangement it can end up with "nobody" taking responsibility, and he felt somewhat abandoned by the process.

Four people had their hepatitis C treatment managed by a liver clinic. They stated it did not matter who managed their treatment and that they would also have had treatment if the GP had managed their care. One man specifically stated that he felt the hospital clinic could handle treatment requirements better and he had discussed his treatment with the specialist because he had the best available information and experience.

The authors concluded that the results of the interviews suggested that:

1. Overall, people were satisfied with their hepatitis C treatment as provided by either the GP, shared care or standard liver clinic arrangement.
2. People were committed to undergoing hepatitis C treatment regardless of the mode in which it was offered.
3. The GP model of HCV treatment service delivery will be successful in contexts where people are able to trust their GP, feel comfortable with their GP's knowledge and expertise, are able to relax and disclose honestly to their GP, and are able to access him/her at almost any time during HCV treatment.
4. People with long-standing relationships with opiate replacement therapy prescribers may have different experiences and preferences for hepatitis C treatment compared with those people who are less involved in therapeutic relationships with their GPs.

5.1.3 Summary

- Patients rated highly the care they received from community prescribers. They reported that they were provided with appropriate information about side effects and offered appropriate support, including information on support services, during treatment.
- Patients reported that shared care arrangements worked well, with the specialists being kept up to date on their progress.
- For patients not on treatment, concerns about the impact it would have on family and friends, the impact it would have on work, and the side effects of treatment were the most common concerns. Fear of liver biopsy was also a concern for some.
- In general patients who had not yet started treatment, indicated it would make no difference if all of the C treatment was managed by the liver clinic.
- For patients whose treatment was managed by a specialist, the most common reason was that they went on a clinical trial.

- Community prescribing is more likely to be successful in contexts where people have an existing and trusting relationship with their GP (such as those on methadone maintenance treatment), and/or people in rural areas where their liver clinic is distant from where they reside.
- One patient reported experiencing discrimination from their specialist. No other patient reported any experience of discrimination from their GP, specialist or any other health care worker during treatment.

5.2 Community prescribers

Input from community prescribers into the evaluation occurred through a survey distributed in 2005, and a focus group held in 2007.

5.2.1 Survey

In January 2005, ASHM distributed a survey to community prescribers participating in the pilot. The survey asked prescribers to assess barriers to patients commencing treatment. ASHM received 65 responses to the survey. An analysis of the themes that emerged from the survey are reported below.

There were four common factors identified by community prescribers as barriers that had hindered uptake of hepatitis C treatment.

Firstly, for many patients treatment was not a priority at this point in time. For some it was a lack of interest or motivation, for others they had competing priorities. Prescribers reported that those patients who were well were more likely to feel there was no urgent need to treat. These patients could wait to see if treatment options improved in the future.

The second key factor that impeded uptake of treatment was that many patients had complex psychosocial issues that needed addressing. Prescribers reported that many patients had chaotic personal lives or poor support networks, which made prioritising a long course of treatment unfeasible. For some patients, addressing accommodation or employment issues took precedence over addressing hepatitis C. Prescribers reported that those patients currently using illicit drugs gave hepatitis C treatment a low priority.

The third common factor mentioned by community prescribers was the requirement that a liver biopsy be undertaken for patients wishing to access hepatitis C treatment. Prescribers reported that patients were not keen to undergo a liver biopsy. Liver biopsy as a prerequisite for hepatitis C treatment was removed in 2006.

The fourth common factor was that community prescribers identified that their patients were not suitable candidates for therapy. This may be related to previous hepatitis C treatment, genotype or HIV coinfection. Another relatively common reason prescribers identified was depression or mental health issues. Alcohol intake was also cited by some prescribers as a reason why the patients were unsuitable at this time for therapy.

In addition to the four factors reported above, other frequently reported impediments to treatment uptake include:

- patients were concerned about the impact of treatment side-effects
- the distance patients had to travel to visit a liver clinic
- the delay in referred patients receiving an appointment at a specialist clinic
- impact on family, friends and work.

A minority of community prescribers indicated that there were problems in local shared care arrangements, particularly around communication from the specialist facilities. They reported that patients were referred only for them to never hear back from the specialist. This became a disincentive to refer patients under the pilot.

5.2.2 Focus group

Method

In February 2007, a focus group was held with 14 medical practitioners who participated in the pilot project. The focus group included medical practitioners who had prescribed hepatitis C treatment to multiple patients, practitioners who had prescribed to one or a few patients, and practitioners who had been trained as part of the pilot project but had not written any prescriptions.

The focus group included sexual health physicians, drug and alcohol specialists, GPs who are opioid treatment prescribers, GPs who are s100 HIV prescribers and GPs with high caseloads of patients with hepatitis C. The focus group included participants from Sydney and rural/regional NSW.

Below are the key themes that emerged from the focus group.

Effectiveness of shared care model

Overall, focus group participants were critical of the model of shared care adopted for the pilot. Participants' criticism of the shared care model was that the model did not adequately facilitate shared care. There were some exceptions, but overall most participants reported very similar experiences regardless of the liver clinic to which they referred patients. Focus group participants reported that it was not uncommon for the diagnostic tests that were conducted by the community prescriber prior to patient referral to the clinic, to be repeated by the specialist at the clinic.

Patients were referred and then their entire treatment was taken over by clinic. And so it hasn't really moved to a shared care model...basically it's the structure they are used to. The patient goes to the clinic, basically all the treatments are repeated which is a huge waste...you've done all the baselines as requested in the protocol, they're all with the patients and...then they'll be serviced in the clinic and the clinic will do the usual whatever it does.

Focus group participants also reported that frequently patients that were referred to specialist liver clinics as part of the pilot project ended up being treated by the liver clinic. This is borne out by patient enrolment statistics that show 38% of patients referred to the liver clinics have been treated for HCV by the liver clinic. Such actions were considered to hamper the implementation of a shared care model.

We've got people at all stages. Some we have prescribed for right throughout their treatment...a large number we have referred them and had them back after they have been treated...the majority that we have referred on – those that have actually made it to the clinics – mostly they have just been treated at the clinic and then sent back after they finished their program.

While focus group participants supported community prescribing, they believed that the model needed to be reviewed so that accredited community prescribers could initiate treatment. Community prescribers believed this would be the most effective way to increase access to HCV treatments, and reduce the burden on hospital liver clinics.

Community prescribers reported that most patients had to wait, on average, two to three months for a first appointment with a liver clinic. Participants reported that this delay in obtaining a first appointment acted as a significant impediment to patients commencing treatment, as patients often lost interest and motivation due to the time lag. It was seen as another barrier that prevented patients from commencing treatment, and another argument in favour of community prescribers being authorised to initiate treatment.

The only way it is going to change is if we can initiate treatment in primary care.

The model adopted in the pilot was compared unfavourably to the model adopted in HIV where community prescribers can initiate s100 HIV treatment. Participants were perplexed as to why a different model was adopted in hepatitis C treatment, particularly when focus group participants who were HIV community prescribers believed HIV treatment, given the number of drugs and need for life-long treatment management, was more complex than hepatitis C treatment. Focus group participants also argued that they believed more GPs were likely to become community prescribers if they were able to initiate treatment.

Focus group participants were keen to highlight that even if GPs who are accredited prescribers can initiate treatment, they would not be managing the more complex cases of hepatitis C treatment. They would continue to refer complex cases to specialists, or refer patients when difficulties arise, as they do with other issues that may arise within primary care that are beyond their 'comfort' levels to treat.

Relationship with participating specialists

While there were exceptions, overall community prescribers reported that communication between participating liver clinics and themselves needed to be improved. Focus group participants reported that after patients were referred to liver clinics, they frequently received no correspondence from the liver clinics about the patient they had referred, or when they did receive the communication it was too slow in coming. Pilot protocol required that letters must be sent from specialists to community prescribers following each specialist review. Prescribers reported that they felt this did not occur in the majority of cases.

Focus group participants reported that when they had a close personal relationship with the specialist, communication and collaboration tended to be much stronger. Generally, most participants believed the pilot had little impact on facilitating relationships between specialists and community prescribers.

Supporting patients on treatments

Focus group participants acknowledged that patients often require a great deal of support prior to and when undergoing treatment. Participants did not report difficulties in referring patients to appropriate services. More generally, participants believed that general practice was a highly suitable environment in which to manage and provide support to people on hepatitis C treatment.

Patient education

While ASHM provided patient education resources to community prescribers, focus group participants identified that there needed to be more health promotion interventions to promote hepatitis C treatment to patients, as well as resources that explained to patients their options in terms of accessing hepatitis C treatment through a community prescriber. Participants reported that patient knowledge of hepatitis C treatment was generally quite low or outdated.

Pilot administration

Focus group participants had few criticisms of the administrative aspects of the pilot. The systems, procedures and protocols implemented were seen to be effective and appropriate. They believed that their criticisms of the lack of effective shared care between general practice and liver clinics were not due to pilot referral procedures being inappropriate.

Skills development

Focus group participants reported positively on the training provided by ASHM. They believed it provided them with the skills necessary to undertake community prescribing.

Focus group participants reported that if community prescribing is to continue once the pilot ends, then it is critical that there is continuity so that their skills in treating hepatitis C are not lost and quality can be maintained.

Summary

This has been a great trial. I took part in a predecessor to this called Hep Care. Its been ten years since I first tried to prescribe for hepatitis C. That's how long it took me to write a script.

Focus group participants supported community prescribing. However, they believed that the model adopted by the project hindered the provision of effective shared care arrangements between community prescribers and specialist liver clinics.

The key issue is that the more barriers and steps required the fewer people who make it – greater attrition rate at each step.

There was strong support among focus group participants for community prescribers to be authorised to initiate treatment for hepatitis C. It was believed that such an initiative would likely have a positive impact on the number of people with hepatitis C accessing treatment.

5.3 Collaborating specialist centres

5.3.1 Specialists

All participating specialists were offered an opportunity to provide input into the evaluation. Input was received from five specialists. This included two specialists who received a significant number of pilot patient referrals.

Effectiveness of the shared care model

Feedback on the shared care model adopted by the pilot project was mixed.

Some of the specialists who provided input indicated that they believed the pilot has worked well overall. They reported no concern regarding the level of care provided by community prescribers. They generally indicated that they were supportive of community prescribing and believed it should continue.

Some of the specialists who supported the pilot indicated that they believed for access to hepatitis C treatments to be increased, then any future model of community prescribing would need to give consideration to supporting GPs being able to initiate patients on to treatment.

Other specialists who inputted into the evaluation expressed scepticism of the value of the model. They believed the shared care model had not been effective. They were critical of the level of care provided. They did not support the continuation of community prescribing.

Some questioned the model. They did not see any value in the model focussing on GPs being enabled to write scripts, when they believed the focus needed to be on ensuring appropriate support for patients considering treatment. They questioned whether GPs had the amount of time required, appropriate access to ancillary services and the skills required to offer patients the treatment support they required. They believed that specialist centres had more capacity to meet the needs of patients in this regard, particularly given the experience and skill of CNCs and particularly as ancillary support services required were often hospital-based. And, not unexpectedly, they reported that it was easier to work with liver clinic nursing staff than GPs in the community.

I think we need to spend more resourcing successful clinics, our numbers are limited by the number of patients our existing clinic nurses can treat, not by medical staff, more prescribers will not change that, I would have more confidence working with my nurses on site than trying to work with GPs (who probably have much more limited experience are off-site).

Some specialists stated that they believed hepatitis C treatment and management required specialist care.

Cancel this model. Biggest waste of resources. HCV is a moving beast that demands specialist care. The very interested and committed GPs can work out their own partnerships with specialist colleagues.

There were also some criticisms that the pilot did not provide an opportunity for private specialists to be involved.

Relationship with community prescribers

While some indicated that communication between themselves and some community prescribers had been very good, others identified that communication between the specialist clinic and some community prescribers was not always as effective as it could have been. However, specialists generally reported that when further support was needed, community prescribers did make appropriate contact with the specialist centre.

One specialist indicated he received inappropriate patient referrals as part of the pilot – 'inappropriate' in that for a range of reasons the patient was not an appropriate candidate for treatment. He reported that there were difficulties in accessing the GP to discuss the referrals.

Training of community prescribers

Specialists reported that they believed the training ASHM provided to GPs was appropriate. Most specialists reported that the pilot had a positive impact on up-skilling GPs to meet the hepatitis C treatment needs of their patients, regardless of whether they undertook community prescribing or not.

One specialist did express concern that if community prescribing were to continue, that trained and accredited GPs would not be able to keep up with changes in treatment regimes.

Administration of the pilot

There was some criticism of the administration systems established to support the implementation of the pilot. Some specialists indicated that these systems needed to be simplified and the amount of paper work reduced. Although some that made these criticisms acknowledged that ASHM had worked to address these concerns, others still wanted to see further simplification of systems.

5.3.2 Clinical Nurse Consultants

A focus group was held in November 2006 with eight clinical nurse consultants and/or clinical nurse specialists from liver clinics that participated in the pilot project. The focus group included participants from St Vincent's Hospital, Royal Prince Alfred Hospital, John Hunter Hospital, Canberra Hospital, Westmead Hospital and Greater Western Area Health Service Methadone Clinic. Participants were asked to provide comments on all aspects of the administration and implementation of the pilot.

One of the underlying themes that emerged from the focus group was the importance of recognising the key role of nurses within liver clinics. Focus group participants reported that nurses play a pivotal role in supporting patients in undertaking treatment. As reported below, focus group participants reported that the role of nurses was not well recognised and the initial implementation of the pilot failed to adequately engage them in the process. While the issue was rectified during project implementation, focus group participants were keen to ensure any future shared care models would recognise the important role nurses play within liver clinics in supporting patients, as well as the key role they can play in supporting and linking with community prescribers.

Below is a summary of the other key themes that emerged.

Effectiveness of model

Overall, most focus group participants reported that the pilot model of shared care worked well. There were, however, criticisms of the implementation of the model during the early stages. Focus group participants reported that early referral and communication systems with community prescribers didn't work well initially, but that these improved over time.

Participants identified that the advantage of community prescribing is that for many patients it is the preferred mode of service delivery, as it is more convenient for patients, particularly for patients who are on a methadone maintenance program. They identified that in such cases patients already have an existing and strong relationship with their GP. Focus group participants believed that community prescribing, over time, had the potential to increase access to treatment and reduce demands on hospital services.

A significant cause of concern for focus group participants was that GPs may not be able to provide the support required by patients undergoing treatment. The limited time available during consultations in general practice was considered an impediment, as was the experience of GPs in providing this support. Focus group participants reported that nursing staff in liver clinics were more experienced in providing this support. It was also believed that nursing staff in clinics were better able to support patients' access to other ancillary services, as most of those services were also hospital based. Focus group participants were keen to ensure GPs had appropriate nursing staff to support the management of patients on hepatitis C treatment.

Administration of the pilot

Overall, focus group participants praised ASHM for their administration of the pilot. They noted that ASHM staff had worked hard to facilitate positive outcomes for all partners involved in the implementation of the pilot.

In general, focus group participants did not report that the administrative demands of the pilot (e.g. paper work) were burdensome. However, they did report that participation in the pilot did result in an increased workload for nursing staff. There was acknowledgement that early in the pilot implementation demands were greater as systems and processes were being established, but that over time, as systems were implemented, the workload decreased. Another part of the increased workload related to providing support for participating GP prescribers. Again, it was felt that over time such needs declined as community prescribers became more skilled.

Some stated that as the pilot increased the workload for nursing staff, consideration should have been given to providing additional nursing support. They stated that this would have also enabled them to better support GPs participating in the pilot.

While ASHM received enhancement funding for implementation of the pilot, the funding did not include provisions for additional enhancements to public hepatitis C clinical services. NSW Health, separately from the pilot, makes enhancements to area health services for the provision of hepatitis C clinical and related services. Area health services are expected to provide hepatitis C clinical services from current dedicated hepatitis C funding and general area health service funds.

Some focus group participants argued that if community prescribing continued, then eventually the patient load of liver clinics would increase. Therefore, any future community prescribing model would need to consider enhanced funding of clinical services to ensure they were able to cope with this increased demand. This, however, is perhaps only true if the current model of community prescribing were to continue.

Engaging CNCs

The implementation of the pilot in 2003 focussed on training, accreditation and support for participating GPs. Shortly after community prescribing commenced in May 2004, it became evident that the involvement of CNCs from participating liver clinics would be critical for the effective functioning of the pilot. In May 2004, ASHM convened a meeting of CNCs who would be able to provide ongoing support to the pilot and facilitate better relationships between clinics and local GPs.

Focus group participants were critical that ASHM had failed to engage with CNCs at the commencement of the pilot project. It was believed that the involvement of CNCs from the commencement of the pilot would have resulted in more effective referral and communication systems between liver clinics and GPs.

What I found disappointing about this project was it was designed to enhance the GP skills to get them to do share care arrangements with the patients. But it looked at it from the wrong angle, the reality is that the nurses are the lynchpin of treatments...nurses weren't recognised...if they had engaged us as part of the process at the beginning it may have actually worked well.

After the initial lack of engagement in the pilot, ASHM's subsequent efforts to involve CNCs were praised. The problem was largely seen to have been rectified by ASHM's subsequent efforts.

Referral and tracking system

The most critical comments from focus group participants related to the referral system established between participating GPs and liver clinics. Focus group participants reported that the referral system didn't work well.

I think that was one of the problems with the pilot. The pilot had to work with totally different arrangements in every single site and they're quite different arrangements, and with limited resources in the pilot. I think there were generic very broad procedures put in place that just didn't really work in practice because of the fact that each site has such different mechanisms for how they accept patients, how they assess patients and how they monitor them on treatment.

Focus group participants reported that it was difficult to identify which patients were part of the pilot project. This may explain why many patients were lost to follow up.

There appeared to be a lack of clarity as to the referral process. Nurses reported they could not be sure what GPs had told patients when they were referring them to the clinic. When referral letters were received from GPs participating in the pilot, nursing staff were unsure if patients had been provided with the clinic contact details and had been told that they needed to then contact the liver clinic themselves, as is normal practice.

Some nurses stated that, as the pilot progressed, referral systems improved, particularly once all participants had become more familiar with the reporting and administrative demands of the pilot.

Impact of the pilot on increasing access to treatments

The primary goal of the pilot was to determine the feasibility of establishing community prescribing for hepatitis C treatment. While increasing access to hepatitis C treatment was part of the rationale of the project, the pilot was not intended to be evaluated by increased numbers accessing hepatitis C treatment. Focus group participants did, however, express disappointment over the low numbers of patients who accessed hepatitis C treatment.

Focus group participants put forward a range of reasons for why the pilot did not achieve a higher level of community prescribing. A significant portion of these reasons related to patients' lifestyle, and had little to do with the pilot project itself. Some patients have a chaotic lifestyle that acts as a significant impediment to undertaking treatment. For others, treatment at this point in their life is not a high priority, particularly when there is a lack of urgency due to a minimally-symptomatic or asymptomatic condition. For others treatment may have some priority attached to it, but it was difficult to identify an optimal time to commence treatment.

Focus group participants identified other reasons for the low level of community prescribing related to GP interest and ability to become involved. In some cases nurses could identify GPs who undertook the training primarily because they were interested in developing their skills in hepatitis C, rather than becoming a community prescriber. Others may have intended to undertake community prescribing until they realised the impact it would have on their workload. Some nurses reported that GPs did not complete the assessment required to become accredited due to the work it would involve.

Focus group participants reported that some GPs had explicitly stated they would not participate in community prescribing unless they were authorised to prescribe from the outset, as was the case in HIV medicine.

Despite the low number of patients accessing treatment, nurses reported many other positive outcomes of the pilot which are important. One of these outcomes identified by

focus group participants is that the pilot project was very effective at improving hepatitis C knowledge among GPs.

I think the aim was good. And that there were so many GPs who were interested. I think the basis of it was great. There was interest from GPs.

The training provided to GPs was also believed to have a positive flow-on effect to people with hepatitis C. Focus group participants reported many more patients had become better informed about their treatment options even if at this time they chose not to treat.

Additional concerns about community prescribing

Focus group participants discussed that one drawback of the pilot was that, initially, they received inappropriate referrals from GPs (e.g. patients with high diabetes, significant mental health issues). This was viewed as an issue that would be overcome as GPs became more experienced.

It was also suggested that the pilot may have been too ambitious, and that it should have targeted fewer sites.

There were concerns that if community prescribing were to continue, patients could get less access to trials. However, this does not appear to have happened during the pilot, in which participating specialists recruited a significant number of patients into clinical trials.

There was acknowledgment from some focus group participants that some patients prefer to see a specialist, as hospitals are seen as 'one-stop-shops' where all their needs can be met.

Delays in commencing community prescribing

There was over a year's delay from the time GPs were first trained to when they commenced prescribing. Anticipation of pegylated interferon being listed as a highly specialised drug was a significant factor in the delay of treatment prescription. Focus group participants believe the delay had a detrimental impact.

Ironically I think the pilot was about three years too early but it was an essential thing just to raise awareness of hepatitis C treatment within the GP community. But the pilot has sort of run this length of time and now they're just starting to go 'oh yeah hepatitis C, yeah interferon yes treatment is available'. So we are getting a lot more referrals from GPs probably as a result of the programs ASHM has run.

Prescriptions

There was an expectation the specialists would write a prescription that enabled treatment to be accessed for one month only.

Focus group participants reported that specialists tended to write repeat scripts that enabled patients to receive drugs for two to three months. This was seen as appropriate largely as it was more convenient for patients, and reduced the risk of doses not occurring because of the failure to receive a new prescription.

Future model

Focus group participants supported community prescribing.

I think even though there's been lots of negatives along the way, it has been a really good worthwhile exercise. And I can see lots of positive. And its nice to have the opportunity to begin to feel this can shift to the community.

There was agreement that community prescribing has to be part of the process to increase access to treatment for people with hepatitis C.

The reality is we are treating 2,000 a year and we are going to have to start treating 10,000 a year according to the estimates. The only way it is going to happen is if GPs are initiating therapy as well.

Participants believed the current model needs to be changed if community prescribing is to increase access to treatment for people with hepatitis C. The most significant change that would have that impact would be to allow accredited GPs to initiate treatment. Participants thought the other positive influence this would have, would be to encourage more GPs to become community prescribers.

Focus group participants believed that to further increase access to treatment, more workforce development needs to occur with the drug and alcohol sector to ensure they were skilled and knowledgeable on hepatitis C treatment. Participants also indicated that workforce development initiatives targeted at nursing staff are important given the role nurses play in facilitating community prescribing. They also believed that nurse practitioners could play an increasing role.

Another strategy identified to increase the uptake of treatment was to target GPs who already have a high caseload of patients with hepatitis C. It was felt that such doctors would already have a good and trusting relationship with their patients. For focus group participants this meant targeting current methadone prescribers and other drug and alcohol service providers.

Summary

- Community prescribing was supported by the nurses involved in the pilot, who identified it as an important strategy that could assist in increasing access to treatment for people with hepatitis C and reducing demands on hospital liver clinics. However, nurses were concerned that community prescribers may not be resourced to provide the support required to patients undergoing treatment.
- Nurses were keen to ensure that any future shared care model recognises the important role nurses in liver clinics play in supporting patients undergoing treatment, as well as the pivotal role they play in linking with and supporting community prescribers.
- Nurses identified GPs' interest and workload as factors that impacted on the low level of community prescribing. It was also reported that some GPs stated they would not participate in community prescribing unless they were authorised to prescribe from the outset.

5.4 Stakeholders

A range of stakeholders were involved in various aspects of project planning and implementation. They include the NSW Department of Health, non-government organisations such as the Hepatitis C Council of NSW, pharmacists at public hospitals, and members of the ASHM HCV Clinical Sub-Committee. Given their involvement in the project, their views and experiences on the pilot project were sought.

Effectiveness of the model

In general, stakeholders were supportive of community prescribing. Community prescribing was recognised as an important strategy in increasing access to hepatitis C treatment.

Stakeholders were keen to ensure that the lower than expected number of patients who were treated through the pilot would not be interpreted as the model not having been effective. They believed the pilot achieved its aim of demonstrating that administrative arrangements for a shared care model for the treatment of hepatitis C can be effectively implemented.

A range of reasons were put forward as to why there was lower than expected enrolment. Some of these factors have been canvassed earlier, and related to personal and social factors that impact upon patients' choices about treatment. Apart from the personal factors that influence patients' choices, stakeholders believed that restrictions on GPs being able to initiate treatment was a significant impediment. Some stakeholders also reported that community prescribers' enthusiasm for the pilot waned as patients referred under the pilot often ended up being treated by the liver clinic.

While numbers of people accessing treatment may have been lower than expected, stakeholder identified that a very positive outcome of the pilot was that the hepatitis C treatment knowledge of GPs was improved. This was seen to have a positive impact on the health care they were able to provide to people with hepatitis C.

Stakeholders reported, from their experience and involvement in the pilot, that they did not believe standards of care provided under shared care arrangements were lesser than those provided through liver clinics.

Advantages and disadvantages of the pilot

Stakeholders identified that there were many advantages to community prescribing. The advantages included:

- reduced burden on hospital liver clinics
- increased access to treatment for people with hepatitis C
- improved choice accessing treatment
- people with hepatitis C often already have a good and trusting relationship with their GPs
- increased convenience in accessing treatment through their GP.

A disadvantage of the model, according to some stakeholders, was that GPs may not be able to provide the same access to other hospital services that patients might require, such as dieticians, psychiatric services etc. The same stakeholders, however, indicated that they generally felt community prescribers were better than liver clinics at ensuring patients were offered support services provided by non-government organisations.

A concern expressed by some was that the shared care model was dependent on the relationship between specialists and community prescribers. The pilot was perceived to function more effectively where these relationships were strong.

Some stakeholders felt that more should have been done to promote awareness of the community prescribing pilot to people with hepatitis C. It was thought this might have facilitated a larger uptake among people with hepatitis C.

Public hospital pharmacies

As noted earlier, dispensing of highly specialised drugs for hepatitis C treatment was from public hospitals. The pharmacists who participated in the evaluation reported few concerns in relation to the pilot.

Pharmacists were aware of the requirements for signed s100 declaration forms to seek reimbursement through the HSD Program and to retain the forms for auditing purposes. They reported no concerns about these administrative requirements, as most were already familiar with the HSD Program.

One pharmacist reported that, to increase the convenience to patients, consideration should be given to enabling scripts to be filled by community pharmacies. It was acknowledged, however, that this was beyond the terms of reference for the pilot model.

Administration

Stakeholders were critical of some of the paperwork required to participate in the pilot. It was perceived as unnecessarily bureaucratic and cumbersome. As noted earlier, ASHM responded to these criticisms throughout pilot implementation by revising and simplifying patient enrolment forms. However, stakeholders reported that some GPs found the process overly-complicated and were overwhelmed by the large volume of information associated with the pilot, and as a result they were disinclined to participate in the pilot project.

Future model

Some stakeholders argued that for community prescribing to be successful, GPs needed to be able to initiate treatment, in particular as GPs are more likely to become involved in community prescribing if they are able to initiate. They also felt that the delays in patients being able to obtain their first liver clinic appointment, which would enable the specialist to initiate treatment, acted as an impediment to the effective uptake of treatment among patients.

If community prescribing were to continue then some argued it was important to target GPs with an interest in hepatitis C to become community prescribers. It was believed that those who already have a high caseload of patients with hepatitis C and doctors working in the drug and alcohol field are the most appropriate candidates for community prescribing.

Some stakeholders also reported that in the future nurse practitioners may be able to expand their already significant role in hepatitis C treatment.

There was an understanding from the outset that the program would be run with existing clinical resources. As such, there was no funding in the program to provide additional nursing support even in the establishment stages, and when funds for this purpose were offered by the pharmaceutical industry, the steering committee agreed that they could not be accepted.

6. EVALUATION FINDINGS

6.1 Administration of the pilot

In general, the pilot project was well administered. However, some stakeholders indicated that the systems adopted during the pilot could have been simplified to reduce the administrative workload. ASHM did respond to these criticisms during project implementation by adjusting procedures and protocols as required (e.g. reviewing and simplifying the patient registration form).

One problem identified relatively early during the pilot was the failure to engage with CNCs within liver clinics. Pilot implementation may have proceeded more smoothly if nurses had been involved from the commencement. ASHM recognised this deficit and took appropriate actions to rectify the issue. It is important that any future model recognises the pivotal role played by nurses working in liver clinics, and the important role they can play in supporting community prescribers.

Another problem that hindered the implementation of the program was the delay between training and accreditation of community prescribers (early 2003) and when pegylated interferon became available (late 2003). This delay prevented consolidation of skills acquired during training, as community prescribers waited until pegylated interferon was listed on PBS. The first community prescription was written in May 2004. In hindsight, it may have been beneficial to delay training until such time as participants' newly acquired skills could be utilised. It is unclear the extent to which the delay may have also resulted in less engagement and enthusiasm from prescribers for enrolling patients in the pilot.

Referral processes and communication between liver clinics and community prescribers were serious challenges in implementing the pilot. Referrals were frequently lost to follow-up; approximately 31% of those referred to liver clinics were lost to follow-up, although this maybe because patients did not attend their liver clinic appointment and have yet to return to see their GP. GPs reported that they often referred patients to the liver clinic but received no communications from the liver clinic about the status of their patient. In hindsight, there may have been advantages in restricting the pilot to only a few tertiary sites as this may have enabled more effective implementation of communication mechanisms.

6.2 Adequacy and acceptability of community prescribing

Adequacy of care provided to patients by community prescribers

Specialists, who completed case audits, reported favourably on the level of care provided by community prescribers. They reported that community prescribers discussed treatment issues, such as dose reduction, in an appropriate and timely manner with liver clinic staff. However, a few specialists interviewed or surveyed during the evaluation reported that they were critical of the level of care provided by community prescribers.

Patients who received care from community prescribers rated the care they received very favourably. They indicated that their community prescriber provided them with appropriate information about side effects and offered support, including information on support services, during treatment.

There was some concern expressed by stakeholders that patients of community prescribers would not have appropriate access to care and support services. However, the case audits conducted by the specialists indicated that community prescribers made

appropriate referrals to other services as required. Patients confirmed that they received appropriate support from their GP and referrals when needed.

Early in project implementation there were some reports about referrals of patients to liver clinics who were not deemed appropriate candidates for treatment. This was perhaps to be expected to some extent in the early stages. One reason for this might be the significant time that elapsed from when community prescribers were first trained to when community prescribing began, but it is also feasible that prescribers were referring such clients so that the clinic could undertake an assessment of whether the client was appropriate.

Acceptability of community prescribing to patients

Community prescribing was acceptable to patients.

Patients who were treated by their GP demonstrated a strong preference for community prescribing as they already had an existing and trusting relationship with their GP. In many cases this was because their GP was prescribing opioid replacement treatment and/or because the patient was co-infected with HIV and their GP was an s100 HIV prescriber.

For patients who had not yet treated, they indicated that if their hepatitis C treatment was managed solely by the specialist it would make little difference to their decision to treat.

For those patients whose hepatitis C treatment was managed by a clinic, a common reason this occurred is because they chose to participate in a clinical trial. However, it should be noted that there were a few who chose to be treated at the clinic for a range of other reasons. These reasons included that they could get all their treatment needs met at one site, the belief the clinic offered more support and/or because the specialist clinic was in close proximity to their residence.

Acceptability of community prescribing among GPs

There is considerable interest among GPs in community prescribing of s100 HCV treatment. In NSW and ACT, 140 medical practitioners were trained in community prescribing. At the end of December 2006, there were still 81 accredited medical practitioners participating in the project. After the initial training was conducted in 2003, an additional advanced training course was held in October 2005 due to further expressions of interest by medical practitioners.

Among community prescribers, the least acceptable aspect of the model was the restriction on their authority to initiate HCV treatment. Prescribers argued this hindered the development of an effective model of community prescribing, while presenting an additional barrier to increasing access to treatment for people with hepatitis C (particularly given waiting times for first appointments at liver clinics). Patient enrolment figures highlight that under the shared care model implemented in the pilot many of the patients referred to liver clinics ended up being treated for HCV by the liver clinics – 31% had had scripts written by community prescribers and 38% of referred patients had been treated for HCV by the liver clinics (another 31% were lost to follow-up).

While there is considerable interest among GPs in the pilot, nearly a third of those who completed the advanced training course did not become accredited prescribers. A range of factors is believed to have contributed. Nurses who participated in the evaluation focus group reported that some GPs were interested in undertaking the training primarily to improve their knowledge and skills rather than to become a community prescriber. Another factor identified was that some GPs were hesitant to become involved in

community prescribing because they decided that it was too time consuming or difficult, particularly if they had few cases. A small proportion of GPs failed to pass or resubmit the case studies to receive accreditation (six GPs).

Nurses reported that some GPs explicitly stated that they would not participate in community prescribing unless they were authorised to prescribe from the outset. This is also compatible with feedback ASHM received from some of the GPs they trained.

Acceptability of community prescribing among specialists

Community prescribing is acceptable to some specialists but not acceptable to other specialists.

Some specialists supported the pilot and believed it worked well. Some of those that supported the model, however, believed that any future model of community prescribing needed to give consideration to enabling trained and accredited GPs to initiate hepatitis C treatment with patients.

There is a range of reasons why some specialists did not find community prescribing acceptable. Some did not believe that the model of shared care adopted was effective. They questioned whether GPs were able to provide the support and access to ancillary services required by patients. Others argued that hepatitis C treatment required specialist care.

Nurses associated with liver clinics found community prescribing to be acceptable. They expressed some concern regarding the level of support community prescribers were able to offer patients undergoing treatment, and wanted to ensure appropriate access to ancillary services and other community based services be ensured if community prescribing were to continue. They also emphasised the pivotal role nurses can play in providing support to community prescribers.

Nurses who participated in the focus group believed that any future model of community prescribing would need to consider training and accrediting GPs to initiate treatment.

6.3 Impact of the pilot

The pilot aimed to demonstrate that administrative arrangements could be implemented to enable community prescribing for HCV treatment. Even though the rationale of community prescribing is to increase access to hepatitis C treatment, the initial pilot rationale did not intend for the pilot to be evaluated against increased numbers accessing hepatitis C treatment. Despite this, stakeholders expressed some disappointment regarding the limited impact of the pilot on increasing access to treatments. Of the 236 pilot patients enrolled in the pilot, nearly half did not commence treatment. The factors that contributed to the lower than anticipated level of uptake of treatment are identified below.

While the pilot did not meet expectations in terms of the numbers of patients who accessed treatment, it did have other positive outcomes that in the long term may contribute to increased access to treatment by people with hepatitis C. In particular, the pilot had a significant impact on the knowledge and skills of medical practitioners in providing care to people with hepatitis C.

Medical practitioners who participated in the pilot reported that the training provided them with the knowledge required to identify when a patient is suitable for treatment and to manage a patient on antiviral therapy. Nurses support this self-assessment of learning by participants by reporting that the pilot had a very positive impact on improving

hepatitis C knowledge among GPs. They felt that as GPs were more aware of hepatitis C treatment this had a positive flow-on effect to their patients; even if patients in the immediate future chose not to treat, they would be more aware of their options to treat down the track.

Factors that impacted upon the low uptake of treatments

There is a range of factors that have impacted upon the lower than anticipated uptake of treatment. Some of the impediments to treatment uptake have been well canvassed elsewhere^{vii} and are not inherently due to the model of community prescribing that was adopted. In research conducted in association with the implementation of the pilot in an inner Sydney drug dependency treatment practice, they reported that on average it took 18 months from the identification of a patient as a 'referral priority' to treatment decision.^{vi} This, perhaps, indicates that it is not unusual that, in the short period of time the pilot has been running, nearly half of the enrolled patients have not commenced treatment.

The evaluation identified a range of personal factors that impeded uptake of treatment among people with hepatitis C:

- treatment was not a priority for patients
- patients minimally symptomatic or asymptomatic condition had no sense of urgency
- lifestyle made treatment not feasible at this time (e.g. psychosocial issues needing to be addressed, chaotic lifestyle)
- concern regarding impact treatment will have on family, friends and employment.

The evaluation identified a range of clinical-related factors that impeded uptake of treatments:

- fear of liver biopsy
- fear of adverse side effects from treatments
- not suitable candidate due to previous treatment, genotype, HIV coinfection
- not suitable candidate due to depression or mental health issues.

Some of these factors may be amenable to change, others are less likely to be. For example, as reported earlier, the removal of the prerequisite for prospective patients to undertake a liver biopsy is having a positive impact on increasing access to HCV treatments.

Three additional factors that arose during consultation were perhaps more related to the model adopted by the program. In rural areas, the distance patients had to travel to visit a public specialist centre was considered to be an additional impediment. Prescribers reported that in rural areas this can result in patients travelling significant distances. They also reported that financial constraints resulted in some patients being unwilling to undertake such travel.

Another impediment that was reported was the time lag between patients being worked-up by doctors and the first appointment occurring with a specialist centre so that treatment could be initiated. Waiting-time for first appointments at liver clinics can vary from six weeks to four months. Community prescribers reported that this was another obstacle that acted as a disincentive for some patients to comment treatment.

Another important factor that may have contributed to the lower than anticipated uptake of treatment was poor knowledge of treatment among people with hepatitis C, resulting in low consumer demand for treatment. While nurses reported that they believed knowledge of treatment improved among patients as a result of increased knowledge and skills among GPs participating in the project, research published in 2005 highlighted that

there remain large gaps in knowledge of treatment of hepatitis C among people with hepatitis C.^{vii} The research found that only a minority of participants were aware that treatment for HCV infection could be curative, and that the impact of HCV genotypes on duration and outcomes of treatment for HCV infection was poorly understood. Also most participants believed, incorrectly, that being a current injecting drug user was an exclusion criterion for treatment. Uptake of treatment through a community prescribing model could increase, if knowledge and understanding of treatment for HCV infection were improved more generally among people with hepatitis C.

6.4 Other issues that arose

The NSW Department of Health administers access to the Highly Specialised Drugs Program in the public health system. Under the program, highly specialised drugs are generally dispensed from a hospital pharmacy affiliated with an accredited hepatitis C treatment centre.

During the evaluation, it was reported that difficulties were experienced in organising for the drugs to be dispensed from some hospital pharmacies. It was reported that some hospital pharmacies were reluctant to stock s100 drugs due to a range of factors including costs, storage requirements and administrative workload. It appears that in most cases these were hospitals that were not affiliated with a hepatitis C treatment centre. There was an expectation that ASHM's role extended to negotiating with hospital pharmacies to stock hepatitis C treatment. This was not the case. However, ASHM did ensure it provided information to pharmacies on the pilot and requirements regarding the s100 declaration form, as well as a list of accredited prescribers.

6.5 Summary of pilot effectiveness against stated aims

Overall, the pilot demonstrates that administrative arrangements can be put in place to train, accredit and support community prescribing of HCV s100 treatment.

Below, key findings of the evaluation are reported against the three stated aims of the pilot.

1. Whether the mechanism in place for the training, accreditation and ongoing support of HIV s100 prescribers could be appropriately transferred to the HCV setting.

Findings

Effective mechanisms for the training, accreditation and support of HCV s100 prescribers were established:

- An Introductory and Advanced training curriculum was developed and implemented to train medical practitioners in HCV s100 community prescribing.
- A procedure was established to assess medical practitioners' competency at HCV treatment management.
- An accreditation process for community prescribers was established with the NSW and ACT Departments of Health.
- Medical practitioners demonstrated considerable interest in community prescribing with over 140 trained, and 81 accredited community prescribers at the end of 2006. Practitioners reported that their participation in the pilot increased their skills to provide appropriate care to patients.
- Accredited community prescribers were provided with ongoing support through regular update sessions, project information sheets and ongoing contact with

ASHM staff. Prescribers reported that they were adequately supported by ASHM staff.

2. Whether arrangements could be established between public hospital based specialists and GPs to allow GPs to conduct the appropriate pre-tests necessary to precede biopsy.

Findings

Arrangements were established to enable community prescribers to conduct the appropriate work-up prior to treatment initiation:

- It was found that arrangements needed to reflect local procedures and requirements, so site-specific protocols were developed in collaboration with specialists. The protocols included pathology required for specialist reviews and time points for specialist reviews.
 - Specialists reported that generally the protocols were well adhered to, the work-up conducted by community prescribers was adequate and community prescribers ensured test results were available to specialists as required.
 - A problem that arose was that community prescribers reported some specialists repeated the work-up that had already been conducted by the prescriber.
 - There were communication problems between GPs and specialist clinics, particularly in ensuring that pilot patients were identified and community prescribers were kept informed of patient status.
3. In the case of patients going on to s100 therapy, provide the appropriate management to support and review them through the duration of their therapy.

Findings

Generally, specialists and patients reported favourably on the level of care provided by community prescribers:

- The case audits conducted by specialist centres identified that community prescribers maintained close contact with clinic staff during patient treatment, and that community prescribers contacted liver clinic staff when they identified that dose reduction was required or when there were abnormal test results.
- Patients reported that they felt well supported by their GP during treatment. Staff at specialist hepatitis C treatment centres did express some concern regarding whether community prescribers were able to adequately meet the treatment support needs of patients.

7. FUTURE MODEL

The pilot project effectively proved that administrative arrangements can be put in place to train, accredit and support community prescribing of HCV s100 treatment. Furthermore, as the consultations undertaken as part of this evaluation demonstrated, there is much support for the continuation of community prescribing.

The terms of reference indicated that consideration should be given to the future model for community prescribing that should be adopted. Preceding sections have already referred to a number of key issues which need to be considered if community prescribing were to continue into the future.

Based on the findings from this evaluation, and input from key stakeholders, any future community prescribing model should:

- continue to provide a training and accreditation program, as developed during the pilot, by an appropriate training provider contracted by the appropriate jurisdictional health authority
- ensure the training and accreditation program complies with nationally agreed education standards and competencies on prescribing hepatitis C treatment
- develop a continuing education program for accredited prescribers, including annual updates
- link accredited prescribers to authorised hepatitis C treatment centres
- recognise the key role nurses from hepatitis treatment centres play in linking with and supporting community prescribers
- enable community prescribers to link to specialists working in public or private hospitals with appropriate hepatitis C specialist facilities
- ensure patients of community prescribers are well supported and have full access to ancillary services provided by hepatitis C treatments centres and other community-based support services
- support the training of practice nurses in hepatitis C management
- support accredited community prescribers initiating hepatitis C treatment.

Any future model needs to give consideration to authorising accredited community prescribers to initiate HCV treatment. As highlighted by a number of GPs and stakeholders during the evaluation, a model of GPs initiating treatment for drugs available under the Highly Specialised Drugs Program already occurs in HIV and has proven to work effectively. During the evaluation, a number of stakeholders reported that they believed the restriction on community prescribers being able to initiate treatment was a factor that led to some GPs choosing not participating in the pilot.

The restrictions on community prescribers being authorised to initiate treatment was also perceived as having a detrimental impact on the number of people with hepatitis C accessing treatment. The requirement that patients be initiated on to treatment by a specialist was seen as another barrier to increasing access. In addition, this was significantly exacerbated by the delay patients experienced in receiving a first appointment at liver clinics (often two to three months). Community prescribers reported that some patients lost interest and motivation in commencing HCV treatment due to such delays.

Any initiative towards enabling community prescribers to initiate treatment will need to be accompanied by appropriate clinical guidelines, training and accreditation.

As the pilot was initially planned for an 18-month period, it was unnecessary to implement a continuing medical education program to ensure that community prescribers maintained accreditation (although it should be noted that regular update sessions for

community prescribers did occur through the pilot implementation). However, any continuation of the community prescribing model should include regular and satisfactory participation in continuing medical education programs as a requirement for continuing prescriber accreditation. During the evaluation most participants suggested this would probably involve update sessions at least annually, and more frequently if there were significant treatment developments.

Under the pilot model, community prescribers were required to enter a shared care arrangement with a specialist attached to a public hospital hepatitis C treatment centre authorised by NSW Health. Some community prescribers expressed a clear preference for linking with specialists at private treatment facilities, especially when such relationships already existed, and particularly in rural areas where often public specialists were not available within close proximity. As arrangements with specialists attached to private specialist centres under the Highly Specialised Drugs Programs are administered by the Commonwealth, consideration should be given by the Commonwealth to including such specialists in any future model of community prescribing that is adopted.

The pilot model enabled patients of accredited GPs to have full access to services provided by liver clinics to their patients. Any future model of community prescribing needs to continue to ensure this is the case, as well as ensuring GPs are aware of, and have access to, the range of other services in the community that can provide support to patients undergoing treatment. Another important part of ensuring patients are well supported is supporting and training practice nurses in hepatitis C management. Furthermore, some stakeholders identified that any future community prescribing model needed to further explore options that could enhance the services provided by GPs through the placement of nursing staff within general practice, whether this be through collaboration with a specialist liver clinic or Australian Government grants that support general practice employing practice nurses (in particular geographic locations) or other initiatives.

Community prescribers and other stakeholders argued that there needed to be more health promotion interventions aimed at improving knowledge and understanding of hepatitis C treatment amongst people with hepatitis C. They were keen to ensure that, if community prescribing continues, it should be accompanied by social marketing campaigns that outline to patients their options in terms of accessing treatment. Developing such campaigns and resources is a role that could be fulfilled by non-government organisations given their experience in developing culturally appropriate and accessible education resources.

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ⁱⁱ Sievert W. An overview of anti-viral therapy for chronic hepatitis C infection. In Crofts N, Gore D, Locarinini (eds). Hepatitis C: An Australian perspective. Melbourne: IP Communications, 2001.

ⁱⁱⁱ Cheng W. Trials of pegylated interferon and ribavirin: outcome by genotypes. Melbourne: Hepatitis C Council of Victoria, Summer 2003 Newsletter.

^{iv} Batey R, Locarnini S, Dore G and Crawford D., 2004, A case for removing liver biopsy from the S100 Guidelines for gaining access to therapy for chronic hepatitis C (Unpublished paper)

^v Treloar C, Hopwood M. s100 Hepatitis C Community Prescribing Pilot – Interviews with people undergoing treatment.

^{vi} Hallinan R, Byrne A, Kingsley A, Dore G. Referral for chronic hepatitis C treatment from a drug dependency treatment setting. Drug Alcohol Dependence 2006; doi: 10.1016/j.drugalcdep.2006.09.018.

^{vii} Doab A, Teloar C, Dore G. Knowledge and attitudes about treatment for hepatitis C virus infection and barriers to treatment among current injection drug users in Australia. Clinical Infectious Diseases 2005; 40: S313-20.