ACI NSW Agency for Clinical Innovation

NSW GOVERNMENT Health

REFERENCE DOCUMENT

The clinical management of people living with hepatitis C

ACI Gastroenterology Network

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Cover image: Hepatitis C viruses. Coloured transmission electron micrograph (TEM) of hepatitis C virus particles (orange) infecting cultured liver cells (brown). The virus consists of a core of RNA (ribonucleic acid) enclosed in a capsid, and surrounding by a glycoprotein envelope. Magnification: x30,000 when printed at 10 cm wide. Thomas Deernick, NCMIR/Science Photo Library.

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Foreword

The Agency for Clinical Innovation (ACI) collaborates with clinicians, consumers and managers, other pillar organisations and the NSW Ministry of Health to design and promote better healthcare for NSW. In 2014, the NSW Hepatitis C Strategy 2014-2020, a plan to reduce the burden of hepatitis C virus (HCV) infection in NSW, was launched. A key target of this strategy is to increase the number of people transitioning from assessment and diagnosis of HCV to undertaking treatment for HCV.

Viral hepatitis C continues to be a significant public health issue in Australia. Nationally, there are an estimated 310,000 people exposed to HCV and 230,000 people living with HCV, of whom 58,000 have moderate to severe liver disease. By 2030, it is estimated 414,000 people will be living with HCV.

Due to the recent availability of interferon-free treatments, demand for treatment will increase in NSW. As outlined in the NSW Hepatitis C Strategy 2014-2020, the priority populations needing to transition from screening to treatment include people who inject drugs, especially new initiates; Aboriginal people; people in custodial settings; young people at risk of injecting; people from culturally and linguistically diverse (CALD) backgrounds; and people living with HCV.

Screening for HCV is available in a number of settings, capturing 75% of infections[10] yet only 1-2% of those diagnosed transition into treatment. Individuals with HCV infections are cared for in many healthcare settings including tertiary hospital clinics, Aboriginal community controlled health services, rural and remote clinics, and drug and alcohol programs in primary healthcare and in custodial facilities.

Direct acting antiviral treatments were listed on the Pharmaceutical Benefits Scheme in March 2015 and endorsed (funded) by the Federal Government in December 2015. This new generation of therapies has a 95-97% cure rate, effective across genotype.

Some some people living with HCV have reported positive experiences with the care they have received during interferon-based HCV treatment. However, historically, there has been dissatisfaction with the severity of some side-effects; the inability to access services, particularly for people in regional and remote communities; and the long duration of the course of treatment.

To maximise the potential to treat HCV, it would be sound to suggest that treatment be aligned with the services that are achieving robust screening profiles. A principle-based clinical management approach executed by multidisciplinary services would assist to ensure clinician continuity and support for people living with HCV. It is important for healthcare providers to have the skills, knowledge and resources to deliver cost-efficient and accessible services structured to meet holistic care and community needs.

I am pleased to introduce *The clinical management of people living with hepatitis C*. This approach supports a person-centred approach to improving the treatment of hepatitis C in NSW. On behalf of the ACI, I would like to thank the Viral Hepatitis Working Group and the different bodies that lent their voices, insight and expertise to the development of this new approach to care.

Nigel Lyons
Chief Executive

Section 1

Executive summary

There is a body of evidence that describes the benefits of treating hepatitis C virus (HCV) infection for people living with HCV, their families and the community. The burden of disease associated with HCV (cirrhosis and hepatocellular carcinoma) is growing.[5] While no cure is absolute, positive therapeutic outcomes and improvements to quality of life can be achieved through treatment, with a subsequent decrease in complications from chronic disease and hepatic deterioration. However, these facts alone appear insufficient to persuade people to pursue treatment.

Until direct acting antivirals (DAAs) became available, the reality was that only 1-2% of diagnosed individuals elected to undertake treatment. It is anticipated that this figure will increase, and the system will need to adjust to meet the gap between the numbers of people being screened and the likely increase in the volume of the priority populations who will be seeking treatment.

When considering the differences between screening and treating percentages, it is timely to consider expanding the co-location of screening and treatment services. This strategy would complement the recent Federal Government endorsement of DAA therapies.

Hepatitis C at-risk populations are largely disenfranchised. Generally people in this cohort are compelled by external factors that allow little personal autonomy, while at the same time they face stigma associated with their diagnosis and lifestyle. Available and accessible services to meet the complex needs of this cohort are therefore essential.

Regardless of the size of a site or facility, the aim of a service should be to provide screening and treatment in a co-located person-focused environment.

1.1 Key principles of clinical management of people living with hepatitis C

Three key principles underpin the clinical management approach.

1. People are provided with equitable access to holistic care.

Meaning, the right care, at the right time, in the right place, by the right provider. (Care is delivered by clinicians who are trusted and in settings that meet a person's needs.)

2. Risk stratification is a method used to determine applicable care, incorporating concepts of integrated care.

The three stages of risk stratification are relevant for people with HCV infection. Targeting, identification and selection is the method used to support the tailoring of integrated care strategies and interventions for HCV priority populations[7] (see Figure 7).

3. Services offer health promotion, disease prevention, point-of-screening testing and treatment.

This is achieved through:

- co-locating services enabling point-of-access screening, early intervention and streamlined referral pathways:
    - place nurses at and in screening services to assess, triage and refer people for treatment in the appropriate (to clinical need) setting, for example primary healthcare, hospital clinic and specialist services
- employing a multidisciplinary approach to treatment planning and delivery
- linking care by establishing partnerships between and with Local Health Districts (LHDs), Specialty Health Networks (SHNs) Primary Health Networks (PHNs), Aboriginal and community controlled health services (ACCHS), rural and remote services, non government organisations (NGOs) and Multicultural HIV and Hepatitis Services:
    - expand and develop integrated care collaborative partnerships

- providing effective case management and post-treatment follow-up:
    - the choice and duration of DAA regimen, as well as on-treatment monitoring and post-treatment follow-up is determined by the presence of cirrhosis – accurate assessment of the stage of liver disease is essential for treatment and long-term care.

1.2 Recommendations

The clinical management approach will guide local service development and planning. Four key recommendations are highlighted.

1. Local teams should consider approaches to building a greater collaborative approach for local service planning, including actively engaging affected populations and the primary care sector.

2. Local teams should work together to define communication pathways, including:

- establishing standard operating procedures
- standardising clinical criteria for referral and transfer of people living with hepatitis C to, from and between services
- diversifying treatment pathways to allow people living with HCV greater access to services
- building a case management approach provided by multidisciplinary and cross-jurisdictional teams.

3. Local teams should work together to consider how to grow service provision through:

- increasing capacity in primary care
- expanding the provision of nurse-led HCV care
- introducing peer support workers at screening and assessment services.

4. Monitoring and evaluation of the clinical management approach should be undertaken locally including use of an agreed minimum data set.

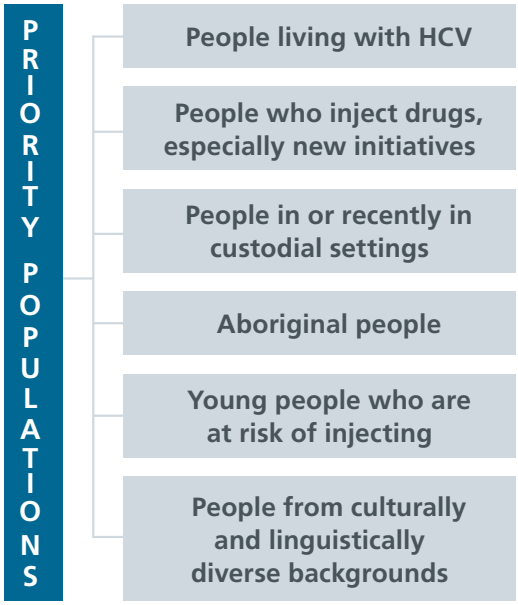
Section 2

Background

There are many complexities associated with the treatment of HCV.

- Current service provision, including funding, is cross-jurisdictional and tends to be fragmented and non-integrated.
- The priority at-risk populations, including people who inject drugs, Aboriginal people and people from CALD populations (Figure 1), are largely disadvantaged and disenfranchised.
- Funding of DAAs was approved by the Federal Government in December 2015 and implementation in NSW began on 1 March 2016.
- There needs to be an understanding that people can be treated for HCV but may also require ongoing care for liver disease.

FIGURE 1: PRIORITY POPULATIONS AS HIGHLIGHTED IN THE NSW HEPATITIS C STRATEGY 2014-20



In concert with these complexities is the need for clinician education and training and an expansion of links with primary healthcare, rural and remote services; Aboriginal and community services; justice health services; and CALD services.

Since 2003, due to a variety of factors such as improvement in opioid substitution programs, greater acceptance of and investment in needle and syringe programs, and the dynamic nature of the illicit drug market, there has been an annual decline in the number of new HCV infections nationally. While this is encouraging, NSW still has a need to further mitigate the impact of HCV infection across priority populations. In 2014, the ACI was funded by the NSW Ministry of Health - Centre for Population Health to lead the development of a model of care for HCV[11].

Delivery of healthcare in NSW is complex. There are multiple and often cross-jurisdictional service providers with differing funding models, governance structures, patient records and data collection capabilities and capacities. LHDs and SHNs are funded by the state while PHNs, formerly Medicare locals, are federally funded, and NGOs can receive federal, state or a combination of funding.

Collectively, and in collaboration, healthcare entities have responsibility for the coordination of healthcare across primary, community and acute care settings. These entities include general practitioners (GPs), ACCHSs, Aboriginal medical services, (AMSs), NGOs (for example, Hepatitis NSW, NSW Users and AIDs Association (NUAA)), rural and remote services and private healthcare professionals and insurers.

This can lead to duplication and waste, generate competition for funding between services, and limit cooperation and sharing of resources and knowledge and skills[12, 13]. Conversely, it can also create clinical champions and foster innovation and excellence through collaboration and provide person-centred care.

NSW Health is well positioned to redesign services by placing people living with HCV at the forefront of the redesign and by moving to integrated services that have the potential to improve treatment rates in priority populations.

2.1 Overview of hepatitis C in NSW

HCV is a viral infection of the liver and is categorised as a blood-borne virus. It is a major health issue, with approximately 81,940 people in NSW living with HCV.[5, 14] By 2030, if there are no changes to incidence rates the number of people living with HCV is expected to grow to over 161,000.[11, 15] The most common path of HCV transmission is through shared drug injection equipment that has been contaminated with infected blood.[16] Unlike Hepatitis A and B, there is no vaccine to protect against HCV.

Of those exposed to HCV, approximately 25% will clear the virus spontaneously within the first 6-12 months. For the remainder, without treatment, the virus attacks the liver, resulting in 10-15% of the affected population progressing to cirrhosis with a further 5% at risk of developing hepatocellular carcinoma (HCC) and liver disease requiring liver transplantation.[17-19]

While 75% of infections are diagnosed, treatment rates sit at approximately 1-2% of the infected population.[20] The reasons people do not seek treatment are complex (Figure 2). Currently, the majority of HCV treatment is carried out in tertiary hospital programs with oversight from a HCV treating specialist.

There are two predominant objectives of treatment. Firstly the eradication of HCV by achieving sustained virologic response (SVR), defined as the persistent absence of HCV RNA in serum six months after completing antiviral treatment.[11] The second objective is to prevent progression to cirrhosis, HCC and decompensated liver disease, which ultimately require liver transplantation.[15, 21]

FIGURE 2: LOW TREATMENT VOLUME FACTORS IN NSW (PRE INTRODUCTION OF DAAS)

Factors reported as having contributed to low HCV treatment volumes in NSW include:

- complex interferon-based treatment regimes
- the length of the time for the course of treatment (24-48+ weeks)
- the anticipated approval and ultimate availability of new (DAA) therapies
- the lack of treatment centres
- the stigma and discrimination often associated with this population
- cultural myths attributed to the treatment by the priority populations[8, 9]
- co-morbidities, for example mental health issues and diagnoses.

A snapshot of hepatitis C in Aboriginal communities

Aboriginal communities have been identified as a priority, at-risk population requiring support to access services for the treatment of HCV. A formal Aboriginal Health Impact Statement was completed for *The clinical management of people living with hepatitis C*. Consultation occurred with identified AMS, the ACI Chronic Care for Aboriginal People team and the NSW LHD and SHN Aboriginal health directors and managers.

Census data shows that approximately 172,624 Aboriginal people (or 31.5% of the national total) reside in NSW, resulting in NSW having the largest Aboriginal population. Approximately a third of this population reside in the Greater Sydney region (31.5% = 54,746), and 67.8% or 116,961 are located in other parts of the state.[22]

HCV rates

Approximately 11,000 Aboriginal people are living with chronic HCV. Data from 2013 indicates that 7.4% (796 of 10,715) of newly diagnosed cases of HCV are amongst Aboriginal people nationally. Of note, more than 59% of newly reported cases do not detail Aboriginal status. For newly diagnosed Aboriginal people, HCV is reported at 142 per 100,000, compared with 41 per 100,000 for the non-Aboriginal population. Injecting drug use is indicated in 78% of newly diagnosed cases, and Aboriginal injecting drug use populations in major cities within the 20-29 years age group are at higher risk of transmission.[23]

Custodial snapshot

Aboriginal people are over-represented in the custodial population. In September 2015, there were 9,841 Aboriginal adult prisoners in Australia. This represented 29% of the total prison population, of which 90% (8,860) were males and 10% (981) were females.[24]

A 2010 survey found that 18% of newly incarcerated Aboriginal prisoners tested positive for HCV (n=651).[25] Women were more likely to test positive than men, and a positive status becomes more common with age for all prisoners.[25]

Injecting drug patterns

The Australian National Council on Drugs report *Injecting drug use and associated harms among Aboriginal Australians* (2011) highlights that Aboriginal people self-report higher risk behaviours compared with non-Aboriginal people who inject drugs, particularly sharing needles (21% versus 16%), being injected by others (18% versus 13%) and injecting in public places (54% versus 49%).[26]

Identified barriers

ACI research shows that a variety of local issues impact on service capacity. Information obtained via discussions with an AMS highlighted the following issues:

- Aboriginal people often present with many co-morbidities
- there is a large degree of stigma associated with HCV in Aboriginal populations as it is associated with injecting drug use
- medical service staff require more comprehensive and ongoing training in HCV management
- medications were held at hospital pharmacies only, and the financial cost to a person of dispensing the medication is a barrier
- treatment courses were lengthy
- staff want and need more control over the delivery of treatment programs.

Advice gained from consultations with AMS providers, lead GPs and NSW Health Aboriginal directors/managers was that community involvement and cultural sensitivity is paramount in the delivery of HCV services. Services that offer a flexible structure (for example, a hybrid service provision with a mix of drop in and booked appointments) and have an interdisciplinary combination of staff — medical, nursing, allied health and Aboriginal health workers — is optimal.

The HCV nurse-led clinical pathway offers this framework to LHDs and partner service providers. An adjunct included in the clinical management approach is the peer support worker model, which could support Aboriginal people to increase their use of services and improve HCV cure rates among this population.

2.1.1 Hepatitis C medications

The treatment of HCV has evolved over the past decade. HCV medication regimens were based on genotype — a description of the specific genetic structure of HCV. There are six major HCV genotypes identified, each of which can be further subdivided into subtypes (1a, 1b, 2a, etc.). In Australia, the predominant genotypes are 1 and 3 [27-29] (Appendix 2).

Historically interferon (IFN) was used as a monotherapy. This was followed by dual therapies such as ribavirin (RBV) and IFN or IFN with added polyethylene glycol (PEG) molecules (PEG-IFN). Protease inhibitors (PI) emerged as a third feature of combination therapy and were standard treatment in NSW in 2015.

DAAs target specific HCV enzymes. Clinical trials have shown a significant improvement in patient outcomes and high cure rates,[1, 30, 31] and these therapies are effective against genotypes that were previously difficult to treat.[32]

The Therapeutic Goods Administration approval of DAA therapies in Australia is a major influence on the development of this clinical management approach. Preparation by LHDs, SHNS and PHNS to deliver DAAs will improve outcomes. While the advantages are significant, challenges exist in introducing DAAs into NSW (Figure 3).

FIGURE 3: ADVANTAGES AND CHALLENGES OF DIRECT ACTING ANTIVIRAL THERAPIES

Advantages

- cure rates of 95-97%
- single dose or in combination
- 12-week treatment regimen, compared with one year for previous regimens[1-4]
- effective against all genotypes
- oral regime, potentially one tablet once a day
- reduced drug resistance
- increased safety and tolerability
- potential long-term reduction in treating cost per person.

Challenges

- restricted prescribing rights (potentially)
- potential increased demand on treatment centres
- liver disease and the risk of HCC continues with the presence of cirrhosis
- potential short-term increases in treating cost per patient.

Although there will be a potential increase in cost per person and additional demand on the healthcare system, DAAs will benefit people living with HCV. Introducing DAA medications into treatment regimens will increase the cure rates of HCV by achieving a sustained virologic response in affected populations, and mitigate progression to cirrhosis, HCC and liver disease requiring liver transplantation.[15, 21] Collectively, a simplified treatment regimen with reduced side-effects and a higher cure rate will entice more people to seek treatment for their HCV. As treatment rates increase, the incidence of HCV in NSW will fall, reducing the burden on the health system.[18, 33, 34]

Section 3

Methodology

The ACI Gastroenterology Network was tasked with the development of the HCV Model of Care, and a project manager was recruited to develop the model, which was subsequently adopted as the accepted clinical management approach.

The project included:

- a non-systematic international literature review
- a self-administered service capacity survey of 11 sites across NSW (Appendix 2)
    - The services selected offered a mix of metropolitan and regional clinics, drug and alcohol services, Aboriginal health services, GP-initiated services and nurse-led services. Survey participants were asked to provide feedback on the total number of hours spent per person on existing Pharmaceutical Benefits Scheme (PBS) listed, IFN-containing regimens and provide hypothesised expert opinion on IFN-free DAA regimens
- Ten site visits to explore the strengths and challenges in delivering HCV services in NSW (Appendix 2)
- a business as usual (BAU) analysis to understand the potential economic impact of the model of care (Appendix 3).

Section 4

Case for change

It is estimated that there are 81,940 people in NSW with HCV.[20] If this estimate is used as a baseline figure, it would mean that only 819 (1%) to 1638 (2%) of these people seek treatment for their HCV annually in NSW.[5, 11]

The longer term consequences of untreated HCV are chronic liver disease, cirrhosis, uncompensated cirrhosis and potentially HCC. These are conditions that have a high per capita healthcare and social cost.[35]

In Australia, the burden of liver disease caused by the HCV continues to rise. Notably, deaths from primary liver cancer, for which untreated hepatitis C is a major driver, are rising faster than for any other type of cancer.[14]

To reduce the health burden of HCV-related liver disease and improve outcomes and quality of life it is necessary to realign HCV treatment services in NSW. The endorsement of DAA use for treatment of HCV by the Federal Government will complement a realignment of HCV treatment in NSW.

Data shows that up to 75% of people with HCV have been diagnosed.[20] These results are attributable to screening that has been conducted predominantly in primary healthcare settings. Evidence-based practice suggests that point-of-screening assessment is advantageous for early detection, early triage and early initiation of treatment.[5]

NSW currently has a number of services that provide screening and treatment options for people who have HCV. However, the services are fragmented and often work in isolation, which can contribute to suboptimal care, higher costs due to duplication and poor quality of care.[12]

Integrated healthcare systems have been advocated as a template for service design and care delivery, especially when trying to engage with a disadvantaged population cohort.[12, 13] The intended outcome of integration is to improve access, the quality of experience and care, and the continuity and efficiency of services.[12] If service integration can be maintained over time, it has the potential to become sustainable and ultimately add value to the HCV continuum of care.[13] Service integration is not one dimensional, nor is it easily achieved.

Section 5

Data and economic analysis

5.1 ACI Business as usual analysis

The ACI Health Economics and Evaluation Team conducted a *Business as usual analysis for the viral hepatitis C model of care* (Appendix 3). The analysis used what was known of the current and projected resource use for the specific cohort.

It is important to note that the BAU analysis was completed prior to endorsement of DAA therapies by the Federal Government.

5.1.1 Key points from the business as usual analysis

The BAU analysis projects costs based on no modification to the current system of treating people who have HCV. The analysis indicates that under a BAU scenario the treatment for HCV will require a greater amount of public hospital resources in NSW. If BAU trends continue, the analysis suggests a net present value of total inpatient resource use equivalent to $1.2 billion over a five year period (2013-14 to 2019-20).

The key points for consideration are described below.

- HCV is predominantly focused in marginalised populations in NSW. Prisoners, Aboriginal and Torres Strait Islander communities, people who inject drugs and people from CALD backgrounds bear a greater burden of HCV than other groups within society. Healthcare services have not always been successful at reaching these groups.
- The prospect of the impending availability of the latest generation of treatments (DAAs) has also resulted in healthcare providers and people living with HCV postponing treatment, as the new pharmaceuticals have a much shorter duration of treatment, much higher efficacy and are associated with fewer side effects. Pharmaceuticals, including Sofosbuvir, have recently been recommended for inclusion on the PBS by the Pharmaceutical Benefits Advisory Committee (PBAC).
- Despite the relatively high cost of the pharmaceuticals involved, the pharmaceuticals that underlie the ACI model of care (now, *The clinical management of people living with hepatitis C*) have been shown to be a cost-effective treatment in a number of different settings including the United States[36], United Kingdom[37], France[38], Italy[39], Switzerland[40], Belgium[41], Sweden[42] and the Netherlands. The treatments have been shown to be cost effective with regards to the resources required to obtain health gains through such treatment, both for people in the early stages of HCV as well as for people with later manifestations of liver disease, including those with cirrhosis and those waiting for liver transplantation.
- The increasing use of inpatient resources by individuals suffering from the later stages of liver disease highlights the potential importance of early diagnosis and treatment, avoiding disease progression and relatively costly inpatient settings.
- Avoiding the latter stages of liver disease that develop from chronic HCV will not only have significant quality-of-life benefits for NSW people living with HCV, but also large resource-use implications.
- Pharmaceuticals used for treatment of HCV are subsidised under the PBS only when prescribed by a specialist or by a limited number of participating Shared Care accredited GPs. As a result, treatment is predominantly provided in tertiary specialist settings, or through specialist visits to outreach sites.
- This current system has limited capacity to halt the foreshadowed burden of liver disease or to meet the expected treatment demand.
- The estimated resource implications associated with HCV treatment under a BAU situation have a net present value of between $1.2 billion and $1.8 billion between 2013-14 and 2019-18 (Appendix 3).

5.2 Service capacity survey

In 2013-14 a *self-administered* survey looking at the projection of service capacity using DAA IFN-free treatment regimens was undertaken by 11 sites (Appendix 2).

The results of the self-reported service capacity survey suggest that providers have capacity to treat additional people under a DAA regime. Providers currently provide 24.5 hours of treatment to 103 people. Under a DAA regime, providers suggest they will be able to treat 602 people with an average of 6.5 hours for each person.

TABLE 1: ESTIMATED CURRENT AND PROPOSED CAPACITY FROM SURVEY RESPONDENTS FOR TREATING HCV PATIENTS

NSW CENTRES	CURRENT CAPACITY		PROPOSED CAPACITY	
	PI + PR (Hours)	Total Number of Patients on PBS Treatment Regimes	INF free (Hours)	Capacity to treat in IFN free regime
Royal Prince Alfred	36.0	**100**	**5.0**	**720**
Westmead	22.0	**180**	**5.3**	**1300**
Wollongong	19.5	**43**	**8.8**	**300**
Liverpool	**34.5**	**60**	**6.0**	**600**
St George	16.3	60	5.8	500
AMS Western Sydney	48.0	5	21.0	25
Kite Street - Orange	22.0	20	7.0	152
John Hunter	25.0	140	11.0	300
Newcastle - ETHOS	27.0	10	19.0	25
Northern NSW	19.0	140	3.0	500
Justice Health	5.5	200	3.5	1000
Total	**274.8**	**958**	**95.3**	**5422**
Average	**25.0**	**89**	**9**	**493**
Average (Tertiary Clinics Only)	24.5	103	6.5	602

*__PI__, Protease inhibitor; __PR__, pegylated interferon plus ribavirin; __INF__ interferon
Columns 1+2 represent current treatment capacity and Columns 3+4 represent *hypothesised* service capacity.

FIGURE 4: SERVICE CHALLENGES SHARED BY SURVEY PARTICIPANTS

Qualitative feedback received from participants included common services challenges faced by all sites:

- limited clinic space
- long waiting lists
- high no-show rates
- old diagnostic equipment (the Ministry of Health is in the process of state wide distribution of fibroscans to support HCV assessment and diagnosis)
- ongoing staffing issues.

5.3 Broad recommendations from the business as usual analysis

The analysis is based on data extracted from NSW administrative datasets.

The implementation of the HCV clinical management approach with DAAs may expedite the projected savings.

- The earlier the treatment the higher the likelihood of preventing or halting progression to chronic disease and the earlier the treatment the higher the likelihood of reducing high (and increasing) inpatient costs of having to treat progressive liver failure and complex co-morbidities.

Expanded options for service provision may:

- increase the number of GP prescribers
- diversify treatment locations to include point-of-screening services
- increase the practice scope of nurses.

Section 6

Clinical management of people living with hepatitis C

The underpinning goal and desired outcome of the clinical management of people living with hepatitis C is to increase the number of people being treated for HCV and to decrease the number of new infections occurring annually in NSW.

To complement an expected improvement in treatment volume following the Federal Government's endorsement of DAAs, any plans to realign and redesign services will require placing the individual at the forefront of planning development (Figure 5).

Screening for HCV in NSW is available in a number of settings, with 75% of infected people being identified through these services.[20]

Unlike screening, the majority of treatment for HCV in NSW (currently) occurs in tertiary hospital programs under the care of a HCV treating specialist. Additional treatment is conducted through a small number of primary care medical practitioners under the HCV s100/Shared Care program; in collaboration with opiate substitution programs; in the justice and forensic mental health sector; and at limited rural and remote sites and ACCHS.

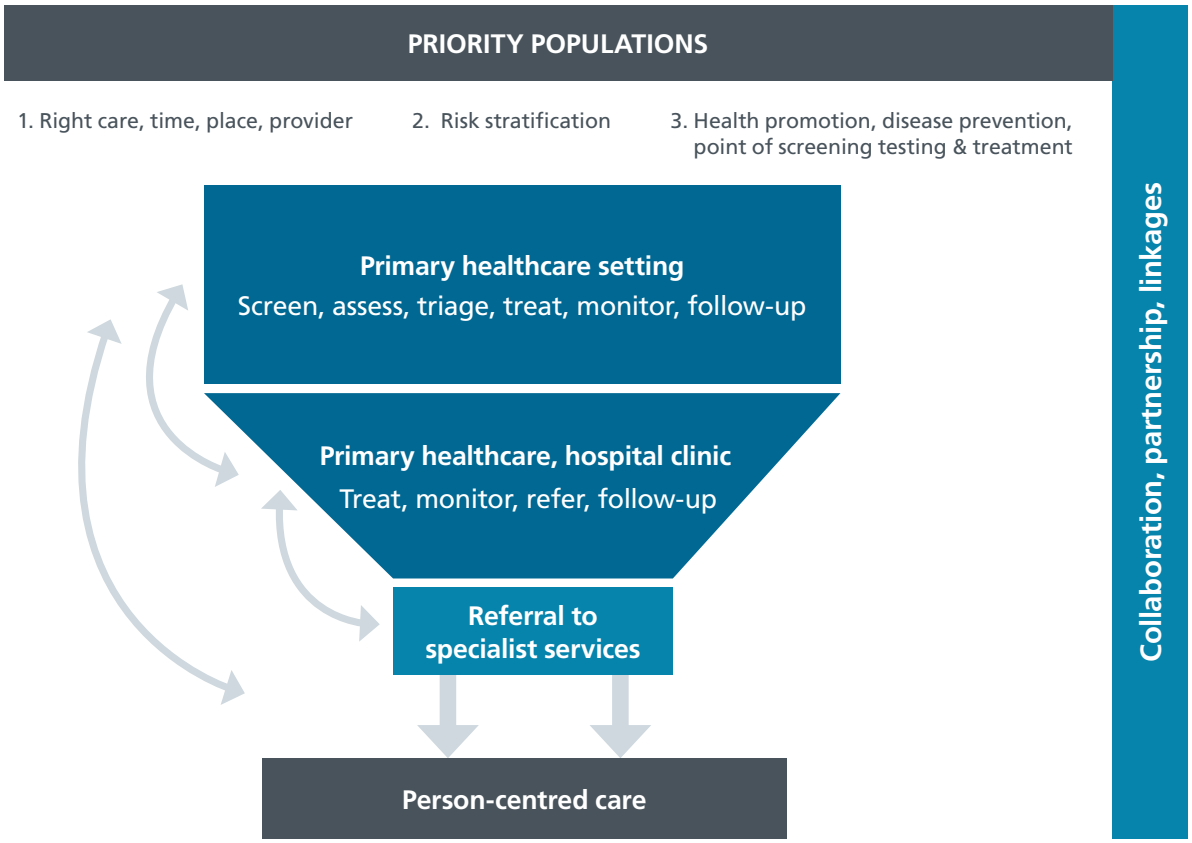
The HCV priority population is not centrally located around a tertiary hospital, but there is no question that tertiary referral and specialist expertise might be needed at some point during a continuum of care.

For a variety of reasons, many people living with HCV do access care related to their HCV via their GP. As has been stated, this is a marginalised stigmatised priority population with complex needs and life priorities different from the mainstream population. Diversifying the treatment models as well as building the capacity of people who provide services, particularly drug and alcohol, mental health, Aboriginal and CALD services, may significantly increase the number of people seeking and undertaking treatment. A peer support model may provide the assistance required to build capacity (Figure 6).

There are three key principles that underpin the clinical management approach.

1. People are provided with equitable access to holistic care.
2. A risk stratification methodology is used to determine applicable care.
3. Services offer health promotion, disease prevention, point-of-screening testing and treatment.

FIGURE 5: CLINICAL MANAGEMENT OF PEOPLE LIVING WITH HEPATITIS C



6.1 People are provided with equitable access to holistic care

The HCV clinical management approach is designed to provide the priority population as a whole with the right care, at the right time, in the right place and by the right provider. Care is delivered by clinicians they trust and in a setting that meets a person's needs — integrating their care across the service spectrum.[7, 11]

The concept of person-focused care examines the personal preferences and needs of the individual to help guide the development of care that is person-centred and has a population health focus. The goal of population-based care is to identify and work towards improving the health and care needs of a defined or wholly described population.[12]

Continuity of care is a favourable consequence of person-focused care delivery strategies. Ideally, service provision allows a person to see the same clinicians and healthcare providers over a longitudinal time frame. Using risk stratification methodology and concepts of continuity of care will inherently include provision for referral to secondary care (that is, community youth services, home and community care, Indigenous and mental health services, and CALD support services) and tertiary care for the complex person living with HCV.

Equity of access to health services is especially significant for priority populations that are socially disadvantaged (for example, HCV) and who have higher burdens of morbidity and complex needs.[12]

When considering the complexity of the HCV cohort, it is reasonable to suggest that the most effective way of improving the treatment volume would be to provide treatment initiation options in primary healthcare settings. Collaborative service linkages and clinical partnerships would be established to develop risk stratified and integrated care options to most effectively treat people based on their disease stage and progression. It is essential to ensure that care is flexible and meets the needs of people living with HCV and clinicians. Ideally, using the concepts of person-focused, population-based care, treatment is available where screening is carried out.[12]

6.1.1 Peer support workers

The concept of peer education in Australia is not new and has been successfully utilised in a wide range of contexts and with diverse populations, including parenting education, youth homelessness, sex workers, HIV medicine and Aboriginal health.[43, 44] In NSW, peer support workers (PSWs) can be found in AMS (Aboriginal health workers), sexual health clinics (sexual health educators), needle and syringe programs (health education officers) and other population-based programs.

Behaviour change occurs as a result of a variety of factors, not only based on knowledge, but also on the opinions and actions of trusted peers. Peer educators can communicate and understand the lived experience, offering a different perspective, and they may serve as valuable mentors for change. PSWs bring an innate understanding of the shared experience and can use this to reassure and promote the benefits of treatment.

FIGURE 6: PEER SUPPORT WORKERS

Peer education has played an important role in reducing the risk of HCV transmission in Australia. Peers are credible, trusted sources of information and can assist in connecting with some hard-to-reach populations by overcoming some of the physical and socio-cultural barriers.
With appropriate training and support, people with or at risk of HCV are well placed to communicate prevention messages. Continued peer education and support by and for people who inject drugs is needed.[5, 6]

The benefits of PSWs are that:[6, 43]

- PSWs offer an individual, experience-based credibility to service provision
- marginalised populations are influenced by well-designed and properly supervised peer-led interventions
- PSWs assist in building relationships between service providers and clients
- PSWs can provide a valuable link to health information by delivering health promotion messages in a language that the cohort is familiar with
- serving as a PSW provides individuals with an opportunity to develop their skills and improve their own knowledge — PSWs often change their own behaviour after becoming peer educators.

The NUAA, the state-wide drug user organisation, has developed a PSW program called Liver Mates. This work stemmed from their partnership work on the Enhancing Treatment of Hepatitis C in Opiate Substitution Settings (ETHOS) research project, where the provision of PSWs was seen by service users as offering additional support and enhancing the atmosphere of the clinic.[6]

Incorporating PSWs into NSW services can enhance service delivery in a number of ways. Examples include:

- the development of relationships between NUAA, PSWs, clients, service providers and wider communities
- the delivery of components of services by people who identify as peers — examples of programs include:
    - Hepatitis NSW telephone-based peer support program HepConnect
    - Hepatitis NSW Live Well chronic disease self-management program.

Incorporating a PSW program into the delivery of HCV services in NSW offers an opportunity to provide a person-centred care approach to managing the cohort. When looking to introduce a PSW program, services are encouraged to consult with current PSW service providers and educators (NUAA, AMS and Hepatitis NSW) to seek advice; however, it is suggested that the following points be considered:

- PSW programs to be integrated with other programs to form a comprehensive strategy
- PSWs to be employed by the local service provider
- process and outcome evaluation strategies to measure PSW performance to be incorporated into the service outcome evaluation
- core competencies for PSWs to be established, including performance targets
- training and professional development programs to be state wide
- PSWs to be active participants in the planning, implementation and evaluation of local programs.

6.2 Risk stratification — who to treat and where to treat them

Keeping the patient experience at the forefront, local services should provide '…seamless, effective and efficient care that responds to all of a person's needs, across physical and mental health, in partnership with the individual, their carers and family'.[7] Risk stratification is an approach that is central to linking people identified at the highest risk of health deterioration to the most appropriate evidence-based integrated care.[45]

With previous medication options, people with less advanced fibrosis responded better to treatment than those with more advanced liver disease. With DAAs, sustained virologic response rates are equally impressive regardless of the stage of liver disease, offering those with cirrhosis and HCC greater opportunity for cure and improved quality of life.[32, 46]

The PBS listing of DAAs does not include treatment restrictions based on liver disease stage or treatment history[47], and people with cirrhosis require care and ongoing monitoring by liver clinics and specialist clinicians. When considering burden of disease and risk severity, this is appropriate; however, there remains a large cohort of patients who do not have advanced fibrosis who could benefit from early intervention away from a tertiary centre, ultimately reducing the epidemic curve of the virus.[35]

Risk stratification (Figure 7) is a method or process that can be used to specifically tailor integrated care strategies to target those who will benefit most. While most individual services may use elements of risk stratification to target a specific population, the concepts of risk stratification can be used across services (Figure 8) to develop a standardised or uniform approach to integrating HCV service delivery across NSW.

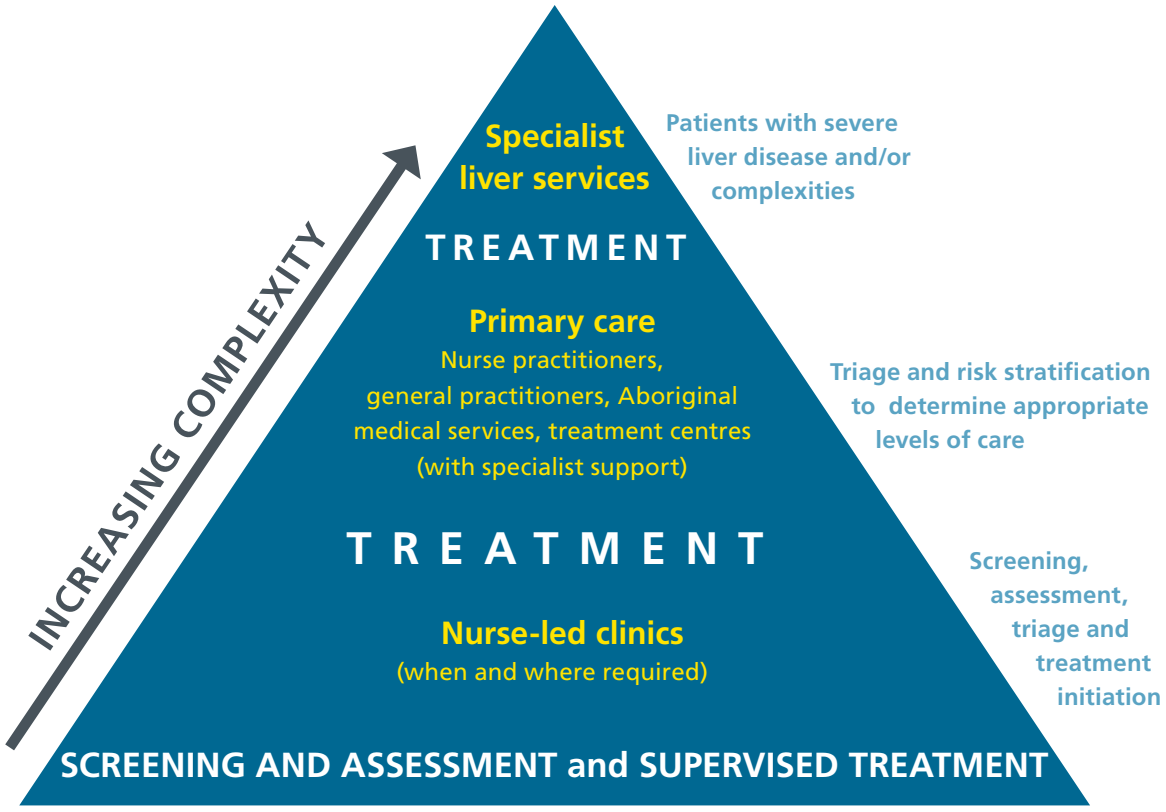
FIGURE 7: ACI INTEGRATED CARE APPROACH TO RISK STRATIFICATION

In the NSW Health integrated care context, 'risk stratification' is defined as: a systematic process to target, identify and select patients who are at risk of poorer health outcomes, and who are expected to benefit most from a particular intervention or suite of interventions.

There are three stages of risk stratification:

- **Targeting** — choose and quantify the cohort of patients at risk of poorer health outcome (for example, potentially preventable hospitalisations) that are considered a priority for targeting with different or additional interventions.
- **Identification** — identify individuals within the target cohort. This is achieved through manual or automated searching of routinely collected clinical and demographic data held in electronic databases using a standardised set of risk predictors.
- **Selection** — use a selection tool to undertake further assessment of each identified patient's modifiable risk, and match their needs to the most appropriate integrated care interventions. This can be administered via telephone or face to face, and generally requires information not held in the electronic medical record (eMR).[7]

FIGURE 8: A PATIENT JOURNEY SHOWING RISK STRATIFICATION



6.3 Greater collaboration and extending establishment of HCV treatment in the primary care setting

The priority population requires a system that can accommodate their needs from screening through to end-stage liver failure and at each stage along that continuum.

Considering the identification rate of HCV achieved through screening services, it is timely to consider the expansion of assessment and treatment into those settings. It is opportune to examine the existing factors associated with screening services; to look at the respective environments that make them user friendly to the priority population; and to ask why people are more comfortable about accessing those services in preference to current assessment and treatment services.

Expansion and development of collaborative partnership frameworks among tertiary, secondary and primary healthcare providers and NGOs is needed to allow service integration[12]. This requires multidisciplinary and interdisciplinary collaboration among all levels of healthcare provision to establish new, or to reinforce and strengthen existing, service integration[12].

There is a need for stakeholders to clearly articulate a mutually agreed mission and vision that reflects the needs of the individual, provides a cross-jurisdictional seamless service (including treatment), and is sustainable — establishing standards of practice, pooling of skills and expertise[5].

Regardless of the setting, the treatment of HCV must always be multidisciplinary and interdisciplinary, and a clinician's scope of practice has to be sufficiently flexible to adapt to the needs of the priority population and the availability of resources.

6.3.1 Extending HCV treatment in the primary care setting

The BAU economic analysis (Appendix 3) conducted by the Health Economics and Evaluation Team highlights the challenge of containing future costs for inpatient care if the current rate of treatment uptake by HCV sufferers is maintained. The burden of disease relative to the progression to decompensated cirrhosis and HCC is expected to continue to rise. The BAU analysis contains projections for how an increase in the volume of people receiving treatment could be amplified with the use of DAAs.

However, increasing capacity is not solely about enhancing the volume of people being treated for HCV. It is also about broadening the clinician group able to prescribe and administer the most effective treatment available. Increasing capacity should also be concerned with creating an environment that enhances consumer engagement and will accommodate an increase in the volume of people receiving treatment.

A cogent strategy for increasing the volume of people being treated for HCV is to co-locate medically supervised or nurse practitioner (NP) -supervised nurses with screening services (for example, outpatient clinics, opiate substitution clinics, community health, NGOs, needle and syringe programs, ACCHS, drug and alcohol services, sexual health clinics, rural and remote services, and CALD services). In concert with this, the number and locations of prescriber partnerships could be expanded.

The approach to care that an LHD selects to treat HCV should be locally identified and defined to meet the needs of its specific priority population, and it has to be a component of broader disease management and integrated care strategies with all service delivery jurisdictions being involved in the planning and execution[7].

Examples of clinical pathways include primary healthcare; nurse-led triage and follow-up; and multidisciplinary hub (Appendix 4). Some of these approaches are already being utilised to differing degrees across LHDs. In reality, all of these approaches to HCV care delivery incorporate components of integrated care and risk stratification, and the clinical management approach supports a nurse-led multidisciplinary treatment pathway for HCV (Appendix 4).

An equally important strategy that would encourage greater engagement by the priority population is the use of PSW programs.[6]

6.4 Potential benefits of the clinical management approach

The clinical management approach aims to support LHDs and primary healthcare providers to streamline access to curative treatments in NSW and facilitate achievement of service level agreements regarding HCV treatment numbers and HCV treatment initiation volumes. The key focus of the clinical management approach is to increase the capacity to provide treatment.

Potential benefits of the clinical management approach include:

- **accessibility** for an individual — that is, point-of-screening early detection and treatment initiation, not waiting for an appointment to attend a specialist clinic
- continuity of care for the individual and healthcare clinician — the individual sees the same clinician and team members over a longer period of time. Because of the nature of speciality clinics in secondary and tertiary level settings, there is often a substantial wait before a person is seen. This delay can lead to frustration and anxiety and can manifest as an intolerance of the system, with the result that a person may not stay to be seen.
    - Conversely, an environment that enables a person to see a familiar clinician in a known setting with minimal delay may increase the potential for compliance with treatment
- **comprehensive** care — with respect to providing tailored referral to specific services, in addition to secondary care for HCV (that is, community youth services, home and community care, AMSs, mental health and CALD support services)
- **coordination** of care — timely referral for specific intervention based on clinical need across services, departments and jurisdictions (for example, deterioration in hepatic function and psychosocial intervention)
- **key factors** for a successful model include defined communication pathways, criteria for referral, uniform follow-up guidelines and a coordinated approach to care
- **not 'one size fits all'** — it is important to reiterate that the clinical management approach is principle-based and service providers are encouraged to tailor their services to meet the needs of their specific priority population while achieving the underpinning principles of the clinical management approach.

Determination of success of *The clinical management of people living with hepatitis C* will be demonstrated by meeting, maintaining and sustaining the principles upon which the document is based. The development and design of a collaborative partnership with primary healthcare and NGO services would be determined by the service requirements of each LHD.

It is anticipated that the use of *The clinical management of people living with hepatitis C* will demonstrate a number of benefits for people living with HCV:

People have confidence that the system will deliver best care:

- they experience a seamless transition from detection to treatment
- care and support are person-focused
- treatment provider options are available and suit an individual's needs (HCV specialist, GP and NP); defined referral criteria and clinical pathways are in place
- appropriate infrastructure is in place
- access to identified programs and care (dietitian, social work, etc.) is integrated and multidisciplinary
- treatment and diagnostic equipment suits specific needs — fibroscans are available for use by nurses at point-of-access screening
- community awareness campaigns that address stigma and discrimination are developed and used
- optimal medication compliance is achieved by offering treatment via a variety of settings.

Individuals understand their own journey:

- they contribute to their own treatment and support plans
- they have access to peer support
- they have access to specialist cultural and language support
- easy-to-understand educational materials are available
- treatment pathways meet the desired outcomes
- support programs are developed using multiple technologies (for example, telephone support and e-forums).

Individuals have improved health through coordinated care structure, including:

- standardisation of operating procedures
- coordinated service delivery model
- regular health service provider training opportunities.

Individuals have improved quality of life with access to support, including:

- support for adjusting to receiving a diagnosis of HCV
- preparation for treatment through nurse-led management
- provision of ongoing advice, information and support to carers, families and communities
- improvement in quality of life by having access to curative treatment.

Section 7

Key considerations and recommendations

The clinical management of people living with hepatitis C will guide local service development and planning. Four key recommendations are highlighted.

1. Local teams should consider approaches to building a greater collaborative approach for local service planning, including actively engaging affected populations and the primary care sector.
2. Local teams should work together to:

- define communication pathways
- standardise clinical criteria for referral and transfer of people to, from and between services
- diversify treatment pathways to allow people greater access to services
- build a case management approach provided by multidisciplinary and cross-jurisdictional teams.

3. Local teams should work together to consider:

- how to expand treatment capacity in primary care
- how to increase the scope of practice for nurses providing HCV care
- the introduction of peer support workers at screening and assessment services.

4. Monitoring and evaluation of the use and efficacy of *The clinical management of people living with hepatitis C* resource should be undertaken locally, including the use of an agreed minimum data set.

Section 8 – Appendices

Appendix 1: HCV medications, January 2016

PEGYLATED INTERFERON ALFA				
Brand Name	**Generic Name**	**TGA Status**	**PBS Status**	**Pharma**
PegIntron	Peginterferon alfa-2b	Approved	Listed	Merck
Pegasys	Peginterferon alfa-2a	Approved	Listed	Roche

IFN is a protein made by the immune system — it interferes with viral reproduction. IFN signals the immune system to recognise and respond to microorganisms, including viral and bacterial infections. Infected cells release IFN to trigger the immune response.

NULEOSIDE ANALOGS				
Brand Name	**Generic Name**	**USA Status**	**AUS Status**	**Pharma**
Ibavyr	Ribavirin	Approved	Listed (1 Mar 16)	Generic or in combination with peginterferon

RBV plays an important role in HCV combination treatment with Peginterferon. It slows down the growth of the virus.

NS3/4A PROTEASE INHIBITORS (PIS)				
Brand Name	**Generic Name**	**TGA Status**	**PBS Status**	**Pharma**
Olysio	Simeprevir	Approved	Only in combination with Peginterferon alfa and RBV; all oral awaited	Janssen
Sunvepra	Asunaprevir	Phase III (FDA 7 Apr 2014)	Not listed	BMS
	Paritaprevir	Approved	Awaited	AbbVie
	Grazoprevir	Awaited	Awaited	Merck

PIs block a protein required for HCV replication — they bind to the viral protease. Currently used in genotype 1 patients, future may see pan-genotypic.

NUCLEOSIDE AND NUCLEOTIDE NS5B POLYMERASE INHIBITORS				
Brand Name	**Generic Name**	**TGA Status**	**PBS Status**	**Pharma**
Sovaldi	Sofosbuvir	Approved	Listed (from 1 Mar 2016)	Gilead

NON-NUCLEOSIDE NS5B POLYMERASE INHIBITORS				
Brand Name	**Generic Name**	**TGA Status**	**PBS Status**	**Pharma**
	Dasabuvir	Approved	Awaited	AbbVie

Active against NS5B protein but via a different mechanism to the nucleoside/nucleotide versions.

NS5A INHIBITORS				
Brand Name	**Generic Name**	**TGA Status**	**PBS Status**	**Pharma**
Daklinza	Daclatasvir	Approved	Listed (from 1 Mar 2016)	BMS
	Ledipasvir	Approved	Listed (from 1 Mar 2016)	Gilead
	Ombitasvir	Approved	Awaited	AbbVie
	Velpatasvir	Awaited	Awaited	Gilead
	Elbasvir	Awaited	Awaited	Merck

Blocks the NS5A protein which has a role in replication and multiple functions in the virus's life cycle.

COMBINATION DRUGS				
Brand Name	**Generic Name**	**TGA Status**	**PBS Status**	**Pharma**
VieKira Pak	ABT450 (NS3) with Ritonavir + Ombitasvir (NS5A) + Dasabuvir (NS5B) + ribavirin	Approved	Awaited	AbbVie
Harvoni	Sofosbuvir + Ledipasvir	Approved	Listed (from 1 Mar 2016)	Gilead
	Grasoprevir + Elbasvir	Awaited	Awaited	Merck
	Sofosbuvir + Velpatasvir	Awaited	Awaited	Gilead
	Elbasvir	Awaited	Awaited	Merck

Combination therapies designed as one pill per day all oral treatment containing a mix of the above classes of medications. Objective is to be IFN+RBV free.

NEW IFN-FREE REGIMENS							
NSW Health service	Total number of assessments per year	Capacity to treat all	Medical / nursing occasions of service (non-treated)	Capacity to treat in IFN-free regime	IFN free total hours per patient prior to treatment	IFN-free total hours per patient on treatment	IFN-free total hours per patient post treatment
RPA	1100	Y	3.5 (2 hrs)	720	1.5	2	1.5
Westmead	865	N	2.5 (1.5 hrs)	1300	2.75	2	0.5
Wollongong	300	Y	2 (2 hrs)	300	3.5	4	1.25
Liverpool	800	Y	3 (1.75 hrs)	600	1.5	3	1.5
St George	120	Y	2 (45 mins)	500	2.25	1.75	1.75
AMS Western Sydney	100	N	6 (3 hrs)	25	5	9	6
Kite Street - Orange	200	N	6 (3 hrs)	152	6	2	1
John Hunter	450	Y	2 (1.75 hrs)	300	4	4	2
Newcastle - ETHOS	25	Y	3 (2 hrs)	25	5	10	4
Northern NSW	700	Y	3 (2 hrs)	500	1.5	1	0.5
Justice Health	500	Y	N/A	1000	2.5	0.5	0.5
Total				**5422**	**35.5**	**39.25**	**20.5**
Average				**493**	**3**	**4**	**2**

Appendix 2: Assessing the capacity of the HCV treatment service questionnaire

Position:			
Service:		**LHD:**	
Length of Time in Position:			

For following questions please respond reflecting on your current program. Estimate according to current capacity within your program allocation (clinical hours, staff mix and availability etc.)

The following questions are related to *Interferon (IFN)-based medication regimes.* Please estimate according to your best judgement.	
Based on your experience, how many patients do you treat per year in an IFN regime (estimate)?	
How many hours per patient (average) prior anti viral therapy (AVT)? *(Inclusive of all specialties; direct and indirect contact)*	
How many hours per patient (average) on AVT? *(Inclusive of all specialties; direct and indirect contact)*	
How many hours per patient (average) post AVT? *(Inclusive of all specialties; direct and indirect contact)*	
TOTAL HOURS:	
The following questions are related to *IFN-Free medication regimes.* Please estimate according to your best judgement.	
How many patients with HCV come through your clinic (new and existing) per year?	
Could you treat all of these?	☐ Yes ☐ No*
*If No, reason?	
Medical Only: On average how many OOS / hours for non-treated patients per year? Medical Only: Medical / Nursing:	
How many patients can your service treat in an IFN-Free regime (estimate)? Calculation: Total number of available treatment hours ____ + Total number of hours for non-treated ____ divided by Time per patient _____ equals total service capacity: _____	
How many hours per patient (average) prior AVT? *(Inclusive of all specialties; direct and indirect contact)*	
How many hours per patient (average) on AVT? *(Inclusive of all specialties; direct and indirect contact)*	
How many hours per patient (average) post AVT? *(Inclusive of all specialties; direct and indirect contact)*	
What percentage (%) of patients requires long term follow up post SVR?	
TOTAL HOURS:	
General Questions	
Within the current IFN based medication regimes, what percentage (%) of referrals are seen by your service within 3 months?	
What are the local issues that impact service capacity (e.g. Clinic Space/Availability; Access to a Fibroscan)?	

SURVEY RESPONDENT DATA					
NSW health service	Total hours per patient prior to treatment	Total hours per patient on treatment	Total hours per patient post treatment	Total hours	Total number of patients on IFN-containing treatment regimens
RPA	5	26	5	36	100
Westmead	6	14	2	22	180
Wollongong	6.25	9.5	1.25	17	43
Liverpool	5.5	25	4	34.5	60
St George	4	11	1.25	16.25	60
AMS Western Sydney	6	36	6	48	5
Kite Street - Orange	6	12.5	3.5	22	20
John Hunter	6	15	4	25	140
Newcastle - ETHOS	5	14	8	27	10
Northern NSW	6	12	1	19	140
Justice Health	2.5	2.5	0.5	5.5	200
Total	**58.25**	**177.5**	**36.5**	**272.25**	**958**
Average	**5**	**16**	**3**	**25**	**87**

Site visit results

A total of 10 site visits were conducted. Strengths and challenges were identified in all services. Each site had sought to deliver care individualised to their local cohort, using a unique mix of staff according to LHD resources. Care was universally delivered by skilled practitioners in a variety of settings responsive to local needs. Common challenges faced by all sites visited included limited clinic space, long waiting lists, high no-show rates, old diagnostic equipment and ongoing staffing issues.

Summary of lessons learned from site visits and survey analysis

Current treatment

- Current medication regimes have low treatment rates.
- Individuals experience delays in commencing treatment due to inefficient referral processes, limited access to treatment centres and inadequate staffing levels.
- Sites vary in the availability of fibroscan to assess liver scarring, which delays treatment.
- Managing non-treated clients within tertiary hospital clinics has a significant impact on service provision (in terms of occasions of service and clinician availability).
- HCV treatment centres are congested with people care issues that could be transferred to primary care providers.

DAA treatment

- Expand the level of providers to include GPs and NPs.
- Diversify treatment locations.
- Increase scope of practice of registered nurses.

Prepared by the Health Economics and Evaluation Team for the Gastroenterology Network

A3: Business as usual analysis for the viral hepatitis C model of care

ACI Gastroenterology Network

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Section 1

A3: Executive summary

There are approximately 90,000 people living with hepatitis C in NSW. The ACI's Hepatitis C Model of Care (MoC) proposes a reorganisation of current treatment processes in NSW local health districts (LHDs) to provide more effective and efficient treatment. The MoC is based on multidisciplinary teams facilitating patient access to new, highly-effective pharmaceutical treatments.

The Australian Government's Pharmaceutical Benefits Advisory Committee (PBAC) has just recommended these drugs for inclusion on the Pharmaceutical Benefits Schedule (PBS). If this is agreed to by the Commonwealth, use of these treatments will primarily be funded through the PBS if these patients are seen in appropriate non-admitted settings including in the community or as privately referred non-inpatients at hospital outpatient clinics. A decision on this is not due to the end of this year (at the earliest). If successful this will significantly change the treatment, outcomes and funding arrangements for hepatitis C.

The cost-effectiveness of these new treatment regimens have been shown in a number of different countries and health systems. There is, however, limited understanding of the resources currently being utilised by this patient cohort in NSW and the potential impact the new treatments, supported by the Hepatitis C MoC, will have on NSW Health resource use.

This paper presents what is known of the current and projected resource-use for the patient cohort prior to the implementation of the ACI MoC. The analysis is based on data extracted from NSW administrative datasets. If business as usual (BAU) trends continue, the analysis suggests a net present value of total inpatient resource use equivalent to $1.2B from 2013/14 to 2019/20 with an additional $27-56M on outpatient treatment. Once the MoC is finalised and the source of funding determined for the new pharmaceuticals this BAU analysis can be included in a cost benefit analysis if required.

Over the period 2008/09 and 2012/13:

- There were, on average, over a 1,000 patients per month admitted to NSW Public Hospitals with hepatitis C.
- Around a third of the 90,000 people with hepatitis C had a hospital stay (32,000 different patients) with just over two admissions each on average over the period.
- 58% of hospital people living with hepatitis C were male (and 64% of separations).
- HCV patients have a relatively high average length of stay (ALOS) and are relatively expensive. The ALOS for this patient cohort was 8.07 days (for over-night admitted patients only the average length of stay was 9.73 days) and there was an average inpatient resource use across the state for these patients of $138 million per year. The average cost per separation of seeing one of these patients in a NSW inpatient facility was over $9,800 — just over twice the average cost of a separation of $4,671.
- 19% of admissions were day-only and this remained largely stable over the period.
- There is uncertainty over the level of resource use in publicly-funded outpatient clinics. Designated Hepatitis C Tier 2 clinics were only recently introduced and data shows that there were almost 91,000 encounters at an average cost of $264 (total cost of approximately $24M across the state). It is likely that this is an underestimate of activity and costs in the sector.

Section 2

A3: Introduction

Demonstrating that resources allocated to improving health in NSW are used for cost-effective purposes is a key aim of the NSW ACI. This report contributes towards this goal through an analysis of the projected level of resource use under a BAU situation. The BAU projections outline the estimated resource use if current care practices are maintained into the future.

This analysis includes:

- an overview of hepatitis C in NSW
- an outline of the MoC and its application and the current treatment situation in NSW
- analysis of the demand for hepatitis C treatment in NSW
- the resource use implications of the BAU case.

This analysis indicates that under a BAU scenario the treatment for hepatitis C will require a greater amount of public hospital resources through NSW. If BAU trends continue, the analysis suggests a net present value of total inpatient resource use equivalent to $1.2B from 2013/14 to 2019/20.

2.1 Hepatitis C in New South Wales

There are approximately 90,000 people infected with hepatitis C across NSW.[1,2] Hepatitis C has significant impacts on the quality of life of those infected with the disease and those close to them.[3,4] An increasing number of patients are progressing to later stages of liver disease as a result of chronic hepatitis C[2], which has large implications for the quality of life for the patient and also their demand for healthcare.

As is described in the MoC, for those exposed to HCV, approximately 25% will clear the virus spontaneously within the first six to twelve months. For the remainder, without treatment, the virus attacks the liver resulting in 10-15% progressing to cirrhosis and 5% at risk of developing hepatocellular carcinoma (HCC) and liver disease requiring liver transplantation. Hepatitis C is a major risk factor for primary liver cancer. Hepatitis C is also the single biggest driver of demand for liver transplantation in Australia.

Traditional care for these patients has been characterised by low-levels of treatment across the patient cohort. Studies have suggested that approximately 2% of those infected with hepatitis C access care. There are a number of reasons for this. Hepatitis C is predominantly focused in marginalised populations within NSW. Prisoners, Aboriginal and Torres Strait Islander communities and people who inject drugs bear a greater burden of hepatitis C than other groups within society.[2] Healthcare services have not always been successful at reaching these groups. Further, existing treatments have side effects associated with significant loss of quality of life for patients.[4] The prospect of the new treatments included in the MoC has also resulted in healthcare providers and patients holding off on accessing treatment as the new pharmaceuticals have much shorter durations of treatment, much higher efficacy and are associated with fewer side-effects.

[1] Kirby Institute., HIV, viral hepatitis and sexually transmissible infections in Australia Annual Surveillance Report 2012 National Notifiable Disease Surveillance System. 2012 Kirby Institute, University of New South Wales.

[2] Commonwealth of Australia, Fourth National Hepatitis C Strategy (2014–2017). 2014: Canberra.

[3] Strauss, E., & Dias Teixeira, M. C. (2006). Quality of life in hepatitis C. Liver International, 26(7), 755-765. doi: 10.1111/j.1478-3231.2006.01331.x

[4] Chhatwal, J., Kanwal, F., Roberts, M. S., & Dunn, M. A. (2015). Cost-effectiveness and budget impact of hepatitis C virus treatment with sofosbuvir and ledipasvir in the United States. Annals of Internal Medicine, 162(6), 397; .

2.2 ACI model of care

The new ACI MoC for treating viral hepatitis C is based around restructuring existing staff within LHDs in order to facilitate better care for patients. The central component of treatment will be access to pharmaceutical treatments that may be available through the PBS by the end of the year. The MoC is designed to facilitate treatment to those individuals who need it most to keep them healthy and out of hospital.

The MoC is based on a multi-disciplinary team working together to facilitate access to highly-effective pharmaceutical treatments. The specific treatments are described in the MoC. While the effectiveness of these treatments have been described in the MoC itself, the resource use implications of this patient cohort have not been investigated in the NSW context.

The pharmaceuticals, including Sofosbuvir, have recently been recommended for inclusion on the PBS by the PBAC. The increasing use of inpatient resources of individuals experiencing these latter stages of liver disease highlighted below demonstrates the potential importance of early diagnosis and treatment, avoiding disease progression and avoiding relatively costly inpatient settings.

2.2.1 Cost-effectiveness in different jurisdictions

Despite the relatively high cost of the pharmaceuticals involved, the pharmaceuticals that underlie the ACI MoC have been shown to be cost-effective in the treatment in a number of different settings including the US[5], UK[6], France[7], Italy[8], Switzerland[9], Belgium[10], Sweden[11], The Netherlands[12] and others. The treatments have been shown to be cost-effective with regards to the resources required to obtain health gains through such treatment both in early stages of hepatitis C as well as for patients with later manifestations of liver disease including those with cirrhosis and those waiting for liver transplantation.[13]

Under the assumption that the treatments included in the MoC are included on the PBS, the threshold for the MoC to be considered cost-effective from a NSW Health point of view will be far below that of these jurisdictions. This results from the fact that NSW Health will not be responsible for funding the treatments but rather facilitating access to appropriate medical professionals and care. Details of the funding breakdown for people living with hepatitis C is included in Appendix 1. There is, however, limited understanding of the resources currently being utilised by this patient cohort in NSW and the potential impact the new treatments, supported by the Hepatitis C MoC, will have on reduced inpatient admissions. This report aims to provide an estimate of the resource utilisation of these patients under a BAU case. The estimates and assumptions used in this analysis are described below.

[5] NICE. (2015). Sofosbuvir for treating chronic hepatitis C: NICE technology appraisal guidance 330. In NICE (Ed.). UK

[6] Leleu, H., Blachier, M., & Rosa, I. (2015). Cost-effectiveness of sofosbuvir in the treatment of patients with hepatitis C. Journal of viral hepatitis, 22(4), 376-383. doi: 10.1111/jvh.12311

[7] Cure, S., Guerra, I., Cammà, C., Craxì, A., & Carosi, G. (2015). Cost-effectiveness of sofosbuvir plus ribavirin with or without pegylated interferon for the treatment of chronic hepatitis C in Italy. Journal of Medical Economics, 1-26. doi: 10.3111/13696998.2015.1040024

[8] Pfeil, A. M., Reich, O., Guerra, I. M., Cure, S., Negro, F., Müllhaupt, B., . . . Schwenkglenks, M. (2015). Cost-effectiveness analysis of sofosbuvir compared to current standard treatment in swiss patients with chronic hepatitis C. PloS one

[9] De, G. K., Delwaide, J., & Michielsen, P. (2014). The Costs-Effectiveness Of Sofosbuvir Verse Standard Of Care (Soc) In Chronic Hepatitis C From A Belgian Reimbursement Perspective. Value in Health, 17(7), A371. doi: 10.1016/j.jval.2014.08.845

[10] Cure, S., & Guerra, I. (2014). Cost-Effectiveness and Long-Term Outcomes of Sovaldi (SOFOSBUVIR) for the Treatment of Chronic Hepatitis C Infected (HCV) Patients from a Swedish Societal Perspective. Value in Health, 17(7), A675. doi: 10.1016/j.jval.2014.08.2508

[11] Novak, A., Drenth, J. P. H., & de Knegt, R. J. (2014). The Pan-Genotypic Costs-Effectiveness Of Sofosbuvir in Hepatitis C Virus. Value in Health, 17(7), A676. doi: 10.1016/j.jval.2014.08.2514

[12] Cortesi, P. A., Mantovani, L., Ciaccio, A., Rota, M., Cesana, G., Strazzabosco, M., & Belli, L. S. (2014). The Cost-Effectiveness Of Sofosbuvir And Ribavirin Treatment In Hcv-Infected Patients Listed For Liver Transplantation. Value in Health, 17(7), A367-A368. doi: 10.1016/j.jval.2014.08.826

[13] Razavi H, Waked I, Sarrazin C, Myers RP, Idilman R, Calinas F, et al. The present and future disease burden of hepatitis C virus (HCV) infection with today's treatment paradigm. *J Viral Hepat*. 2014;21(s1):34-59.

Section 3

A3: Economic impact in NSW

The estimated resource implications associated with people living with hepatitis C under a BAU situation have a net present value of between $1.2 and $1.8B between 2013/14 to 2019/20. These results are based on the calculation and assumptions outlined in the sections below. Further details regarding the methodology of this analysis are outlined in Appendix 2.

3.1 Demand for hepatitis C care

As highlighted above, it is estimated that 90,000 people are infected by hepatitis C in NSW and the patient cohort is characterised by low treatment levels with an estimated 2% of this group accessing treatment for their hepatitis C. This population is projected to slowly increase, with a 5% growth projected between 2013 and 2030.[14] This section outlines what is known about current treatment provided in NSW from data extracted from the Admitted Patient Data Collection for inpatient treatment and outpatient data. Further details on the data extraction process are outlined in Appendix 3.

3.1.1 General characteristics of inpatient cohort

As is described in Table 1, between 2008/09 and 2012/13 there were just under 67,000 separations in NSW Public hospitals relating to this patient cohort, an average of just over 13,000 separations per year.

There were 32,000 different patients over the period of the analysis, with each patient being admitted an average of 2.1 times over the period of the analysis; 58% of these patients (64% of total separations) were male.

The average length of stay per episode was 8.04 days and there was an average total cost of inpatient treatment per year for these patients of $138M (the total cost for the admitted patient cohort over this time period was $690.3M). For over-night admitted patients (that is the patient cohort excluding same-day separations) only the average length of stay was 9.73 days.

Patients are primary admitted overnight with only 19% of total admissions for this patient cohort being same-day admissions and this remained largely stable over the period of the analysis. The average cost per separation of seeing one of these patients in a NSW inpatient facility was over $9,800. For same-day patients the average cost was slightly over $1,500. The average cost per separation for all non-day-only patients was $12,457. In contrast, as is described in Section 4.1.2, the average cost per outpatient encounter in Tier 2 Hepatitis C Designated Clinics was $264.

Of the total separations, 32,000 had Compensated Cirrhosis (CC), just under 24,000 had End Stage Liver Disease (ESLD) and fewer than 400 patients had Non-Cirrhotic Liver Disease (NCLD). Once again, these groupings are not mutually exclusive.

Inpatient resources are predominantly used for patients with latter stage manifestations of hepatitis C — CC (these patients had an average National Weighted Activity Unit (NWAU) value of 2.5 which equates to a cost of just under $11,700 per separation in 2013/14 dollars) and ESLD (average NWAU of 3.08, average cost per separation of over $14,300). While the average NWAU weighting for patients classified with NCD is very high at 4.08, this is heavily impacted by a few outliers with very long lengths of stay and very high NWAU weightings combined with the relatively low number of these patients (the average for these patients drops to 2.3 when data from 2008/09 is dropped from the analysis). Further analysis of the Admitted Patient Data Collection (ADPC) shows that patients admitted with ESLD were admitted on average just over 2.3 times over the analysis period, while CC patients were admitted over 2.1 times. NCD patients on average had one separation over the analysis period.

As mentioned in the introduction the literature suggests that of those exposed to HCV, without treatment, 10-15% will progress to cirrhosis and 5% will be at risk of developing HCC and liver disease requiring liver transplantation. Avoiding the latter stages of liver disease that develop from chronic hepatitis C will not only have significant quality of life benefits to NSW patients living with Hepatitis C but also large resource-use implications.

[14] Razavi H, Waked I, Sarrazin C, Myers RP, Idilman R, Calinas F, et al. The present and future disease burden of hepatitis C virus (HCV) infection with today's treatment paradigm. *J Viral Hepat*. 2014;21(s1):34-59

A3: TABLE 1 - INPATIENT ACTIVITY DATA 2008/09 - 2013/14 NSW PUBLIC HOSPITALS											
Financial year	Total separations	Annual growth rate	Total bed days	Bed days growth rate	ALOS (days)	Day only admissions (% of total)	Total NWAUs	Average NWAU	Average cost per separation*	Total cost* ($M)	Annual growth rate in cost
2008/09	12,047		105,833		9	2,308 (19.2%)	27,964	2.3	$10,843	130.62	
2009/10	12,848	6.7%	101,941	-3.7%	8	2,478 (19.3%)	28,348	2.2	$10,306	132.41	1.37%
2010/11	13,290	3.4%	110,156	8.1%	8	2,662 (20%)	30,208	2.3	$10,617	141.10	6.56%
2011/12	13,732	3.3%	109,474	-0.6%	8	2,730 (19.9%)	28,991	2.2	$9,861	135.42	-4.03%
2012/13	14,809	7.8%	109,182	-0.3%	7	2,685 (18.1%)	32,278	2.2	$10,181	150.77	11.34%
Total 2008/09 - 2012/13	**66,726**	**5.3%**	**536,586**	**0.8%**	**8**	**12,863 (19.3%)**	**147,789**	**2.2**	**$10,346**	**690.32**	**3.65%**
Average 2008/09 - 2012/13	**13,345**	**5.3%**	**107,317**	**0.9%**	**8**	**2,573 (19.3%)**	**29,558**	**2.2**	**$10,362**	**138.06**	**3.81%**
2013/14	25,687	73.5%	176,487	61.6%	7	4,964 (19.3%)	49,162	1.9	$8,940	229.64	52.31%
Total 2008/09 - 2013/14	**92,413**	**16.4%**	**713,073**	**10.8%**	**8**	**17,827 (19.3%)**	**196,950**	**2.1**	**$9,955**	**919.96**	**11.95%**

*2013/14 dollars

3.1.2 Outpatient data

Due to the nature of hepatitis C and the patient cohort, it is expected that most treatment would occur in an outpatient or non-admitted setting. There was uncertainty around the numbers of outpatients receiving treatment in NSW.

Data extracted from the Activity Based Management (ABM) portal for hepatitis C specific public outpatient centres show that there were 90,981 encounters in NSW in 2013-14 at a cost of around $24 million. This is likely to be an underestimation of total outpatient activity as there are a number of non-hepatitis C specific clinics where these patients may be treated (these data came from 26 facilities across the state). The data does not show how many individual patients were treated in these clinics. As such this figure is used as a lower bound for the level of outpatient activity in the system. When combined with the
average annual cost of inpatient treatment, this suggests a total of $162M for care of these patients in NSW public hospitals.

Research carried out during the development of the MoC surveyed the capacity of providing hepatitis C treatment across a number of facilities and LHDs. Northern NSW, Justice Health, eight hospitals and AMS Western Sydney responded to the survey. Across these sites and areas there were 958 patients being treated at the time of the survey. It was estimated that each of these patients received approximately 25 hours of total care (including care prior to beginning treatment, during treatment and post treatment). Estimates from the literature suggest approximately 2000 patients are being treated for hepatitis C in NSW. This would suggest that the surveyed facilities account for approximately half of all treatment for this patient cohort in NSW. No cost data was included in the survey.

Given the uncertainty around these figures, sensitivity analysis was used varying the size of outpatient costs to provide a range of potential outcomes.

3.2 Business as usual projections

To determine the impact of the new MoC, hypothetical situations were modelled forward to 2019/20 assuming both the implementation of the MoC across NSW and the situation if the MoC is not implemented, called here the BAU case.

Two methodologies were compared to give a sense of potential outcomes (summarised in Table 2 with further detail included in Appendix 2). First, the patient data from 2008/09-2012/13 was used to project the total number of separations forward until 2020. Similarly the historical trend in ALOS for these patients and NWAU patterns were used to project the potential resource implications going forward for this population. While there has been a decrease in ALOS and average NWAU per patient over time it is assumed in the analysis below that current ALOS and average NWAU is maintained. This was done to account for the likely increase in patients with latter stage manifestations of liver disease over the period of analysis. This is considered a relatively conservative estimate for this patient cohort due to the observed spike in the 2013/14 data. Secondly, 2013/14 data is used along with population projections estimates to provide a less conservative estimate of the size of the cohort. These methodologies were based on historical growth rates rather than prevalence figures as the characteristics of the patient cohort means there is a high degree of uncertainty around the level of treatment being accessed and the proportion of patients progressing to acute care in hospitals.

A3: TABLE 2 - INPATIENT BUSINESS AS USUAL PROJECTIONS				
Financial Year	Separations (high)	Separations (conservative)	Cost (high)	Cost (conservative)
2008/09	19,990	12,047	178	131
2009/10	21,413	12,848	191	132
2010/11	22,176	13,290	198	141
2011/12	22,939	13,732	205	135
2012/13	24,892	14,809	222	151
2013/14	25,687	15,268	229	158
2014/15	26,722	15,908	238	164
2015/16	27,756	16,549	248	171
2016/17	28,791	17,190	257	177
2017/18	29,826	17,831	266	184
2018/19	30,860	18,472	275	191
2019/20	31,891	19,112	285	197

3.2.1 Based on 2008/09–2012/13 data

Using the historical data to predict the number of separations and resource use for this patient cohort treated as inpatients, suggests that by 2019/20 there could be over 19,000 separations for this patient cohort, with 120,000 separations between 2013/14 and 2019/20. If resource use averages are maintained over this period it is projected that there would be over 150,000 bed days used by this patient cohort with a total NWAU use of over 42,000 (almost $200M in 2019/20).

This is likely to be a conservative estimate due to the data issues around the 2013/14 numbers as well as the likely presentations of an increasing number of patients with later stages of liver disease.

Using a discount rate of 5%, the analysis suggests a net present value of total resource use equivalent to $1.2-$1.8B from 2013/14 to 2019/20, an average of over $170M per year.

3.2.2 Patient cohort based on 2013/14 inpatient data and population projections

As noted above, there was a substantial increase in the number of patients being coded as having hepatitis C in 2013/14. This increase was expected and was the result of coding-practice changes that were implemented in that year. Thus the increase was thought to be the result of these coding changes rather than a substantial increase in the growth rate in the number of patients presenting with Hepatitis C in NSW.

If this is the case then it is likely that similar patients were treated prior to 2013/14 but were not coded as having Hepatitis C. As such, the analysis in the section above, which is based on patient data up until 2012/13 is a conservative estimate of the resources used to treat this patient cohort. As a potential upper-bound for these estimates, the patient cohort was projected forward and backwards using the higher 2013/14 patient data. The growth in the other components of the patient cohort (that is the DRG categories not impacted by the coding change) were used to project the numbers of inpatients until 2019/20. The lower average NWAU per separation of 2013/14 was applied to these numbers.

Using this technique, it is projected that almost 32,000 separations could occur for this patient cohort in 2019/20 at a total cost of over $280M. The net present cost of the resource use with a discount of 5% is estimated at $1.52B, an average of almost $215M per year

Table 2 shows the projected separations and resource use (in terms of costs) for this patient cohort using these two methods.

3.2.3 Outpatient projections

Outpatient projections (Table 3) were based on the current estimates of cost per patient encounter and the projected size of the patient cohort going forward. Results from the literature suggest that the hepatitis C population in Australia is growing slowly (expected to increase 5% between 2013 and 2030).[15] The survey across 11 facilities and LHDs across NSW which suggested that approximately 5000 patients are assessed for Hepatitis C treatment each year in these areas and facilities each year while about 1000 were undergoing treatment at the time of the survey. Given the low levels of treatment in this patient cohort is projected to grow modestly over time here in line with policy aims of increased treatment. Due to the uncertainty around the outpatient data three different estimates are provided to show the potential range of resource use for this population.

A3: TABLE 3 - OUTPATIENT BUSINESS AS USUAL PROJECTIONS

Financial Year	Outpatient encounters	Total Cost (low)	Total Cost (mid)	Total Cost (high)
2013/14	91,000	24	24	24
2014/15	92,820	25	32	51
2015/16	94,676	25	32	52
2016/17	96,570	25	33	53
2017/18	98,501	26	34	54
2018/19	100,471	27	34	55
2019/20	102,481	27	35	56

15 Razavi H, Waked I, Sarrazin C, Myers RP, Idilman R, Calinas F, et al. The present and future disease burden of hepatitis C virus (HCV) infection with today's treatment paradigm. *J Viral Hepat*. 2014;21(s1):34-59

Section 4

A3: Conclusion

The ACI Hepatitis C MoC has the potential to free-up resources for use in alternative patient groups while improving patient care for people living with Hepatitis C in NSW. Given that PBAC has approved the use of these treatments through the PBS, the MoC will facilitate the use of highly effective treatments to those in NSW who can most benefit from their adoption.

Facilitating the use of such treatments will be a highly cost-effective use of NSW resources in this area. Further analysis that examines cost effectiveness from a NSW Health view point and compares this to the BAU analysis can occur once the funding source for the new treatments is known.

Section 5

A3: Appendices

Appendix 1 — Funding context for treatment of hepatitis C

Hepatitis C services in NSW are funded jointly by the State and Commonwealth Governments as well as a co-payment from patients in some circumstances. The specific funding arrangement for a given patient will depend on where the patient is treated.

- **Admitted as a public inpatient to a public hospital** — NSW Health is responsible for the provision of healthcare services. The cost of associated pharmaceuticals would are currently met under the S100 high cost drug program under the PBS.
- **Elects to be a private patient in a public hospital** — the accommodation costs are funded by health insurance funds (if the patient elects to use private health insurance) or by the patient themselves and treatment costs funded by a combination of the Medical Benefits Schedule (MBS), NSW Health (if all costs are not covered) and potentially the patient.
- **Seen in an outpatient or day-only setting** — the clinician bills the MBS for patient care and pharmaceuticals are funded through S100 (High Cost Drugs) arrangement under the PBS with a relatively small co-payment from patients (approximately $37 per script filled)[16]. However, PBAC has recommended that Sofosbuvir be approved for inclusion on the general PBS meaning that when the treatments are listed on the PBS they are likely to be available to be prescribed from both tertiary hospital settings and primary care facilities more generally.

Pathology and diagnostic services are similarly funded by both the NSW and Federal Governments. If a patient is referred specifically to a publicly run diagnostic or testing service (as is discussed in the MoC) by a GP or other primary health provider then the service is provided under the MBS and reimbursed by the Commonwealth Government.

At present, the pharmaceuticals used for treatment of Hepatitis C are only subsidised under the PBS when it is prescribed by a specialist medical practitioner, or by a limited number of GPs who are accredited to prescribe treatment in a shared-care arrangement with a specialist. As a result, treatment is predominantly provided in public tertiary specialist settings, or by specialist visits to outreach sites. This service model has limited capacity to halt the foreshadowed burden of liver disease or meet the expected treatment demand. For people living in rural and regional NSW, in particular, specialist hepatitis C doctors may not be easily accessible. In addition to these supply restrictions, demand for treatment has been low among people living with hepatitis C.

Appendix 2 — Methodology of analysis

The analysis above was conducted from the perspective of the NSW public health system. The patient cohort was defined by the Gastroenterology Network using relevant ICD-10, DRG and procedure codes and is described in the MoC itself and Appendix A. This cohort comprises individuals presenting with Hepatitis C at NSW public hospitals and associated outpatient clinics. At the request of the Network, to allow for comparison to other systems, the patient cohort was broadly categorised into three groups for the analysis: (1) CC; (2) ESLD; and (3) NCLD. The patients included in these groups are provided in Appendix B. These groups are not mutually exclusive.

Inpatient data was extracted from the ADPC for the years 2008-09 to 2013-14. 2008-09 was used as the starting year for the analysis as data collection methods for this dataset improved from this year onwards and this was the first year that Activity Based Funding (ABF) information was collected.
Outpatient data was extracted from the ABM Portal for Tier 2 Hepatitis C designated clinics. Due to poor data collected for these clinics in prior years, the analysis is based on 2013-14 data and supplemented by surveys of clinicians of the ACI's Gastroenterology Network around the level of patients treated in outpatient settings in NSW. Effectiveness of the new MoC was estimated from the literature.

Historical data was projected forward to predict the size of the patient cohort until 2019/20. This time frame was chosen because to align with the current NSW Hepatitis C strategy. NWAU information assigned to each patient was used as a proxy for the costs facing the health service provider and modelled over the same timeframe to estimate the resource utilisation associated with implementing the ACI hepatitis MoC.

The NWAU price is escalated for projections at 3.5%, based on the average annual cost escalation for NSW Health over a seven-year period, as advised by NSW Health Finance & Business Management branch. When present values are presented, a discount rate of 5% was used as is recommended by NSW Health.

Appendix 3 — Data quality

A significant proportion of patient data were missing NWAU information (approximately 18% of the total separations of this cohort). Where NWAU data was missing for particular patients, an average of NWAU values for patients with that length of stay was assigned as an estimate. This was used rather than an average for the DRG for the patient as significant differences were observed between the length of stay assigned to patients with missing NWAU data and those with NWAUs assigned for certain DRG codes.

While a significant proportion of NWAU information was missing, these were concentrated over 15 specific lengths of stay ranging between 0 and 18 days. There were 50 separations with NWAU values assigned for patients with a LOS of 0 while all other categories had a minimum sample of at least 600 separations (maximum of 5142) so the average information for NWAU data was considered robust enough to use for estimation purposes. Simple regression analysis suggests that 86% of NWAU variance was explained using length of stay information for this cohort.

Due to a combination of data collection issues and the marginalised nature of this patient cohort, the data analysis presented above presents only a part of the story. These patient groups are unlikely to be seen in acute care settings before their health has significantly deteriorated as a result of the disease. As mentioned above there was only one year of robust data for specifically designated outpatient Hepatitis C tier 2 clinics. These data are supplemented by surveys conducted by the ACI Gastroenterology Network to provide more information over the numbers of patients being treated in these settings. Where possible and needed, the results of the data analysis are supplemented with relevant findings from the literature.

With regards to the admitted patients, coding practice changes in 2013/14 greatly increased the numbers of patients being coded as having Hepatitis C. In particular there was a dramatic increase in the numbers of patients being coded with B18.2 Acute Viral Hepatitis C. While this increase was anticipated, there has not been a chance to test the validity of the data over multiple years so different scenarios are presented below using both the data up until 2012/13 as a conservative estimate and separate analysis using the much higher 2013/14 numbers. A summary of the relevant coding practice changes is included in Appendix A3. Estimations of increased presentations of the patient cohort as a result of the MoC were estimated from the literature and targets outlined in the NSW Hepatitis C Strategy 2014-2020 and the MoC itself.

Appendix 4 — Patient cohort

All adults (18 and over) admitted to public hospitals in NSW and ambulatory clinics from 2008/09 onwards with the following ICD diagnoses:

- acute viral hepatitis C (B17.1)
- chronic viral hepatitis C (B18.2)
- ascites (R18),
- bleeding oesophageal varices (I98.x)
- hepato-renal syndrome (K767)
- hepatic encephalopathy or hepatic failure (K704, K720, K721, K729) and
- primary liver cancer or HCC (ICD10 C22.0)

And the following DRGs

H60A	Cirrhosis and Alcoholic Hepatitis W Catastrophic CC
H60B	Cirrhosis and Alcoholic Hepatitis W Sev/Mod CC
H60C	Cirrhosis and Alcoholic Hepatitis W/O CC
H61A	Malignancy of Hepatobiliary System, Pancreas W Catastrophic CC
H61B	Malignancy of Hepatobiliary System, Pancreas W Catastrophic CC
H63A	Disorders of Liver Except Malig, Cirrhosis, Alcohol Hepatitis W Cat/Sev CC
H63B	Disorders of Liver Except Malig, Cirrhosis, Alcohol Hepatitis W/O Cat/Sev CC

Appendix 5 - Patient cohort by disease progression

Patients were divided into three groups.

1. **Non-cirrhotic liver disease**
   a. acute viral hepatitis C (B17.1)
2. **2. Compensated cirrhosis**
   a. chronic viral hepatitis C (B18.2)
   b. ascites (R18).
3. **3. End Stage Liver Disease**
   a. bleeding oesophageal varices (I98.x)
   b. hepato-renal syndrome (K767)
   c. hepatic encephalopathy or hepatic failure (K704, K720, K721, K729)
   d. primary liver cancer or HCC (ICD10 C22.0).

Appendix 6 – Relevant coding practice changes

Source: ACS Chronicle – First Edition to Eighth Edition

0104 Viral hepatitis

A public submission (P118) was received regarding hepatitis C. Information provided in this standard was outdated due to advances in antiviral therapy. Once described as an incurable infection, current advances in antiviral therapy have improved outcomes for people living with hepatitis C significantly and the possibility of successfully treating (i.e. attaining SVR [sustained virological response]) HCV infection is achievable. SVR is defined as the absence of HCV RNA in serum 24 weeks after discontinuing therapy.

Following comments received from ITG members and internally, National Casemix and Classification Centre acknowledged that clinical advice regarding hepatitis carrier status needed to be updated and reflected in ACS 0104 viral hepatitis. It was initially decided to incorporate changes regarding hepatitis C alone; however after further consideration it was deemed unwise to amend this section of the standard in isolation. Consequently, the entire standard was reviewed for currency and clinical appropriateness.

Definition

- Updated definitions of hepatitis A, B, C, D and E
- Removed all references to carrier status

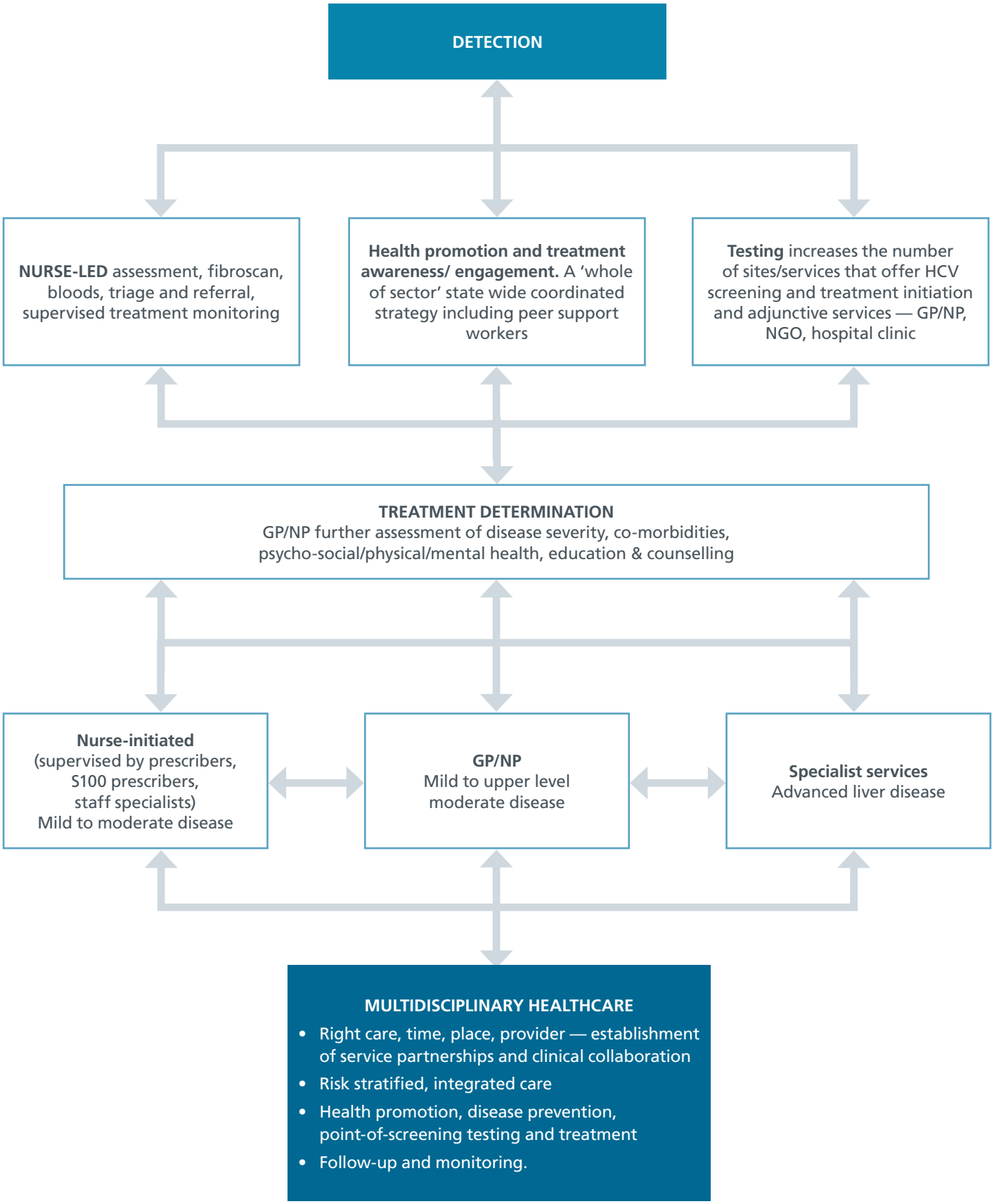
Classification

- Amended sentence "Viral hepatitis or hepatitis carrier status should always be coded even if the criteria for additional diagnosis are not met" to "Viral hepatitis should always be coded when documented except when hepatitis C is documented with terms such as ‘cured’, ‘cleared’ or ‘with SVR’, see 4. Cured/cleared hepatitis C below."
- Revised classification table.
- Included classification advice for the following categories:
  1. past history of hepatitis
  2. manifestations of hepatitis
  3. hepatitis complicating pregnancy, childbirth and puerperium
  4. cured/cleared hepatitis C.
- Created examples for manifestations of viral hepatitis and cured/cleared hepatitis C.

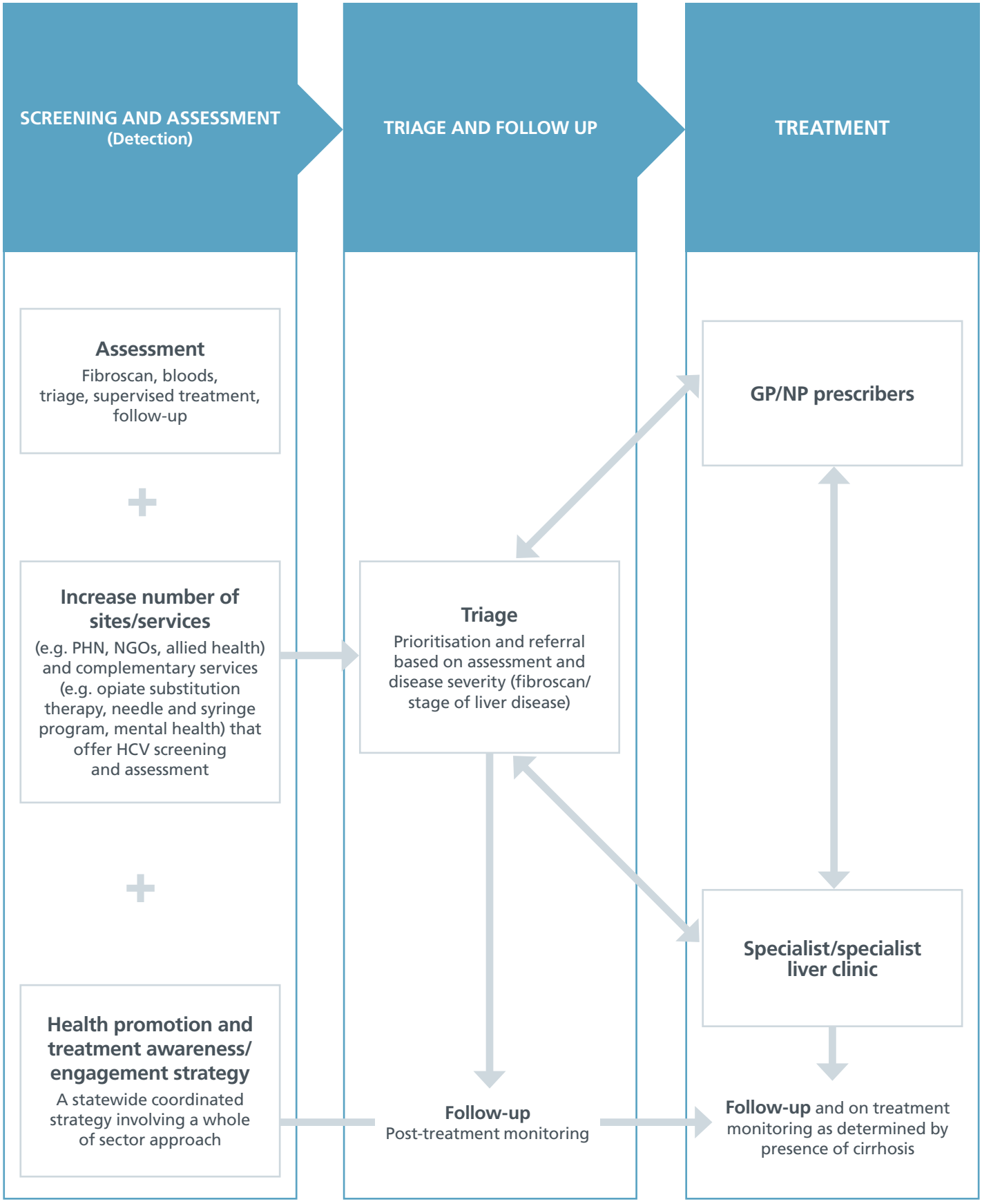
ACS reference symbols were added at B94.2 and Z86.18 in ICD-10-AM Tabular List to support these changes.

Appendix 4: Pathways

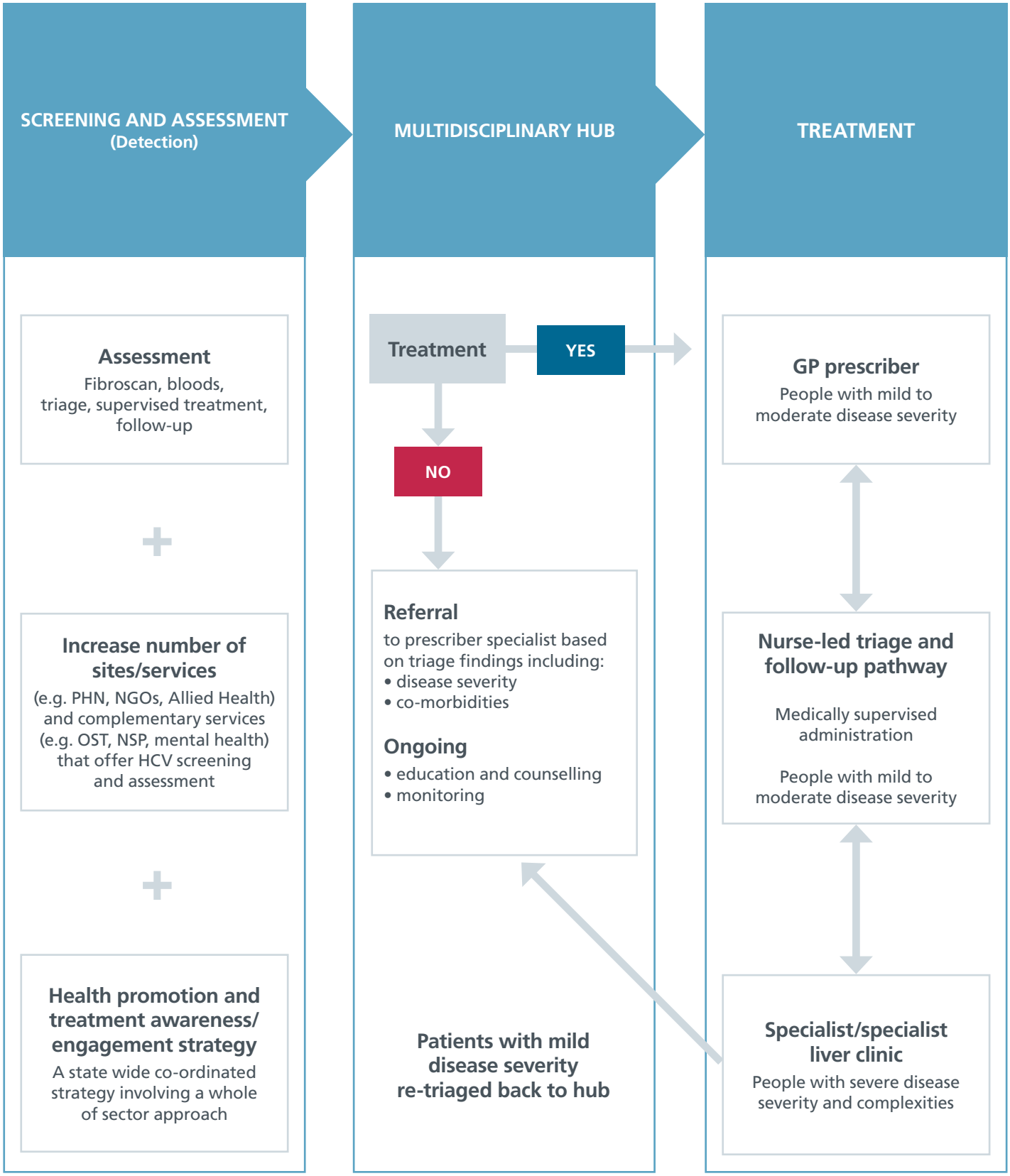
Nurse-led multidisciplinary clinical pathway for hepatitis C



Nurse-led multidisciplinary clinical pathway for hepatitis C



Multidisciplinary hub clinical pathway for hepatitis C



Section 9

Glossary and definitions

GLOSSARY	
When we say...	**We mean...**
ABF	Activity Based Funding
ABM	Activity Based Management
ADPC	Admitted Patient Data Collection
ACCHSs	Aboriginal community controlled health services
ALOS	average length of stay
AMS	Aboriginal medical services
AVT	anti viral therapy
BAU	business as usual
CALD	culturally and linguistically diverse
CC	compensated cirrhosis
CNC	clinical nurse consultant
DAA	direct acting antivirals
ETHOS	Enhanced Treatment for Hepatitis C in Opiate Substitution Settings Study
GP	general practitioner
HCC	hepatocellular carcinoma
HCV	hepatitis C virus
ICD-10	International Statistical Classification of Disease and Related Health Problems 10th Revision
IFN	interferon
LHD	local health district
LOS	length of stay
MBS	Medical Benefits Schedule
MHAHS	Multicultural HIV and Hepatitis Service
NGO	non-government organisation
NP	nurse practitioner
NSP	needle and syringe program
NUAA	NSW Users and AIDS Association
OST	opiate substitution treatment
PBAC	Pharmaceutical Benefits Advisory Committee
PBS	Pharmaceutical Benefits Scheme
PEG-IFN	pegylated interferon
PI	protease inhibitors
PSW	peer support worker
RBV	Ribavirin
SVR	sustained virologic response

DEFINITIONS	
When we say...	**We mean...**
Primary healthcare	Primary healthcare in the Australian context can be defined in a number of different ways, both as the first level of care and as a particular approach to care. Primary healthcare is often the first level of contact people have with the health system in relation to their health. It is those parts of the health system that focus on protecting and promoting the health of people in communities, and is often engaged in working with issues regarding health in a preventative manner. It is also the place where health problems are commonly identified, managed or referred in the context of early intervention. Clearly the broader definition of primary healthcare encompasses more than primary medical care. It includes community health services, Aboriginal health services and broader preventative programs. Using them interchangeably may suggest that those components of primary healthcare other than primary medical care are less important. (Professor Mark Harris, *Croakey*, 17 June 2010)
Integrated care	The NSW Health definition of integrated care from the strategy is: Integrated care involves the provision of seamless, effective and efficient care that reflects the whole of a person's health needs; from prevention through to end of life, across both physical and mental health, and in partnership with the individual, their carers and family. It requires greater focus on a person's needs, better communication and connectivity between healthcare providers in primary care, community and hospital settings, and better access to community-based services close to home. (The Integrated Care Strategy 2014-17) Integrated care is about integrating an individual's journey through the healthcare system. It involves accommodating the person and coordinating their experience with and within the healthcare system.

The terms patient, priority population, consumer and client are used interchangeably throughout this document.

Section 10

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