Infections & Immunology and Digestive Health Networks

Hepatitis C Virus Model of Care

Government of **Western Australia**
Department of **Health**

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Executive Summary

Hepatitis C, a viral infection of the liver, is now a major health issue world wide, with significant morbidity and mortality. Hepatitis C virus (HCV) is a blood-borne virus which is transmitted from person to person by blood to blood contact.

As one of the most common notifiable conditions in WA it is a significant public health issue. In Australia, almost 265,000 people are affected by HCV and 16,000 new cases are reported each year. In Western Australia, approximately 20,000 people have chronic HCV, with approximately 1,100 new cases reported in each of the last five years, mostly in patients aged 20 to 34 years. Injecting drug use is the most commonly reported risk factor in both newly acquired and unspecified infections.

Only about a quarter of those infected with HCV will clear the virus spontaneously within 6-12 months. The remainder who go on to develop chronic HCV are at risk of progressive liver disease. To date, there is no vaccine to protect against HCV but recent achievements in treatment have resulted in a sustained virological response (SVR) or "cure" for 50 - 80% of the people treated with chronic infection.

About 10-15% of patients with chronic HCV will develop cirrhosis and 5% of those will develop hepatocellular carcinoma. It was estimated that in Australia in 2005, 210 people were diagnosed with liver failure and 105 were also diagnosed with hepatocellular carcinoma related to HCV. Unfortunately, less than 1% of the people affected by chronic HCV have accessed treatment. To have any impact on controlling the current epidemic the number of patients treated has to increase from the current 2,000 Australia wide to 10,000 per year.

Several strategies have already been employed in an effort to increase patient access to and uptake of treatment in metropolitan, rural and remote areas. Several strategies aimed at prevention, diagnosis and early intervention have been implemented in accordance with *The WA Hepatitis C Action Plan 2006-2008*, *a policy framework promoting prevention education and awareness.* The *Action Plan* outlines a framework for action in several areas, including prevention, education and awareness. These include measures to reduce the number of new cases of HCV infection, increase patient access to HCV treatment, decentralise treatment services and minimise both the personal and social impacts of HCV on individuals and the broader WA community.

People who inject drugs, people in custodial settings and Aboriginal and Torres Strait Islander people who engage in high-risk behaviours have been identified as priority populations at risk of HCV. Therefore, one of the aims of the *Action Plan* focuses on harm reduction, whereby policies, programs and interventions have been designed to reduce drug related harm to individuals and communities. One such intervention is the Needle and Syringe Exchange Program.

The management of chronic HCV and its complications requires multi-disciplinary teams, already adopted by the three tertiary hospitals in WA and a well planned and coordinated human resource and infrastructure planning approach. The current model of care has evolved over the past 10 years to incorporate advances in new medical technologies for the management of patients with chronic HCV. It provides increased accessibility and equity of care across all health care sectors for people with chronic HCV and in particular, those living in rural and remote areas, those in prisons and ethnic minority groups. Strategies include a Hepatitis C GP Shared Care

Program, enhanced GP training and education, improved telehealth services, Nurse Practitioner and nurse-led clinics and satellite clinics.

The proposed model of care, an extension of the current model, has been developed through collaboration, discussions between both the Infections & Immunology and Digestive Health Networks and has involved a wide consultation process with major stakeholders. The new model of care focuses on a state wide approach, using evidence based best practice to support the provision of equity of care across all sectors. The strategies recommended in the model of care extend from primary prevention to the time of diagnosis of HCV and progression through to liver failure or transplantation and are crucial for the management of people with chronic HCV.

The model integrates the patient's journey through the health care service and consolidates innovative strategies in a co-ordinated multidisciplinary approach. This new approach examines alternatives in resource utilisation across the health care system, including the expanded role of nurses in the management of chronic HCV and the introduction of nurse practitioners and clinical nurse consultants.

The development of a Hepatitis C database has been identified as an integral factor in adopting a state wide approach in managing patients. It would provide greater community outreach capability and reinforce the shared care service delivery goal by improving access to Hepatitis C treatment across WA. The Hepatitis C GP Shared Care Program, telephone, on-line and video conferencing (telehealth) services as well as the development and maintenance of e learning programs will need to be further established to meet the needs of rural and remote areas. To be effective state wide, treatment services for HCV must include increased access in metropolitan, rural and remote areas. This will involve the establishment of Ambulatory care centres, satellite treatment centres, regional hepatitis services and co-ordinated prison programs established to facilitate treatment for patients who currently have limited access to treatment. By employing regional nurse specialists to complement the existing metropolitan services, this will facilitate enhanced service delivery in these areas. The need will continue for ongoing collaboration amongst tertiary centres in implementing innovative strategies, including education programs, research and patient management.

The proposed new model of care acknowledges the current education, prevention and harm reduction strategies, treatment and care services that are already being provided and expands on these by adopting a patient centred, state wide multidisciplinary team approach. In doing so, this new model aligns with the strategic direction of evolving care to local communities with ongoing support from the tertiary centres, as well as providing the patient with safe, high quality health care.

Strategic Intent

The strategic intent of the Hepatitis C Model of care is to:

- Reduce the number of people contracting HCV by enhanced prevention and intervention strategies, and
- Increase the current number of patients receiving treatment at least to levels that have an impact on the epidemic curve.

To achieve these strategic aims there is a need to address the gaps between the current and future Models of care.

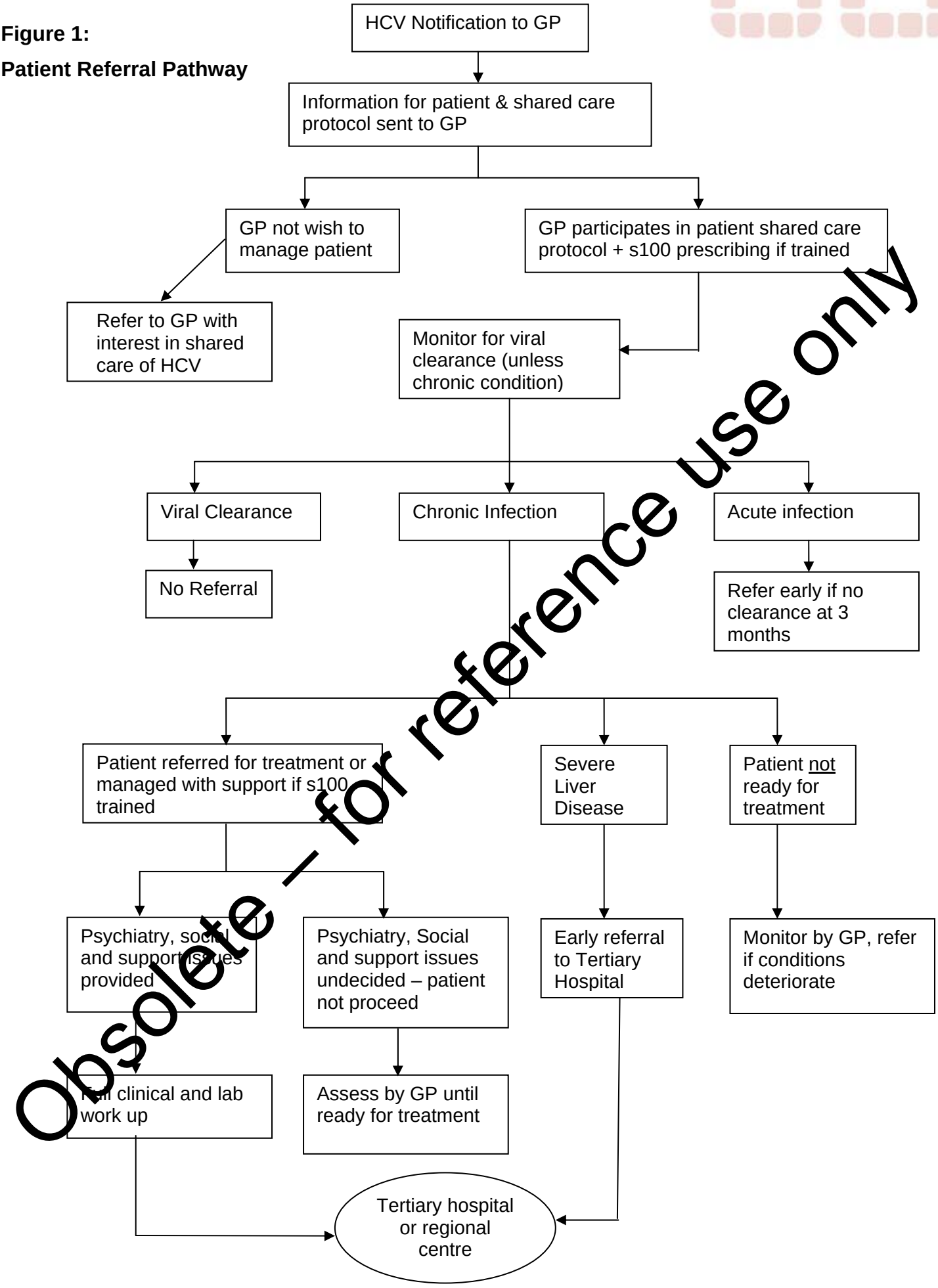
Gaps between the current and future model of care

Identified gaps between current and future models of care include:

- A need to further enhance primary prevention strategies to reduce the number of new cases of Hepatitis C;
- The need to increase the number of patients on treatment to levels that impact on the epidemic curve, for WA this will mean increasing the number on treatment from 350 to at least 1000 p.a.;
- A clearly articulated patient journey process that illustrates level of support and clinical service delivery across the continuum of care (refer figure 4 below);
- Increase the care provided outside the tertiary setting;
- The need to increase shared care and develop programs to support GP S100 prescribing;
- The need for a state wide database to monitor patient outcomes in metropolitan, rural and remote settings;
- More medical and nursing support to general hospitals and regional areas, with hub and spoke links to tertiary centres to manage difficult cases and complications of treatment, and
- Improved surveillance systems for both Hepatitis C and Hepatocellular Cancer (HCC).

Figure 1:

Patient Referral Pathway



Key Recommendations of the Future Model of Care

Primary Prevention

The key recommendations for primary prevention are:

- The implementation of prevention and health promotion strategies in high risk populations, including marginalised groups;
- Supporting partnerships between stakeholders to develop and deliver harm reduction strategies appropriate to Aboriginal communities in Western Australia;
- Maintain a strong focus on quality school-based education and harm prevention strategies;
- Increase awareness of HCV and prevention measures in the general community and particularly among young people, and
- Continue to improve access to the Needle and Syringe Program through increased number of fixed site outlets, needle and syringe vending machines, pharmacies and other outlets.

Secondary Prevention and Early Detection

The key recommendations for secondary prevention & early detection are to:

- Continue to promote programs aimed at reducing the stigma and barriers associated with HCV infection;
- Develop and continue to support peer based education programs on the changing guidelines for eligibility criteria, treatment algorithms associated with HCV therapy;
- Develop an effective and co-ordinated education (e learning) program;
- Strengthen programs targeted at maximising the number of people being treated within the corrective setting, by reducing barriers such as cost, availability of transport, security issues & patient dignity;
- Increase access to drug and alcohol withdrawal and treatment programs associated with HCV populations in prison and other settings;
- Provide ongoing support and training to General Practitioners in delivering safe, accessible treatment options for people living with HCV;
- Continue to enhance disease notification and surveillance systems;
- Improve HCV testing, pre and post discussion and counselling support services including early intervention programs, particularly in high risk populations, and
- Continue health reform to ensure an enabling environment for secondary prevention and early detection.

Disease Management and Tertiary Intervention

The key recommendations for disease management & tertiary intervention are to:

- Establish a viral hepatitis collaborative to co-ordinate state wide clinical services to ensure that evidence-based best practice is implemented across all sectors;
- Develop State wide guidelines and referral pathways for use by primary care medical practitioners in the management of people with chronic HCV complications;
- Expand the use of communication technology to improve accessibility and the equity for people living with HCV, especially those in rural in rural and remote areas;
- Enhance Metropolitan based tertiary HCV clinical capacity and service delivery;
- Maximise the role of General Practitioners (GPs) in HCV management, and
- Develop a Hepatitis C database to assist in the implementation of a co-ordinated state wide Hepatitis C Model of care.

Workforce Planning and Development

The key recommendations for workforce planning development are to:

- Create effective multimodal education programs incorporating appropriate technology to be made more accessible to all medical practitioners and health care workers to increase treatment uptake;
- Create more medical and nursing support to general hospitals and regional areas, with hub and spoke links to tertiary centres to manage difficult cases and complications of treatment;
- Train and support GPs to provide HCV shared care services in both metropolitan and rural/remote areas;
- Increase training of GPs, Nurse Practitioners (NPs) and Clinical Nurse Consultants to reduce the clinical workload of specialists to allow greater focus on co-morbid patients with end stage liver disease complications, and
- Increase training opportunities for people who provide services to those with or at risk of HCV infection, including an understanding of the nature and extent of HCV-related discrimination.

1.0 Introduction: Overview of Hepatitis C Virus (HCV)

Hepatitis C, a persistent viral infection of the liver, is now a major health issue world wide, with significant morbidity and mortality. Hepatitis C is a blood-borne virus (BBV) which is transmitted from person to person by blood to blood contact.

As one of the most common notifiable diseases in WA it is a significant public health issue. There is no vaccine to protect against hepatitis C (HCV), in Western Australia about 20,000 people are affected, with 1,100 new cases reported each year for the last five years[17].

Only about a quarter of those infected with hepatitis C will clear the virus spontaneously within 6-12 months. People who develop chronic HCV are at risk of progressive liver disease. About 75-80% of people infected with HCV develop chronic infection and about 10-15% develop cirrhosis over 15-20 years [21; 29; 35]. Effective treatments for HCV are available through a combination of pegylated interferon and ribavirin and can lead to a Sustained Virological Response (SVR) or "cure" in 50-80% of patients, depending on viral genotype and stage of fibrosis. There is also evidence that early implementation of therapy can prevent the complications of cirrhosis [21; 22; 25; 32; 33].

The complications of chronic hepatitis C infection can be hepatic, extra-hepatic or independent of liver disease. There is a spectrum of clinical presentations, which illustrates the importance of recognizing hepatitis C as a multi-system disease rather than an organ-specific infection. The hepatic complications of chronic hepatitis C infection relate principally to the development of complications of cirrhosis, such as ascites, variceal haemorrhage, hepatic encephalopathy and hepatocellular carcinoma. Many of these complications require a multidisciplinary team approach. Cirrhosis associated with HCV is the most common reason for liver transplantation in the western world, including Australia. Extra-hepatic complications include arthropathy, cryoglobulinemia, porphyria cutanea tarda, diabetes and lymphoma. General functioning and well-being are more impaired from independent complications such as depression and fatigue in patients with HCV than in the general population [11; 16.]

The *National Hepatitis C Strategy 2005-2008* notes that improving treatments and increasing availability is central to the response of hepatitis C infections in Australia. It is estimated that only 1% of people living with HCV currently access treatment. About 2,000 people with chronic HCV infection have received combination antiviral treatment each year in Australia since 2000, with approximately 25% in stage F0/1(mild disease) 50% in stage F2/3 (moderate scarring), and 25% with cirrhosis (severe scarring). To make any impact on controlling the epidemic, the number of people in treatment will have to increase from 2,000 to 10,000 per year. In Western Australia several strategies have been implemented to try to increase access to treatment in metropolitan, rural and remote areas, as well as disadvantaged minority groups such as those in custodial settings, drug and alcohol rehabilitation centres and culturally and linguistically diverse (CALD) groups.

It is evident that HCV related mortality and morbidity will have a large impact on the Australian healthcare system. In 1997 it was estimated that the cost of the

HCV epidemic was $107.5 million rising to $154.1 million over 50 years for every 100 new infections (Commonwealth Department of Health and Aged Care, 2004). One modelling study of HCV in 2001 suggested that the incidence of hepatitis C-related liver failure and hepatocellular carcinoma will more than triple in Australia by 2020.

1.1 Key Objective

The broad objective of developing an integrated Model of Care is to ensure people get the right care, at the right time, by the right team and in the right place.[1] The aim of this document is to describe a Model of best practice care and services within the WA health care system for a person or population group prior to infection and as they progress through the stages of testing, treatment and care for HCV infection:

- **Primary prevention** – to limit the incidence of disease and disability in the population by measures that eliminate or reduce causes or determinants of departures from good health, including controlling exposure to risk and the promotion of factors that are protective of health. This should also articulate early intervention strategies – i.e. school based education advising people about not putting themselves at risk of HCV.
- **Secondary prevention and early detection** – to reduce progression of disease and ongoing transmission through early detection, usually by testing at an asymptomatic stage and early intervention.
- **Disease management and tertiary intervention** – to improve function and minimise the impact of established disease, and prevention or delay of complications and subsequent events through effective management and rehabilitation.(3)

1.2 Outcomes of an effective model of care:

- To improve the quality of life for people with HCV;
- To provide optimum care for patients with HCV-related liver disease;
- To increase awareness and health promotion strategies to reduce the risk of HCV infection, especially in high risk population groups;
- To increase the levels of HCV screening and testing in the general community but particularly within high-risk population groups;
- To increase the levels of (or proportion of) people with HCV being regularly monitored;
- To improve access to appropriate health care services;
- To increase the uptake in treatment of HCV in order to increase the number of people with eradicated disease;
- To reduce the rates of HCV infection in WA and thereby impact the epidemic curve;
- To improve access to ancillary support services for people living with HCV, including mental health support services, and
- To increase the number of skilled practitioners in the workforce.

[1] Department of Health. *An Overview of the Model of Care*, WA Health Networks

1.3 Methodology

The Infections & Immunology Health Network and Digestive Health Network were tasked with the development of a Model of Care for HCV. The Project Leader was recruited from the Executive Advisory Groups and a working group formed to develop a draft, which was circulated to key stakeholders throughout WA, for input and comment (Appendix 3). The final draft was endorsed by the Executive Advisory Groups of the Infections & Immunology and Digestive Health Networks (see Appendix 1 & 2).

The HCV Model of Care was guided by existing policy documents:

- Western Australian Hepatitis C Action Plan 2006-2008;
- National Hepatitis C Strategy 2005-2008;
- Hepatitis C Virus Projections Working Group: Estimates and Projections of the Hepatitis C Virus Epidemic in Australia 2006;
- Metropolitan Clinical Services Planning Report – Hepatology Working Party Report 2006 (unpublished);
- National Aboriginal and Torres Strait Islander Sexual Health and Blood-borne Viruses Strategy 2005-2008;
- Western Australian Aboriginal Sexual Health Strategy 2005-2008;
- Declaration on patient-centred healthcare, as adopted by the Health Consumers' Council (WA) which outlines five principles – respect, choice and empowerment, patient involvement in health policy, information, access and support, and
- WA Aboriginal Health Impact Statement and Guidelines.
- Proposed WA Hepatitis C Shared Care Service Delivery Model.
- Communicable Disease Control Directorate. 2008 Needle and Syringe Program Review 2007. Department of Health, Western Australia
- Drug and Alcohol Office 2008 Aboriginal blood-borne virus scoping project literature review and report on fieldwork undertaken in Kalgoorlie and Bunbury 2008. Department of Health, Western Australia.

2.0 Burden of Disease (Specifically the Economic, Social and Personal cost of Hepatitis C)

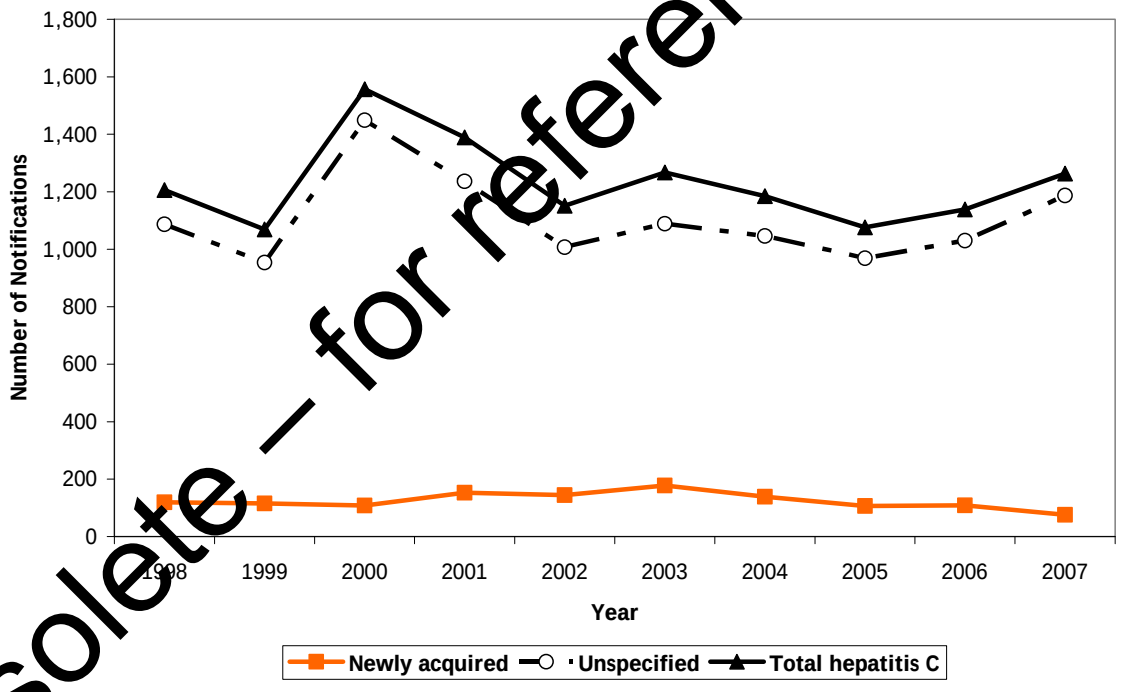
2.1 Notification Trends over Time and Distribution by Disease Status (Figure 2)

Unless otherwise noted, the following epidemiological analysis is extracted from the report 'The Epidemiology of Notifiable Sexually Transmitted Infections and Blood-borne Viruses in Western Australia, 2007' (Department of Health, WA).

Hepatitis C notifications are classified as:

- **Newly acquired** - evidence of infection having been acquired in the 24 months prior to diagnosis, and
- **Unspecified** - infections of unknown duration and cases which remain infectious for more than six months.

Figure 2: Number of hepatitis C notifications by disease status, WA, 1998 to 2007.



Source: Communicable Disease Control Directorate

- Newly acquired hepatitis C:
  - Notifications increased from 119 in 1998 to a peak of 178 in 2003. In 2007 there were 76 notifications, representing a 44% decrease from the previous five-year average of 135.4 notifications per year.
- Unspecified hepatitis C:
  - Notifications increased substantially from 954 in 1999 to 1,449 in 2000 following the inclusion of laboratory-notified cases. Notifications then declined for two years before plateuing again after 2002. There was a 15% increase in notifications from 2006 (n = 1,030) to 2007 (n =

1,187), representing a 15% increase from the previous five-year average 1,028.2 notifications per year.

2.2 Notification Trends over Time and Sex Distribution

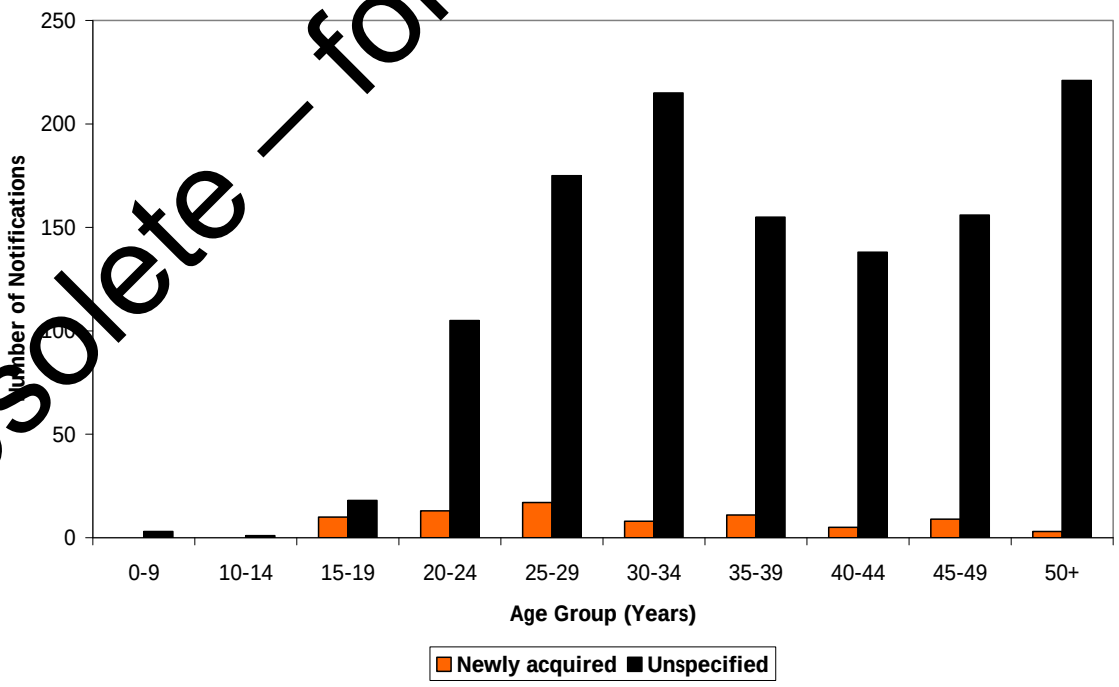
- Newly acquired and unspecified hepatitis C notifications have been considerably lower in females than in males since 1998 (average male to female ratio for newly acquired notifications = 1.8:1 and for unspecified notifications = 1.7:1).
- During the previous 10-year period, newly acquired hepatitis C notifications increased in males (average annual increase of 1%) and decreased in females (average annual decrease of 6%).
- Unspecified hepatitis C notifications for both males and females increased during the same time period (average annual increase of 3%).

2.3 Distribution by Age (Figure 3)

In 2007:

- 53% of newly acquired hepatitis C notifications occurred in people aged 15 to 29, whereas unspecified hepatitis C notifications occurred mostly in people aged 30 to 34 and 50 or over (37% of notifications, collectively).
- While 13% of newly acquired hepatitis C notifications were reported in adolescents aged 15 to 19, only 2% of unspecified hepatitis C notifications were reported in the same group.

Figure 3: Number of hepatitis C notifications by disease status and age group, WA, 2007.



Source: Communicable Disease Control Directorate

2.4 Regional Distribution (Appendix 4)

In 2007:

- The highest age-standardised rate (ASR) of newly acquired hepatitis C was reported from the Great Southern region (6 per 100,000 population), due to male cases as there were no female cases reported from this region. While the highest ASR of newly acquired hepatitis C among males was reported from the Great Southern region (13 per 100,000 population), there were very few notifications among females with the highest ASR reported from the South Metropolitan region (3 per 100,000 population).
- The highest unspecified hepatitis C ASR occurred in the Kimberley region (90 per 100,000 population), where the rate was 1.6 times higher than the WA ASR of unspecified hepatitis C (58 per 100,000 population). The highest ASR of unspecified hepatitis C among both sexes was also reported from the Kimberley region (112 per 100,000 population for males and 65 per 100,000 for females).

These comparisons should be interpreted with caution as such low age-standardised rates of notification can be variable and imprecise.

2.5 Notifications by Aboriginality

In 2007:

- The proportion of hepatitis C notifications that were not identified by Aboriginality varied by disease status, with 91% of newly acquired notifications identified compared with 62% of unspecified hepatitis C notifications identified.
- Despite the fact that hepatitis C ASRs in Aboriginal people (newly acquired hepatitis C = 14 per 100,000 population in 2007; unspecified = 118 per 100,000 population in 2007) were many times those of non-Aboriginal people (newly acquired hepatitis C = 3 per 100,000 population in 2007; unspecified = 33 per 100,000 population in 2007), the vast majority of hepatitis C notifications occurred in non-Aboriginal people

2.6 People in custodial settings

Incarceration is now considered an independent risk factor for HCV because of the high rates of HCV amongst prisoners on entry to prison, and the many opportunities for HCV transmission to occur (i.e. unsafe injecting, tattooing, and violence) in the prison environment. The high rates of HCV and transmission within the prison environment pose considerable health risks to prisoners, prison staff and the general community (to which prisoners return after imprisonment).

The Department of Corrective Services participated in the 2005 National Prison Entrants Survey. There were 612 participants across four States of Australia and survey results indicated that:

- 35% of prisoners surveyed tested positive for HCV antibody (83% in females);
- 59% reporting a history of injecting drug use (IDU);
- 3% injected in prison, and

- 369 reported a tattoo (69 in previous 12 months).

Western Australia had 112 participants from Hakea, Bandyup and Roebourne Prisons with an overall hepatitis C prevalence of 20% (80% in females) with 58% reporting a history of injecting drug use. In WA, 17% reported being tattooed by a prison inmate within the previous 12 months [14].

2.7 Enhanced Hepatitis C Surveillance

The aim of enhanced surveillance of C notifications is to obtain additional information on the method of diagnosis, reasons for testing and risk factors for infection. In 2007, enhanced surveillance forms were sent to the notifying doctors of all newly acquired infections and a randomly selected one-third of diagnosing doctors of unspecified infections.

In 2007, a total of 1,263 hepatitis C infections were notified. Of these, 446 cases (35% of notifications), comprising 75 newly acquired and 371 unspecified infections were targeted for enhanced surveillance. Sixty-eight per cent (n = 51) of enhanced surveillance forms for newly acquired cases were returned completed, while the corresponding proportion for unspecified cases was 51% (n = 191).

The most commonly reported reason for hepatitis C testing for both newly acquired (81%; n = 43) and unspecified (56%; n = 106) infections was a history of risk factors, such as IDU or incarceration. IDU was the most commonly reported risk factor in both newly acquired (85%; n = 45) and unspecified (77%; n = 145) infections.

2.8 Projections of Economic, Social and Personal cost of Hepatitis C

The number of people living with chronic HCV and liver cirrhosis is projected to increase through 2015 and beyond. The models suggest that for antiviral treatment to begin to decline, approx 700 people with cirrhosis alone will need to be treated each year.

The Working Group [34] estimated that of the 264,000 people living with HCV in Australia at the end of 2005:

- 67,000 (25%) had cleared their HCV infection;
- 154,000 (58%) had chronic HCV infection and stage F0/1 liver disease;
- 38,000 (15%) had chronic HCV infection and stage F2/3 liver disease, and
- 5,300 (2%) were living with HCV-related cirrhosis.

During 2005 it was estimated that:

- 210 developed liver failure, and
- 105 developed HCC related to HCV.

The Working Group [34] estimates that tripling the number of people receiving treatment would be required to decrease the number of people living with chronic HCV and stage F2/3 liver disease or cirrhosis by 2015. To reduce the number of people living with early-stage liver disease 5,000 people with stage 0/1 and 4,000 people with stage 2/3 liver diseases need to be treated each year [34].

2.9 Uptake of Hepatitis C Treatment in 2006

The current standard treatment of HCV is a combination therapy of pegylated interferon and ribavirin. This treatment is available as a government subsidised therapy under the Pharmaceutical Benefit Scheme (PBS) and can significantly reduce the HCV viral load and even clear the virus, thus avoiding the subsequent burden of disease associated with chronic HCV infection.

Prior to April 2006, treatment was restricted to people with a liver biopsy result showing significant HCV-related liver damage. Since the removal of the biopsy pre-requisite and the extension of eligibility to people with minimal liver damage on 1 April 2006, there has been a clear upward trend in the number of patients seeking and accessing treatment for HCV [9] as shown in Figure 4 below.

Figure 4: Sales of Pegylated Interferon and Ribavirin Treatment for Hepatitis C in Australia, March 2005 to November 2006 [9].

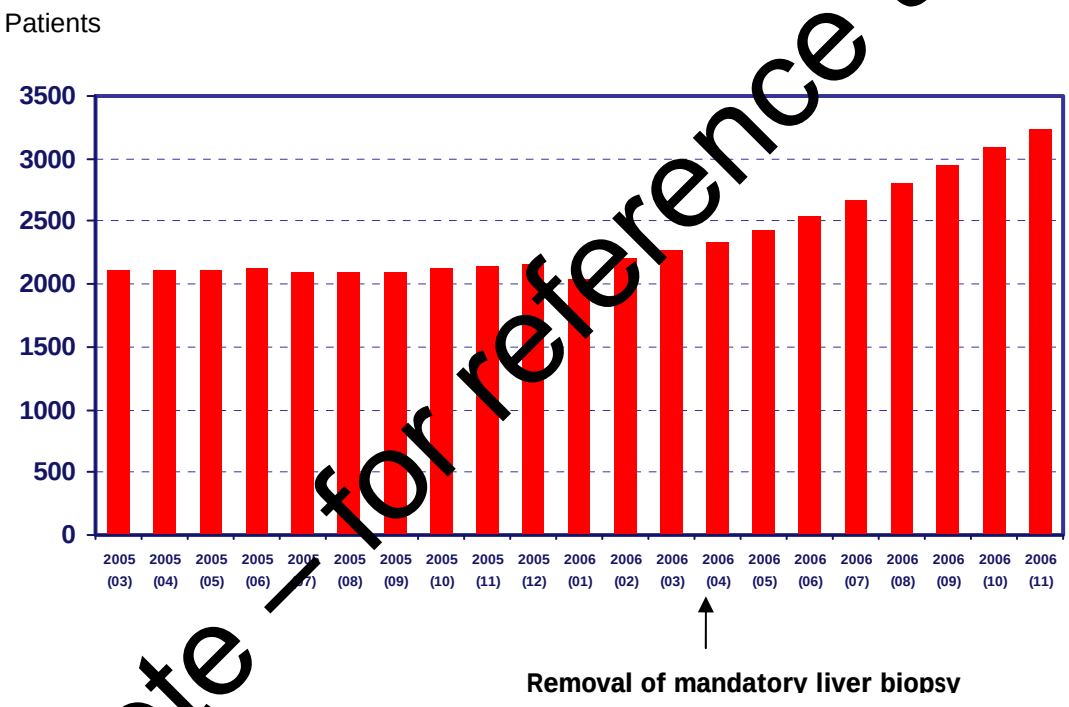


Table 1 Estimates the quality of life lost to HCV infection in 2005 by stage of liver disease [4]. For instance in 2005 it is estimated that a total of 500 quality of life years were lost due to liver failure whilst an estimated 29,200 quality of life years were lost due to mild chronic HCV.

Table 1: Estimated quality of life lost to HCV infection in Australia in 2005, by stage of liver disease.

(Hepatitis C Virus Projections Working Group: Estimates and Projections of the Hepatitis C Virus Epidemic in Australia 2006)

HCV Projections Working Group

Table 22. Estimated quality of life years lost to HCV infection in Australia in 2005, by stage of liver disease

	Definition	Person years in 2005	QALY adjustments[2]	QALYs lost
Mild chronic HCV	Fibrosis 0/1	153,900	0.81	29,200
Moderate chronic HCV	Fibrosis 2/3	38,100	0.81	7,200
Compensated cirrhosis	Fibrosis 4	3,600	0.76	900
Liver failure[1]	Cirrhosis progressed to decompensation	1,600	0.69	500
HCC	Cirrhosis progressed to HCC	105	0.67	40
Total		264,000		37,800

1. Person years of liver failure in 2005 calculated at 42% of cumulative incidence of liver failure and HCC minus cumulative HCV-related mortality, which assumes average duration of survival with HCC is around 12 months and that 58% of liver failure cases involve multiple complications including HCC (Benvegnù et al, 2004).
2. Thein et al, 2005

2.10 Economic, Social and Personal costs of disease

The prevalence cost of diagnosing and treating hepatitis C paid for by the government in 2004/05 was obtained by multiplying the estimated number of people at each stage of hepatitis C across Australia by the respective unit cost of each stage[9]. For the purpose of this costing estimate, the unit costs, including the unit cost of pharmacotherapy, have been weighted to take into account that most chronic cases remain undiagnosed or untreated or both. The costing includes all medical, hospital, laboratory and pharmaceutical costs. The total prevalence cost is around $78.9m in 2004/05 prices (Table 2).

Table 2: Estimated treatment costs of hepatitis C by stage of progression using 2004/05 prices

	Annual unit cost	No. persons	Total cost
Chronic hepatitis C, stage 0/1 liver disease	239	166,000	39,674,000
Chronic hepatitis C, stage 2/3 liver disease	239	36,000	8,604,000
Hepatitis C-related compensated cirrhosis	448	8,800	3,942,400
Hepatitis C-related liver failure[a]	78,639[b]	236	18,558,804
Hepatitis C-related HCC[c]	118,146	69	8,152,074
TOTAL		211,105	78,931,278

(Applied Economics, 2005)[3]

[a] Cost of transplant in year in which the transplant occurs (2004/05).

[b] Incident cost of transplant ($157,278) x proportion of cases treated by transplant, assuming 50% of cases receive a transplant.

[c] Weighted for the proportion of cases treated by surgery and those which are not.

Table 2 illustrates that hepatitis C cases which are not treated and subsequently lead to liver failure and hepatocellular cancer have weighted costs $78,639 and $118,146 per case, respectively. In comparison, the weighted cost of pharmacotherapy treatment is $239 per person per year, a weighted cost taking into account the proportion of people actually accessing the treatment.

3.0 Current Service Provision

The Western Australian Hepatitis C Action Plan 2006 – 2008 outlines current service provision and provides a framework under which HCV education, prevention, treatment and care can be developed and implemented, as well as identifying key actions to be addressed.

3.1 Primary Prevention

Primary prevention goals include reducing the number of new hepatitis C infections, increasing access to HCV testing and treatment options and minimising the personal and social impacts of HCV for individuals and the broader WA community.

Strategies are based on the guiding principle of harm minimisation, which aims to reduce drug-related harm to individuals and communities through a wide range of policies and programs. Harm reduction interventions encompass a variety of approaches including needle and syringe programs (NSPs). People who inject drugs, people in custodial settings and Aboriginal people who engage in high-risk behaviours are identified as priority populations at risk and key stakeholders of primary prevention strategies.

Key strategies identified in the Western Australian Hepatitis C Action Plan 2006 – 2008 include:

- Continue to promote and improve access to sterile injecting equipment via needle and syringe exchange programs in pharmacies, hospitals, needle and syringe vending machines, prison settings and other outlets;
- Provide information and advice about all aspects of HCV to all people with particular emphasis on Aboriginal people and youth;
- Support partnerships between key stakeholders to develop and deliver harm reduction strategies appropriate to Aboriginal communities;
- Promote strategies which encourage safe injecting drug use, and
- Strengthen understanding in the community of the health, social and economic cost of harm reduction programs such as needle and syringe programs.

Current prevention programs include:

- Needle and syringe exchange programs. 4.2 million needles and syringes were distributed in 2006 through the Western Australian Substance Users Association (WASUA) and the Western Australian Aids Council (WAAC) comprising 54%, pharmacies 38%, and other services such as rural hospitals 8%;
- Hepatitis WA provides education and awareness programs for the general community, at-risk populations and the workforce;
- Peer education programs, treatment referral and other services for people who inject drugs;
- Drug and Alcohol Office programmes aimed at preventing uptake of injecting drug use and providing treatment services, and
- Education programs for GPs and other health professionals;

3.2 Secondary prevention and early detection

Secondary prevention and early detection aims to reduce progression of disease and ongoing transmission through early detection, usually by testing at an asymptomatic stage. Effective management of individuals undergoing screening and/or treatment for hepatitis C requires medical practitioners and people to develop an ongoing partnership involving:

- Taking a holistic approach and treating the person with many potential interacting issues rather than a single disease[50];
- Discussing behaviours and the risk of further transmission;
- Providing advice and information on the full range of medical and non-medical approaches to managing Hepatitis C, and
- Empowering individuals with sufficient information to make informed decisions that best suit their lifestyle, occupational and social needs.

Hepatitis C is a condition that has implications not only for an individual's physical health, but also for their social, psychological and emotional well being[8, 31]. Medical treatment of the hepatitis virus requires an understanding of the Psychosocial (as well as the medical) needs of people living with HCV.

3.2.1 Strategies to further reduce the risk of transmission include:

- Adopt safer injecting practices such as always using new injecting equipment;
- Ensure tabletops and preparation areas are clean to prevent microscopic transmission;
- Always wash hands before and after injecting;
- Do not assist others to inject, or share mix, spoons, tourniquets or filters;
- Avoid sharing razors and toothbrushes to reduce the risk of household transmission;
- Avoid giving blood, and
- Avoid obtaining new tattoos or body piercing.
- In female patients consider treatment before becoming pregnant to reduce the risk of vertical transmission

Other possible topics for discussion will depend on the individual's situation, but may include vertical transmission (if pregnant), work issues, insurance, disclosure and discrimination. Each individual will have differing information needs and post-test counselling should be considered an essential component of the assessment and treatment plan.

3.2.2 Testing

3.2.2.1 Assessing the Need for a Hepatitis C Test

The National Hepatitis C Testing Policy recommends testing for hepatitis C antibodies should be routinely offered to the following groups:

- People who have ever injected drugs;
- People who have been incarcerated in a custodial institution;
- People who were transfused with blood or blood products before February 1990;

- People who have been transfused with blood or blood products overseas;
- People who have had a potential occupational or environmental exposure to hepatitis C (for example, a needle-stick injury) and, where possible, the exposure source with their specific informed consent;
- Health care workers who engage in exposure-prone procedures;
- People with abnormal liver function tests or evidence of liver disease with no apparent cause;
- People with extra hepatic manifestations of hepatitis C infection;
- Renal dialysis patients, and
- People who request testing in the absence of an identified risk factor.

For some individuals and groups, testing for hepatitis C may be considered and offered on the basis of an individualised risk assessment, including:

- People with a history of tattooing or body piercing, taking account of multiple tattoos or body piercings and the settings in which the procedures took place;
- People born in countries where there may be a high prevalence of hepatitis C infection, and
- The sexual partners of people with hepatitis C.

3.2.2.2 Issues to consider during Hepatitis C pre-test discussion

Comprehensive discussion prior to testing is crucial to the effective management of people considering undergoing testing for hepatitis C. The pre-test discussion provides an opportunity to:

- Provide relevant, up to date information to assist in making an informed decision about testing;
- Discuss the testing procedure, implications of test results (such as positive, negative, false positives, indeterminate results) and provide the client with the option of not being tested;
- Explain the probability of a positive test based on risk status;
- Check the client's understanding of the information provided;
- Discuss the probability of spontaneously clearing the virus, factors affecting disease progression and options for treatment;
- Assess the possible response of the client to the test outcomes and review the level of support they have available;
- Provide pre-test psycho-social support given the impact of a positive HCV diagnosis on a pregnant woman from a personal and social perspective;
- Provide and discuss information to prevent further transmission based on current lifestyle factors, and
- Potential health outcomes relative to test results and the range of medical and other services available in the occurrence of a positive test result.[8]

3.2.2.3 Post-Test Counselling

Post-test counselling provides medical practitioners with the opportunity to clarify information already provided to the patient, reinforce risks factors for infection, and further establish the clinician-patient relationship.

Additional appointments or arranging a direct referral to other support services and the establishment of a management plan should be agreed, including frequency of follow-up appointments and testing.

The initial assessment of a person with hepatitis C should incorporate general psychosocial review and involve information and education concerning:

- The natural history and progression of hepatitis C infection;
- Transmission risk reduction strategies (not sharing blood contaminated sharps; needles, syringes, injection paraphernalia, razors, refraining from blood donation);
- Treatment strategies;
- The need for contraception if on treatment and for 6 months post-treatment
- Prevention of diseases that may arise from the risks that gave rise to hepatitis C infection (vaccination against hepatitis B);
- Practical measures to maintain a well balanced diet;
- The use of alcohol and other drugs. An alcohol and drug assessment should elicit client concerns (or lack thereof) regarding their use of alcohol and other drugs. Recommendations regarding alcohol use should be consistent with NHMRC guidelines, that is, people with HCV should consider drinking alcohol infrequently and well below recommended levels for their gender[13], and
- Resources and supports available for the physical, social and psychological aspects of hepatitis C infection including ways of dealing with potential discrimination.

A range of support services is available for people undergoing hepatitis C testing and for people living with hepatitis C including:

- Trained and experienced hepatitis C counsellors;
- A local drug user organisation or drug and alcohol treatment service;
- Hepatitis WA;
- A psychiatrist or psychologist;
- A dietician;
- A gastroenterologist or infectious diseases physician, a general physician with an interest in hepatitis C, or a hepatitis clinic, and
- A complementary or alternative therapist experienced in hepatitis C management.

3.2.3 Diagnosis

The early diagnosis of chronic HCV infection is critical in preventing progressive liver disease and its complications, as well as reducing the pool of

infection in the community. Factors affecting disease severity include, but are not limited to:

- Age at infection;
- Alcohol intake;
- Duration of infection;
- Steatosis (fat in the liver), and
- Increased iron store.

3.2.4 Early Intervention

Of the people infected with HCV, 75% will progress to chronic HCV infection of variable severity. Of 100 people with chronic HCV infection:

- 44 will develop liver disease;
- 10-15 will develop cirrhosis, and
- 5 will develop liver failure or liver cancer.

Patients who undergo treatment at an earlier stage of disease with a lesser degree of fibrosis have higher rates of response to treatment with combination therapy of pegylated interferon and ribavirin. In patients planning pregnancy consideration should be given to treatment beforehand to reduce the risk of vertical transmission if the patient responds to treatment.

Hepatitis C and Discrimination

Discrimination may result from conscious and overt decisions or unconscious beliefs and attitudes[14]. Discrimination may be either Direct (treating a person with Hepatitis C less favourably than others) or Indirect (a requirement, condition or practice which appears neutral has a disproportionate impact on an individual who has hepatitis C) [47]

Discrimination is a significant issue for people with hepatitis C and is often associated with the relationship between hepatitis C and injecting drug use[14]. Discrimination can and does occur within the health care setting[2, 13, 47]. Information and advice concerning individuals' rights regarding discrimination and complaints processes are available from Hepatitis Councils, drug user organisations and anti-discrimination services in each State and Territory.

3.3 Disease management and Tertiary Intervention

Disease management and tertiary intervention aim to improve function and minimise the impact of established disease, and the delay of complications and subsequent events through effective management and rehabilitation.[4]

Increasing the uptake of treatment is a priority for the response to HCV infection in Western Australia and some of the barriers identified are:

- Lack of knowledge of improved treatments and outcomes;
- Side effects of treatment;
- Physical location of treatment services;
- Cultural and language barriers;
- Incarceration, and
- Experiences of discrimination in healthcare settings.

In the last decade there has been rapid improvement in treatment efficacy. The Sustained Virological Response or “cure” rate has improved from 10-15% to the current 50-80%. However, the drugs used in the treatment of chronic HCV are associated with significant and varied adverse events, some of which are potentially serious and require urgent and expert attention.

Although liver biopsy is no longer mandatory (since 1 April 2006) for the treatment of chronic HCV, it is still an important tool in the assessment of people to determine their risk of developing severe liver disease and the potential benefit of therapy, which is influenced by genotype. In the presence of cirrhosis the risk of hepatocellular carcinoma is increased and long term surveillance for this primary liver cancer is warranted.

3.3.1 Tertiary Service

3.3.1.1 Management of chronic hepatitis C

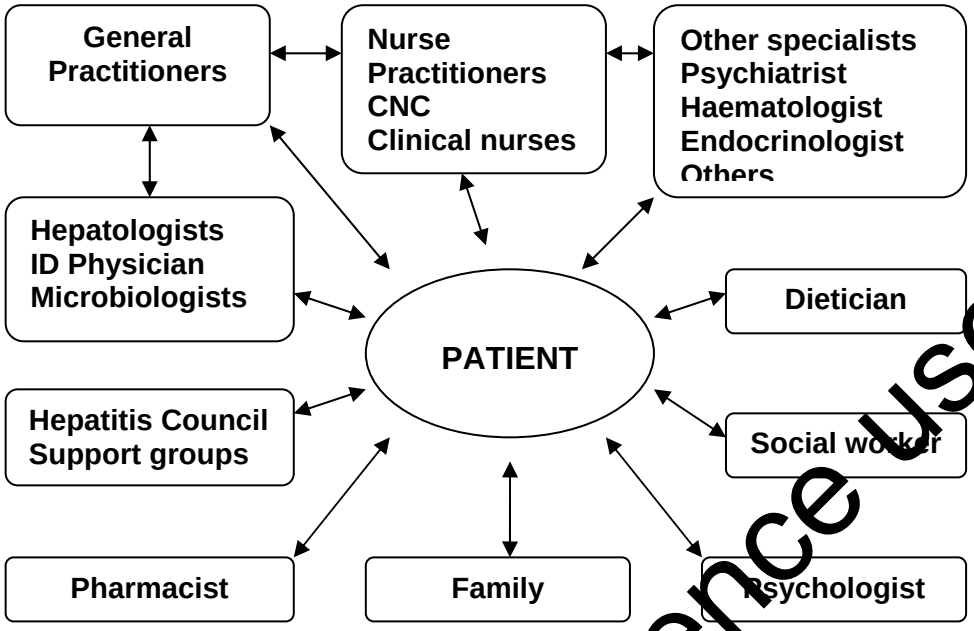
Current service delivery at all three metropolitan tertiary hospitals includes the development and use of protocols and clinical guidelines based on emerging best practice evidence, pathway care algorithms, adverse event monitoring and hospital admissions monitoring of client safety. All three tertiary centres collaborate in education programs and research, as well as participate in the WA Liver Transplant Assessment Panel and clinics.

Currently, none of the three Tertiary Hospitals achieve the recommendations of 1 FTE clinician per 1000 hepatitis patients in a region [35]. Continuing professional development of GPs participating in Hepatitis C Shared Care and proposed HCV treatment is a goal in reducing the demand on tertiary hospital services. Ongoing support of Hepatitis C shared care and devolution of services to regional areas will assist GPs in meeting future demands and ensuring patient safety. There is an increasing need for the training of GPs, Nurse Practitioners (NPs) and Clinical Nurse Consultants to provide greater community based patient care with appropriate support.

Multidisciplinary team approach

Teams include members from the disciplines of general practice, hepatology/infectious disease, nursing, pharmacy, dietetics, social work, psychologist, peer support, and specialists from other disciplines as required, such as psychiatry, haematology, etc. (see Figure 5). The multidisciplinary teams aim to enhance patient care through efficient referral systems, standards for best practice care and collaborative patient management.

Figure 5: Multidisciplinary team in the Management of Chronic Hepatitis C



ID = Infectious Disease
CNC = Clinical Nurse Consultants
Source: Health Networks Branch

GP shared care program (for HCV)

The GP Shared Care Program for HCV is a combination GP and tertiary institution patient management program. Patients are initially assessed by the GP, and then referred to the specialist clinic for further investigation and initiation of therapy. Ongoing care and monitoring are provided by the referring GP using program-specific protocols that detail the patient's management plan.

A state wide HCV database underpins an effective Hepatitis C GP Shared Care Program, which in its current form is time-consuming. It has the potential to reduce duplication of tests, improve communication and can be further enhanced to include state wide hepatocellular carcinoma surveillance.

Education programs to register GPs and allow them to prescribe the restricted medicines (S100 drugs) used in the treatment of chronic HCV support these initiatives. This is currently being pursued with a view to establish e-learning modules and clinical placements at tertiary centres.

Nursing services

Western Australia has the first designated role in hepatology for a Nurse Practitioner in Australia [36]. The extended scope of practice includes the ability to:

- Instigate limited investigations, referrals and prescriptions;
- Practise independently within approved protocols;
- Provide training and mentoring for rural colleagues, and

- Provide support services to GPs.

There are Clinical Nurse Consultants in the metropolitan area whose role is to provide support to Hepatitis Nurse Coordinators, who in turn support GPs, other health professionals and patients in rural areas and facilities (i.e. prisons) with a high prevalence of HCV infection.

These positions improve access and treatment for patients by assisting with coordinating care that is devolved from the tertiary setting to reduce the demand (and cost) on specialist clinics.

Information and Communication Technology

The use of appropriate communication technology for improving access and equity of health services is in its infancy. In May 2006 a RPH based state wide Telehealth service was instigated by a hepatologist and Nurse Practitioner and provided real time access for specialist appointments in metropolitan clinics.

Culturally and Linguistically Diverse (CALD) programs

Facilities for CALD patients include patient education brochures in different languages, facilitating treatment programs, and participating in the up-skilling of community health care workers and staff. Patient support groups, in particular, Vietnamese support groups, established through the initiatives of the tertiary centres have been very successful.

3.3.1.2 Management of complications of liver disease

Preventing the complications of chronic HCV infection involves principally treating the infection through the processes outlined above. Education of treating general practitioners, nurse practitioners, clinical nurse consultants and physicians is required to ensure recognition of extra-hepatic manifestations. Subsequent management generally requires referral to a tertiary centre for specialist review (hepatologist, rheumatologist and haematologist) and treatment. Due to the generally poor response to many of the extra-hepatic manifestations to therapy, further clinical research is recommended to improve the treatment options for this patient group.

Pre-transplant clearance of HCV and appropriate immunosuppression are important to prevent recurrence post transplant. Future strategies need enhanced promotion of organ donation for liver and other organ transplantation.

Liver transplantation

Liver transplantation for chronic HCV cirrhosis continues to be the most common reason for liver transplantation in Australia. Half of all liver transplants are now for HCV-related cirrhosis (i.e. 10-12 per year), and this figure is expected to increase exponentially in line with the prevalence of HCV in priority population groups.

In WA the number of End-stage Liver Disease with HCV-related cirrhosis is estimated to be approximately 500. Of these approximately 50 per year will develop de compensation or complications in their liver disease, i.e. ascites, variceal haemorrhage, porto-systemic encephalopathy or hepatocellular carcinoma [39].

People with de compensated cirrhosis from HCV are increasingly being treated with modified protocols, in conjunction with the Liver Transplant Service to reduce the incidence of post-transplant recurrence. However, recurrence of HCV in the liver graft can result in early recurrent cirrhosis and de compensation of the transplanted liver. Treatment with combination therapy may be undertaken, but viral eradication is considerably poorer in the post-transplant setting.

These complications result in significant morbidity and mortality and frequently require inpatient management [5; 19]. Many of these will require assessment for Orthotopic Liver Transplantation (OLT) and HCV is now the leading indication for OLT in Western Australia and constitute a major cost to the community.

WA has a well-established liver transplant program and has introduced the living-related liver donor program to meet the demand for people with end-stage liver disease. People with de compensated HCV cirrhosis are treated with the aim of eradication of the virus prior to liver transplantation to prevent post-transplant recurrence.

3.3.2 Custodial Settings

Prison Health Services aim to offer care to prisoners which parallels that which is offered in the broader community. This standard includes programs to provide:

- Assessment;
- Prevention including vaccination;
- Harm minimisation including needle & syringe programs;
- Drug & alcohol services;
- Mental health services;
- Hepatitis C treatment services;
- Vaccination and education for families, and
- Through care for after release.

3.4 Surveillance

3.4.1 Surveillance for people at risk

Surveillance mechanisms are crucial for monitoring the prevalence and incidence of HCV, to identify people at risk and allow effective targeting of prevention and treatment programs. Surveillance also provides data to assist in evaluation of interventions and increase knowledge of long-term consequences of HCV infection.

In WA, the provisions of the Health Act 1911 require the attending medical practitioner or nurse and the responsible pathologist from all laboratories to forward information on notifiable diseases to the Department of Health, WA

(DoH). Since 2002, statutory infectious disease notification data has been maintained in a state wide electronic database (Western Australian Notifiable Infectious Diseases Database [WANIDD]).

3.5 Research

Research provides an evidence base for the development of public policy and programs for the needs of people at risk or infected with HCV. Western Australia currently supports strategic national and local research into treatment and care issues relating to HCV by:

- Participation in multi-centre national and international clinical trials on refinement of current treatment regimes, new drugs and predictors of response to treatment;
- Involvement in the development of protocols in clinical trials including national and international trials;
- Inter hospital collaborative studies between Royal Perth, Sir Charles Gairdner and Fremantle Hospitals, and
- Collaborative studies across disciplines on basic mechanisms of immune response, viral resistance and complications associated with treatment.

3.6 Workforce Development

Population Health Units, clinical services, GP Divisions, community-based organisations, professional health bodies and commercial companies contribute to a program of workforce development and training for various target groups. This includes health care providers (medical, nursing and Aboriginal health workers), educators, custodial staff, Needle and Syringe Program and Drug and Alcohol services.

3.6.1 General Practice training

Continuing education programs are essential for General Practitioners to keep abreast of the changing guidelines for eligibility criteria for treatment, treatment algorithms and significant adverse and sometimes serious events associated with therapy. These programs have been achieved through:

- Education programs and workshops through tertiary centres;
- Western Australian initiated Asian-Pacific conferences targeting GP, nurses and health care workers particularly in rural areas;
- Australian Association of HIV Medicine (ASHM) education Seminar;
- Department of Health support of education programs;
- The School of Medicine at University of Queensland was contracted by STI BBBV to provide education for GPs and nurses for shared care with the tertiary centres 2006-07, and
- The development of e-learning programs for GPs, nurses and health care workers is currently underway with a view to improve GP shared care and GP prescribing.

3.6.2 Nursing

Nurses play a central role in coordination of the Hepatitis C program in tertiary centres and are usually the first point of contact. With increasing sub specialisation, nurses working in the area of viral hepatitis continue to have important roles to play in education and the management of patients and attain a level of knowledge, which would allow them to practise independently within approved protocols, as in the case of Nurse Practitioners [36].

3.6.3 Others

Education of other health care workers in affiliated agencies and drug and alcohol rehabilitation centres requires programs to include relevant information to cater specifically for the needs of the centres.

4.0 Future Model of Care

Current service delivery for HCV is well established, effective and practical in tertiary settings. However, with less than 1% of people with HCV accessing treatment it is clear that services are not readily available to everyone with, or at risk of HCV infection.

The state wide model of care is tabulated under the following:

- Prevention in population at risk;
- Secondary prevention and early detection;
- Disease Management and Tertiary Intervention;
- Primary care clinical service provision;
- Training and workforce development;
- Complications of liver disease including cirrhosis, and
- End stage liver disease.

4.1 Primary Prevention

Increase public knowledge of HCV through:

- Information and awareness raising such as resource distribution and media opportunities, including national 'Awareness Weeks';
- Developing a HCV awareness public campaign, targeting high risk populations groups;
- Increased engagement with people already infected with HCV to ensure they are receiving appropriate monitoring and treatment;
- Continuing to support agencies to provide education and information in the general community, and
- Continuing to include HCV education in the school curriculum.

Improve access to education and information for targeted groups including:

- Injecting drug users (IDUs);
- Aboriginal and Torres Strait Islander people;
- Prisoners;
- People from CALD backgrounds, and
- Young people.

Increase training opportunities for people who provide services to those with or at risk of HCV infection, including an understanding of the nature and extent of HCV-related discrimination such as:

- Health care providers;
- Welfare workers;
- Youth services, including educators;
- Justice workers;
- Drug and alcohol services;
- Mental health services;

- Aboriginal services, and
- CALD services.

Improve access to HCV prevention strategies, for example:

- Support and expand access to NSP in accordance with recommendations of the NSP Review (2008), including additional fixed sites, vending machines, pharmacies and other outlets;
- Improve access to hepatitis A and B vaccination in custodial settings;
- Support services to improve capacity for testing, counselling and referral to treatment, and
- Identify and address barriers to accessing services that prevent HCV transmission.
- Implement a comprehensive approach to address the enablers and barriers to prevention and education services, and access to NSP for Aboriginal people who inject drugs.

4.2 Secondary Prevention and Early Detection

Promote HCV testing using best practice principles by:

- Promoting distribution and use of the National Hepatitis C Testing Policy, and
- Including information on appropriate testing practices in all HCV training.

Improve access to HCV testing, especially in custodial settings by:

- Increasing the opportunities for appropriate testing in a range of settings;
- Assess the potential barriers that may prevent effective testing and treatment strategies, including stigma and discrimination, and
- Developing an effective communication strategy to overcome these barriers.

Enhance the capacity of primary health care providers to test and commence a treatment program of patients with and/or at risk of HCV infection by:

- Increasing the knowledge of HCV-related information, treatment and support services and referral pathways for both people living with HCV and service providers;
- Provide training in appropriate HCV testing procedures, and
- Develop appropriate referral and treatment pathways for people when first diagnosed with HCV infection (Figure 1).

To complement existing GP based services, access to testing and referral to treatment is available through some drug and alcohol treatment settings, metropolitan sexual health clinics and some rural public health units. In some regions specialist hepatitis C nurses can facilitate testing and treatment access. The creation of a statewide hepatitis C shared care program facilitated by regional nurse-led care will facilitate access to hepatitis C tests and treatment access.

Health consumers can access information about testing and 'hepatitis C friendly GPs' from the Hepatitis WA telephone information line. The WA Substance Users' Association also provides information to clients about GPs with experience in providing services to injecting drug users.

4.3 Disease Management and Tertiary Intervention

Identify and address barriers to the uptake and completion of treatment through:

- Investigating barriers and enablers and devise strategies to address them in partnership with relevant sectors;
- Enhancing the Education of health care providers, and
- Promoting public awareness of tertiary prevention and complications of liver disease.

Increase the proportion of people with HCV accessing treatment

- Promote the improved efficacy of treatment to health care providers and people with HCV
- Improving the access to treatment services through:
  - Expanding the GP Shared Care Program;
  - Appointing a multidisciplinary team to coordinate care state wide (metropolitan and rural settings) and a mentoring partnership with rural colleagues using telehealth services;
  - Establishing HCV services in locations with appropriate services, ie Sexual and Migrant Health and Drug & Alcohol services;
  - Facilitating treatment and support for people with HCV in custodial settings who are willing and eligible to participate, and
  - Increasing capacity of GPs from CALD backgrounds to provide HCV care and support.
- Implement state wide web-based learning for health care providers to enable:
  - General Practitioners to attain prescriber status through training modules and clinical placement in tertiary centres;
  - Increased the participation of GPs in the shared care program especially in rural areas, and
  - Increase training of nurses in metropolitan, rural and remote centres and prisons to provide support for Medical Practitioners.
- Implement a state wide web-based Hepatitis C data base to:
  - Promote effective use of resources and test duplication;
  - Facilitate GP shared care program, and
  - Assist in the provision of safe and comprehensive patient care.

Establish a viral hepatitis collaborative including clinicians from Hepatology, Infections and Immunology and Digestive Health Networks, Microbiology and Infectious Diseases and nurses from each of the tertiary sites, area health service representatives, GP's, Communicable Disease Control Directorate

(CDCD) Sexual Health and Blood-borne Virus Program (SHBBVP) and a consumer representative to co-ordinate state wide clinical services.

Define the role of tertiary centres in the;

- Management of the patient journey including:
  - Complications of liver disease;
  - Extrahepatic manifestations of chronic Hepatitis C, and
  - Addressing cofactors i.e. obesity, alcohol.
- Development and dissemination of clinical protocols, guidelines and algorithms;
- Provision of training and education for health care providers in the management of chronic hepatitis C and its complications;
- Provision of continuing education for health care providers and maintenance of appropriate levels of competency, and
- Develop and implement strategies which respond to the changing needs.
- Coordination of HCV services state wide, including:
  - Custodial settings, secondary centres, step down facilities, co-located or ambulatory care services, rural services, and Shared Care programs.
- Maintenance of a secure internet based HCV database.
- Promote and participate in HCV-related research

4.4 Hepatitis C treatment in Prisons

Implement prison based primary prevention and treatment programs including:

- Programs targeted at maximising the number of prisoners being treated within the corrective setting and help reduce barriers such as cost & availability of transport, security issues & improving patient dignity;
- The provision of Needle and Syringe Exchange programs;
- Promoting partnerships between Departments of Health and Corrective Services that will allow the treatment of Hepatitis C positive prisoners to be managed in a cost effective manner;
- Training of GPs in Shared Care Programs and S100 prescribers;
- Training of Specialist BBV nurses in testing, treatment and management of people with HCV, including Nurse Practitioners;
- Developing systems for prisoners upon release through care to liver specialists, pharmacotherapies and drug and alcohol treatment programs in the community to make the transition easier, and
- Strategies to improve cross jurisdictional approach to addressing HCV

All prisoners should routinely be offered entry and exit BBV testing as well as the ability to request testing at any time during their term of incarceration. This testing should be accompanied by pre & post test counselling and hepatitis A & B vaccination as necessary.

All WA prison entrants are to attend HIP HOP (Health in prison, Health outa prison) education designed for delivery at entry and prior to release. However, this program needs to be complemented by the provision of a needle and syringe program (NSP) and tattooing services so they can practice harm minimisation. The introduction of a NSP will reduce risk behaviours and prevent disease transmission related to injecting drug use.

Drug and alcohol withdrawal and treatment strategies need to be made available to all prisoners for identified substance abuse issues and should be complemented by the introduction of co-morbidity (mental health and substance use) specialist nurses. Working closely with drug & alcohol services in the community will provide community links for prisoners and these services need to include patient's families for more holistic care.

4.5 Surveillance

4.5.1 Support the national Hepatitis C surveillance mechanisms through:

- The Western Australian Hepatitis C Action Plan (developed from the National Hepatitis C Action Plan) that details mechanisms to improve surveillance of high risk groups for Hepatitis C;
- Supporting national strategies to increase testing in high risk groups;
- Laboratory notification of positive HCV antibodies;
- Long term surveillance for hepatocellular carcinoma across WA and incorporating this component into the Internet–based HCV database;
- Promoting standardisation of surveillance data collection across WA, and
- Ensuring surveillance mechanisms capture Aboriginal status.

4.5.2 Surveillance for hepatocellular carcinoma

A surveillance program for hepatocellular carcinoma (HCC) in high risk groups which include hepatitis C associated cirrhosis is recommended and guidelines have been developed by several international bodies including the American Association for the Study of Liver diseases (AASLD) [12]. Surveillance involves 6-monthly ultrasound and alpha-fetoprotein (AFP) measurements.

4.5.3 Promoting hepatocellular carcinoma surveillance by:

- Establishing a State wide hepatocellular carcinoma surveillance program;
- Incorporating this requirement into the HCV database to ensure a streamlined approach, with an automated processes of 6-monthly recall of abdominal ultrasound and alpha-fetoprotein treatment for high-risk groups;
- Ensuring effective therapeutic options are available for those with early diagnosis;
- Adopting mechanisms to capture abnormal Ultrasound and elevated alpha-fetoprotein, and

- Implementing mechanisms for fast-tacking of referral to tertiary centre for patients where a multi-disciplinary team approach can discuss the most appropriate treatment modality for individual cases.

4.6 Research

Increase in research support into barriers in uptake of treatment in metropolitan, rural and remote areas, custodial settings and rehabilitation centres, including:

- Evaluation of current modalities increasing access to treatment especially around multi-modal education programs;
- Social research into the uptake of drugs and particularly injecting, how to inject safely, how injecting drug users can be engaged in health care systems, barriers to uptake of treatments, monitoring psycho-social impacts of treatments, issues relating to adherence;
- Promoting research into innovative strategies to increase treatment uptake;
- Providing opportunities for collaborative research into the basic mechanisms in viral or host factors in determining treatment outcome;
- Encouraging and promote investigator initiated research projects in Western Australia into different aspects of care in patients with chronic hepatitis C, and
- Providing opportunities and facilities to promote high quality and coordinated research.

4.7 Workforce Development

The state wide model of care for Hepatitis C should incorporate the following factors in addressing workforce development:

- Effective treatment options now available for treatment of chronic hepatitis C;
- Small proportion of those infected with hepatitis C (<1%) access treatment, in particular those in remote and rural areas and Aboriginal and Torres Strait Islander people;
- Western Australia covers an area of 2.5 million square kilometres and presents significant logistical challenges;
- Capacity constraints across the health workforce in terms of resourcing to meet the current (and anticipated future) Hepatitis C load;
- Innovative strategies already in progress but require adequate support for these to have the maximum benefit i.e. Nurse Practitioner, GP shared care;
- Western Australia has developed strategies that have been or will be adopted by other states in Australia i.e. Hepatitis C GP Shared Care Program, and
- Hepatitis C Telehealth service can be developed to its full potential with adequate workforce and resource support.

For a successful state wide model for Hepatitis C management, inclusions of the following are essential:

- Medical specialists in tertiary and secondary centres to lead:
  - Management of patients with more complex problems related to Hepatitis C;
  - Multi-disciplinary team in the management of complex problems;
  - Education and training of junior hospital doctors, General Practitioners, Nurses (esp. Senior nurses – NP and CNC);
  - Coordination and support of secondary centres, General Practitioners and other health care professionals, and
  - Development of clinical protocols, guidelines and continuing educational updates for those involved in the care of people with Hepatitis C.
- General Practitioners in metropolitan, rural and remote areas to assist through:
  - Involvement in Hepatitis C GP Shared Care in collaboration with tertiary centres;
  - Enhancing Accredited Prescribers access;
  - Training in the management of patients with adverse events result of antiviral therapy, and
  - Management of patients who develop complications of liver disease (compensated).
- Nursing services enhancement such as:
  - Nurse Practitioners with increased scope of practice, Clinical Nurse Consultants, Hepatitis Nurse Co-ordinators;
  - Provision of training of NP requires postgraduate training at Curtin University (2 years) with a period of internship at tertiary centres;
  - Training of Regional Hepatitis Nurse Consultants/ co-ordinators especially in rural and remote areas with support of senior nurses and specialists from tertiary centres. Support for GPs in regional centres, and
  - Training of nurses in affiliated centres and Drug and Alcohol Rehabilitation centres and to appropriate levels of competency and maintenance of competency.
- Other support services including:

Administrative and support staff with skills require to support a state wide program, including project officers to undertake audits and research

4.8 Education and Training

Current service delivery includes a limited Shared Care Program, but there is an increasing need for the training of health care workers (GPs, Nurse Practitioners and Clinical Nurses) and community based support services that work with people with or at risk of HCV infection. This includes Drug and Alcohol services, Multicultural services and Mental Health services.

Other non-healthcare related professions targeted for education and training in HCV infection are welfare workers, and those in educational settings.

Flexible and distant learning using the electronic medium offers the opportunity of those with interest in chronic HCV an opportunity to learn and participate in the care of the patients. Education and training can be undertaking at one's own pace and at one's convenience without having to travel long distances. Some e-learning programs are available through the website http://hepc.ecu.edu.au . This form of learning has gained popularity in many fields and has been well established in some areas of medicine. This form of learning is complementary to the traditional methods of education and training and can be incorporated into training at different levels of expertise.

The management of chronic hepatitis C is multi-facetted and with the evolving understanding of the basic mechanisms in host and viral factors involved in treatment response, it is vital that clinical specialists are appropriately trained to cope with the increasingly complex regimes.

General practitioners and general practice is a cornerstone in the provision of hepatitis C testing, referral and treatment. To support GPs an on-line Hepatitis C shared care and s100 prescriber training program has been developed and rolled-out by Edith Cowan University. In addition, resources are available to GPs to assist pre-test and post-test discussion and that take into consideration stigma and discrimination associated with hepatitis C.

4.9 Adequate Care

4.9.1 Best Practice Guidelines

Best practice guidelines have been established to optimise patient care. With evolving and improved management strategies, it is essential to adopt the most effective treatment and mode of delivery of services across all sectors.

Nursing care in the field of hepatology will also be guided by HCV algorithms and by the recent development of competency standards by the Australasian Hepatology Association (AHA). These standards are currently in draft form and being trialled around Australia and will:

- Provide guiding principles which will reflect how the hepatology nurse can practice;
- Provide principles with which the specialist hepatology nurse can mentor and educate other health professionals, and
- Inform the policy and procedures for hepatology nursing.

4.9.2 Clinical care and management of liver disease

The ability to provide up to date care is based on the development of appropriate guidelines or principles that underpin the delivery of that care.

Current pathways and clinical protocols for complications of chronic HCV need regular review and modification as new medical technologies and new drug therapies emerge. State wide guidelines and pathways for referrals should be developed for primary care medical practitioners in the management of patients with chronic HCV complications.

Medical care has been enhanced in the tertiary and primary health centre by the development of HCV algorithms and the development of e-learning will provide a unique opportunity to:

- Present HCV algorithms and potential pathways of care on line, and
- To widely distribute the HCV algorithms and pathways of care.

Management of specific complications of liver disease would include:

- Ascites;
- Variceal haemorrhage;
- Hepatic encephalopathy;
- Hepatocellular carcinoma;
- Extrahepatic manifestations of chronic hepatitis C;
- Arthropathy;
- Cryoglobulinaemia;
- Diabetes Mellitus;
- Porphyria Cutanea Tarda (PCT), and
- Lymphoma.

4.9.3 Multidisciplinary Team

The involvement of an integrated approach when managing patients with chronic liver disease is of paramount importance. The ability to link in with existing services in the metropolitan and rural and remote setting will ultimately improve patient outcomes and reduce duplication of services. The utilisation of a multidisciplinary team approach to management of these patients will:

- Improve access to care by devolving care out of the tertiary setting;
- Increase numbers of people on treatment;
- Enhance care in the rural and remote setting;
- Promote coordination between agencies leading to increased referrals, and
- Identify systemic problems in the delivery of care and seek to solve the issue.

4.9.4 Practical aspects of the Patient Journey (Figure 6)

The model identifies the concepts of Community based care, General Practitioners, Secondary and Tertiary care settings as the most important aspects in achieving the best care for patients. This model also incorporates a collaborative approach between tertiary referral centres, primary health settings, regional health services, prison services and those services offered by other health professionals.

The future model of care and encompassing a component of the patient journey for people living with HCV is the patient referral pathway, presented in figure 1. In WA there is approx 1,000 notifications of HCV per year (refer figure 2) and there are about 20,000 patients nationally currently infected with HCV.

Improving the efficacy of the patient journey will result in improved referrals and patient outcomes, enhanced shared care arrangements, improved communication between the tertiary and primary care sectors and allow more people to be appropriately assessed and treated.

People at risk of HCV should receive pre and post test discussion and be tested for HCV. If diagnosis is confirmed, then people should be counselled about the impacts of living with HCV treatment and support options. Effective treatment is now available and only between 20-50% of those who receive treatment fail to respond and may progress to end stage liver disease.

An overview of the future hepatitis C model of care is displayed in Figure 7.

Figure 6. Patient Journey

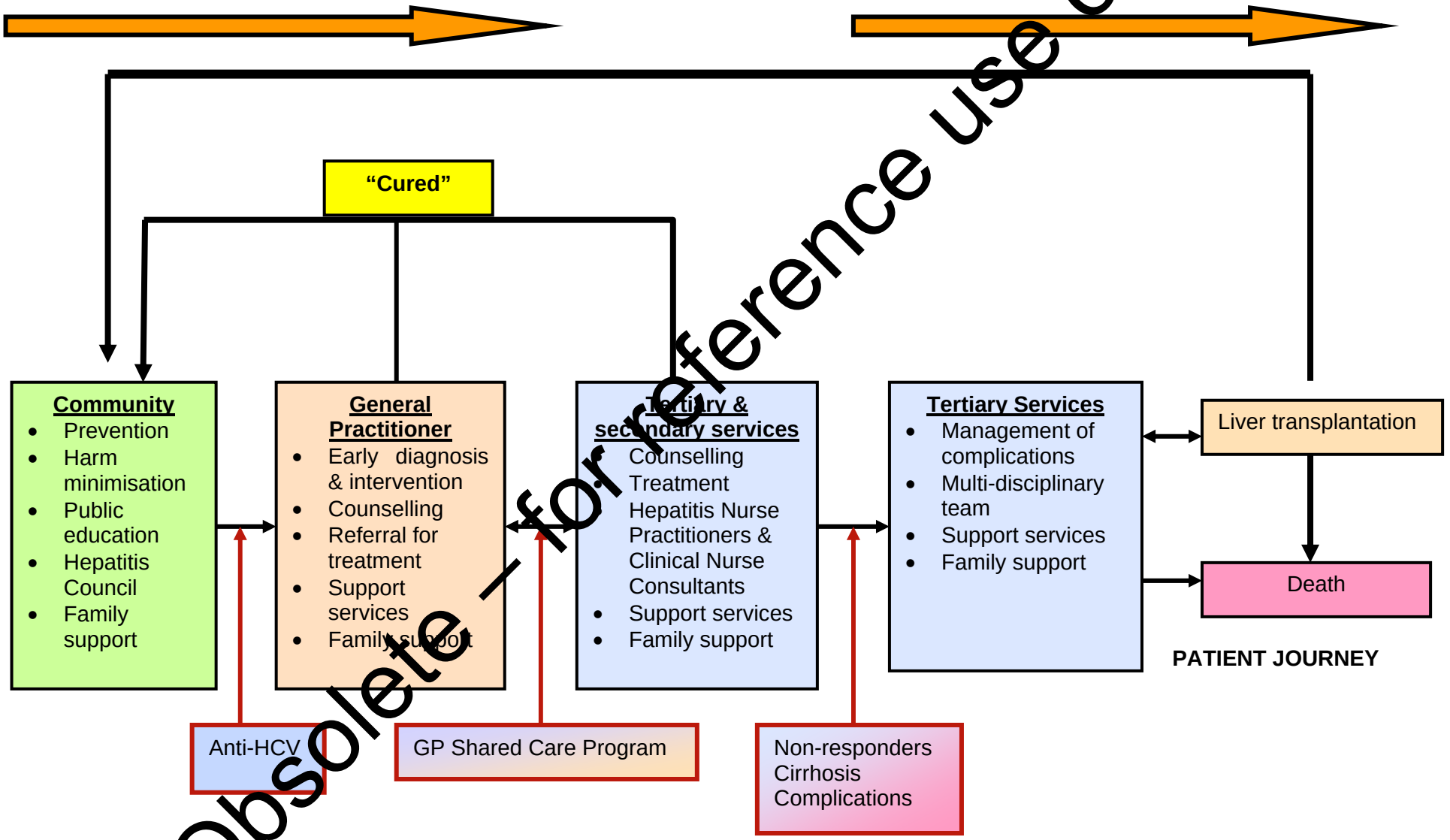
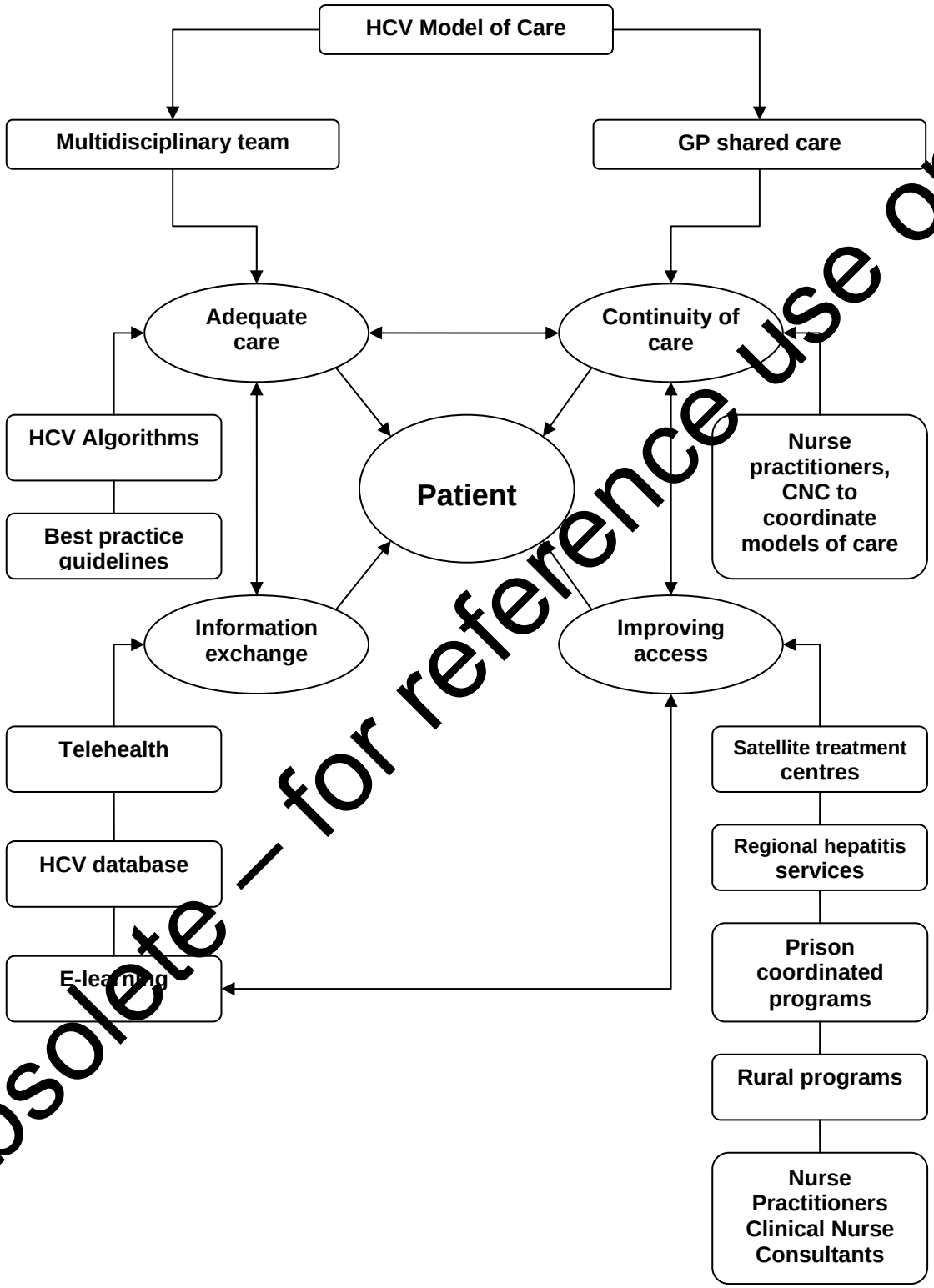


Figure 7: Future Model of Care for Patients with HCV



Source: Health Networks Branch

4.9.5 Horizon Scan

4.9.5.1 New antiviral therapies

The development of molecular based therapies for the treatment of HCV infection is an area of major interest, given that a significant number of patients do not respond to the current standard of care (combination therapy with interferon and ribavirin). Alternative therapies are needed for non-responders and those that relapse from the standard therapy.

Important lessons can be learnt from the experience of previous approaches to antiviral therapy to treat HIV and HBV infection. The issue of antiviral resistance, particularly when used as single agents should be noted from the experience of treating patients with HIV and HBV infection. There will need to be some pressure applied to those developing new antiviral for HCV not to progress down the line of single drug therapy.

4.9.5.2 Potential new therapies for hepatocellular carcinoma

- **New Drugs**

Patients with inoperable hepatocellular carcinoma generally have a poor prognosis. Currently there are many clinical trials examining new drugs which specifically target pathways in hepatocellular biology. Most of the clinical trials are in early stages of development and include inhibitors of growth factors, enzyme inhibitors, anti-proliferative agents, immunomodulators and those with direct anti-tumour effect. One agent which has received particularly attention is Bevacizumab (Avastin) which is a monoclonal antibody against vascular endothelial growth factor, which inhibits tumor growth by blocking the formation of new blood vessels. It has been approved for the treatment for metastatic colonic cancer and non-small cell lung cancer [10, 27] It has been found to be effective in hepatocellular carcinoma [42].

- **New treatment**
  - **Selective Internal Radiation Therapy (SIRT)**

Selective Internal Radiation Therapy is a minimally-invasive, radiation-based procedure directed against primary or metastatic liver tumors. Patients with advanced liver cancer do not respond well to systemic chemotherapy. Using SIRT, a very high dose of radiation is delivered to the liver without damaging other organs.

SIRT has been used successfully for treating secondaries in the liver from colonic cancers and there is limited experience for its use in primary liver cancers [24; 44; 46; 29].

  - **Combined therapy**

Combination of cytotoxic drugs with embolisation, either TACE or SIRT has the theoretical advantage of treatment with dual modalities to improve survival. Studies are currently in progress examining combined therapy.

4.9.5.3 Non-Invasive Assessment of Hepatic Fibrosis

Difficulties associated with liver biopsy have increased the focus on non-invasive markers of fibrosis that are accurate, easy to use, reliable and inexpensive. To date, the absence of a robust non invasive marker has provided the most significant barrier to clinical trial development of pharmacological strategies to combat hepatic fibrosis.

Currently available non invasive markers are useful in excluding cirrhosis however biopsy remains the most reliable method to assess for lower levels of fibrosis. Available fibrosis markers, when used independently, appear to lack sensitivity and specificity to detect earlier stages of fibrosis.

- **Conventional Ultrasound**

Routine abdominal ultrasound is carried out in nearly all patients with chronic hepatitis C to assess structural abnormalities, and to look for cholestasis, portal hypertension and hepatocellular carcinoma.

- **Serum Markers of Hepatic Fibrosis in HCV**

Overall, the detection of advanced fibrosis with the more recent serum marker panels has been considered good to excellent among individual studies. Combined indirect and direct serum marker panels can avoid the need for biopsy in up to 50% of cases. Based on its potential for widespread clinical availability and economic cost, there is incentive to enhance the diagnostic performance of serum marker tests.

- **Transient Elastography (TE)**

TE is a non-invasive method that has been proposed for the assessment of hepatic fibrosis in patients with chronic liver diseases, by measuring liver stiffness. TE is a rapid and user-friendly technique that can be easily performed at the bedside and is a very promising tool for the early detection of cirrhosis. In studies comparing TE with standard laboratory tests and other non-invasive fibrosis markers, TE had the best diagnostic performance for early detection of cirrhosis in patients with chronic hepatitis C avoiding liver biopsy in 90% of cases. Combining TE with serum markers appears to increase diagnostic accuracy and TE is particularly desirable in patients with bleeding disorders, such as haemophilia.

- **Magnetic Resonance Imaging (MRI) of Hepatic Fibrosis**

Over the past decade, a number of technological advances have been made in developing clinical applications for MRI of the liver. Recent improvements have focused on exploiting the physiological and biomechanical properties of human liver tissue to improve the detection of liver fibrosis.

In the future, cost and available expertise will play important roles in determining the utility of MRI-based technologies for detecting hepatic fibrosis. In addition the advantages of less expensive and more readily available methods (e.g. serum markers) needs to be balanced against any incremental benefit in diagnostic accuracy that imaging would produce.

Key elements to achieve a state wide HCV model of care are:

- Prevention and early intervention strategies.

Improve consolidation and implementation of prevention and health promotion strategies in high risk groups in accordance to WA Hepatitis C Action Plan. Implementation, prevention and health education strategies for priority target groups and community groups including school-based education, marginalised populations and representative organisations.

- Coordinated, multi-modal education programs.

Coordinated multi-modal education programs accessible to all stakeholders are one of the key factors to increase treatment uptake especially in rural and remote areas. It would supplement the current extensive but not well co-ordinated education program. Web-based learning offers flexibility and interactive learning opportunities, especially those in rural and remote areas.

- State wide HCV data-base

Health care providers of HCV clients would be registered users, allowing them to access patient information in real time using a secure internet-based database, and would improve coordination of care. A state wide HCV data-base is essential for a co-ordinated state wide Hepatitis C Model of care. It has the potential to reduce duplication of tests and allows direct communication of information between those caring for the patient.

- Communication Technology (ie Telehealth) services
- Telehealth provides an opportunity to substitute face to face assessments and enables equity of care for patients in rural and remote areas. Extension of Telehealth Hepatitis Clinics to patients who currently cannot access treatment through medical and nursing clinics (and include demonstration of injection techniques)

Expansion of the existing service to sites throughout Western Australia would impact positively on patients in rural areas (decrease travel expense, loss of income and inconvenience), support local health care providers in providing services for HCV and 'at risk' patients, and provide better continuity of care between the primary and tertiary setting.

The use of telehealth in the management of chronic HCV, in particular, treatment is in its infancy. Telehealth Service, through the use of interactive real time video conferencing and digital photography, is an innovative strategy that can improve accessibility and equity of health services for patients with HCV living in remote and rural areas.

References

1. Alter M.J. Prevention of spread of hepatitis C. *Hepatology 2002;* 36:93-98.
2. Anti-discrimination Board of New South Wales (November 2001) C-change: Report of the enquiry into hepatitis C related discrimination].
3. Applied Economics Pty Ltd. 2005, *Economic Evaluation of Hepatitis C in Australia,* report prepared for the Australian Government
4. Asian Pacific Association for the Study of the Liver consensus statements on the diagnosis, management and treatment of hepatitis C virus infection. J Gastroenterol Hepatol. 2007 May;22(5):615-33.
5. Asian Pacific Association for the Study of the Liver (APASL) Hepatitis C Working Party, McCaughan GW, Omata M, Amarapurkar D, Bowden S, Chow WC, Chutaputti A, Dore G, Gane E, Guan R, Hamid SS, Hardikar W, Hui CK, Jafri W, Jia JD, Lai MY, Wei L, Leung N, Piratvisuth T, Sarin S, Sollano J, Tateishi R.
6. Australian Government Department of Health and Ageing 2002, Return on Investment in Needle and Syringe Programs In Australia, Commonwealth of Australia, Canberra. Available at ***http://www.health.gov.au/internet/wcms/publishing.nsf/content/health-pubhlth-publicat-document-roireport-cnt.htm Accessed August 2007***.
7. Australian Government Department of Health and Ageing. (2000). Hepatitis C: Informing Australia's Response. Canberra: Commonwealth Department of Health and Ageing.
8. Australian Institute for Primary Care (2001). National Hepatitis C Resource Manual. Canberra: Australian Institute for Primary Care, Commonwealth Department of Health and Ageing.
9. Batey, B., Dore G., (2007), PowerPoint presentation, *Changes in Treatment Uptake: 2006 Onwards*, presented at the ASHM Hepatitis C Think Tank, Sydney, 27 March 2007. Available at http://www.ashm.org.au/uploads/hepc-think-tank-report-07.pdf. Accessed August 2007.
10. Bergsland EK, Fehrenbacher L, Novotny W et al. Bevacizumab (BC) + chemotherapy (CT) may improve survival in meta-static colorectal cancer (MCRC) subjects with unfavorable prognostic indicators. Paper presented at American Society of Clinical Oncology Annual Meeting. San Francisco, CA; 2001 May.
11. Bernstein D, Kleinman L, Barker CM, Revicki, DA, Green, J. Hepatology 2002: 35: 704-8
12. Bruix J & Sherman M. Management of hepatocellular carcinoma (AASLD Practice Guidlelines). Hepatology 2005;42(5) 1208-1236
13. Burrows, B. and Bassett, B (1996). Meeting the needs of people in Australia living with hepatitis C. National Hepatitis C Councils Education Reference Group.
14. Butler T, Boonwaat L & Hailstone S 2004, *National Prison Entrants' Blood-borne Virus Survey*, Centre for Health Research in Criminal Justice & National Centre in HIV Epidemiology and Clinical Research, University of New South Wales.

15. Colin, C., et al. (2001). Sensitivity and specificity of third-generation hepatitis C virus antibody detection assays: an analysis of the literature. Journal of Viral Hepatitis, 8(2): pp. 87-95.

16. Davis GL, Baalart LA, Schiff ER. Assessing health-related quality of life in chronic hepatitis C using the Sickness Impact Profile. Clin Ther 1994; 16: 334-43

17. Department of Health 2007 *Epidemiology of Notifiable STIs and BBVs, WA 1997-2006*,., DoH, Perth.

18. Elliot R 2007, Deadly disregard: government refusal to implement evidence-based measures to prevent HIV and hepatitis C virus infections in prisons. CMAJ 2007; 177:262-264.

19. Everson GT. Management of cirrhosis due to chronic hepatitis C. J Hepatol. 2005;42 Suppl(1):S65-74.

20. Forestier N , Reesink HW, Weegink CJ, McNair L ,. Kieffer TL, Chu H, Purdy S, Jansen PLM[3], Zeuzem S. Antiviral activity of telaprevir (VX-950) and peginterferon alfa-2a in patients with hepatitis C Hepatology 2007; 640 – 648

21. Fried MW, Shiffman ML, Reddy KR et al. Peginterferon alfa-2a plus ribavirin for chronic hepatitis virus infection. N Eng J Med 2002; 347:975-982.

22. Fried MW, Shiffman M., Reddy K.R., Smith BM, Marinos G, Goncales A., Diago, SA, Carosi TL, Dhumeaux W, Craxi C. & Hoffman J. Peginterferonalfa-2b plus ribavirin compared with interferon alfa-2b plus ribavirin for initial treatment of hepatitis C: a randomized trial. Lancet 2001; 358:958-965.

23. Gane E. Treatment of recurrent hepatitis C. *Liver transplantation 2002; 8* (10):28-37.

24. Gray BN, Van Hazel G et al. Randomized trial of SIR-Spheres plus chemotherapy versus chemotherapy alone for treating patients with liver metastases from primary large bowel cancer. Annals of Oncology.2001,12:1711-1720

25. Hadziyannis SJ, Sette Jr H, Morgan TR et al. Peginterferon alfa-2a in combination with ribavirin: A randomised study of treatment duration and ribavirin dose. *Annals of Internal Medicine* 2004;140(5):346-357.

26. Harrison SA. Small Molecule and Novel Treatments for Chronic Hepatitis C Virus Infection. Am J Gastroenterol 2007;102:1–7)

27. Herbst RS, Johnson DH, Mininberg E et al. Phase I/II trial evaluating the anti-vascular endothelial growth factor monoclonal antibody bevacizumab in combination with the HER-1/epidermal growth factor receptor tyrosine kinase inhibitor for patients with recurrent non-small-cell lung cancer. *J Clin Oncol.* 2005

28. Kenny-Walsh, E. (1999). Clinical outcomes after hepatitis C infection from contaminated anti-D immune globulin. N Engl J Med, 340: pp. 1228-1233.

29. Lau WY, Ho S, Leung TWT. Internal Radiation Therapy through the Hepatic Artery. In: Multi-Treatment Modalities of Liver Tumours. Ed: N Habib, Kluwer Academic/Plenum Publishers, London 2002. pp 323-344

30. Lee, S.C., et al. (2000). Improved version 2.0 qualitative and quantitative AMPLICOR reverse transcriptase PCR tests for hepatitis C virus RNA: calibration to international units, enhanced genotype reactivity and performance characteristics. J Clin Micro, 38: pp. 4171-4179.

31. Loveday, S., G. Deakin, and D. Neophyton. (1999). Meaning for the person. Australian Family Physician (Special Issue: Hepatitis C: A Management Guide for General Practitioners). 28: pp.SI 51 – SI 56.

32. Manns MP, McHutchison JG, Gordon SC et al. Peginterferon alfa-2b plus ribavirin compared with interferon alfa-2b plus ribavirin for the initial treatment of chronic hepatitis C: a randomised trial. *Lancet 2001;* 358:958-965.

33. McHutchison JG, Manns M, Patel K. Adherence to combination therapy enhances sustained response in genotype-1 infected patients with chronic hepatitis C. *Gastroenterology* 2002; 123(4):1284-1286.

34. Ministerial Advisory Committee on AIDS, Sexual Health and Hepatitis Hepatitis C Sub-Committee, 2006. *HCV Projections Working Group: Estimates and Projections of the HCV Epidemic in Australia 2006.* National Centre in HIV Epidemiology and Clinical Research, The University of New South Wales Available at http://www.nchecr.unsw.edu.au/NCHECRweb.nsf/resources/HCVPWG2006/$file/HCVPWGRepAug06.pdf Accessed August 2007.

35. National Centre in HIV Epidemiology and Clinical Research (NCHECR). HIV/AIDS, viral hepatitis and sexually transmissible infections in Australia Annual Surveillance Report. The University of New South Wales. NCHECR; 2005

36. Nazareth Saroj, Piercey Carol, Tibbett Patricia and Cheng Wendy. Nurse Practitioners in the management of chronic hepatitis C in Australia – the first of its kind, beginning of a new era. Advanced Australian Journal of Advanced Nursing 2008, 25(4):107-113

37. Noto H, Raskin P Hepatitis C infection and diabetes. J Diabetes Complications. 2006 Mar-Apr;20(2):113-20.

38. Poynard T, Bedossa P, Opolon P et al. Natural history of liver fibrosis progression of patients with chronic hepatitis C. *Lancet 1997;* 349:825-832

39. Razali K, Thein HH, Kerr J, Cooper-Stanbury M, Dolan K, Dore G, George J, Kaldor J, Karvelas M, Li J, Maher L, McGregor S, Hellard M, Poeder F, Quaine J, Stewart K, Tyrrell H, Weltman M, Westcott O, Wodak A, Law M. Modelling the hepatitis C virus epidemic in Australia. Drug Alcohol Depend. 2007 Jul 30;

40. Rodger, A.J., et al (2000). Assessment of long term outcomes of community-acquired hepatitis C infection in a cohort with sera stored from 1971-1975. Hepatology, 32: pp. 582-587.

41. Sansonno D, Dammacco F. Hepatitis C virus, cryoglobulinaemia, and vasculitis: immune complex relations.Lancet Infect Dis. 2005 Apr;5(4):227-36.

42. Schwartz JD, Schwartz M, Kinkhabwala M et al. Bevacizumab in hepatocellular carcinoma in patients without metastasis and without invasion of the portal vein. Paper presented at American Society of Clinical Oncology Gastrointestinal Symposium. San Francisco, CA; 2004 Jan.

43. Sharara, A.I., C.M. Hunt, and J.D. Hamilton. (1996). Hepatitis C. Annals of Internal Medicine, 125: pp. 658-668.

44. Stubbs, R.S. and Cannan, R.J. Selective internal Radiation Therapy with 90Yttrium Microspheres for Primary and Metastatic Cancer Confined to the Liver. In: Multi-Treatment Modalities of Liver Tumours. Ed: N Habib, Kluwer Academic/Plenum Publishers, London 2002. pp 305-321.

45. Trepo, C. (2000). Genotype and viral load as prognostic indicators in the treatment of hepatitis C. J Viral Hepatitis, 7: pp. 250-257.

46. Wan-Yu L, Shih-Chuan T, Jih-Fang H and Shyh-Jen W. Effects of (90)Ymicrospheres on Liver Tumors: Comparison of Intratumoral Injection Method and Intra-Arterial Injection Method. Journal of Nuclear Medicine.2002,41(11):1892-1897.

47. Ward, J., M. Coleborne, and T. Fort. (2000). Hepatitis C and Discrimination. Hepatitis C: Informing Australia's Response. Canberra: Commonwealth Department of Health and Aged Care.

48. Ware J, Bayliss MS, Mannochiccia M. Health-related quality of life in chronic hepatitis C: impact of disease and treatment response. The Interventional Therapy Group, Hepatology 1999: 30: 550-5

49. Watson J 2001, *Hepatitis C: A Study of Prevalence in WA Prisons,* Hepatitis Council of WA, Perth.

50. Watson, K. (1999). Counselling. Australian Family Physician, 28: pp.SI 69-SI 70

51. Zuckerman E, Yeshurun D, Rosner I. Management of hepatitis C virus-related arthritis. BioDrugs 2001;15(9):573-84.

Appendices

Appendix 1: Executive Advisory Members for the Infections and Immunology Health Networks

Dr James Flexman	Network Co-Lead, Consultant Clinical Microbiologist, PathWest and Royal Perth Hospital; Clinical Associate Professor, Microbiology and Immunology, UWA
Dr Lewis Marshall	Network Co-Lead, Sexual Health Physician, Fremantle Hospital; Clinical Senior Lecturer, Sexual Health Medicine, UWA
Dr Wendy Cheng	Head of Liver Service, Royal Perth Hospital
Ms Crystal Connelly	Clinical Nurse and Clinical Trial Coordinator, Royal Perth Hospital
Dr Charles Douglas	Public Health Physician, WA Country Health Service, Goldfields
Dr John Dyer	Head, Infectious Diseases Service, Fremantle Hospital, South Metropolitan Area Health Service
Prof Martyn French	Head of Clinical Service, Clinical Immunology, Royal Perth Hospital; Consultant Immunologist, PathWest Immunology, Royal Perth Hospital; Clinical Professor, School of Surgery and Pathology, UWA
Ms Michele Kosky	Executive Director, Health Consumers' Council
Ms Trish Langdon	Executive Director, WA AIDS Council
Dr Tony Keil	Head, Department of Microbiology, Pathwest Laboratory Medicine, King Edward Memorial Hospital for Women and Princess Margaret Hospital for Children
Dr Sandra Thompson	Aboriginal health Council of Western Australia
Dr Paul Van Buynder	Director, Communicable Disease Control Directorate, Department of Health

Appendix 2: Executive Advisory Members for Digestive Health Network

Professor John Olynyk	Clinical Lead and Chair Academic and Research representative, University of WA Head of Department of Gastroenterology, Fremantle Hospital
Ms Samantha Boggs	Dieticians Association of Australia and Joondalup Health Campus
Dr Wendy Cheng	Gastroenterologist and Hepatologist, Head of Liver Service, Royal Perth Hospital
Dr Hooi Ee	Gastroenterologist, Sir Charles Gairdner Hospital
Prof David Fletcher	Department of Surgery and Radiology, Fremantle Hospital and University of WA; Clinical Director of Surgery, South Metropolitan Area Health Service
Dr Tim Free	WA Country Health Services Executive Executive representative
Ms Iren Hunyadi	Consumer representative
Dr Nick Kontorinis	Gastroenterologist and Hepatologist, Royal Perth Hospital
Assoc Prof Ian Lawrance	Gastroenterologist, Fremantle Hospital; Senior Lecturer, University of Western Australia
Dr John Lindsey	WA Country Health Services representative, General Physician, Albany
Dr Deboah McKay	Fremantle Division of General Practice
Ms Amanda McKnight	Clinical Nurse Specialist, Sir Charles Gairdner Hospital

Appendix 3: HCV working Group – Infections & Immunology and Digestive Health Networks

Title	First Name	Surname	Position	Affiliation
Dr	Wendy	Cheng	Head, Liver Service	Royal Perth Hospital (Project leader)
A/Prof	James	Flexman	Clinical Microbiologist*	Royal Perth Hospital
Dr	Nick	Kontorinis	Hepatologist	Royal Perth Hospital
Dr	Lorenzo	Tarquinio	Hepatologist	Royal Perth Hospital
Ms	Saroj	Nazareth	Nurse Practitioner	Royal Perth Hospital
Ms	Crystal	Connelly	Infectious Disease Coordinator	Department of Corrective Services
Ms	Marion	McInerney	Clinical Nurse Consultant	Royal Perth Hospital
Prof	John	Olynyk	Professor of Gastroenterology	Fremantle Hospital
A/Prof	Lindsay	Mollison	Head, Hepatitis Service	Fremantle Hospital
Dr	John	Dyer	Head, Infectious Disease	Fremantle Hospital
Dr	Lewis	Marshall	Sexual Health Physician *	Fremantle Hospital
Ms	Leanne	Totten	Clinical Nurse Consultant	Fremantle Hospital/STI BBV
Ms	Gim	Andrews	Clinical Nurse Consultant	Fremantle Hospital
Ms	Lynette	Booth	Clinical Nurse Consultant	Fremantle Hospital
A/Prof	Gary	Jeffrey	Medical Director, Liver Transplant Service	Sir Charles Gairdner Hospital
A/Prof	Luc	Delriviere	Surgical Director, Liver Transplant Service	Sir Charles Gairdner Hospital
Dr	Gerry	MacQuillan	Hepatologist	Sir Charles Gairdner Hospital

Title	First Name	Surname	Position	Affiliation
Dr	Leon	Adams	Hepatologist	Sir Charles Gairdner Hospital
Dr	David	Speers	Infectious Disease Physician	Sir Charles Gairdner Hospital
Ms	Barbara	Chester	Clinical Nurse Consultant	Sir Charles Gairdner Hospital
Ms	Joanne	Young	Clinical Nurse	Sit Charles Gairdner Hospital
Dr	Ralph	Chapman	Medical Director, (GP representative)	Department of Justice
Dr	Cathy	Mews	Hepatologist (Paediatric)	Princess Margaret Hospital
Dr	Jaye	Martin	Rural Physician	Broome
Dr	Noel	Plumley	Addiction Medicine Physician	Next Step Drug & Alcohol Service
Dr	John	Edwards	GP representative	GP Division
Mr	Michael	Doyle	Aboriginal Health Council	Department of Health
Ms	Chrissy	Ryan	Hepatitis C Resource Officer	WA Substance Abuse Association
Dr	Sam	Galhenage	Consultant Gastroenterologist	Fremantle Hospital
Ms	Lisa	Bastian	Manager, Sexual Health & Blood–borne Virus Program	Department of Health
Dr	Susan	Carruthers	Chairperson	Hepatitis Council

Appendix 4: Number and ASR of hepatitis C notifications by region and sex, WA, 2007.

Region	Disease status	Sex						Rate ratio (Male:Female)
		Male		Female		Total		
		Number	ASR	Number	ASR	Number	ASR	
Goldfields	Newly acquired	0	0.0	0	0.0	0	0.0	N/A
	Unspecified	14	44.3	11	40.8	25	43.1	1.1
	Total hepatitis C	14	44.3	11	40.8	25	43.1	1.1
Great Southern	Newly acquired	3	12.5	0	0.0	3	6.3	N/A
	Unspecified	15	63.8	10	42.7	25	53.9	1.5
	Total hepatitis C	18	76.2	10	42.7	28	60.2	1.8
Kimberley	Newly acquired	0	0.0	0	0.0	0	0.0	N/A
	Unspecified	21	112.1	11	65.1	32	90.3	1.7
	Total hepatitis C	21	112.1	11	65.1	32	90.3	1.7
Midwest	Newly acquired	0	0.0	0	0.0	0	0.0	N/A
	Unspecified	21	68.6	12	45.2	33	57.5	1.5
	Total hepatitis C	21	68.6	12	45.2	33	57.5	1.5
North Metropolitan	Newly acquired	25	5.7	8	1.8	33	3.8	3.2
	Unspecified	269	62.1	172	39.9	441	51.1	1.6
	Total hepatitis C	294	67.8	180	41.8	474	54.9	1.6
Pilbara	Newly acquired	0	0.0	0	0.0	0	0.0	N/A
	Unspecified	19	74.7	7	33.0	26	59.0	2.3
	Total hepatitis C	19	74.7	7	33.0	26	59.0	2.3
South Metropolitan	Newly acquired	25	6.5	12	3.2	37	4.9	2.0
	Unspecified	269	72.3	146	40.1	415	56.2	1.8
	Total hepatitis C	294	78.8	158	43.4	452	61.1	1.8
South West	Newly acquired	3	4.4	0	0.0	3	2.2	N/A
	Unspecified	56	80.0	36	55.0	92	67.7	1.5
	Total hepatitis C	59	84.4	36	55.0	95	69.9	1.5
Wheatbelt	Newly acquired	0	0.0	0	0.0	0	0.0	N/A
	Unspecified	16	47.9	15	48.9	31	48.4	1.0
	Total hepatitis C	16	47.9	15	48.9	31	48.4	1.0
Other	Newly acquired	0	N/A	0	N/A	0	N/A	N/A
	Unspecified	29	N/A	9	N/A	38	N/A	N/A
	Total hepatitis C	29	N/A	9	N/A	38	N/A	N/A
Unknown	Newly acquired	0	N/A	0	N/A	0	N/A	N/A
	Unspecified	23	N/A	6	N/A	29	N/A	N/A
	Total hepatitis C	23	N/A	6	N/A	29	N/A	N/A
WA (Total)	**Newly acquired**	**56**	**5.3**	**20**	**2.0**	**76**	**3.7**	**2.7**
	Unspecified	**752**	**71.9**	**435**	**43.0**	**1,187**	**57.7**	**1.7**
	Total hepatitis C	**808**	**77.3**	**455**	**45.0**	**1,263**	**61.3**	**1.7**

Notes:
Number = Number of notifications reported to the DoH
ASR = Age-standardised notification rate per 100,000 population
Rate ratio (Male:Female) = Male to Female rate ratio = ASR (Male) / ASR (Female)
Other = Interstate + overseas
Unknown = Unknown residential address
Total hepatitis C = Newly acquired hepatitis C + Unspecified hepatitis C
N/A = Not applicable

Source: Epidemiology and Surveillance Program, Communicable Disease Control Directorate (CDCD)

Glossary

AHA	Australian Hepatology Associates
ASR	Age-standardised notification rate per 100,000 population
ASHM	Australasian Society for HIV Medicine
BBV	Blood-borne Virus
CALD	Culturally and Linguistically Diverse
CDCD	Communicable Disease Control Directorate
CN	Clinical Nurse
CNC	Clinical Nurse Consultants
DoCS	Department of Corrective Services
DoH	Department of Health (WA)
DoHA	Department of Health and Ageing (Australian Government)
DYHS	Derbarl Yerrigan Health Service
FH	Fremantle Hospital
GESA	Gastroenterological Society of Australia
GP	General Practitioner
HCC	Health Consumers Council
HCV	Hepatitis C Virus
HCWA	Hepatitis Council of WA
HIV	Human Immunodeficiency Virus
HRQL	Health Related Quality of Life
IDUs	Injecting Drug Users
IGCAHRD	Inter-governmental Committee on AIDS, Hepatitis C and Related Diseases
IAPO	International Alliance of Patients' Organisation
MACASHH	Ministerial Advisory Committee on AIDS, Sexual Health & hepatitis
NCHECR	National Centre in HIV Epidemiology and Clinical Research
NGOs	Non-Government Organisations
NP	Nurse Practitioner
NSEP	Needle and Syringe Exchange Program
NSP	Needle and Syringe Program
PathWest	PathWest Laboratory Medicine WA (formerly the PathCentre)
PHU	**Population Health Unit**
RPH	Royal Perth Hospital
SCGH	Sir Charles Gairdner Hospital
SHBBV	Sexual Health and Blood-borne Virus Program
SVR	Sustained virological response
WA	Western Australia/Western Australian
WAAC	Western Australian AIDS Council Inc.
WACHS	WA Country Health Services
WACRRM	WA Centre for Remote and Rural Medicine
WANIDD	**Western Australian Notifiable Infectious Diseases Database**
WASUA	Western Australian Substance Users' Association
WAVHC	WA Viral Hepatitis committee

Age Standardisation - Weighted average of age specific rates according to a standard distribution of age to eliminate the effect of different age distributions and thus facilitate valid comparison of groups with differing age compositions.

S100 Prescribers - In addition to the drugs and medicinal preparations available under normal PBS arrangements listed in (the) Schedule, a number of drugs are also available as pharmaceutical benefits but are distributed under alternative arrangements where these are considered more appropriate. These alternative arrangements are provided for under section 100 of the *National Health Act 1953*.

Ascites - Abnormal build up of fluid in the abdomen. Ascites can occur as a result of a number of conditions, including severe liver disease and the presence of malignant cells within the abdomen.

Variceal bleeding or **haemorrhage -** refers to bleeding from abnormal vascular connections usually found in the oesophagus (esophagus) or stomach.

Hepatic encephalopathy - Brain dysfunction directly due to liver dysfunction, most often recognized in advanced liver disease. Hepatic encephalopathy may cause disturbances of consciousness and progress to coma.

Hepatocellular carcinoma - A malignant growth made up of liver epithelial cells that tend to infiltrate the surrounding tissues and give rise to metastases (Liver cancer).

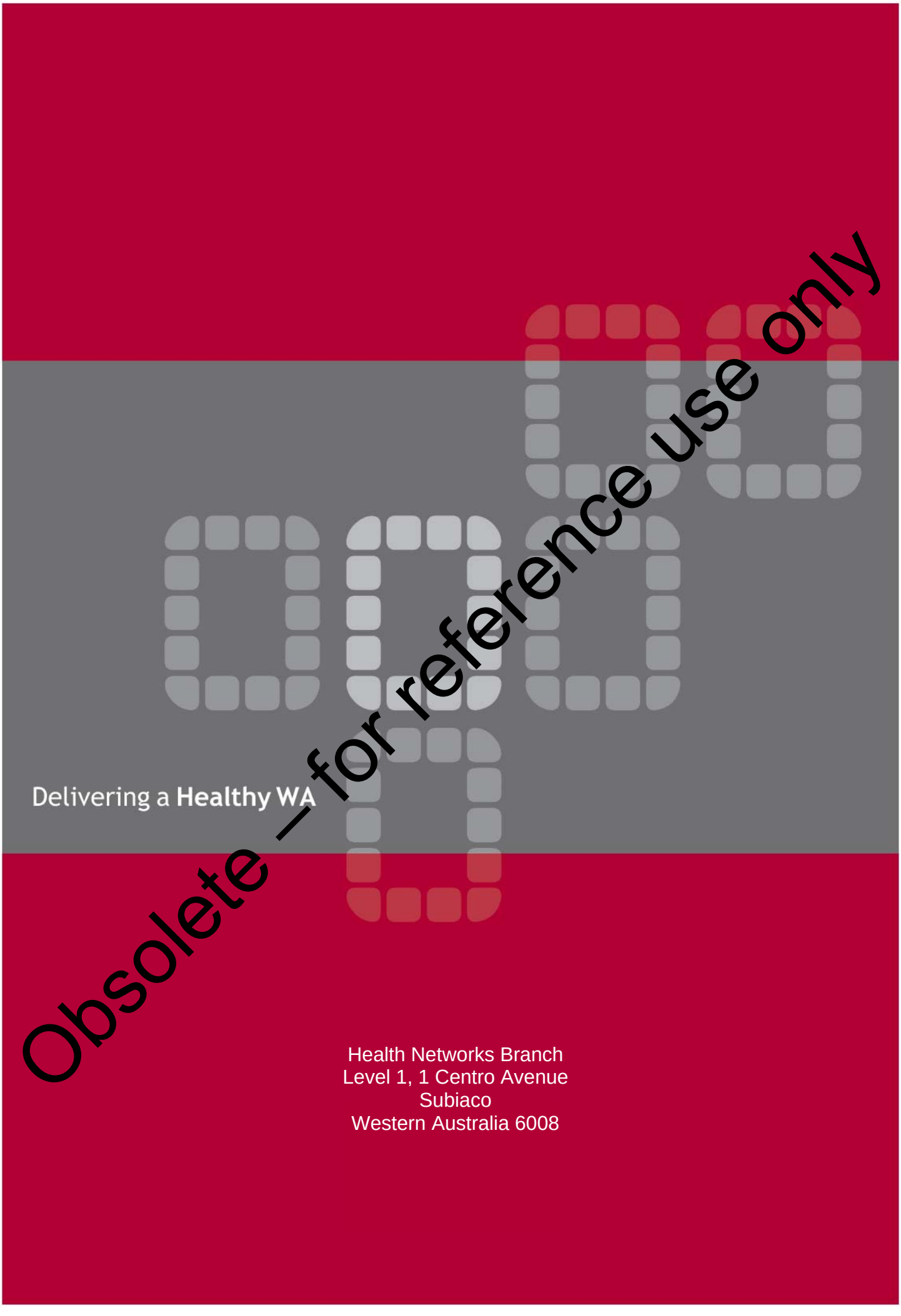
Arthropathy - Any disease of the joints. Usually presents as an inflammatory response to the liver disease.

Cryoglobulinemia - increased blood levels of abnormal proteins called cryoglobulins that can inflame blood vessels and thicken blood.

Diabetes mellitus - A condition characterized by Hyperglycaemia resulting from the body's inability to use blood glucose for energy. Where this occurs as a result of another disease it is also known as secondary diabetes.

Porphyria cutanea tarda - Disorder of heme biosynthesis due to a defective liver enzyme (uroporphyrinogen decarboxylase). Symptoms include photosensitivity; hepatic dysfunction; discolored teeth, gums and skin; excessive hair; and psychiatric symptoms that result from porphyrin accumulation in the blood.

Lymphoma - Cancer originating in the lymph nodes, spleen and other lympho-reticular sites.



Health Networks Branch
Level 1, 1 Centro Avenue
Subiaco
Western Australia 6008