CHAPTER SIX

DIAGNOSING HEPATITIS C

The Committee was asked to comment on current diagnostic practices and related policies. While a number of those giving evidence referred to this issue in a general manner, two witnesses spoke in depth on the issue. The Committee has therefore drawn heavily upon the evidence and submissions from these experts: Dr Dominic Dwyer, medical virologist at the Centre for Infectious Diseases and Microbiology Laboratory Service at Westmead Hospital; and Dr William Rawlinson, Associate Professor, University of NSW and Senior Medical Virologist of South Eastern Area Laboratory Services, Virology Division of the Department of Microbiology, Prince of Wales Hospital.

6.1 WHO SHOULD BE TESTED?

Chapter Three identified the population groups most 'at risk' of contracting Hepatitis C. These are the groups that will be the focus of testing. The NHMRC report identifies those groups of people that should be offered testing by a clinician if HCV is suspected or a patient requests it including:

- people who have ever injected drugs;
- people who have been transfused with blood or blood products;
- people with abnormal liver function tests or evidence of liver disease, with no other apparent cause;
- people with occupational exposure to HCV such as needlestick injuries;
- people with certain unexplained extrahepatic conditions; and
- people who have been in prison (NHMRC, 1997:29).

The NHMRC also recommended the following groups of people may be at increased risk of HCV infection, and testing can be considered:

- people with tattoos or other body piercing (including acupuncture), where standard infection control guidelines may not have been followed;
- household contacts who share a razor or toothbrush with a HCV infected person;
- people born overseas, especially in Mediterranean countries, Middle East, South -East Asia, Africa, South America and other developing nations;
- children of people infected with HCV;
- sexual contacts of people infected with HCV (overall risk is low);

- health care workers and others in contact with blood;
- renal dialysis patients;
- people who have practised unsafe sex with multiple partners (the risk here is uncertain, but overall low); and
- people who specifically request a test - some people who have no specific admitted risk factors for HCV infection may request a test. They may have hidden risk factors and their request normally should be granted (NHMRC, 1997:29-30).

6.2 TESTING FOR HEPATITIS C

Farrell informed Committee Members that:

> *an important part of diagnostic management in some patients with Hepatitis C is the provision of specialised diagnostic tests. These include, amongst others, PCR to detect the virus directly, genotyping and quantification of HCV. The latter are expensive tests but are useful in planning interferon treatment* (Farrell submission)*.*

Diagnostic tests for Hepatitis C can be divided into two categories:

- serological assays that detect the antibody to Hepatitis C (anti-HCV); and
- molecular assays that detect, quantify and/or characterise HCV RNA genomes within an infected patient (Gretch, 1997:43S).

The following discussion will identify the various diagnostic tests available and current shortcomings in the delivery of diagnostic services.

6.2.1 ANTIBODY TESTS

A person is considered to be infected if HCV antibody positive. Antibodies are usually detected four to six weeks after the initial infection. Seroconversion after initial infection (ie becoming antibody positive) can take some time with the 'window period' ranging from 2 to 26 weeks (mean 10 weeks) after infection. This period of time can be very significant in some groups such as injecting drug users.

Serological assays can be subdivided into screening tests for anti-HCV such as the enzyme immunoassay (EIA) and supplemental tests such as the recombinant immunoblot assay (RIBA).

Three generations of anti-HCV tests have been developed and each generation has resulted in an improvement in the sensitivity of detecting anti-HCV. The first generation tests were not particularly sensitive as Batey informed the Committee:

> *we were struggling in the early days with tests which gave us a fifty percent false positive rate, so people were not game to make radical statements knowing that half the patients who thought they had Hepatitis C may not have had Hepatitis C . . .* (Batey evidence, 27 October 1997).

Second and third generation tests have now been developed and the assays currently available are more sensitive and more specific than tests used before 1993. The second generation tests are at least 90 to 95 per cent specific and sensitive. The NHMRC considers these tests to be "reasonably accurate" (NHMRC, 1997:30). Problems still occur though. False negative (ie somebody is infected with HCV but has a negative antibody test) results occur occasionally (NHMRC, 1997:30) or according to Rawlinson, in a "small number" of cases (Rawlinson submission).

The main screening assay for detecting anti-HCV is the enzyme immunoassay (EIA). The EIA has many advantages in the diagnostic setting, including ease of use, low variability, ease of automation and relatively low expense (Gretch, 1997:43-44S). Rawlinson summarised this test as:

> *a well established technology which, with the use of newer second and third generation tests, delivers rapid, reproducible results* (Rawlinson submission).

The rate of false negative results of the anti-HCV tests has created a need for supplemental or confirmatory tests. The recombinant immunoblot assay (RIBA), for example, was developed to aid in the diagnostic evaluation of seemingly healthy individuals who test positive in the anti-HCV screening assay (Gretch, 1997:43S). Immunoblots are a more sophisticated test than the anti-HCV test. They are more labour intensive and therefore more expensive (Rawlinson submission).

As Table Twenty-One shows, both EIA and RIBA tests are relatively inexpensive and are useful for screening populations for previous infection with HCV. They do not distinguish between recent and past infection.

In commenting on the number of tests performed by his laboratories at Westmead, Dwyer told the Committee that:

> *We do about twelve and fifteen thousand hepatitis tests a year. In the first six months of 1997 we have done about ten thousand. It is difficult to predict what would happen but our testing numbers increase generally year by year, and given the increasing publicity, the increasing availability*

of treatment, I would expect to continue to see more every year. I could not predict how many it would be but we will certainly see more every year (Dwyer evidence, 10 October 1997).

TABLE TWENTY-ONE
TESTS AVAILABLE FOR DIAGNOSING AND ASSESSING HCV INFECTION

TEST	FEATURES	APPROXIMATE TOTAL COST ($AUS)
Antibody Detection: HCV antibody	Now use 2nd and 3rd generation tests Only detects past infection Many different commercial assays Assays based on genotype 1 currently will be positive in uninfected and infected neonates or infected mothers (EIA enzyme immunoassay)	$12.00
HCV immunoblot	Confirmatory assay More time consuming than anti-HCV test Fewer suppliers	$50.00
Antigen Detection: HCV-PCR	Commercial assay usually Problems with contamination Qualitative assay	$70.00
HCV-bDNA	Commercial assay only Qualitative assay	$70.00
HCV genotyping	Done using line probe assay Problems distinguishing some subtypes In-house assays using single stranded conformational polymorphism In-house PCR followed by DNA sequencing	$135.00 - $150.00 $50.00 $50.00
HCV serotyping	Murex kit detects genotypes 1-6. Does not detect types 6-11 as well as some genotyping	$135.00 - $150.00
HCV quantification	Viral load measures used as a surrogate for response to therapy	$150.00

Source: Rawlinson submission

In terms of the adequacy of these tests, Dr Dwyer informed the Committee that:

> *the performance of Hepatitis C antibody testing in most major laboratories is just fine. Most major laboratories, now that the antibody tests have improved in quality over the last few years . . . perform these tests very well . . . I think things are adequate* (Dwyer evidence, 10 October 1997).

6.2.2 ANTIGEN DETECTION

Molecular assays have been designed to confirm indeterminate antibody results, aid in management of therapeutic trials, make diagnoses before seroconversion, or as a surrogate measure of infectivity. The primary assay is a polymerase chain reaction (PCR) test, a highly sensitive test of the genetic material of the virus, that detects the virus rather than the antibody to the virus.

There are three types of PCR test:

i. HCV PCR viral detection test which looks for the virus. It can be called a 'qualitative' test;

ii. the HCV PCR viral load test looks for the virus and estimates the number of HCV viruses per ml of blood. It may be called a 'quantitative' test; and

iii. HCV PCR genotype test which looks for the virus and determines the particular subtype(s) present (Hepatitis C Council, 1998:2).

The development of polymerase chain reaction methods for detecting Hepatitis C RNA has provided a potential means of assessing infected people in terms of their infectiousness: a person is considered to be infected and infectious if HCV antibody and HCV PCR positive; a person is considered to be infected but not infectious if HCV antibody positive and HCV PCR negative. The risk of transmission from people who are positive for Hepatitis C but have negative results by PCR is considered by Dore, Kaldor and McCaughan (1997:333) to be "extremely low".

The sensitivity and specificity of PCR testing has improved over time. However false-positive and false-negative test results are possible (NHMRC, 1997:30).

The NHMRC proposes that the following are possible clinical applications for PCR testing for HCV RNA:

- assessment of in determinant EIA results;
- early detection of acute Hepatitis C;
- assessment of response to interferon therapy;

- study of transmission (as a research tool);
- investigation of immunocompromised patients whose antibody levels may be low or undetectable;
- determination of chronic infection status;
- determination of infectiousness (as a marker); and
- testing of anti-HCV-positive sources in cases of occupational exposure to assist in determination of transmission risk (NHMRC, 1997:30).

A rebate is available under the Medicare Benefits Schedule for the basic PCR HCV viral detection test, as opposed to the other two that detect viral load or genotype. Medicare covered PCR tests are available only in limited situations including:

- people who have had a positive HCV antibody test and who have normal liver function test results on two occasions six months apart, or
- people who have inconclusive HCV antibody test results, or
- people who have weakened immune systems (such as HIV/AIDS) and want to confirm whether they are Hepatitis C positive or not; or
- people who have experienced a risk exposure (such as a needlestick injury) and want to confirm during the 'window period' whether they have contracted HCV (Hepatitis C Council, 1998:1).

By comparison, ANCARD advised that PCR testing and viral load testing have become "routine" for HIV/AIDS populations (ANCARD submission). Such differences prompted ANCARD to conclude that diagnostic approaches to Hepatitis C are "a little confused" (ANCARD submission).

Further detail of each of these three tests is provided below.

- **Qualitative Tests for HCV RNA**

PCR viral detection tests are mainly used as a confirmatory test when an HCV antibody test is inconclusive. They are also used to check within the six month 'window period' following a risk incident (when antibody tests are unreliable), if a person has contracted HCV. The test can also be used to determine potential infectivity in the event of consistently normal liver function tests (Hepatitis C Council, 1998:2).

- **Quantitative Tests for HCV RNA**

Measuring the level of circulating HCV RNA in serum or plasma specimens represents a potentially important tool for assessing and managing HCV infection, particularly those patients on interferon therapy. The level of circulating HCV RNA in a patient's plasma or serum is referred to as the viral load and is presumably a reflection of both the rate of viral replication and the rate of viral clearance by the infected host.

During interferon therapy, this test can monitor whether the therapy is working effectively or not. Initial PCR viral load testing as early as two to four weeks into treatment will identify people who wouldn't respond over the full 12 month period (Hepatitis C Council, 1998:2).

In addition to the quantitative PCR test, signal amplification technologies, such as branched DNA (bDNA) assay, have been developed to assess HCV RNA levels (Gretch, 1997:44S). The bDNA assay is less sensitive than PCR at detecting the HCV virus, but it is less prone to contamination than PCR.

- **HCV Genotype Testing**

Tests to determine HCV genotype fall into two general categories: screening tests that detect point mutations within the HCV genome; and confirmatory tests that evaluate larger segments of HCV genes (Gretch, 1997:44S). HCV can also be subclassified based on the antigenic reactivity to viral proteins. HCV serotyping assays involve reacting a patient's antisera with recombinant antigen in an immunoblot format. The potential advantages of HCV serotyping tests are low cost and ease of testing compared with molecular genotyping assays (Gretch, 1997:44S).

Genotyping using the Line probe assay (LiPA) or PCR and DNA sequencing is essential for HCV diagnosis and therapy. As has been discussed in Section 2.1.5 different genotypes respond differently to interferon therapy. Therefore

> *if no genotyping were done before commencing individuals on interferon therapy, at least half of them would respond poorly because they carry genotype 1* (Rawlinson submission).

When asked to comment on the adequacy of diagnostic services of the more refined tests Dr Dwyer informed that Committee that:

> *the more refined services, PCR, genotyping for Hepatitis C, I think the services are not adequate because they are not funded. For example, most of the genotyping that we would have done at our hospital, and a lot of PCR is actually being done in the context of drug trials . . . Apart from that there has been virtually no real funding . . .* (Dwyer evidence, 10 October 1997).

Dwyer elaborated further:

> *One reason why we have had to keep a very tight grip on how many tests we actually allow doctors to order is because we cannot fund it. I think what will happen is that there will be an increased drive from doctors and from patients probably to ask for these more specialised tests and if they are not funded there would be no way we could provide the service. Take genotype for Hepatitis C, which I think will turn out to be a very important test, possibly even more important than the PCR. There is no funding for that now . . . There will be more demand for it because people will say "I need to know what my genotype of Hepatitis C is" and there will be more demand for us to do it . . .*(Dwyer evidence, 10 October 1997).

Given this current funding situation, Dwyer concluded that:

> *I think from that point of view it is quite inadequate and I think it will become more so unfortunately* (Dwyer evidence, 10 October 1997).

The issue of funding for diagnostic tests will be considered in the following section.

In summary, EIA for anti-HCV is the most practical screening test for the diagnosis of Hepatitis C infection. The need for, and the choice of, confirmatory tests depends on the clinical setting as is suggested in Table Twenty-two. As that table shows, and as will be discussed in Chapters Seven and Eight, the response to treatment should include documentation of viral clearance by qualitative PCR assay.

TABLE TWENTY-TWO
DIAGNOSTIC EVALUATION OF HEPATITIS C

	RIBA	QUAL[1] PCR	QUANT[2] PCR	bDNA	HCV GENOTYPE
Confirmation of diagnosis	+	+	±	-	-
Assessment of severity of liver disease	-	-	-	-	-
Evaluation for treatment	-	-	+	+	-
Determination of response to treatment	-	+	-	-	-
Monitoring progress of liver disease	-	-	-	-	-

1. Qualitative 2. Quantitative

Source: Lok and Gunaratam, 1997:49S

In February 1998 the ANCARD Hepatitis C Clinical and Virological Advisory Panel and the Clinical Trials and Treatment Advisory Committee (CTTAC) met to finalise CTTAC's recommendations on testing requirements in relation to Hepatitis C management and therapy. The Hepatitis C testing protocol developed is reported in Table Twenty-three. The meeting also agreed upon the following points:

- viral load testing (quantification) was required before treatment but not during or after treatment;
- viral load testing will indicate outcome of treatment response;
- genotype testing should be performed to advise therapy;
- genotype testing could be performed to assist counselling; and
- qualitative tests should be performed following therapy (Report of Meeting of the ANCARD Hepatitis C Clinical and Virological Advisory Panel, the Clinical Trials and Treatments Advisory Committee and Invited Participants, February, 1998).

TABLE TWENTY-THREE
PROPOSED HEPATITIS C TESTING PROTOCOL

	FORMS OF TESTING RECOMMENDED
Initial Detection: Anti-HCV+	Qualitative PCR
Therapeutic Intervention:	Quantitative PCR Genotype
• S100 indications	
• Anti-HCV x 2	
• Treatment - 12 weeks of therapy	Qualitative PCR
• End of 12 months of treatment	Qualitative PCR
• 6 months follow up	Qualitative PCR
• 18-24 months follow up	Qualitative PCR

Source: Report of Meeting of the ANCARD Hepatitis C Clinical and Virological Advisory Panel, the Clinical Trials and Treatments Advisory Committee and Invited Participants, Melbourne, 2 February, 1998.

6.3 LABORATORIES

The submission from the Centre for Infectious Diseases and Microbiology Laboratory Service at Westmead Hospital suggested that:

> *given the social and economic impact of Hepatitis C in NSW and Australia, the development of an appropriate laboratory structure, including reference laboratories, is essential. This is required to ensure accurate diagnostic testing, the ability to participate in epidemiologic and applied research and to guide cost effective antiviral therapy* (Centre for Infectious Diseases and Microbiology Laboratory Service submission).

The following discussion outlines the current laboratory structure and inadequacies raised during the course of the Inquiry.

Public hospital and private laboratories currently perform the routine HCV antibody testing using either commercial HCV antibody screening test kits (registered with the Australian Register of Therapeutic Goods) or in-house assays.

The PCR test requires a high degree of technical skill. At the time of giving evidence, NSW Health advised that there were 12 diagnostic laboratories approved to carry out PCR testing for HCV. They include:

- Hunter Area Pathology Service
- NSW Blood Transfusion Service
- South Western Area Pathology Service
- St Vincent's Hospital
- Prince of Wales Hospital
- General Clinical Laboratories
- Royal North Shore Hospital
- St George Hospital
- Concord Hospital
- Westmead Hospital
- Sugarman's Pathology
- Royal Prince Alfred Hospital

(NSW Health, tabled document).

The Committee was advised that the structure of the state's public laboratories has undergone change in the last one to two years. Six major public hospital laboratories in NSW have become "hub" laboratories providing laboratory service not only for their immediate area health service but also specialist laboratory services for smaller public hospitals in both rural and metropolitan areas. The Committee heard, for example, that the ICPMR at Westmead provides laboratory services for the health areas of Far Western, Central West and Central Coast (Dwyer evidence, 10 October 1997). In addition, private laboratories tend to send some of the more expensive assays to these hub laboratories. As a result:

> *both private hospital laboratories and the smaller public laboratories send on difficult work to us [hub laboratories] that we perform at our own expense and this has been a big problem with Hepatitis C* (Dwyer evidence, 10 October 1997).

Dwyer also added that hub laboratories have:

> *to find the sort of income within [the] area health service budget to pay for this [service] which has been a particular problem with Hepatitis C* (Dwyer evidence, 10 October 1997).

6.3.1 REFERENCE LABORATORIES

Access to validation and prognostic testing is fundamental to the successful provision of any HCV related clinical service. Such testing needs to be adequately supervised and subject to quality control. It was suggested to the Committee that an appropriate venue for such testing would be reference laboratories. The submission from the Centre for Infectious Diseases and Microbiology Laboratory Service at Westmead Hospital noted, for example, that:

> *the need for state reference laboratories to undertake confirmatory testing, perform HCV RNA assays using new molecular technology, and the provision of genotyping and other expensive assays cannot be overemphasised.*

The Committee was advised that, currently, hub laboratories are carrying out many of the functions of reference laboratories, but are doing so at their own cost (Dwyer evidence, 10 October 1997).

There is considerable support for the establishment of reference laboratories. The NSW Hepatitis C Taskforce, for example, proposed the establishment of two major reference sites to meet NSW needs (NSW Health, 1995:28). The Taskforce report recommended that:

> *tenders should be called for the establishment of two major reference sites in NSW. Selection should be based on the expertise and experience of the laboratories, the ability to interpret tests and to develop new tests. Reference laboratories should also be allowed to charge referring private laboratories for the costs of validation testing* (NSW Health, 1995:6).

The Taskforce envisaged that, since the reference laboratories would be providing a service to the state as a whole, the resources for this development should be met centrally rather than the hospital's local area health service (NSW Health, 1995:28). In advising the Committee on the implementation of the Taskforce recommendations, NSW Health did not make a comment on these specific recommendations (NSW Health, tabled document). The Committee understands however, that the recommendations have not been implemented. McCaughan told the Committee that he and his colleagues were "very disappointed" that the specific recommendations of the NSW Taskforce were not taken up by the NSW Department of Health (McCaughan evidence, 23 March 1998).

The Taskforce further recommended that the proposed reference laboratories be linked with the National HIV Serology Reference Laboratory in Melbourne and other state reference laboratories (such as the Institute of Medical and Veterinary Science, Adelaide; State Health Laboratories, Nedlands, Western Australia and the Victorian Infectious Diseases Reference Laboratory). In responding to this recommendation, NSW Health noted that laboratories authorised to undertake HCV supplemental testing provide data to the National Serological Reference Laboratory for national collation. No comment was made on links to other state reference laboratories (NSW Health, tabled document).

The establishment of reference laboratories was raised during the course of the Inquiry. Dr Dwyer considered the concept of reference laboratories to be "absolutely critical" as "you really need specialised, high tech if you like, laboratory back-up to the routine testing that is done normally" (Dwyer evidence, 10 October 1997). Dwyer called for:

> *a number of laboratories, one or more depending, I am sure you could justify a couple, that provide a reference hospital, or reference laboratory function for everybody else and this reference function helps other laboratories, either public or private, to carry out the more complicated diagnostic testing, or confirmatory testing, or up market molecular testing* (Dwyer evidence, 10 October 1997).

Dr Dwyer elaborated further:

> *with Hepatitis C my feeling would be that you would really only need a couple of reference laboratories in the state at institutions that already are heavily involved in hepatitis patient management and laboratory aspects . . . you would look at say two to three reference laboratories in NSW. Probably the biggest laboratories undertaking Hepatitis C testing in Australia, particularly the back-ups of drug trials and so on would be the ICPMR at Westmead and Prince Alfred Hospital in Central Sydney Area Health Service* (Dwyer evidence, 10 October 1997).

Dr Rawlinson commented that:

> *I think the role of reference laboratories is very important and I think the role of reference laboratories in sorting out Hepatitis C is terms of therapy as well as diagnosis is extremely important and I think that the role of a diagnostic and research laboratory next to each other is also similarly important . . . I actually think that there is a significant role for reference laboratories . . .* (Rawlinson evidence, 27 October 1997).

Rawlinson proposed that:

> *the requirements for doing reference functioning should be attached to a large*

> *teaching hospital, there should be attachment to a university, there should be a large and vigorous virology laboratory and they should have sufficient expertise both in the diagnostic areas as well as within research areas* (Rawlinson evidence, 27 October 1997),

while Dwyer envisaged the reference laboratories coming from the major hub laboratories "already identified" (Dwyer evidence, 10 October 1997).

The submission from the Centre for Infectious Diseases and Microbiology Laboratory Service proposed that participation in state-wide and national quality assurance programs would also be part of state reference laboratory function.

RECOMMENDATION 43:

That the Minister for Health call tenders for the establishment of three major Hepatitis C reference laboratories in NSW. Selection of the laboratories should be based on the expertise and experience of the laboratories, the ability to interpret tests and develop new tests, and their capacity to participate in state-wide and national quality assurance programs. The reference laboratories should be able to conduct validation testing for private laboratories for a fee.

It was suggested to the Committee that funding for reference laboratories should be specific and outside current allocations made to area health services. Dwyer for example suggested that:

> *Reference laboratory function needs to be funded from outside the kind of local area health service budget, which is the way we operate at the moment* (Dwyer evidence, 10 October 1997),

while the Centre for Infectious Diseases and Microbiology Laboratory Service called for "specific funding" for reference laboratories to carry out their functions (Centre for Infectious Diseases and Microbiology Laboratory Service submission).

Funding problems experienced in the past were raised during the course of evidence:

> *for the cost of $3million a year, the [Hepatitis C Taskforce] recommended the funding of diagnostic mini-reference laboratories to do molecular testing in Hepatitis C. I think those laboratories have been funded to the tune of something like $300,000 or $400,000 across the State. The first set of funding, when it was decided, was delivered to health care areas on 30 June of the financial year. Therefore the laboratories that had been doing the testing never saw the funds for that year because they were delivered on 30 June. The following year, 1996-97, the funds were delivered, but the funds for 1997-98 have not been delivered* (McCaughan evidence, 23 March 1998).

Professor McCaughan went on to state that:

> *The last formal discussion of the Hepatitis C Advisory Committee indicated that the funds were unlikely to be delivered for this financial year. So a laboratory such as mine, which gets around $50,000 to $100,000 a year out of that sort of funding, is now already $50,000 to $60,000 over budget because we are doing those tests. The last financial year was okay because the money came in, but we are told that the money is unlikely to come in this year* (McCaughan evidence, 23 March 1998).

It is not anticipated that the establishment of reference laboratories will incur significant expense. It was suggested that:

> *the provision of specialised expensive testing by reference laboratories will minimise expenses, compared to multiple laboratories performing such tests* (Centre for Infectious Diseases and Microbiology Laboratory Service submission).

RECOMMENDATION 44:

That the Minister for Health ensure adequate funding is available to the Hepatitis C reference laboratories proposed in Recommendation 43 and that the funding allocation to the reference laboratories be made from NSW Health funds rather than the local area health services.

6.4 PRE- AND POST-TEST COUNSELLING

Numerous submissions received from those with Hepatitis C described the shock, panic and fear they experienced when they learned they were HCV positive. The Committee heard, for example that:

> *When I was diagnosed with Hepatitis C 12 months ago I felt my life as I knew it and lived it had come to an end. No words can really express the devastation that I felt and still feel when discovering I was positive* (Submission 33);

> *my first reaction was I was going to die. I felt dirty and unclean. I became very afraid of doing things with my children in case I gave it to them* (Submission 7);

and

> *I don't know how to describe those first few minutes/hours to you. I remember feeling lost, alone and very frightened. I really didn't understand what was happening . . . For a long time I felt dirty. I felt/feel violated* (Submission 20).

Others stated that:

> *when I found out I had Hepatitis C I was devastated. I've become anxious and have outbursts of crying and depression* (Submission 23);

and

> *the shame and horror I felt was devastating to the point where the only thing to do was get away from my wife and children and perhaps end my life* (Submission 76).

Counselling is an important component of the management of a patient known or suspected of being infected with HCV. It was suggested by a number of experts that the provision of pre-test counselling may, for many, lessen the trauma that often comes with learning of a positive result. However, the Hepatitis C Council advised that:

> *counselling prior to testing is conducted, if at all, in an ad hoc manner with too few practitioners spending adequate time to provide information and support or to conduct an assessment of the relative risks of HCV infection. Others will conduct testing without ensuring the person has sufficient time or information to understand the implications of a positive test result* (Hepatitis C Council submission).

The NHMRC suggests that counselling should be a "deliberate process" with three general outcomes:

i. to provide psychosocial support;

ii. to prevent the transmission of HCV; and

iii. to optimise treatment outcomes (NHMRC, 1997:64).

The NHMRC document on managing Hepatitis C (1997) provides some guidance for GPs on pre- and post-test counselling. The Council recommends that pre-test counselling needs to be tailored to the individual patient and should be conducted in private with sufficient time to enable discussion of the issues (NHMRC, 1997:65). According to the NHMRC, the aims of pre-test counselling are:

- to assess the risk factors;
- to provide information on clinical signs and symptoms which lead the practitioner to suspect Hepatitis C;
- to enable the patient to make a decision whether or not to have the test;

- to provide information about the test and possible consequences of testing, including notification and confidentiality of results;
- to provide information on testing benefits;
- to establish the ability to give informed consent for the test; and
- to identify support available to the patient (NHMRC, 1997:65).

The following information should be considered for inclusion in pre-test counselling;

- brief information about the history of the virus and an explanation that it was not able to be identified until 1990;
- routes of transmission of HCV and strategies to prevent transmission;
- the test and its limitations;
- the meaning of a positive, negative or equivocal test result;
- advice that HCV infection generally has an indolent course and that if the test is positive, monitoring may be the only action that is required;
- availability of treatment with interferon for some patients who have active infection;
- likelihood of successful treatment with interferon;
- investigations are continuing into other treatments including a Chinese herbal preparation;
- the impact that different cultural beliefs and practices may have should be recognised, and explored at this time;
- the implications of a positive test result for life assurance;
- issues of confidentiality, in particular a clear and full explanation of the legal requirements for reporting of a positive test result which may vary from one state or territory to another; and
- the prognosis (NHMRC, 1997:65).

The Council also recommends that a brief psychosocial assessment would provide the treating practitioner with some understanding of how the person will react to the knowledge of his/her HCV status (NHMRC, 1997:65).

The NHMRC recommend that the results of an HCV test should "always" be given to the patient in person no matter what the reason for the test or whether the result is positive or negative (NHMRC, 1997:65). However, the Committee has heard that test results are given in a number of ways including phone calls made to people while at work or letters sent through the post. There does not appear to be any set criteria to guide health care workers in imparting test results.

In addition to pre-test counselling, calls have been made for post-test counselling. The aims of counselling at this time are to ensure that the patient understands the meaning and implications of the test results and that appropriate referrals and psychosocial interventions are provided if required (NHMRC, 1997:65). As the NHMRC note, these implications differ with the test outcome. If the test is positive or equivocal, the person given the test result has the professional responsibility to provide or arrange for immediate counselling and support. With a negative test result, counselling should provide information to prevent exposure to HCV (NHMRC, 1997:66)

The Hepatitis C Council proposed that pre- and post- test counselling should be a routine practice. It noted that pre- and post-test counselling is "recommended" as part of good practice around testing for HCV. The Council however proposes that this practice could be ensured through the development and implementation of policy guidelines for practitioners. The Council anticipates that:

> *the development and implementation of a policy on testing, which includes confidentiality provisions, could increase the uptake of testing and ensure the legal rights and obligations of practitioners and persons with HCV* (Hepatitis C Council submission).

The ACT Sexual Health and Blood Borne Diseases Strategic Plan (1998) proposes legislating pre- and post-test counselling requirements for HCV. While the Committee fully supports policy guidelines for pre- and post-test counselling, it does not consider the ACT's proposal to be necessary.

RECOMMENDATION 45:

That NSW Health recognise the provision of pre- and post-test information and counselling by health care professionals provides best practice patient management in relation to testing for Hepatitis C. The Committee further recommends that the Ministerial Advisory Committee on Hepatitis C proposed in Recommendation 27 develop a set of policy guidelines for pre-and post-testing for Hepatitis C for health practitioners in NSW and that these guidelines ensure pre- and post test counselling are a routine practice for all people considering HCV testing.

6.5 DIAGNOSIS OF PRISON INMATES

A policy directive (CHS:CMED39) for voluntary blood borne communicable diseases screening program, which tests for HIV, Hepatitis B and C and syphilis, was introduced into the state's correctional system in early 1995. Prior to that time (from 1990 to 1994), screening was not voluntary. During the 1990 - 1994 period:

> *inmates would come in, be told to sit down and stick their arm out and that was it. There was no negotiation on having a blood test done* (Harper evidence, 23 March 1998).

The Committee heard that:

> *the problem with the compulsory system is that, for expediency and efficiency it needs to be done - and was done - as part of the reception and exit process . . . They come in withdrawing, detoxing and have other priorities on their mind rather than consenting and taking in what is being said about the inherent risks in prison for blood borne communicable diseases; tattooing, sharing injecting equipment, sharing razors and those types of things . . . from an educational point of view it was not an opportune time and that was the major reason we changed it from that first-day reception process to the following days when those persons have had time to see the other health professionals and have their immediate needs addressed* (Christensen evidence, 23 March 1998).

Vumbacca informed Committee Members that the compulsory system for HIV testing:

> *created a lot of problems in the system. When people refuse to be tested a number of civil and human rights issues are raised. Under HIV, for instance, we used to get calls from various gaols saying "we have someone here who is refusing to be tested for HIV". The law under the Prisons Act states that they are to be tested, so it gets down to whether you punish that person for refusing to give a blood sample, hold them down physically to take the blood and all those sorts of issues* (Vumbaca evidence, 23 March 1998).

The current Corrections Health Service policy is that:

1. *all new receptions (without exception) receive education, information, harm minimisation strategies and an individual risk assessment relating to communicable diseases.*

   Each new reception is to be offered screening/testing for HIV, Hep B, Hep C and syphilis.

   *Prior to testing pre-test counselling **must** be attended to facilitate informed consent being obtained . . .*

2. *All inmates who identify engaging in at risk activities or behaviours should be offered screening, education and counselling on a three month basis (unless otherwise specified by a Medical Officer)*

3. *All inmates are to receive the results of screening performed by Corrections Health Service. Post-test counselling, education and reinforcement of harm minimisation strategies are to be given with the test results* (Corrective Health Services, undated).

The current voluntary program is, according to witnesses, "a lot harder" than the previous system because:

> *in the pre-test counselling we have to convince them, particularly if they engage in at-risk behaviour, that it is in their best interests to have the testing done and allow us to run with that and sort that out* (Harper evidence, 23 March 1998).

Under the current voluntary screening program,

> *Not everyone knows they are Hepatitis C positive, so we stand proud of the fact that we diagnose a lot of people in prison. The number of people we inform on their entry to gaol is amazing* (Harper evidence, 23 March 1998).

As the policy states, pre- and post-testing counselling are required (Christensen evidence, 23 March 1998):

> *we spent a significant amount of time putting in a pre-test and post-test counselling procedure to prepare inmates for diagnosis, to look at risks and to provide more health education and information than the former compulsory HIV screening program* (Christensen evidence, 23 March 1998).

The Committee was advised that the benchmark for screening is 60 per cent (Christensen evidence, 23 March 1998). However, as Christensen advised, "we never quite reached that point for a number of reasons" (Christensen evidence, 23 March 1998) and Lloyd suggested only that approximately 30 per cent of new inmates choose to be screened (Lloyd evidence, 30 March 1998).

Professor Lloyd considers the current voluntary screening program to be a "good system" (Lloyd evidence, 30 March 1998).

6.5.1 Compulsory Hepatitis C Screening?

Butler's study referred to in Section 3.2 found that 35% of inmates who tested HCV+ told the researchers that they were negative. These inmates didn't know their HCV status (Butler evidence, 23 March 1998) leading Butler to conclude that:

> *I think there is a big pool of people who do not know their hepatitis status, who come into gaol and probably think they are okay. It is that group we need to get inside in some way* (Butler evidence, 23 March 1998).

This statistic, in addition to the small proportion of inmates choosing to undergo Hepatitis C screening led Committee Members to ask those witnesses with experience working in the corrections system if they considered the introduction of compulsory Hepatitis C screening to be an appropriate strategy. There was not much support for the idea. Christensen, for example, said she "would have a problem with a compulsory [Hepatitis C screening] program" (Christiansen evidence, 23 March 1998).

Mr Gino Vumbaca who heads up the Department of Corrective Services's HIV and Health Promotion Unit admitted that, while he could "see the elements that would make it an appropriate strategy" (Evidence, 23 March 1998), he was not however able to give the strategy his full support given the problems that has occurred with compulsory HIV testing.

The Committee accepts the opinion of the experts and therefore does not recommend the introduction of compulsory Hepatitis C screening in the state's correctional system. However, it would like to see the availability of screening promoted widely and inmates strongly encouraged to avail themselves of testing. This issue will be discussed further in Section 8.6 which looks at the development and introduction of a best practice model for the delivery of Hepatitis C treatment and management services to Hepatitis C inmates.

6.6 CONCLUSION

This chapter's discussion has focussed on available testing for the Hepatitis C virus and the laboratory system that supports that testing. In summary the Committee heard that:

> *laboratory testing for HCV is an integral part of any clinical and therapeutic approach to HCV infection. In the short and long term, appropriate testing can save significant money on therapy, can provide the individual with more detailed, accurate knowledge of their likely outcome, with or without treatment, and will provide data for newer treatments, including vaccines* (Rawlinson submission).

Such testing must be backed up with appropriate and adequate pre- and post-test counselling and support irrespective of the test outcomes.

The Chapter also considers the diagnosis of Hepatitis C within the corrections system and, while the Committee was not prepared to support mandatory HCV screening, the Committee strongly supported greater promotion of the current Hepatitis C screening program.