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INFECTED BLOOD INQUIRY

EXHIBIT WITN3939015

The Senate

Community Affairs References Committee

Hepatitis C and the blood supply in Australia

June 2004

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Overview and Recommendations

Hepatitis C is a life changing disease. Infection is often accompanied by serious and debilitating symptoms such as fatigue, lethargy and pain. Some people with hepatitis C clear the virus naturally but this occurs only in a minority of cases. For many, there are uncertain long term health consequences with a number of sufferers developing cirrhosis of the liver, liver failure or even liver cancer. The infection does not only cause serious health problems but can also have a devastating impact on other aspects of the infected person's life, including tension within families, loss of friends, curtailment of social life, restrictions on employment and discrimination.

Infection with hepatitis through blood transfusion was observed during the Second World War. While hepatitis A and hepatitis B were both identified by the early 1970s, the virus causing non-A, non-B hepatitis, as hepatitis C was then known, remained elusive. During the 1980s scientists worked to identify the hepatitis C virus. At the same time debate was occurring world-wide as to the usefulness of surrogate testing of the blood supply. Two tests were suggested, both of which had limitations in identifying blood potentially infected with the hepatitis C virus. These limitations included a high rate of false-positive and false-negative results, markedly different epidemiological contexts between countries which had voluntary blood donors and those which paid donors, and a lack of consensus about the interpretation of test results. As a result, much controversy surrounded the debate on whether or not surrogate testing should be introduced.

The Australian Blood Transfusion Services, with the exception of the Queensland Service, chose not to introduce surrogate testing. The Committee is confident that due consideration was given to pertinent evidence at relevant times, and that decisions taken were reasonable in the circumstances.

It was not until 1988 that the virus was identified. The first specific test for hepatitis C became available in early 1990 and testing was immediately implemented in Australia.

The Committee considers that the most effective means of assisting people infected with hepatitis C through blood transfusion are improvements in services, including wider access to antiviral drugs and financial assistance for costs not covered through existing services. The Committee has recommended the establishment of a national post-transfusion hepatitis C committee. The proposed committee's membership would include representatives from government, the Australian Red Cross Blood Service, hepatitis C support groups and individuals who have acquired hepatitis C through the blood supply. The proposed committee should establish and manage a fund for additional services. Both the proposed committee and the fund should be funded by the Commonwealth and State and Territory Governments. The Committee has also recommended a broad public education campaign to increase public knowledge of hepatitis C. The Committee also considers that recombinant Factors VIII and IX should be available to haemophiliacs.

Over the last decade, major changes in the organisation of the blood service in Australia have occurred. The establishment of the National Blood Authority and the Australian Red Cross Blood Service have led to improvements in the management, safety and co-ordination of the blood supply. The Committee considers that the introduction of a national haemovigilance system would further improve safety of the blood supply.

Recommendation 1

6.21 That the Australian Health Ministers' Advisory Council consider the introduction of mandatory reporting to the Australian Red Cross Blood Service by State and Territory health authorities of instances where a person is diagnosed with hepatitis C and it is judged that the infection was contracted through the blood supply.

Recommendation 2

6.28 That, in order to ensure the safety of patients and continued confidence in the blood supply, the Australian Council for Safety and Quality in Health Care and the National Blood Authority implement, as a matter of priority, a national haemovigilance system.

Recommendation 3

6.66 That the Commonwealth review the criteria access to S100 drugs for those people suffering from hepatitis C to provide for greater access.

Recommendation 4

6.102 That the recommendations relating to the use of recombinant Factor VIII and Factor IX contained in the Report of the Working Party on the Supply and Use of Factor VIII and Factor IX in Australia be implemented as a matter of priority.

Recommendation 5

6.109 That the Commonwealth fund a national hepatitis C awareness campaign to increase the public's knowledge of hepatitis C and that such a campaign emphasise all the means by which the infection may be acquired and the need for early testing and treatment.

Recommendation 6

6.134 That a national post-transfusion hepatitis C committee be established as a priority with the purpose of:

- formulating, coordinating and delivering an apology to those who have acquired hepatitis C through the blood supply;
- establishing an effective Lookback program; and
- improving service delivery through a case management approach that ensures that appropriate medical, counselling and welfare services are

provided, sensitive to the needs of people who have acquired hepatitis C through blood and blood products.

That membership of the committee include representatives of the Commonwealth, State and Territory Governments, the Australian Red Cross Blood Service, representatives of organisations which support people with hepatitis C acquired through the blood supply and individuals who have acquired hepatitis C through the blood supply.

That the committee establish and manage a fund to provide financial assistance for costs not covered through existing services, which could include the costs of visits and transport to general practitioners, prescribed medication and surgical aids, dental, aural, optical, physiotherapy and chiropody treatments, home care and/or home help, and alternative medical treatments, to the people who have acquired hepatitis C through blood and blood products.

That the committee, and the fund it establishes, be jointly funded by the Commonwealth and State and Territory Governments.

CHAPTER 1

INTRODUCTION

Terms of reference

1.1 On 19 August 2003 the Senate referred the following matters to the Committee for inquiry and report:

(a) the history of post-transfusion Hepatitis in Australia, including when Non-A, Non-B Hepatitis (Hepatitis C) was first identified as a risk to the safety of blood supplies in Australia and internationally;

(b) the understanding of Hepatitis C by blood bankers, virologists, and liver specialists during the past 3 decades, including when Hepatitis C was first identified as a virus transmissible through blood;

(c) when the first cases of post-transfusion Hepatitis C were recorded in Australia;

(d) when the Australian Red Cross and the plasma fractionator Commonwealth Serum Laboratories first become aware of infections from blood contaminated by Hepatitis C, and the actions taken by those organisations in response to those infections;

(e) the process leading to the decision by the Australian Red Cross not to implement testing (such as surrogate testing) for Hepatitis C once it became available;

(f) the likelihood that Hepatitis C infections could have been prevented by the earlier implementation of surrogate testing and donor deferral;

(g) the implications for Australia of the world's most extensive blood inquiry, Canada's Royal Commission (the Krever Report);

(h) the implications for Australia of the recent criminal charges against the Canadian Red Cross for not implementing surrogate testing for Hepatitis C in the 1980s;

(i) the Commonwealth's involvement in the provision of compensation to victims of transfused Hepatitis C, including the use of confidentiality clauses in those compensation payments;

(j) the high infection rate of Hepatitis C for people suffering from haemophilia;

(k) the extent to which Australia has been self-sufficient in blood stocks in the past 3 decades;

(l) the importation of foreign-sourced blood plasma for use in the manufacture of blood products, and its potential role in the proliferation of Hepatitis C infected blood;

(m) the number of Australians who have been infected with Hepatitis C through blood transfusion;

(n) the impact that blood-transfused Hepatitis C has had on its victims and their families; and

(o) what services can be provided or remedies made available to improve outcomes for people adversely affected by transfused Hepatitis C.

1.2 The Committee was to report to the Senate by the first sitting day of the 2004 winter session. This was subsequently extended to 17 June 2004.

Conduct of the inquiry

1.3 The inquiry was advertised in *The Australian* and through the Internet. The Committee also wrote to interested individuals and groups inviting submissions. The Committee received submissions from the Commonwealth, organisations and individuals. In total, 93 public submissions and 60 confidential submissions were received. The majority of these submissions were from individuals outlining their personal story on the circumstances of contracting hepatitis C and the impact it has on their lives and that of their families. A list of individuals and organisations who made public submissions is at Appendix 1.

1.4 The Committee heard evidence in Canberra, Melbourne and Sydney (two days). In organising its hearing program, the Committee endeavoured to hear from the major organisations which made submissions to the inquiry, including all the groups who represent or support the individuals who have contracted hepatitis C through blood transfusions. A number of these individuals also gave personal testimonies about living with hepatitis C as part of their daily life. The list of witnesses who appeared at the public hearings is at Appendix 2.

1.5 The Committee also visited the Australian Red Cross Blood Service facilities at Garran, ACT, to examine the process of blood collection, screening, processing and distribution. The Committee appreciated the opportunity to talk to staff and gained a valuable insight into the operation of the Service.

1.6 In Sydney on 27 May 2004, members of the Committee, at the invitation of the Australian Red Cross Blood Service, attended as observers a meeting chaired by Sir Laurence Street. The meeting involved representatives of the Australian Red Cross Blood Service and stakeholder organisations, many of whom had appeared before the Committee to speak on behalf of those affected with hepatitis C. The outcome of the meeting is discussed in Chapter 6.

Background to the inquiry

1.7 Throughout the 1980s and 1990s, there were a growing number of concerns about the challenges facing the supply of blood and blood products both here in Australia and overseas. The transmission of HIV/AIDS and hepatitis C through the blood supply had raised issues about the adequacy of arrangements to ensure the

safety of the blood supply. Community expectations were also rising as was demand for products.

1.8 Three major reviews of aspects of the blood system were conducted in Australia:

- *Commonwealth Review of Australian Blood and Blood Product System,* (McKay and Wells Review), 1995.[1] The review examined consultative mechanisms, coordination and management at the national level, the role of the Australian Red Cross in blood banking and the impact of pricing signals and charging on the supply and demand in blood and blood products.
- *Review of the Australian Blood Banking and Plasma Product Sector* (Stephen Review), 2001.[2] The review examined the blood banking and plasma product sector and made recommendations aimed at ensuring Australia was equipped to meet emerging and future challenges, to provide an adequate and secure supply of safe, high quality blood and blood products and to promote appropriate clinical use. Recommendations included the establishment of the National Blood Authority, strengthening governance and financing arrangements, quality assurance in supply and use, and ongoing monitoring and review.
- *Report of the Expert Advisory Group on Hepatitis C and Plasma in 1990* (Barraclough Report), 2003.[3] The Expert Advisory Group was appointed to examine claims that plasma positive to hepatitis C antibody was used in the manufacture of plasma products for several months in 1990. The Expert Advisory Group found that the blood system was fragmented and there was limited capacity to provide integrated governance and management. However, evidence was not found to establish a connection between the claims investigated and an incident of hepatitis C infection in a recipient of fractionated plasma products. The Expert Advisory Group supported the establishment of the National Blood Authority.

1.9 During this time, the impact of hepatitis C was also being recognised. In 1998, the NSW Legislative Council Standing Committee on Social Issues tabled its report, *Hepatitis C: The Forgotten Epidemic.*[4] The Committee reported on the social and economic impact of hepatitis C, the extent of the disease, the adequacy of policies and

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1 McKay B & Wells R, *Commonwealth Review of Australian Blood and Blood Product System: Final Report*, Department of Health and Human Services, Canberra, 1995.

2 Stephen, Sir N, *Review of the Australian Blood Banking and Plasma Product Sector*, Department of Health and Aged Care, Canberra, 2001.

3 *Report of the Expert Advisory Group on Hepatitis C and Plasma in 1990*, Department of Health and Ageing, Canberra, 2003.

4 Parliament of NSW, Legislative Council Standing Committee on Social Issues, *Hepatitis C: The Forgotten Epidemic Inquiry into Hepatitis C in NSW,* Report No 16, Parliament of NSW, Sydney, 1998.

treatment services, those at increased risk of infection, the risks involved for health care workers and the adequacy of policies and procedures on occupational health and safety.

1.10 Over the last year, Senator Steve Hutchins has, in the Senate and through a series of questions on notice, raised issues relating to the transmission of hepatitis C through blood and blood products.[5]

Governance and blood banking in Australia[6]

1.11 Blood banking in Australia derived from the need to supplement blood and its components following natural deficiency or traumatic blood loss. Broadly, the components of the system currently comprise:

- the volunteer donors;
- the Australian Red Cross, and its operating division, the Australian Red Cross Blood Service (ARCBS);
- CSL Limited, the national blood fractionator and public company; and
- the Commonwealth, State and Territory Governments, which jointly fund and govern the sector.[7]

1.12 The Australian Red Cross has been involved in blood transfusion services since 1929 when the first service was established in Victoria. Similar services were then developed in all States. The Red Cross Division in each State and Territory established and maintained a Blood Transfusion Service (BTS). This reflected the federal system of governance of Australia and the organisation and funding of public health services. Each State or Territory BTS was responsible for the collection, processing, screening and distribution of blood and blood products in their respective geographic areas. Throughout the 1980s and 1990s, there were also other blood banks operating under the jurisdiction of State Departments of Health.[8] For example, the NSW Department of Health hospital system ran 28 country blood banks.[9]

1.13 The Commonwealth's role in the blood service was limited to a contribution to State and Territory Governments of some of the funding for the operation of blood services. The Department of Health and Ageing (DoHA) commented that regulation

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5 Senate, *Hansard*, Question No. 1352, 15.5.03, p.11099; Question No. 1781, 18.9.03, p.15651, 26.1.03, p.18140; Question No. 2003, 24.11.03, pp.17616-17; Question No. 2004, 10.2.04, p.19742; Question No. 2005, 7.11.03, p.17463.

6 Information in this section is drawn largely from the Stephen Review and Barraclough Report.

7 Summarised in the Stephen Review, p.8.

8 *Submission* 64, p.16 (ARCBS).

9 Barraclough Report, p.24; *Submission* 54, Supplementary Submission, 21.5.04, p.4 (DoHA).

of blood services was fragmented, with much of it in the hands of State and Territory Governments.[10]

1.14 At the national level, until the formation of a national blood system, a committee structure was responsible for considering issues relating to safety and the blood supply. Decisions relating to national policy in relation to blood transfusion were coordinated at regular meetings of the Blood Transfusion Service Executive Sub-committee, National Blood Transfusion Committee (NBTC) and the Fractionation Liaison Advisory Group.[11] The Blood Transfusion Service Executive Sub-committee existed with membership including all the directors of the State blood transfusion services, the Medical Chairman of the NBTC (see below), the Medical Director of the Australian Red Cross Society (ARCS), two representatives from the Commonwealth Serum Laboratories, and a representative from the Commonwealth Department of Health and Community Services.

The National Blood Transfusion Committee

1.15 The National Blood Transfusion Committee (NBTC) was formed in 1941 and managed by the Australian Red Cross Society. Membership of the NBTC included representatives from the Red Cross; the directors of the divisional blood transfusion services; two representatives of the Commonwealth Serum Laboratories, including either the managing director or acting managing director; a representative of the Australian Department of Community Services and Health; and the Surgeon General or his nominee (from the Department of Defence). Commonwealth officers regularly attended committee meetings and on a least one occasion, representatives from the NSW Department of Health attended.[12]

1.16 The NBTC's duties included:

- responsibility to the Executive of the Australian Red Cross Society for national projects;
- submission of an annual report to the Executive of the ARCS;
- responsibility for relationships with relevant Departments of the Australian Government; matters of mutual concern to the Society and Commonwealth Serum Laboratories; international blood transfusion matters; and other activities of national concern. The constitution lists 'quality control and standards' as one activity of national concern; and
- review of the operations of the blood transfusion services throughout the society and to advise the council on all matters of policy.

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10 *Submission* 54, p.2 (DoHA). Note: the Commonwealth had responsibility for the ACT prior to self government in 1989.

11 *Submission* 64, p.16 (ARCBS).

12 Barraclough Report, p.24.

1.17 The deliberations of the NBTC and BTS Executive Sub-committee were reported to divisional blood transfusion service committees by individual directors. The divisional committees, who were responsible for the safety of the blood supply within the State or Territory, made final decisions.

1.18 The Barraclough Report stated that the divisional units had autonomy. However, they were influenced by their respective State and Territory health departments. Thus while NBTC and BTS Executive Sub-committees approved policy, it was entirely up to Red Cross Society divisions in the States and Territories, as to whether the policy was implemented.

1.19 DoHA commented that the NBTC 'had no power to impose its policy decisions on the various transfusion services, which sometimes followed their own preferences'.[13]

1.20 Following the 1995 review of the Australian blood and blood product system, steps were taken to establish a national blood service. In 1996, the blood services of the States and Territories united to form a national blood service, the Australian Red Cross Blood Service (ARCBS). The ARCBS was established as the operating division of the Australian Red Cross. With the advent of ARCBS, the NBTC ceased operations.

1.21 The commencement of the *Therapeutic Goods Act 1989* in 1991 saw the Commonwealth begin to play an increasing role in coordination and regulation. Nevertheless, it was only in 2000 that the Therapeutic Goods Administration (TGA) was given the power to regulate fresh blood components manufactured by the ARCBS.[14] The TGA is recognised as the national regulator of the efficacy, safety and quality of blood and blood products. The TGA is responsible for a range of communications activities such as auditing of Good Manufacturing Practice, product recalls, modifications to safety standards and the issuing of directives regarding a range of issues including donor deferrals.[15]

National Blood Authority

1.22 A National Blood Authority (NBA) was established in 2003 with the passage of the National Blood Authority Act. A national authority had been recommended by the Stephen Review and supported by the Barraclough Report.[16] The role of the National Blood Authority is to enhance the management of Australia's blood supply by ensuring that Australia's blood supply is safe, secure, adequate and affordable. The NBA achieves this through the following functions:

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13 *Submission* 54, p.2 (DoHA).

14 *Submission* 54, p.2 (DoHA).

15 http://www.nba.gov.au. Accessed on 21 May 2004.

16 Stephen Review, p.xiv; Barraclough Report, p.5.

- coordinating demand and supply planning for blood and blood products from suppliers on behalf of all States and Territories;
- negotiating and managing national contracts with suppliers of blood and blood products;
- working with all governments to ensure that they get the blood and blood products they require, according to an agreed single national pricing schedule;
- undertaking research to support policy development and operations within the blood sector through transparent evidence-based processes;
- developing and implementing national strategies to encourage better use of blood and blood products;
- promoting adherence to national safety and quality standards; and
- taking responsibility for national contingency planning.[17]

1.23 Under the National Blood Agreement, Commonwealth, State and Territory governments have specified roles and responsibilities.[18] For the States and Territories, these include:

- fostering the development of, and implementing, best practice planning and management systems to promote efficiency in the use and minimisation of wastage;
- ensuring the provision of information and advice to the National Blood Authority in relation to demand for blood and blood products; and
- managing local issues such as those involving clinical practice.

1.24 The Australian Government, through the Department of Health and Ageing, is charged with:

- the Commonwealth's policy and financial participation in the National Blood Authority;
- the National Cord Blood Program, the Bleeding Disorder Registry and the Bone Marrow Transplant Program;
- contracts with the Haemophilia Foundation of Australia and the Australian Haemophilia Centre Directors' Organisation; and
- responsibilities in relation to quarantine as it may affect the blood supply.

1.25 DoHA concluded:

> Thus, at the beginning of the new century, Australia has a blood system operating with a high degree of safety at all levels, underpinned by

17 http://www.nba.gov.au. Accessed on 21 May 2004; National Blood Authority Act, s8.

18 http://www.nba.gov.au/pdf/national_blood_agreement.pdf. Accessed on 21 May 2004.

coordinated arrangements which support strategic national policy direction.[19]

CSL Limited

1.26 Commonwealth Serum Laboratories (CSL) was established by the Commonwealth Government in 1916 to assist with Australia's wartime needs for pharmaceutical vaccines. In 1961, CSL was incorporated as a statutory authority (the Commonwealth Serum Laboratories Commission). In 1991 it was corporatised and converted to a public company (CSL Ltd) while remaining wholly owned by the Commonwealth. In May 1994, the Commonwealth sold CSL by means of a 100 per cent public float.

1.27 CSL's principal activities are the production and distribution of human pharmaceutical products and the manufacture of plasma products sourced from human blood. Plasma collected by the ARCBS from Australian donors is supplied to CSL to be manufactured into plasma derived products. The manufactured products are either returned to the ARCBS for distribution to hospitals and medical practitioners or provided directly to authorised individuals and organisations.

1.28 CSL has two main agreements that relate to the manufacture of plasma products:

- the Plasma Fractionation Agreement was entered into by the Commonwealth and CSL with effect from 1 January 1994 and governs the manufacture of a specified range of plasma products; and
- the Plasma Supply Agreement between the ARCBS and CSL came into effect on 28 April 1994 and covers the supply of plasma by the ARCBS to CSL for the manufacture of plasma products.[20]

1.29 On 23 December 1993, CSL and the Commonwealth entered into formal agreements which provided indemnities for claims arising from the use of some CSL products.

19 *Submission* 54, p.2 (DoHA).

20 See also *Committee Hansard* 5.4.04, p.43 (CSL).

CHAPTER 2

HEPATITIS C IN AUSTRALIA

2.1 This Chapter provides a brief overview of hepatitis and the understanding of blood and blood safety in developed countries, paying particular attention to improvements in diagnostic technology in relation to hepatitis C. It also examines Australia's self-sufficiency in blood stocks, and outlines the factors underlying the increased risk of hepatitis faced by haemophiliacs.[1] The timeline in Table 2.1 outlines the major events in the identification of hepatitis C and the development of tests to detect the virus in blood. The events listed are expanded upon in the remainder of the chapter.

Table 2.1: Timeline of history relating to hepatitis C[2]

Australia	Date	International
	1942	'Serum hepatitis' noted in Second World War
	1947	Two types of hepatitis described
	1965	Discovery of hepatitis B surface antigen
Red Cross starts screening for HBV	July 1971	
	1973	Hepatitis A virus discovered
	1975	Non-A, non-B hepatitis described
Start of first Australian post-transfusion study (published in 1982)	1979	
	April 1981	US Transfusion Transmitted Viruses (TTV) study predicts ALT testing would reduce the incidence of post-transfusion NANBH
	August 1981	US National Institutes of Health study predicts that ALT testing would reduce the incidence of NANBH
	Nov 1981	Canadian Red Cross Blood Transfusion Service advisory committee decides that

1 Information used in this Chapter is drawn largely from the *Report of the Expert Advisory Group on Hepatitis C and Plasma in 1990* (Barraclough Report), 2003 and the *Review of the Australian Blood Banking and Plasma Product Sector* (Stephen Review), 2001. Background information was also drawn from the *Commission of Inquiry on the Blood System in Canada*, (Krever Commission), 1997, Volume 2, Chapter 22.

2 The information in this timeline is based on the Krever Commission, Vol. 2; *Submissions* 54 (DoHA); 61 (AAPA); 64 (ARCBS).

		ALT testing should not be implemented as surrogate testing for NANBH
Post-transfusion study of cardiac patients by Prof Cossart establishes risk of NANBH through blood supply at 1.7%	Jan 1982	
	March 1983	ALT screening considered by US FDA, but no recommendation made.
	1983	Committee of the American Association of Blood Banks rejects implementation of ALT testing. Even so, some blood banks introduce testing.
Red Cross adds questions concerning high-risk sexual and injection behaviour to donor screening	1984	
First case of transfusion related AIDS; introduction of uniform donor declaration by Red Cross	July 1984	
Surrogate testing using anti-HBc for AIDS commenced in NSW	Oct 1984	
Heat-treated Factor VIII developed by Australian Red Cross	Nov 1984	
	Dec 1984	US TTV study predicts that anti-HBc testing would reduce incidence of post-transfusion NANBH
	1985	Introduction of HIV Ab testing
Introduction of HIV testing of donated blood	May 1985	
	July 1985	Preliminary data from the Toronto incidence study show the incidence on NANBH to be 7.6 per cent
	Nov 1985	Majority of US fractionators begin to use ALT-tested plasma to manufacture blood products
	Feb 1986	US FDA Blood Products Advisory Committee recommends that all blood donations for transfusion be tested for both ALT and anti-HBc as surrogate tests for NANBH
	March 1986	American Association of Blood Banks and American Red Cross issue a joint statement recommending that blood collection agencies implement surrogate testing
	April	American Association of Blood Banks

	1986	board of directors decide that both ALT and anti-HBc testing of blood donations should be implemented. Report of results from National Institutes of Health study predicting that anti-HBc would reduce incidence of post-transfusion NANBH Canadian Red Cross Blood Transfusion Service advisory committee recommends against surrogate testing for NANBH, pending further study of data from Toronto incidence study and of the efficacy of HIV-antibody testing as a surrogate test for NANBH
	Nov 1986	Target date for introduction of dual ALT and anti-HBc testing in majority of US blood banks, even though testing not required by FDA.
Start of second post-transfusion hepatitis study (published in 1995); National Blood Transfusion Committee does not support routine surrogate testing	1987	
Queensland Blood Transfusion Service begins surrogate testing	July 1987	
Report on ALT surrogate testing published in Queensland, *Pathology*	1988	
	May 1988	Identification of HCV announced
BTS Executive Subcommittee agreed to start testing for HCV antibody as soon as practicable	Dec 1989	
Hepatitis C becomes notifiable infection in States and Territories	1990	Screening test for hepatitis C licensed in US
Super heat treated Factor VIII available	Jan 1990	
All transfusion services had commenced screening for anti-HCV	Feb 1990	
Agreement between CSL and NBTC not to use anti-HCV repeat reactive plasma in the manufacture of plasma products	June 1990	
	March 1991	US FDA requires anti-HBc testing of blood donations to identify units contaminated with HBV

Second generation kit introduced	May 1991	
	1992	Canadian Red Cross implements second generation HCV antibody testing throughout Canada
NSW BTS reported that only 30.8 per cent of donations found repeat reactive on anti-HCV screening were positive on confirmatory testing	August 1992	
Super heat treated Prothrombinex becomes available	1993	
Report on risk of post-tranfusion/ operative NANBH in Australia immediately before introduction of screening; concluded 1st generation anti-HCV test detected about 85 per cent of infective donations; and surrogate testing offered no additional advantage *Medical Journal of Australia*	July 1995	
Australian Red Cross Blood Service established	1996	
	Nov 1997	Krever Commission report released in Canada
Regulation of fresh blood products commenced under the *Therapeutic Goods Act 1989*	2000	
Introduction of Nucleic Acid Testing for HCV	June 2000	
National Blood Authority established	2003	

History and nature of Hepatitis C

2.2 'Hepatitis' means inflammation of the liver. It can result from overuse of alcohol, reaction to certain medications or infection by bacteria or viruses. There are several different viruses that cause hepatitis, such as hepatitis A (HAV), hepatitis B (HBV) or hepatitis C (HCV). Each of these viruses may produce similar symptoms and they can all infect and inflame the liver. The main difference between the viruses is the mode of transmission, the way they cause liver damage and the effect each has on a person's health.[3]

3 http://www.hepatitisaustralia.com/pages/ABOUT_HEPATITIS.htm; *Submission* 64, p.20 (ARCBS).

2.3 Hepatitis C infection can be either acute, characterised by a short-lasting illness, or chronic, where hepatitis is present for six months or more. Those with acute HCV are commonly asymptomatic and may experience a mild flu-like illness. Some people, between 15 and 45 per cent (the higher proportion being in children), will clear themselves of the virus within four to six weeks of infection. In the remainder, chronic HCV infection occurs and causes the liver disease, chronic hepatitis C. Most people with chronic HCV show few, if any, outwardly visible symptoms. For this reason, many do not know they are infected. The symptoms that may be evident are often general, and include fatigue, lethargy, nausea and abdominal discomfort. The degree to which these symptoms may occur can vary significantly.

2.4 During the acute phase, levels of the virus in the blood rise dramatically until the body's immune response starts producing antibodies in an attempt to destroy the virus. In many cases, the virus successfully tricks the body into producing a poor antibody response. The infection is not brought under control properly by the body and the infection becomes chronic.

2.5 The importance of HCV infection lies in its persistence (or chronicity) and the liver disease it causes. Once a person is chronically infected, the virus is almost never cleared without treatment. In rare cases, HCV infection can even cause liver failure. However, most instances of acute infection are clinically undetectable.

2.6 The natural history of chronic HCV infection can vary dramatically between individuals. Some will have clinically insignificant or minimal liver disease and never develop complications. Others will have clinically apparent, chronic hepatitis. Cirrhosis may develop in about 20 per cent of individuals with HCV. This generally occurs at least 20 years after infection. Some patients with cirrhosis will develop end-stage liver disease. A proportion of individuals with cirrhosis resulting from HCV will also develop hepatocellular carcinoma (primary liver cancer).

2.7 For patients with chronic HCV, it is difficult to predict who will have a relatively benign course and who will go on to develop cirrhosis or cancer. Factors promoting progression of HCV-related chronic liver disease include viral genotype, age and sex of the person infected, alcohol abuse and whether the person is co-infected with another virus.[4] Certain findings on liver biopsy can help in predicting the course of the disease.

2.8 The Barraclough Report noted that, based on studies of HCV infection acquired through routes other than the receipt of contaminated blood or blood products, it has been estimated that of all people with HCV antibodies, around 8 per cent would develop cirrhosis after 20 years following exposure, and 20 per cent would do so after 40 years. Rates of progression to liver cancer were more uncertain, but were about 10 per cent of the rate of progression to cirrhosis. Rates of progression to

4 Parliament of NSW, Legislative Council, Standing Committee on Social Issues, *Hepatitis C: The Neglected Epidemic Inquiry into Hepatitis C in NSW*, Report No 16, 1998, p.24.

cirrhosis in people infected with HCV from a blood transfusion are also generally much higher, as are rates of progression to cirrhosis in people with established chronic liver disease.[5] Progress of the disease is also discussed in Chapter three.

2.9 The public health impact of hepatitis C infection is substantial and the socioeconomic costs to the Australian community are high. HCV also exacts a high personal cost on sufferers as it has a long term impact on quality of life. Further information on living with HCV is contained in Chapter five.

Hepatitis C epidemiology[6]

2.10 Hepatitis C is the most frequently reported notifiable infection in Australia. It is estimated to affect about one per cent of the population, or 150,000 to 200,000 Australians, with an estimated incidence of 8,000 to 10,000 new infections occurring each year. This compares to HIV with an estimated prevalence[7] of 15,900 cases and an incidence of 600 new cases per year.

2.11 The reported number of diagnoses of HCV infection has declined from a peak of 20,465 in 2000 to 15,953 cases in 2002. The reported number of diagnoses of newly acquired infection has declined from 672 cases in 2001 to 434 cases in 2002.

2.12 An estimated 225,000 people were living with hepatitis C infection in Australia in 2002. This includes 133,000 with chronic HCV and early liver disease (stage 0/1), 29,000 with chronic infection and moderate liver disease (stage 2/3) and 6,900 living with HCV-related cirrhosis. An estimated 57,000 had hepatitis C antibodies without chronic infection.

2.13 However, it is likely that many people with hepatitis C remain undiagnosed. It is estimated that 210,000 people in Australia have been exposed to the hepatitis C virus, of whom approximately 90,000 people live in NSW. Approximately 40 per cent of people in NSW who have been exposed to HCV are unaware of their status.

2.14 The main mode of transmission of hepatitis C in Australia is through unsafe drug injecting practices, in particular, the sharing and re-using of injecting equipment. Approximately 80 per cent of infections are attributed to the behaviour associated with injecting drug use, another 5–10 per cent to the transfusion of blood products (prior to 1990) and the remainder to other forms of blood-to-blood contact, such as non-sterile tattooing or other skin-incision procedures.

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5 Barraclough Report, pp.33-34.

6 Much of the data in this section was drawn from the National Centre in HIV Epidemiology and Clinical Research, *HIV/AIDS, viral hepatitis and sexually transmissible infections in Australia Annual Surveillance Report 2003*, pp.11-13. Accessed at http://www.med.unsw.edu.au/nchecr/Downloads/03ansurvrpt.pdf on 12 May 2004.

7 Prevalence refers to total number of people in a population who have the disease at any given time.

2.15 Since 1990, all blood has been screened for hepatitis C and the risk of transmission through the transfusion of blood or blood products in Australia is now very low. The ARCBS modelling estimates the risk of contracting post-transfusion HCV in Australia in 2000-2002 was 1 in 3,112,000.[8] There is currently no vaccine against hepatitis C.

Number of people infected through blood transfusion

2.16 The Department of Health and Ageing (DoHA) stated that it is not possible to obtain comprehensive or definitive figures on the number of people infected with hepatitis C through blood transfusion. Many people with HCV are asymptomatic and may therefore never have been diagnosed.

2.17 DoHA went on to state that 'it is accepted that a history of receiving blood products before the beginning of blood-donor screening is likely to account for a substantial proportion of HCV-infected individuals who are not injecting drug users'. People with haemophilia who received fractionated plasma derivatives before heat treatment procedures were implemented were particularly at risk of being infected with HCV.[9]

2.18 The ARCBS provided the Committee with estimates of those living with hepatitis C gained through blood transfusions. The ARBCS estimated that between 3,500 and about 8,000 Australians live with HCV infection derived through blood transfusion, including an estimated 1,350 haemophiliacs.[10] However, there is no formal reporting mechanism of post-transfusion hepatitis in Australia, as pointed out by the ARCBS:

> Australia does not operate a register where all suspected cases of post-transfusion hepatitis might be found. Some countries have established haemovigilance systems, which collect data in a central agency on all adverse outcomes (infectious and non-infectious) from transfusion, investigate and determine the cause...[I]n the early 1990s, all State and Territory governments established hepatitis C as a notifiable disease...however, these local health authorities do not necessarily record or confirm the route of transmission.[11]

The discovery of HCV

2.19 The transmission of blood-borne infections had been identified as an issue with transfusions since their inception. With the development of methods to monitor liver function, the term 'hepatitis' or inflammation of the liver came into use. With the use of human transmission experiments and more advanced knowledge of the disease,

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8 *Submission* 64, p.27 (ARCBS).

9 *Submission* 54, p.16 (DoHA).

10 *Submission* 64, p. 68; Submission prepared for hearing 7.4.04, p.18 (ARCBS).

11 *Submission* 64, p. 68 (ARBCS).

'infectious hepatitis', which spread from person to person by the faecal–oral route, and 'serum hepatitis', which was transmissible by blood and blood products, were identified. In the 1970s infectious hepatitis became known as hepatitis A and serum hepatitis as hepatitis B. Hepatitis B was thought to cause post-transfusion hepatitis.

2.20 With the discovery of a protein called the B surface antigen (HBsAg), scientists were able to find an antibody which reacted with this particular protein. The antibody was subsequently used in developing tests to screen blood donors for HBV. In Australia, a surface antigen test was developed in 1970 in NSW and used throughout the country to screen donors. Professor Cossart noted that routine screening greatly reduced the incidence of post-transfusion jaundice globally. The ARCBS stated that, following the introduction of screening, the post-transfusion rate of hepatitis declined by around 20 per cent in the United States.[12]

2.21 The hepatitis A virus was identified in the faeces of a person with 'infectious hepatitis' in the early 1970s and HAV antibodies characterised in 1973. A test for antibodies (anti-HAV) then became available to study cases of post-transfusion hepatitis that were negative for HBsAg.

2.22 However, while the incidence of post-transfusion hepatitis was reduced, screening for both HAV and HBV failed to abolish the problem. People were identified with sub-clinical post-transfusion hepatitis. This had a different clinical picture from hepatitis A or B. In 1975 the name 'non-A, non-B hepatitis' (NANBH) was coined. This term was used rather than hepatitis C because at the time it was thought that more than one infectious agent was involved.[13]

2.23 In 1978, NANBH was successfully transmitted to chimpanzees. However, many different groups failed to find a specific virus or a laboratory marker of infection despite much intensive study. It was not until 1988 that a group of scientists at the Chiron Corporation in the United States announced the identification of the virus responsible for NANBH. A lay report appeared in *Nature* and the scientific findings were published the next year.[14] This was the first virus identified by the novel approach of gene cloning, and the researchers named it 'hepatitis C'.

2.24 Retesting of stored samples from past studies of post-transfusion hepatitis soon showed that donors with antibody to the new agent had often been implicated in transmission of non-A, non-B hepatitis. It is clear that HCV has been the cause of

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12 *Submissions* 54, Appendix 3, p.A6 (DoHA); 64, p.21 (ARCBS). It should be noted that the Department of Health and Ageing commissioned Professor Cossart to address Terms of Reference (a), (b) and (f) due to their technical nature. These are at Appendices 2, 3 and 4 of the Department's submission.

13 *Submission* 64, p.22 (ARCBS); see also *Submission* 54, A9 (DoHA).

14 Barraclough Report, p.36.

liver disease for many decades (it has subsequently been found in stored blood from 1948). It was therefore a newly recognised cause of disease rather than a new virus.[15]

Hepatitis C in the blood supply

2.25 As stated above, it was noted in the 1970s that there was another agent or agents that resulted in post-transfusion hepatitis. With the introduction of testing for HAV and HBV, infection rates dropped but some recipients still acquired hepatitis. In 1978 it was observed that, since the introduction of HBV screening in the United States for donor blood, more than 93 per cent of cases of post-transfusion hepatitis were attributable to NANBH.[16]

2.26 Several large scale studies were undertaken to ascertain the likelihood of acquiring NANBH from blood transfusions under a defined set of circumstances. Professor Cossart noted that there were wide discrepancies in studies of post-transfusion NANBH in different countries. An Australian study of cardiac surgery patients in 1982 returned one of the lowest rates while high rates were observed in the United States, parts of Europe and Japan.[17]

2.27 In the United States there were great variations between blood collection centres and studies in the early 1980s attributed this to the use of blood derived from paid donors. Centres which used only volunteer blood had a much lower rate of post-transfusion hepatitis than did those that relied partially or fully on paid donors.[18]

2.28 The ARCBS also described two studies which were designed to define the incidence of post-transfusion hepatitis in the United States and evaluate what factors influenced its occurrence. The first, a multi-centre study published by the Transfusion Transmitted Viruses (TTV) Study Group in 1981, showed an association between NANBH and a heightened level of Alanine Aminotransferase, or ALT, an enzyme specific to liver cells produced in response to hepatitis. An independent study at the National Institutes of Health (NIH), also in 1981, confirmed the findings. In a further series of studies there was an association between NANBH and the presence of HBV core antibodies or 'anti-core', indicating prior HBV infection. This issue was extensively reviewed in the Krever Report. The ARCBS stated that there were predictions made, in the United States, that removing donors with higher levels of ALT and positive for anti-core might reduce the development of NANBH, by about a third, in recipients.[19] Studies relating to surrogate testing are further discussed later in the chapter.

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15 Barraclough Report, p.36.

16 *Submission* 64, p.23 (ARCBS).

17 *Submission* 54, Appendix 3, p.A7 (DoHA).

18 Barraclough Report, p.37; *Submission* 64, p.37 (ARCBS).

19 *Submission* 64, p.23 (ARCBS).

2.29 It was also known that there was a greater risk of transmission of NANBH to haemophiliac patients because the risk of infection was compounded by the use of pooled donations for the production of fractionated products. Witnesses noted that, as a result, hepatitis was common in patients with haemophilia.[20] (The use of fractionated products by haemophiliacs is discussed later in this chapter.) However, it was generally considered that risk was acceptable because there were such significant benefits in using Factor VIII and Factor IX concentrates for the management of haemophilia.[21]

2.30 Following the Second World War, there was awareness in Australia, and around the world, of the risk of hepatitis following transfusion. The ARCBS stated that from the early 1970s the blood transfusion service consistently warned doctors and hospitals of the risk.[22] Studies into the transmission of NANBH were undertaken by Professor Cossart in the early 1980s and by Ismay in the 1990s.[23] Scientific meetings were also held in Australia which addressed NANBH.[24]

2.31 In the 1970s NANBH was considered to be a relatively minor disease with the majority of patients being asymptomatic and without any sign of severe impairment of liver function.

Background to blood and blood products

2.32 Blood is a major body tissue comprising plasma, a yellow, protein-rich fluid that suspends formed elements: blood cells, white blood cells and platelets. Plasma accounts for more than half of the total volume of blood. It is around 90 per cent water and contains a very complex and not fully understood mixture of proteins that perform many bodily functions.

2.33 Organised blood transfusions first emerged in the 1920s, and only whole blood was used. Over time, fractionation processes developed to the point where, today, whole blood is rarely transfused. Fresh blood products are perishable, with a shelf life of between 5 days (platelets) and 35-42 days (red cells). Red cells are the most widely used blood product.

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20 *Submissions* 71, p.1 (ANZSBT); 82, p.8 (HFA).

21 *Submission* 82, p.8 (HFA).

22 *Submission* 64, p.24 (ARCBS).

23 *Submission* 64, p.25 (ARCBS).

24 *Submission* 71, p.1 (ANZSBT).

Table 2.2: Major fresh blood components

Product	Main Uses
Red cells	Replacement of blood loss in trauma and surgery, and occasional treatment of anaemia.
Platelets	Control of bleeding related to platelet deficiencies caused by disease (eg leukaemia) or following severe haemorrhage or as a result of treatment of an underlying malignant disorder
Cryoprecipitate	Treatment of clotting factor and fibrinogen deficiency
White cells	Treatment of sepsis, regeneration of blood cells after chemotherapy.

Source: Stephen Review, p.9.

2.34 Plasma products have a shelf life of between one and three years, and can be divided into three main proteins; Albumin, Immunoglobulins, and clotting factors.

Table 2.3: Principal plasma products

Product	Main uses
Albumin	Treatment of shock, burns, liver disease and kidney disease.
Immunoglobulin for intramuscular injection	Temporary protection from infectious diseases such as measles, rubella, and HAV.
Immunoglobulin for intravenous injection	Replacement therapy for primary immune deficiency disorders, such as Guillain-Barre, and Kawasaki disease.
Immunoglobulin preparations with high levels of specific antibody (hyperimmunes)	Treatment of tetanus or prevention of HBV, chicken pox, haemolytic disease, the newborn or cytomegalovirus.
Factor VIII concentrate	Haemophilia A.
Other clotting factors	Other bleeding disorders such as Haemophilia B.

Source: Stephen Review, p.9.

Blood plasma and safety

2.35 The Barraclough Report provides an overview of issues concerning blood plasma and safety. There are two types of plasma. Recovered plasma is obtained as a by-product of whole blood collection and source plasma is obtained by collecting whole blood from a donor, separating the plasma and returning the cellular material to

the donor. The standards under which recovered plasma is collected are different from those that apply to the collection of source plasma. In particular, the safety issues are influenced by the fact that recovered plasma has to be subject to the same standards as plasma intended for direct transfusion. Source plasma is subject to safety standards that are ultimately related to the safety of the derivatives for which it serves as a raw material.

2.36 The principles underlying current concepts of the safety of blood-derived therapeutics from infection by disease producing organisms, or pathogens, are:

- the selection of donors from populations at low risk of carrying transfusion-transmitted pathogens;
- the screening of such donors using appropriate laboratory tests; and
- the treatment of the products using measures that eliminate any residual pathogens.

Although desirable, it may not be possible to have all of these principles in place concurrently.

2.37 Safety profiles differ for the two broad categories of blood-derived therapeutics – plasma derivatives and blood components. Plasma derivatives are produced from large donor pools. There is thus a greater likelihood of contamination by blood-borne pathogens than for single donor products. However, plasma derivatives are produced by industrial-scale manufacture and subject to intensive processing and quality control. In the production process, steps to eliminate pathogens can be instituted.

2.38 Viruses are the most important contaminants of plasma pools for fractionation. The amount of viral contamination in a plasma pool depends on several factors, and can be minimised through careful donor selection and laboratory screening tests. Laboratory testing measures viral genomic material, as well as the evidence of infection through, for example, antibody tests. Thus the viral load for the important blood-borne pathogens such as HBV and HCV can be reduced to very low levels.

2.39 Since the mid-1980s manufacturers have used various elimination steps that eradicate the important viruses in plasma pools. Because of the large pool size from which these products are derived, the mainstay of their safety from viral infection is the ability of the manufacturing process to eliminate viruses through deliberate steps and/or the biological features of the product.

2.40 Blood components, as opposed to plasma derivatives, are usually derived 'under conditions in which it is not possible to eliminate pathogens'.[25] For these products, the main safety techniques are donor selection and laboratory screening. The

25 Barraclough Report, p.32.

number of patients exposed to each product is much smaller than for plasma derivatives, which assists their safety profile.

2.41 The Barraclough Report concluded that while the safety differential between plasma derivatives and components has changed over the past twenty years, the advent of viral elimination techniques have given plasma derivatives, previously a higher-risk class of products than components, a superior safety profile. This has been achieved with the identification of agents known to cause disease, with the development of tests to identify these agents and with the refinement of existing tests to enhance sensitivity.[26]

Surrogate testing

2.42 Surrogate testing, in the context of blood safety, refers to tests used to detect viruses for which no specific test exists and to supplement specific tests that are insufficiently sensitive.[27]

2.43 During the 1980s two surrogate tests for NANBH were proposed: testing for abnormality of liver function through measurements of the level of alanine aminotransferase (ALT); and testing for markers of previous hepatitis B infection, the test for which was called anti-HBc. Professor Cossart noted that the first test assumed that donors who were infective would have abnormal liver function tests, while the second assumed that past exposure to one blood-borne virus might predict a high probability of exposure to others.[28]

2.44 Witnesses reported to the Committee that before a specific test for HCV was developed there was much debate as to the usefulness of surrogate testing.[29] The Royal College of Pathologists of Australia stated for example, that the decisions around surrogate testing were difficult and controversial as it is neither sensitive or specific.[30] The Australian Centre for Hepatitis Virology (ACHV) concluded that:

> Consequently, any decisions made to introduce (or not) surrogate screening tests were often based on interpretation of what information was available, by individuals (blood bankers) who had the unenviable task of trying to screen the blood supply for an unknown agent with no tools.[31]

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26 Barraclough Report, pp.32-33.

27 Krever Commission, Volume 2, p. 628.

28 *Submission* 54, Appendix 3, p.A10 (DoHA).

29 See, for example, *Committee Hansard* 5.4.04 p.36 (Dr Baird); *Submission* 74, p.1-2 (Professor McCaughan); 86, p.3 (Prof W Cooksley).

30 *Submission* 69, p.1 (RCPA).

31 *Submission* 80, p.2 (ACHV).

Arguments for surrogate testing

2.45 A number of witnesses submitted that surrogate testing should reasonably have been introduced across Australia from around 1986. It was argued that this form of testing represented a useful indicator of HCV status, and that its introduction would have prevented at least some infections through transfusion.[32] It was also noted that surrogate testing was introduced in some other countries, and in Queensland in 1987.

2.46 Those supporting the introduction of surrogate testing pointed to studies conducted in the United States which were reported in 1981. The Transfusion Transmitted Viruses Study reported an association between elevated ALT in donors and the development of NANBH in blood recipients. The study predicted that by excluding donors with elevated ALT, 40 per cent of NANBH might be prevented at a loss of 3 per cent of the donor population. This low degree of supply loss was another advantage of using ALT as opposed to anti-HBc. The investigators concluded that a 'compelling argument' existed for ALT screening and exclusion to take place.[33] In his submission to the Inquiry, Professor James Mosley, the Project Coordinator of the TTV Study, recalled reporting his findings at a conference in Brisbane in 1978. Professor Mosley reported that a number of blood bankers, including at least one senior Australian Red Cross employee, were in attendance.[34]

2.47 A study by the National Institutes of Health in 1981 found an almost identical outcome predicting donor exclusion based on elevated ALT might prevent 29 per cent of transfusion associated hepatitis at the loss of approximately 1.5 per cent of the donor population. However, this study also noted the high incidence of false negative and false positive results, and did not recommend the introduction of ALT testing. It was stated that:

> The ALT testing of donors is thus a tenuous balance between risk and benefit. The balance shifts toward testing when one considers that approximately 30 per cent of [post-transfusion hepatitis] might be prevented...but this is tempered by the realization that 70 per cent will not be prevented and that the prevention of 30 per cent is in some doubt unless confirmed by a randomized clinical trial. The balance also shifts away from testing when one considers the estimated additional $20 million in the annual cost of blood to the United States alone and the potential national loss of 45,000 donors and more than 90,000 units of blood. It is a difficult equation, whose solution will require thought and planning.[35]

2.48 However, the NIH findings in relation to anti-HBc differed to those for ALT. The NIH report concluded:

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32 See for example, *Committee Hansard* 5.4.04, p.26; *Submission* 79, p.2 (TBPAG).

33 Krever Commission, Volume 2, pp.630-32.

34 *Submission* 89, p.1 (Professor Mosley).

35 HJ Alter *et al*, 'Donor Transaminase and Recipient Hepatitis', *Journal of American Medical Association*, 246, no. 6, August 1981, pp.630-34.

> If, as predicted, surrogate screening of blood donors could prevent approximately one third of these cases, then this could represent an annual reduction of 50,000 cases of hepatitis and 2,500 cases of cirrhosis. The potential to achieve this degree of disease prevention now appears to outweigh the disadvantages inherent in the adoption of surrogate tests for the non-A, non-B virus carrier state.[36]

2.49 Later the TTV and NIH studies were re-analysed and an association was shown between the anti-HBc marker in donors and the development of NANBH in recipients.[37]

2.50 The Queensland Government was unable to provide the Committee with information about the decision to introduce surrogate testing. However, Dr Catherine Hyland, of the Blood Transfusion Service in Brisbane, published a study in 1988 which concluded, *inter alia*:

> The recent judgement in a legal suit that concerned the Queensland Red Cross Blood Transfusion Service has indicated that, provided the transfusion service is implementing screening procedures appropriate to published professional knowledge at the time of transfusion, there should not be a case for negligence at law...[I]n the light of this experience, and given the development of an assay that is cheap and convenient, it was decided that concern regarding chronic effects of NANB hepatitis outweighed the arguments against implementation of surrogate testing.[38]

2.51 The Haemophilia Foundation Australia (HFA) commented that, 'it appears that issues such as test sensitivity and specificity, cost and fears about reduced blood supply were considered more important than the seriousness of hepatitis'. The HFA went on to argue that 'if any kind of testing was available that could have potentially saved people from a life threatening virus, efforts should have been taken to implement these. Decisions based on cost effectiveness do not stand the test of time'.[39]

Arguments against surrogate testing

2.52 A number of arguments were put to the Committee as to why surrogate testing was not supported. First, it was argued that surrogate tests are no substitute for specific tests such as antibody tests. Because of the lack of sensitivity and specificity, it is difficult to ascertain their effectiveness in identifying the blood donations that should be excluded.[40]

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36 Krever Commission, Volume 2, p.644.

37 *Submission* 64, pp.36-37 (ARCBS).

38 Hyland *et al*, 'Surrogate testing for non-A, non-B hepatitis in Queensland, Australia: An ALT Microtitre method for screening blood donors', *Pathology*, 1988, pp.271-74.

39 *Submission* 82, p.10; *Committee Hansard* 5.4.04, p.3 (HFA).

40 *Submission* 64, p.36 (ARCBS); see also *Submission* 69, p.1 (RCPA).

2.53 In relation to the two surrogate tests proposed for NANBH it was pointed out that there were problems with both tests. For ALT, it was argued that, by its nature, it was not specific to NANBH. There were a number of reasons why ALT levels may be raised, including individual lifestyle factors such as exercise, alcohol, use of many common medications and simple obesity.[41] The Barraclough Report noted that:

> ALT measures a normal liver enzyme. This is not a measure of the presence of a particular hepatitis virus. Rather, elevated ALT levels may be a sign of liver inflammation, commonly caused by hepatitis. However, as ALT levels are affected by many drugs, including even modest amounts of alcohol, many units of non-infective blood gave abnormal results. Furthermore, at least some infective units had normal values. In addition, an ALT elevation may not mean the person has any medical abnormality.[42]

As a result there would be high levels of donors rejected unnecessarily.

2.54 There was also considerable debate at the time about the significance of raised ALT levels and the ALT cut off level where blood should be discarded. For example, it was known that ALT levels could vary even where the individual was a carrier of the NANBH agent. The person could thus have an ALT level above the cut off on one day and a lower ALT level on another day.[43] Professor Geoff McCaughan, in his submission to the Committee, pointed to a number of reviews published in the mid 1980s which addressed the inadequacies of surrogate testing.[44]

2.55 Professor Cossart referred to a review of the issue of surrogate testing over the past three decades published in 2000 that concluded that 'despite its conceptual appeal, ALT screening had never been substantiated as a routine measure to prevent post-transfusion NANB hepatitis, and its introduction was driven by concern about the emerging problems in recipients rather than evidence of its efficacy'.[45]

2.56 In evidence from CSL, Dr Darryl Maher provided the Committee with a graph generated by the Therapeutic Goods Administration. The graph, reproduced as Figure 2.1, plots the course of viral load in an individual over the days following infection. Dr Maher's explanation of the graph and its consequences for ALT testing is worth quoting at length:

> This is from time zero, the point at which the individual is infected, and this is the course of the infection in days, out to 100 days. The Y axis is the level of virus in the blood. That axis is actually on a logarithmic scale, which means that at each point going up the Y axis we are talking about tenfold more viruses. At this point down here there may be, say, 100 viruses

41 *Submissions* 64, p.36 (ARCBS); 86, p.2 (Prof W Cooksley).

42 Barraclough Report, p.39.

43 *Submission* 64, p.39 (ARCBS).

44 *Submission* 74, p.3-6 (Prof McCaughan).

45 *Submission* 54, p A15 (DoHA).

per millilitre; up here, it would be of the order of 10 million viruses per millilitre – so many, many thousandfold more. After infection, within about a 10- or 11-day period, the virus starts to appear in the bloodstream in the individual – and this is it going up here. The tests that can detect that are the NAT tests, which you have heard about, because they are measuring the virus itself.

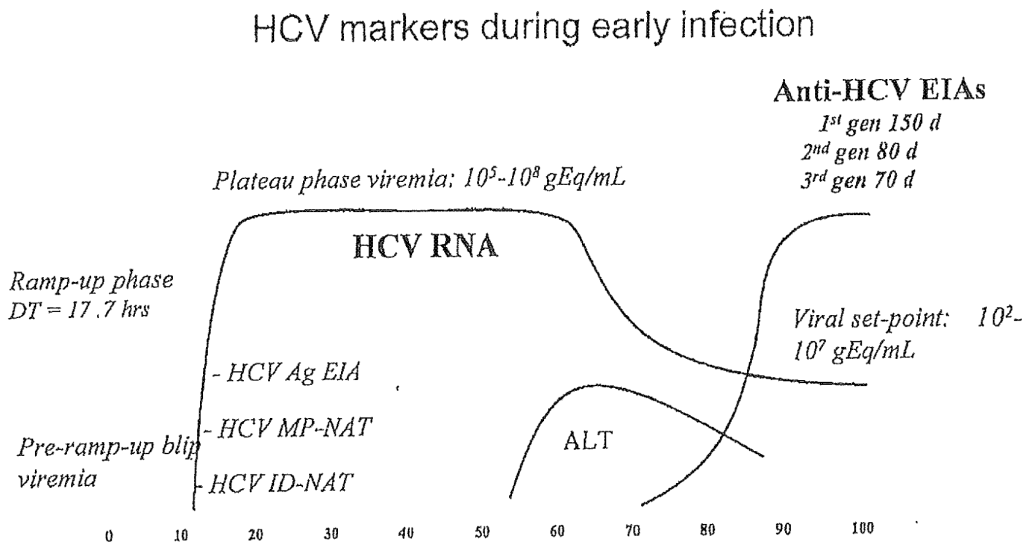
With regard to the earlier tests, let us start with the surrogate testing, the ALT marker. That is a marker of inflammation in the liver, so it only goes up once the infection has taken hold and the liver has become inflamed. You can see the ALT peak on this graph here which shows that it is some 50-odd days after the infection before the ALT starts to go up. So for donors who may have been infected and are at risk of transmitting you have this 55-day period with extremely high titres of virus, and none of these tests—the ALT or, for that matter, the antibody tests – are able to detect it.

The unfortunate irony, in a way, is that the time when the antibody takes off and the ALT is coming up is the time when the level of virus actually starts to fall. So the level of virus in the group that are positive for ALT is about 10,000-fold less than the level of virus in this group of individuals who are in the incubation period before their test becomes abnormal. We are talking about 10,000 to one, so if you have got a 10,000-donor pool you only need to have one person in this period for there to be as many viruses as having all 10,000 of them with a positive ALT test.

That is how dramatic the difference is in the level of virus during that course. This information is in retrospect and it was not available to the committee making decision at the time. I think other reasons drove the decision back then. What I am saying is that, in retrospect, it is very clear that ALT testing would not have reduced the risk of transmission by these concentrates.[46]

46 *Committee Hansard* 5.4.04, pp.47-48 (Dr Maher).

Figure 2.1



Source: TGA additional information, tabled by CSL on 5.4.04.

2.57 In relation to anti-core testing, Professor Cooksley noted that it had the advantage of being positive or negative rather than being a continuous variable. However, the disadvantage was the high rate of false positive and false negative results. Anybody with a past exposure to HBV would be automatically excluded. Thus people from the Mediterranean countries, Eastern Europe, the Middle East, Asia, Pacific region, Africa and South America would have a high likelihood of being excluded as HBV is common in those regions. However, only about half of the HCV-positive donors would be excluded, since the test relies on previous exposure to HBV.[47]

2.58 The need for surrogate testing was also questioned as the studies supporting the introduction of testing were derived from the United States, where the epidemiological context differed significantly from that of Australia.[48] This raised the question as to whether it was appropriate or necessary to introduce surrogate screening in Australia. The Barraclough Report stated:

> The greatest potential benefit from using surrogate tests was in countries where the risk of transfusion transmitted hepatitis was highest, notably in countries that used blood and blood products from paid donors.[49]

2.59 Professor McCaughan also pointed out that not only did Australia have a volunteer donor system but also a successful HIV screening questionnaire programme

47 *Submission* 86, p.2 (Prof W Cooksley).

48 See, for example, *Submission* 74, p.1 (Prof McCaughan).

49 Barraclough Report, p. 40. See also *Committee Hansard* 6.4.04, p.62 (Prof Barraclough).

had been introduced in Australia while in the United States neither precaution was taken.[50] The Barraclough Report also commented on the significance of HIV questionnaires and found that:

> The majority of data supporting the efficacy of surrogate testing were obtained before the introduction of donor screening by questionnaire and serological testing for HIV. Both of these activities were likely to have significantly reduced the effectiveness of the surrogate screening protocol by excluding a significant proportion of the same risk group.[51]

2.60 The ARCBS submitted that 'Australian blood bankers took all questions of safety extremely seriously and thoroughly reviewed and considered the "surrogate marker debate" as it evolved in the United States, Europe and the United Kingdom'. However, it was decided, through the National Blood Transfusion Committee, not to recommend the introduction of surrogate testing 'following an evaluation of the scientific evidence for surrogate testing because the evidence that it would be effective was not convincing'. Surrogate tests were considered to be 'blunt and inaccurate tools with the potential to create blood shortages without any demonstrated benefit to public safety'. Further, surrogate tests had not been proven to be effective in reducing post-transfusion hepatitis.[52]

2.61 In relation to the introduction of surrogate testing in Queensland, the ARCBS stated 'the fact that the BTS in Queensland, having reviewed the same international data and arguments as the other services, reached a different conclusion from the remaining states is evidence of the highly controversial and inconclusive nature of the "surrogate marker debate"'.[53]

Surrogate testing internationally

2.62 The inconsistent approach taken internationally was borne out by evidence on the introduction of surrogate testing overseas which was provided to the Committee. For example, in the United States in 1983 a report from the American Association of Blood Banks concluded:

> While we share the desire of the entire medical community to reduce the incidence of transfusion associated hepatitis, we believe that currently available evidence does not justify either universal testing of donor blood for ALT or the rejection of donors who have elevated levels. Therefore, at this time we do not advise routine donor testing for ALT as a means of reducing the incidence of non-A, non-B hepatitis.[54]

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50 *Submission* 74, p.1 (Prof McCaughan).

51 Barraclough Report, p.41.

52 *Submission* 64, p.39; Submission prepared for hearing 7.4.04, p.12 (ARCBS).

53 *Submission* 64, p.42 (ARCBS).

54 Krever Commission, Volume 2, p.635.

2.63 However, the US Blood Banks adopted surrogate testing at various times up to mid 1987. The US Food and Drug Administration blood products advisory committee found that surrogate testing should be implemented. Despite the recommendation of its own blood products advisory committee, and introduction of surrogate testing by Blood Banks, the FDA did not issue a regulation requiring anti-HBc testing of donated blood until 1 March 1991, and then for the purpose of identifying units contaminated with HBV, not HCV. The FDA never issued a regulation requiring testing for ALT levels, and only a 'handful' of US blood centres implemented it as a matter of course. However, the American Association of Blood Banks recommended in 1986 that testing be introduced and this occurred in 1986-87.[55]

2.64 Few other countries introduced surrogate testing in the mid 1980s. The United Kingdom did not implement surrogate tests. The average rate of post-transfusion hepatitis was believed to be less than one per cent, so low that British blood bankers questioned whether it was cost effective to implement even anti-HCV testing, when it became available.[56] No European countries performed anti-core testing and only parts of Germany and Italy conducted ALT testing. The ARCBS noted that Germany had introduced ALT testing in the 1970s but it still had a very high rate of post-transfusion hepatitis.[57]

2.65 In May 1987, the Council of Europe's Committee of Experts on Blood Transfusion and Immunohaematology concluded that:

> Arguments against the introduction of surrogate testing include the variability of data from one country to another, the non-specific nature of the tests proposed, loss of apparently healthy donors, difficulty in follow up of the donors and the continuation of transfusion-transmitted NANBH in spite of the tests.[58]

2.66 Those in support of surrogate testing argued that the prospect of a reduction in the supply of blood (owing to the need to discard blood which may nor may not have contained HCV) was a major factor in the decision not to introduce surrogate testing.

2.67 The ARCBS stated that the level of donations was a 'major concern' as it was estimated that at least five per cent of voluntary blood donations would be rejected even though they were mostly expected not to be infectious. The false positive result from the ALT test might occur if the donor was overweight, or used alcohol heavily before donating, or was taking certain medicines. The ARCBS also noted that it was during this time that there was concern about the adequacy of the blood supply as the AIDS epidemic had led to a fall in collections.

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55 See, for example, *Submission* 82, p.9 (HFA).

56 Barraclough Report, p.41.

57 *Submission* 64, Submission prepared for hearing 7.4.04, p.12 (ARCBS).

58 *Submission* 64, p.39; Submission prepared for hearing 7.4.04, p.12 (ARCBS).

2.68 In addition, the Blood Transfusion Services were mindful of causing needless alarm in donors by advising them that they may have contracted hepatitis. Many donors would have been referred to medical practitioners for investigation and possibly even a liver biopsy, a procedure with risks of its own, even though the great majority of donors would be healthy.

2.69 The ARCBS also argued that such a move might also have been counterproductive, as lost donors would need to be replaced and a consequent increase in new donors would have brought an increased risk. New donors were known from experience with HIV and HBV to have much higher rates of infectious disease markers than repeat donors were.[59]

2.70 In Queensland, during the three year period of ALT testing over 4,400 donations were estimated to have been discarded. Many new donors were required and the ARCBS stated that this created problems for the Queensland BTS. It added that, in retrospect, it was clear that 92 per cent of the blood Queensland rejected was in fact good blood. The ARCBS concluded that 'essentially surrogate testing was casting a very wide net in which you may have caught just a few of the infectious donors but also a lot of good safe donors got caught as well'.[60]

2.71 It was also suggested in evidence that the costs associated with surrogate testing bore an impact on decisions as to its use.[61] The Tainted Blood Product Action Group (TBPAG) claimed that the ARCBS had:

> [a] desire to place commercial considerations before the primary responsibility of maintaining a safe blood supply...[62]

2.72 The Committee received evidence from the ARCBS addressing the cost of surrogate testing as follows:

> We have examined records from the relevant time held by ARCBS nationally and found only one specific estimate. That was from NSW, the largest Blood Service. NSW estimated that the cost of conducing ALT tests alone for the year 1987-1988 would have been approximately $250,000. This figure did not include any costs associated with replacing lost donors. Based on NSW representing about 33% of Australia's blood collection at the time, one could therefore project the total Australian costs for ALT testing might have been in the order of $750,000 - $800,000 per annum.[63]

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59 *Submission* 64, Submission prepared for hearing 7.4.04, p.13 (ARCBS); see also *Committee Hansard* 5.4.04, p.51 (CSL).

60 *Submission* 64, Submission prepared for hearing 7.4.04, p.14 (ARCBS).

61 *Submission* 82, p.10 (HFA).

62 *Submission* 79, p.2. (TBPAG)

63 *Submission* 64, Response to Questions, 18.5.04, p.2 (ARCBS).

With respect to anti-core testing, the ARCBS went on to provide the following:

> The core antibody test was estimated by Queensland to cost more than ALT testing. In June 1992, it was referred to as having been costed in 1987 at $250,000 per annum for Queensland. Based on Queensland representing approximately 17% of Australian collections in the late 1980s this would equate to a cost of about $1.47 million nationally per annum.[64]

2.73 The ARCBS strongly rejected the claims concerning costs, arguing that cost issues were never a consideration by the (then) Australian Red Cross in their assessment of the usefulness of surrogate testing in the Australian context:

> Commercial considerations played no part in the decision making. It is important to note that cost was not a consideration and has never been claimed to be an issue in the decision making on this surrogate testing in Australia. Red Cross funding at that time was not reliant on the volume of collections therefore any fall in collections did not affect funding.[65]

2.74 Appearing in Sydney, Professor Barraclough summarised what he considered to be an extremely difficult decision making process:

> My view is that the issues were considered effectively by quite serious and concerned people who were trying to balance quite momentous national issues in effect but without adequate scientific knowledge to give them the certainty and security that they would normally have when taking decisions of this nature...[T]he fact that Australia was so early in introducing the first [antibody] test says that people were taking those issues of public safety very seriously.[66]

2.75 Professor Burrell of ACHV concluded:

> In looking back now to assess what might or might not have been instituted at a certain point in time, two further considerations apply. (i) Armed with our current knowledge about HCV, it is hard to fully appreciate the uncertainty and lack of quantitative information available before 1989, and also in the period 1989-1992. Furthermore, the number of false starts and blind alleys that occurred during the 1980's had created a certain sense of caution against immediately adopting possible new measures. (ii) There have been changes in society's tolerance of risk from blood transfusion. Prior to the 1980's, the measurable risk of hepatitis from blood transfusion was acknowledged and enormous efforts were made to reduce this to a lower level, compatible with the requirement to maintain blood supplies. The success of these efforts, the reduction in the risk of transfusion-transmitted HIV, and the institution of nucleic acid screening to even further reduce the transmission of specified agents, have all contributed to a

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64 *Submission* 64, Response to Questions, 18.5.04, p.2 (ARCBS). The ARCBS emphasised that these figures were estimates only.

65 *Submission* 64, Submission prepared for hearing 7.4.04, p.13 (ARCBS).

66 *Committee Hansard* 6.4.04, p.65 (Professor Barraclough).

> current climate where, in balancing cost-benefit issues of blood safety versus possible blood shortage, a particularly high expectation is now required for safety from transfusion-transmission of hepatitis.[67]

2.76 Dr Baird expressed a general view of the majority of medical witnesses, putting it this way:

> ...[I]nternationally there was some wide disparity over what was and what was not appropriate. Some countries were performing testing; others were not. It was purely on the evidence that some people evaluated different evidence in different ways; it was not a universal approach internationally. In retrospect it is easy to look back and say, 'Ah, how progressive' but on the other hand it was not retrospect at the time.[68]

2.77 The Royal College of Pathologists of Australia stated that surrogate testing may have decreased, though not eliminated, the transmission of NANBH but 'this does not mean that the introduction of such testing was appropriate'. The RCPA commented that factors in the decision would be:

- the predicted decrease in the transmission of hepatitis by the introduction of surrogate testing;
- the percentage of donors deferred on the basis of surrogate testing and the impact that this would have on the adequacy of the blood supply
- the impact on the deferred donors themselves, especially as many would not actually have significant illness.[69]

The possible prevention of hepatitis C infections by earlier implementation of surrogate testing and donor deferral

2.78 Submissions from the ARCBS and the paper prepared by Professor Cossart for the DoHA addressed the issue of the number of infections which may have been prevented had surrogate testing and donor deferral been implemented earlier.

2.79 The ARCBS stated that 'it is almost impossible, hypothetically, to quantify the potential benefit of surrogate testing or the impact on the blood supply of its introduction in Australia'. Rather the ARCBS provided evidence on the countries that did introduce surrogate testing and their retrospective view of the benefit.

2.80 In the United States various studies found that:

- 91 per cent of US donors with elevated ALT and 95 per cent with anti-core were HCV negative;

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67 *Submission* 80, p.3 (ACHV).

68 *Committee Hansard* 5.4.04, p.36 (Dr Baird).

69 *Submission* 69, p.1 (RCPA).

- the introduction of surrogate testing in 1986-1990 resulted in little difference in the proportion of multi-transfused patients who developed HCV;
- the most significant drop in the incidence of NANBH occurred with the exclusion of paid donors and the introduction of the HBV surface antigen test in 1970; and
- the combined effect of ALT testing and implementation of anticore as a surrogate test in 1987 was a drop in the incidence of NANBH from 5.5 per cent in 1981 to 4.1 per cent. This change in 'background risk' was significant.[70]

2.81 The ARCBS noted that reductions in post-transfusion NANBH occurred in countries without the introduction of surrogate testing. For example, the rate in Canada declined from 9.2 per cent the early eighties to 3.2 per cent in the late eighties. Other studies from Australia and Europe showed similar results. It was believed that reductions in the risk of NANBH were due to the introduction of other preventative measures. The major measures were the limiting of the amount of blood given to an individual; phasing out of paid donors; and more intense screening of volunteer donors.[71]

2.82 Professor Cossart stated that some anti-HCV positive donations would have been rejected and a proportion of post-transfusion NANBH cases prevented had surrogate testing and donor deferral been implemented during the 1980s. The number of cases prevented and overall effect would have depended on the actual level of the cut off level used to define ALT abnormality; the ethnic and social composition of the donor panel of the time, and the actual rate of post-transfusion NANB hepatitis following transfusion of units retained or rejected.

2.83 Professor Cossart noted that it is not easy to make an assessment in retrospect and even at the time as surrogate testing was only one of four major strategies used during the 1980s to reduce the risk of NANBH after blood transfusion. In addition, few large scale trials on the effect of each measure were undertaken.

2.84 Professor Cossart estimated the hypothetical benefit in Australia from exclusion of donors using surrogate markers:

> If surrogate testing for both raised ALT (>50IU/L) and anti-HBc alone had been introduced during the late 1980s approximately 512 (0.091%) units would have transmitted HCV each year compared with 615 (0.11%) had the same number of donors been deferred on the basis of an arbitrary marker such as the initial of their surname.

The number of cases of hepatitis C prevented would have been substantially less as most patients receive multiple units of blood. Factors which would have attenuated the

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70 *Submission* 64, pp.43-9 (ARCBS).

71 See also *Committee Hansard* 1.4.04, p.2 (ACHV).

impact are that the risk of persistent post-transfusion HCV is less than 25 per cent of the risk of transmission and the risk of chronic HCV related liver disease is still lower.[72]

First generation test for hepatitis C

2.85 The molecular characterisation of the hepatitis C virus in 1989 led to the rapid development of a test for antibody to the virus. Epidemiological studies quickly revealed that HCV was the cause for at least 80–90 per cent of NANBH. The first generation antibody test was subsequently shown to be capable of preventing the transmission of 75 per cent of transfusion-transmitted HCV, the major source of non-A, non-B hepatitis.[73]

2.86 The first tests designed to measure anti-HCV antibodies became available commercially in late 1989. The first HCV kits measured antibody to the C-100 antigen, which is not part of the infectious HCV particle itself, but is made in infected cells as the virus grows. Antibody against the C-100 antigen appears irregularly in acute infection but is usually present in chronic carriers of HCV. Antibodies of this type do not protect against infection, and may cross-react with antigens induced by other related viruses. Professor Burrell stated:

> The first screening test used a very small area of the antigens of the virus and the technology was not as good at dealing with cross-reactions or non-specific binding patients antibody. So some patients in whom the antibodies that had developed did not happen to match up with the narrow range of antigens in the test would have had true antibody but it would not have come up in the test, and that would have given a false negative result. Then there would be other patients in whom the screening test would give a positive reaction. The reason would not be that they had the hep C antibody; the reason would be that they had some other kind of reactivity, that the plasma was sticky or some other unrelated reason.[74]

2.87 The Barraclough Report noted that for many months after the introduction of the tests, there was no independent means of confirming a positive result and this placed transfusion services worldwide in a difficult position. Initial screening of donors revealed a higher rate of positive test results than would be anticipated given the rate of clinical post-transfusion hepatitis. For example, the ARCBS stated that, 'in the first phase, 70 per cent of the people who reacted on the test were false positive; so they did not have HCV at all'.[75] There was also very little knowledge about the significance of a positive test result in terms of the risk of developing significant liver disease or of infectivity to contacts in everyday life. There was consequently no

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72 *Submission* 54, Appendix 4, p.A22 (DoHA).

73 Barraclough Report, p.41.

74 *Committee Hansard* 1.4.04, p.4 (ACHV).

75 *Committee Hansard* 7.4.04, p.60 (ARCBS).

consensus about the most appropriate approach to counselling donors who tested positive for anti-HCV antibodies.[76]

2.88 Australian blood transfusion services decided to introduce screening of donations using the first generation C-100 test in November 1989 with commencement of use of the kits by all Blood Transfusion Services in Australia by 19 February 1990. It was expected that confirmatory tests would rapidly become available given the volume of research being conducted by the Chiron group and others, particularly in Japan.

2.89 Australia was one of the first countries to use the first generation test kits, with most countries introducing the kit during 1990-91. Specifically, these included France and Finland as of May 1990, Canada in June 1990, the USA (Blood Sector) between May and November 1990, the United Kingdom by September 1991 and Denmark by early 1991.[77]

2.90 While there were some reservations expressed on the accuracy of the first generation test, Professor Burrell commented:

> I do not have the percentages in front of me as to what we think their performance was compared to the best standard now, but I am fairly sure that even the first generation tests would have been well in the range of 75 per cent to 95 per cent reliable compared to what we have got now, which is just an extraordinarily large improvement on anything that surrogate markers were attempting to do. The introduction of the first generation test in 1990 was an absolute watershed, moving from being in the dark blindfolded to having a fairly reliable window on what was going on.[78]

2.91 This test is estimated to have prevented 75 per cent of blood-transmitted HCV in the USA, or 40,000 patients per year.

Testing and exclusion of products destined for fractionation

2.92 It is clear that there was a significant divergence of scientific opinion and debate internationally as to the use of plasma testing positive to the newly developed anti-HCV test for the manufacture of plasma products, and the relative safety of immunoglobulin produced with such plasma. Based on the incomplete scientific knowledge of the time, and after wide consultation and detailed discussion of the conflicting evidence, the decision was taken to allow plasma that tested positive to the first generation anti-HCV test to be sent to CSL. This occurred from February 1990, when anti-HCV testing was introduced, through to July 1990.[79]

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76 Barraclough Report, p.41.

77 Barraclough Report, p.42.

78 *Committee Hansard* 1.4.04, p.5 (ACHV).

79 *Submission* 64, Additional information, 10.5.04, p.1-4 (ARCBS).

2.93 The Expert Advisory Group chaired by Professor Barraclough found that positive plasma was allowed to be fractionated for the production of specific products, none of which had been associated with hepatitis transmission provided that particular manufacturing processes were followed. The Group also found that plasma testing positive continued to be stored with CSL until July 1991 for use in research, but that the stockpile was destroyed by May 1994.

2.94 The decision to allow plasma which tested positive to be fractionated for certain products was in accordance with the stated policy of the United States Food and Drug Administration, which considered that the immediate use of the first generation anti-HCV test to exclude plasma for further manufacture was premature.

2.95 However, further consideration by the Red Cross in April and May 1990 led to a reversal of this decision. One key consideration was the publication in *The Lancet* in May 1990 of a letter from the Director of the Scottish Red Cross Blood Service, Dr John Cash, who considered that a continuation of the FDA's policy of inclusion of plasma which tested positive could be regarded as 'a major breach of good manufacturing process'.[80]

Testing and notification policy in the introductory phase[81]

2.96 The Barraclough report commented that in 1990, first generation antibody tests returned a large number of false positive results. Confirmatory tests for hepatitis C were not available for many screened anti-HCV positive donors, particularly in the first three quarters of 1990, and this created difficulties in identifying true positive results. This also lead to greater difficulties in counselling the donors who tested positive. As a result, the Blood Transfusion Service Executive Sub-committee decided in a meeting on 22–23 February 1990 that donors who were repeatedly reactive to anti-HCV screening would not be notified in the first instance. It was agreed at that meeting that donors who were repeat reactive to anti-HCV and had a raised (ALT) at a subsequent donation would be notified and referred to a gastroenterologist.

2.97 As an interim measure, donations testing positive in the C-100 test were retested by the same means. Units which tested positive a second time were withdrawn from routine use and sample was stored for confirmatory tests in the future. An additional test using an assay was called recombinant immunoblot assay (RIBA) was available in limited quantity during the Phase 1 period. The RIBA confirmatory testing commenced in NSW on 3 September 1990, as soon as the kits were commercially available. A small number of trial kits had been provided earlier in the year by Ortho Diagnostics for research purposes.

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80 For further information on the decisions taken regarding fractionated products at this time, see Barraclough Report, pp.60-82.

81 The description of events occurring around 1990 in this section was largely drawn from the Barraclough Report, pp. 5-16; 43-44.

2.98 Donors whose blood repeatedly tested positive to hepatitis C screening tests continued to donate for plasma fractionation products only, until July 1990. Donors were not deferred from making donation until tests that could confirm their HCV status became available. These tests were not universally available until towards the end of 1990, although the first tests became available in September 1990.

2.99 Donor follow-up included further testing at three and six months, including an interview with a blood transfusion service medical officer, to establish if they were still infected.

2.100 The management of anti-HCV (positive) repeat reactive donors was discussed again at a BTS Executive Sub-committee meeting on 18 July 1990. At the meeting it was noted that the majority of blood transfusion services were abiding by the February decision of the BTS Executive Sub-committee. It was agreed that donors should be referred to an appropriate clinician if they were repeatedly reactive to HCV testing as well as showing raised ALT level, and were positive to a confirmation test. It was acknowledged at this meeting that confirmatory tests for HCV antibody were not always available. When confirmatory tests became available and confirmation of HCV positive status was achieved, such patients were counselled, referred to an appropriate clinician and deferred from donation. From December 1990, following discussion at the BTS Executive Sub-committee, repeatedly reactive screening tests were considered as a basis for deferral until true confirmatory tests became available.

2.101 In evidence to the Committee, one witness related his experience of blood donation, expressing concern at being encouraged to donate even after his positive hepatitis status was confirmed.[82] Indeed, the Barraclough Report indicated that, depending on the State or Territory, antibody-positive plasma continued to be shipped to CSL as late at July 1991. However, the Expert Advisory Group concluded that, while donations may have been made, blood testing positive almost certainly was not used by CSL to produce plasma products.[83]

2.102 In a supplementary submission to the Committee, the ARCBS reported that a study was conducted during 1990 to investigate the efficacy of the first generation HCV antibody test, and that some donations made after July 1990 which tested positive to the test were used in that study. The ARCBS indicated that contributors to this study were advised that their donations may also be used for fractionation into products carrying no risk of transmission post manufacture.[84] ARCBS also stated that any plasma testing positive after July 1990, not used for the study, was stockpiled at CSL with a view to its use in the production of a new hyper-immune anti-HCV immunoglobulin. This stockpile was subsequently destroyed, the project unrealised.

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82 *Committee Hansard* 6.4.04, p.37.

83 Barraclough Report, p.12.

84 *Submission* 64, supplementary submission 10.5.04, pp.2-3. (ARCBS).

Second generation testing

2.103 With advances in the understanding of the hepatitis C virus and refinements in molecular technology, a second generation test based on a series of antigens derived from other HCV genes was developed in 1991. Professor Burrell noted that the new tests improved the range of antibodies they detected and could detect closer to 100 per cent of true infections. Approximately half of the donors who tested anti-HCV positive in the first generation test remained positive in the second.

2.104 Professor Burrell went on to state:

> Early on we did not really have any other yardstick. Subsequently, what has become more and more available is a means to detect the virus rather than the antibody. The presence of the antibody usually would be a reflection that the patient had been infected. If infection invariably leads to persistence, as it does with HIV, you can take the presence of antibody as proving the patient is now infected. But, with hepatitis C, we believe that only 65 per cent to 85 per cent of people with antibody are truly infected still and the rest have their antibody but have cleared the virus.[85]

Testing for hepatitis C today

2.105 In testing for hepatitis C, a sample of blood is taken and tested to determine whether the person's body is producing antibodies to the virus. After exposure to the virus it can take up to six months before antibodies can be detected. This is known as the window period.

2.106 An HCV RNA test, sometimes called PCR (polymerase chain reaction test), is now used. This tests for the presence or absence of the virus itself (the viral RNA). The test is generally used when assessing people for treatment and can also be used where an antibody test result is indeterminate. Professor Burrell stated:

> There are still problems with that test because that only has a certain sensitivity and, if a patient has a fluctuating level of virus, there may be times when the level goes under the sensitivity level and then comes up again. So they may appear negative and then be positive a week later.[86]

2.107 As to the overall quality and accuracy of testing in 2004 by the ARCBS, Professor Elizabeth Dax, Director of the National Serology Reference Laboratory, which is charged with assuring the quality of HIV and HCV tests in Australia, stated:

> Not only does the ARCBS strive to put in place the most appropriate methods but they are certainly followed rigorously, in a batch-by-batch way, on a continuous basis. I think all the tests and innovations have been

85 *Committee Hansard* 1.4.04, p.4 (ACHV).

86 *Committee Hansard* 1.4.04, p.5 (ACHV).

> put in place not only promptly but in a very controlled manner and in such a way that they have been able to be checked on a continuous basis.[87]

Conclusions

2.108 The Committee received evidence that there was widespread controversy surrounding the use of surrogate testing in respect of hepatitis C. The Committee considers that this inhibited the ability of authorities around the world in making decisions on its implementation. Australia was no exception, and a good deal of time and resources were spent in search of a definitive outcome, to little or no avail.

2.109 There is evidence to suggest that the relevant authorities in Australia could have instigated surrogate testing prior to the introduction of the antibody test in 1990. However, the Committee was presented with much compelling evidence as to why surrogate testing was not introduced.[88] It seems to the Committee that, based on the information available at the time, it was open to the relevant bodies to take the decisions they did. It is in this context that the concept of equipoise arises, whereby, to quote Professor McCaughan:

> If on the balance of the evidence you do not know what to do, then either choice is ethically acceptable.[89]

2.110 The difficulty associated with the decision making process at the time was also acknowledged by the Hepatitis C Council on New South Wales:

> On balance while we regret, in the strongest possible terms, that hepatitis C infections arose as a result of this decision, we do not believe that negligence or at fault activities occurred.[90]

2.111 The Committee therefore considers that, at the relevant times, decisions made in relation to surrogate and antibody testing were not inappropriate. The Committee is confident that due consideration was given to pertinent evidence at relevant times, and that decisions were reasonable in the circumstances.

Australia's self sufficiency in blood stocks

2.112 The Department of Health and Ageing (DoHA) stated that the aim of national self-sufficiency in blood supply has been part of official Australian policy since 1975.[91] The policy for self-sufficiency arose out of an international concern that some commercial fractionators were buying plasma from persons in developing countries.

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87 *Committee Hansard* 5.4.04, p.29 (Professor Dax).

88 See, for example, *Committee Hansard* 6.4.04 p.65 (Professor Barraclough); *Committee Hansard* 5.4.04, p.46 (Dr Maher).

89 *Committee Hansard* 6.4.04, p.94 (Prof McCaughan).

90 *Submission* 81, Additional Information 9.6.04 p.4 (Hepatitis C Council of NSW)

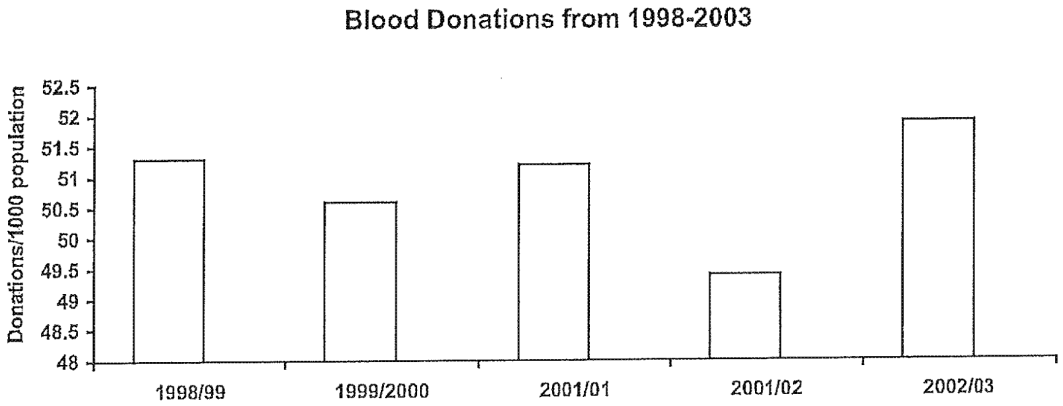
91 *Submission* 54, p.12 (DoHA).

This posed a risk both to the paid donors and to the recipients of products made from plasma.

2.113 Australia's aims in relation to blood and blood products are set out in the recent National Blood Agreement between the Commonwealth and State/Territory Governments where one of the policy aims is 'to promote national self-sufficiency'.[92]

2.114 The Committee heard that, in developed countries such as Australia, self sufficiency could be taken to imply a sufficient supply of both fresh blood components and fractionated plasma products such as albumin, clotting factors and immunoglobulins. This would normally be achieved through a national blood program without the need to source products from other countries. A blood donation rate of 50 per 1000 population is the general minimum donation rate required for a developed country to meet this objective. In Australia, this translates to around 20,000 donations per week being needed to keep supplies at sufficient levels.[93]

Figure 2.2: Blood Donations from 1998-2003



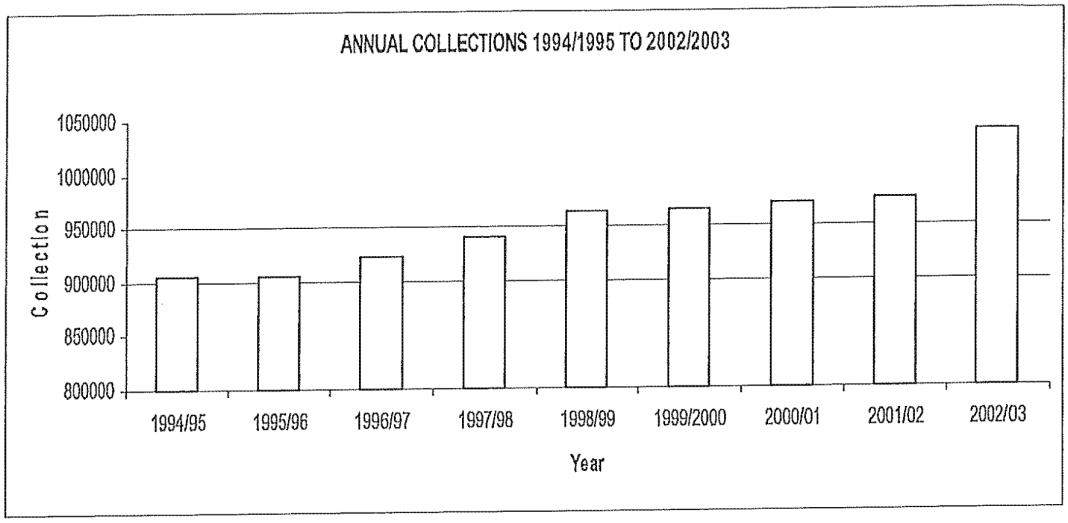
Source: Annual Report 2002-03 Australian Red Cross Blood Service, p.13.

2.115 Figure 2.3 shows the total number of blood collections from 1994-95 to 2002-03.

92 *Submission* 54, p.12 (DoHA).

93 *Submission* 64, p.62 (ARCBS).

Figure 2.3: Blood collections 1994-95 to 2002-03



Source: Annual Report 2002-03 Australian Red Cross Blood Service p.13.

2.116 According to the ARCBS, Australia is in the minority of developed countries which are able to stay fully self sufficient in fresh blood stocks, and almost completely self sufficient in plasma products.[94] This is especially noteworthy as Australia's donors are all voluntary and totally un-remunerated.

2.117 The mid-1980s saw a considerable tightening of donor eligibility, due to the advent of HIV/AIDS. This inevitably led to a reduction in the donor pool, and by 1988 total collections had fallen by 16,000 over the preceding year. It should be remembered that it was around the time of this decline that the prospect of surrogate testing, and the attendant reduction in yield, was being considered in Australia. This reduction in yield was an important concern for those considering the introduction of the testing.[95]

2.118 Tightening of donor eligibility also had an effect on the supply of plasma intended for fractionation, although the ARCBS submitted that 'by and large' the demand for plasma products was still met from within Australia.[96] The ARCBS notes

94 Since 1990, various plasma products have been imported due to low demand. For a more detailed discussion, see *Submission* 64, p.64 (ARCBS).

95 *Submission* 64, p.62 (ARCBS). A state-by-state précis of the blood supply scenario in the 1980s is also available in the ARCBS Submission.

96 *Submission* 64, p.64 (ARCBS).

that certain specialised products, such as Factor VII and Factor XI, which were required by a small number of patients per year, were imported.[97]

2.119 Australia's near total self-sufficiency was lauded by the Stephen Review, which found that:

> Under these [largely self-sufficient] circumstances, continuing high levels of safety and quality should be achievable, as long as careful national policy measures and strong regulatory oversight are maintained.[98]

2.120 Australia's goal of self sufficiency of blood stocks drew criticism from the Haemophilia Foundation, which was supportive of the increased use of recombinant therapies, manufactured overseas, to completely eradicate the risk of blood-borne virus transmission.[99] This is discussed further in Chapter 6.

Blood from overseas being used in Australia

2.121 It was submitted by the TBPAG that CSL had 'mixed Australian blood with blood from several foreign countries for distribution in Australia'.[100]

2.122 The TBPAG refer to an Australian National Audit Office Report relating to unauthorised processing of foreign-sourced blood plasma by CSL, occurring in the mid 1990s.[101] The ANAO report does not conclude that products derived from foreign-sourced plasma were used in Australia, nor does it conclude that cross-contamination between foreign and domestic plasma batches occurred.

2.123 In evidence Dr Maher advised that, prior to 1984, CSL blended Australian and New Zealand plasma for the manufacture of clotting agents where supply was insufficient from either country. Dr Maher pointed out that similar standards were applied in each country to the screening of volunteers and donation testing. Dr Maher then stated:

> Apart from the New Zealand example, CSL has never imported or purchased plasma for the purpose of manufacturing products for therapeutic use in Australia.[102]

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97 For detailed information on all blood products imported into Australia, see Senate, *Hansard,* Question No.1781, 18.9.03, pp.15652-3.

98 Stephen Review, p.xi.

99 *Committee Hansard* 5.4.04, p.7 (HFA).

100 *Submission* 74, p.19 (TBPAG).

101 Australian National Audit Office, *Report on the Commonwealth Management and Regulation of Plasma Fractionation*, ANAO, 1999.

102 *Committee Hansard* 5.4.04, p.45 (Dr Maher).

Collection from prison inmates

2.124 The TBPAG raised the Australian Red Cross state divisions' collection of blood from prison inmates.[103] The Committee understands from information provided to the Senate that this practice had ceased by the following approximate dates: New South Wales, mid 1970s; South Australia, 1975; Western Australia, early 1980s; Victoria, 1983; and Tasmania, 1983.[104]

The global plasma market

2.125 Australia's experience of blood donation stands in contrast to many other developed nations. In the United States, blood and plasma has for many years been imported from Europe to supplement the supply required to service major centres like New York. While paid donation has now been phased out for fresh blood products, it was a feature of the American blood supply for many years, and remains an important element in harvesting plasma.[105]

2.126 One critical feature of systems relying on paid donation, compared with those that are totally voluntary, is the marked increase in the rate of post-transfusion hepatitis. Indeed, it was this phenomenon which led to the phasing out of paid blood donation in the U.S, and which played a critical role in Australian authorities deciding not to proceed with surrogate testing in the mid- to late-1980s.[106]

2.127 Many nations in Europe are self sufficient, but the UK has struck difficulty in maintaining supply of plasma, most recently due to the threat of Creutzfeldt-Jakob Disease being transmitted through the donor pool. As a result, the UK continues to rely on importation of American (paid) donations.[107]

The special case of haemophiliacs

2.128 Haemophilia is an inherited bleeding disorder which affects about one in 10,000 people. People with haemophilia do not bleed any faster than normal, but they do bleed longer, due to a deficiency in blood clotting factor. Depending on severity, haemophiliacs may bleed only after surgery, only after injury or dental work, or may bleed for no reason at all. In severe cases, bleeding can occur into muscles and joints, causing extreme pain.

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103 *Submission* 74, p.21 (TBPAG). See also *Committee Hansard* 6.4.04 p.39 (TBPAG).

104 Senate, *Hansard*, Question No. 1781, 18.9.03, p.15651. There are no records indicating that Queensland ever collected blood from prisons *Submission* 64, Supplementary Information 9.6.04 (ARCBS).

105 *Submission* 64, p.63 (ARCBS). The United States operates dual collection systems; one for fresh blood and one for plasma.

106 *Submission* 64, pp.44,47,63 (ARCBS).

107 *Submission* 64, p.63 (ARCBS).

2.129 Haemophilia A is the most common form of haemophilia and is due to a deficiency of Factor VIII. Haemophilia B is due to a deficiency of Factor IX. The amount of Factor VIII or Factor IX transfused each year is dependent on the severity of the haemophilia and frequency of bleeding. Von Willebrand disorder is another inherited bleeding disorder. Treatment includes infusions of a clotting factor concentrate that contains von Willebrand factor.

2.130 Until 1964, haemophilia had been treated with blood plasma. In 1964, a concentration of Factor VIII by freeze thawing of plasma (known as cryoprecipitate) was developed. From the late 1970s, Factor VIII concentrate was made by CSL. A Factor IX concentrate called Prothrombinex was also developed by CSL. Prothrombinex was the major form of treatment of haemophilia B until it was replaced with a purer Factor IX concentrate (Monofix).[108] The pooling of thousands of donations of plasma is used to manufacture Factor VIII and Factor IX concentrates.

2.131 The HFA noted that factor concentrates have revolutionised haemophilia treatment. They can be made from human blood (called plasma-derived products) or manufactured using genetically engineered cells that carry a human factor gene (recombinant products).[109]

Hepatitis C in the haemophilia community

2.132 The HFA reported that following treatment with contaminated blood clotting factor concentrates, 85 to 90 per cent of people with haemophilia have been infected with hepatitis C. HFA went on to state that it is likely that up to 90 per cent of people with haemophilia A and haemophilia B developed NANBH with their first treatments of non-heat treated factor. There are also more than 250 people with haemophilia who were infected with HIV and many of these people are co-infected with HCV.[110]

2.133 The HFA stated that many people with haemophilia in Australia were known to have hepatitis from the use of blood products and any symptoms they had 'were lived with'. Many did not experience any serious symptoms and the risks inherent in plasma pooling were balanced against the benefit of the utility of concentrates. Hepatitis was seen as an unfortunate consequence, but an acceptable risk of blood products. The HFA concluded that

> [I]n reality, people with haemophilia had no choice of whether or not to use plasma products. When they have severely painful joint or a life threatening bleeding episode, the decision is clear to use the available treatment products, even if the treatment may have associated risks.[111]

108 *Submission* 64, pp.58-59 (ARCBS).

109 *Submission* 82, p.3 (HFA).

110 *Submission* 82, p.5 (HFA).

111 *Submission* 82, p.8 (HFA).

2.134 The very high prevalence of hepatitis C among people living with haemophilia can be ascribed to the following three factors:

- the inability to inactivate virus present in plasma and cryoprecipitate;
- the inability to inactivate NANB hepatitis in pooled plasma products, prior to the early 1990s; and
- regular use of a number of blood products which were manufactured from a large number of donations.

2.135 In October/November 1984, CSL adopted a method of preparation of Factor VIII (used to treat haemophilia A) which allowed for the Factor to be pasteurised by heating at 60°C for 72 hours, thereby destroying some contaminating viruses eg HBV and HIV. Similar treatment was applied to Factor IX from January 1985.

2.136 The first limited supplies of super heat-treated Factor VIII (80°C for 72 hours) became available in January 1990, after reports from Europe of transmission occurring through Factor heated at the lower temperature.[112]

2.137 Prothrombinex concentrates were heat treated at 60°C for 72 hours from 1985 onward. Super heat-treated Factor IX concentrates (heating at 80°C for 72 hours, shown to inactivate HCV virus) did not become available in Australia until 1993.[113]

2.138 CSL acknowledged the risks associated with use of Factors VIII and IX prior to 1989 and 1992, adding that:

> [W]ith hindsight...the hepatitis C virus–or Non-A, Non-B hepatitis as it was known then–was most probably present in every plasma pool throughout the seventies and the eighties...[i]t is unfortunate that scientific knowledge of hepatitis C was not sufficient early enough to prevent infection in the majority of severe haemophilia A and haemophilia B patients treated prior to the 1990s.[114]

2.139 CSL pointed out that the introduction of heat treatment was initially controversial. It was argued by some that such practices could lead to an increase in HAV and HBV positive people who developed inhibitors, a potentially life-threatening complication characterised by resistance to replacement therapy. There would also be a reduction in yield. However, the discovery that HIV was heat sensitive, could be inactivated at 60 degrees, and could otherwise be transmitted through transfusion, was persuasive.[115]

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112 *Confidential Submission* 51, p.17.

113 *Submission* 64, pp.58-61 (ARCBS).

114 *Committee Hansard* 5.4.04, p.43 (CSL).

115 *Committee Hansard* 5.4.04, p.57 (CSL).

2.140 CSL went on to remind the Committee that, at the time most heat treatment was introduced, HCV was still not identified as being a single virus, and that it was not until the late 1980s that it became clear that 60 degree heat treatment was insufficient to inactivate the virus which, in 1990, came to be known as hepatitis C.[116]

2.141 This delay was of concern to the HFA, who submitted that:

> There was a considerable delay before Prothrombinex [the Factor IX based product], heat treated to 80° C, was introduced in mid 1993. This caused frustration and anxiety for clinicians and patients. Some clinicians kept their patients on cryoprecipitate to minimise the risk of larger plasma pools. PTX heat treated to 60° was insufficient to inactivate hepatitis C.[117]

2.142 The HFA also stated that Bio Products Laboratory in the United Kingdom had increased heat treatment factor VIII to 80 degrees, which prevented transmission of NANBH, in 1985. However, CSL did not replicate the process until 1989.[118]

2.143 CSL pointed to the added difficulty of inactivating virus in Factor IX, saying that fortification against the 80 degree heat treatment necessitated a substantial reformulation of the product to guard against the occurrence of thrombosis in recipients.[119]

2.144 The HFA and CSL both stated that there has been no known infection since additional heat treatment of Factor VIII concentrates in 1989 and Factor IX in 1993.[120]

2.145 The use of recombinant Factor VIII and IX is discussed further in Chapter 6.

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116 *Committee Hansard* 5.4.04, p.57 (CSL).

117 *Submission* 82, p.13 (HFA).

118 *Committee Hansard* 5.4.04, p.4 (HFA).

119 *Confidential Submission* 51, pp.28-29.

120 *Submission* 82, p.17 (HFA); *Committee Hansard* 5.4.04, p.53 (CSL).

CHAPTER 3

THE IMPACT OF HEPATITIS C

> I am no longer the happy person my family and friends knew, I am now quiet and withdrawn most of the time. This disease has devastated my life and my family.[1]

3.1 The diagnosis of hepatitis C is often accompanied by a severe emotional and psychological response. People with hepatitis C face deteriorating health and the prospect of an early death. They also face a range of social and economic problems. The impact is not limited just to those who have contracted HCV: their families and friends are also affected.

Health issues

3.2 For those with hepatitis C, the health issues vary as there is no single typical course or natural history of the disease. It is a broad spectrum of disease presentations and outcomes.[2] Hepatitis C has also been described as a 'silent' disease with many people being unaware that they have the infection. Most people will be free of symptoms for the first ten years or more after their initial infection.[3]

3.3 Hepatitis C infection involves an initial (acute) phase of infection, which usually lasts from two to six months. This phase is often asymptomatic with only about 20 per cent of cases having symptoms.[4] Between 65 and 85 per cent of people infected will develop a long-term (chronic) infection. Many of those with chronic infection will have long term health consequences. For the remainder, the hepatitis C virus is cleared from the body. Antibodies to the virus persist after viral clearance, declining over time.

3.4 Chronic hepatitis C is determined by persistently abnormal serum enzymes and/or viraemia. People with chronic hepatitis C can remain well for some time without any liver damage or symptoms. The Hepatitis C Council of NSW advised that 'it is only in the relative long term – 10, 15 or 20 years later – that people start to notice an impact on their physical health'.[5] For those with chronic hepatitis, some will progress to cirrhosis, liver failure or liver cancer. The Council provided the following information:

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1 *Submission* 8, p.5.

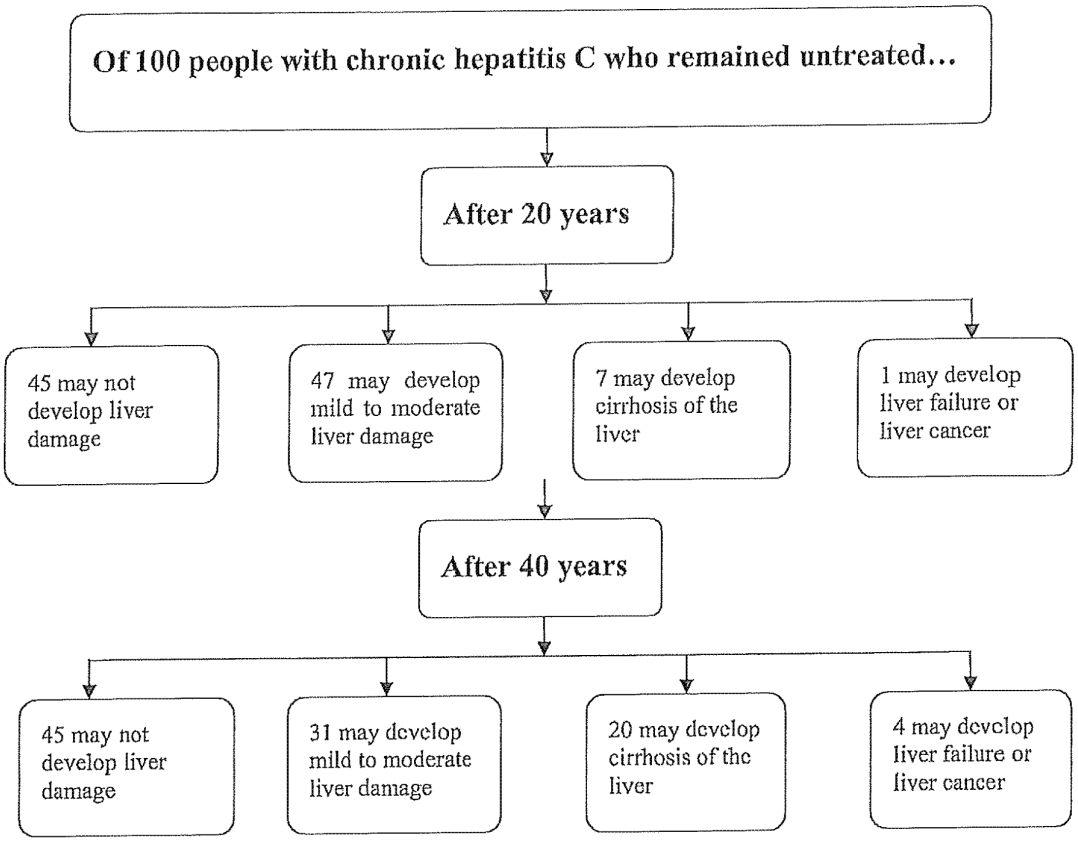
2 Parliament of NSW, Legislative Council, Standing Committee on Social Issues, *Hepatitis C: The Neglected Epidemic Inquiry into Hepatitis C in NSW*, Report No 16, 1998, p.23.

3 www.hcptatitisaustralia.com

4 *Committee Hansard* 6.4.04, p.4 (Hepatitis C Council of NSW).

5 *Committee Hansard* 6.4.04, p.4 (Hepatitis C Council of NSW).

Figure 3.1: Chronic hepatitis C outcomes chart (natural history)



Source: Submission 81 (Hepatitis C Council of NSW).

3.5 The hepatitis C virus does not directly damage the liver. The liver damage results from repeated attempts by a person's immune system to destroy infected cells within the liver. The liver forms scar tissue (fibrosis) in response to the hepatitis C related inflammation.

3.6 There are six main genotypes of hepatitis C which are generally recognised with many sub-types (around 10 in total). The most common genotypes in Australia are 1a, 1b and 3a.[6]

3.7 The symptoms of chronic infection can range from mild to severe. They can occur occasionally or can be continuous. The most common symptoms are fatigue and lethargy. Other symptoms include nausea, poor appetite, muscle aches, weakness, weight loss, abdominal pain and jaundice.

3.8 The symptoms of chronic hepatitis C are distressing and debilitating. Fatigue may be so persistent and overwhelming that it leads to diminution of quality of life as

6 www.hepatitisaustralia.com

employment and participation in family life becomes difficult. One hepatitis C sufferer described her situation:

> I was always feeling unwell and fatigued, the fatigue would get so extreme that I would fall asleep while feeding or changing my baby. I would fall asleep so easily that I had advertently put my baby's well-being at risk on a number of occasions.[7]

Another witness stated:

> I couldn't hold down a job any more! Too tired, very sensitive to noise, criticism, totally unbalanced, low energy, unable to concentrate for long, terribly sick when I drank alcohol, blurred vision due to fatigue, housework didn't get done, crying a lot, unable to get out of bed, didn't want to cook meals, low self esteem, muscle degeneration, pain in the body...dragging myself round for years and still do![8]

And:

> Most days I spend 14-16 hours in bed, I can barely think or read a book or follow events of any kind, I am clinically depressed, suicidal, I am extremely moody, volatile, angry, confused, in constant pain, my friends and family have no idea of how much I am suffering.[9]

Treatments

3.9 Treatment of hepatitis C depends on the different stages of the infection. Two conventional treatments are interferon (monotherapy) and interferon and ribavirin (combination therapy). To undertake monotherapy and combination therapy a person must meet certain criteria, including a liver biopsy showing evidence of fibrosis and raised ALT levels.

3.10 The Department of Health and Ageing (DoHA) stated that Pharmaceutical Benefits Scheme (PBS) and the Pathology Services Table of the Medicare Benefits Schedule (MBS) offer affordable access to hepatitis C treatments and investigation of hepatitis C infection. The hepatitis C antibody test may be reimbursed under the MBS. Qualitative nucleic acid testing which provides a measure of viral load can be reimbursed within certain criteria. Drugs for the treatment of hepatitis C are made available through the Section 100 arrangements (Highly Specialised Drugs Program) under the PBS. The Commonwealth approved Section 100 listing for pegylated interferon from 1 November 2003.[10]

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7 *Submission* 58, p.1.

8 *Submission* 51, p.1.

9 *Confidential Submission* 52, p.1.

10 *Submission* 54, p.23 (DoHA).

3.11 The Hepatitis C Council of NSW stated that the treatment can result in total viral clearance. Studies indicate that if the person does not have cirrhosis in the first instance, hepatitis C will not recur. Those people who have cirrhosis and who have successful treatment can go on to develop liver cancer or liver failure, even though the virus is not present in their bloodstream, but occurs only in a small percentage of cases.

3.12 The Hepatitis C Council of NSW indicated that the success rates for the majority of people treated with pegylated interferon and ribavirin average around 50 per cent. The result differs depending on what genotype of the hepatitis C the person has. The more common genotypes include genotype 1 which responds less well to hepatitis C treatment. Genotypes 2 and 3 respond much better to combination therapy. The success rate for these 'is around the 60 per cent, 70 per cent or 80 per cent mark. That averages out to between 50 per cent and 60 per cent sustained viral response'.[11]

3.13 However, many people undertaking treatment report significant side effects. These include muscle aches, mood changes, fever, chills, headaches, nausea, dry mouth, loss of appetite, inability to sleep and depression. The side effects vary for each person but at their worst can be acute:

> The side effects were very severe and debilitating, causing blinding headaches, extreme nausea and exhaustion...He suffered with deep depression and at times was suicidal.[12]

3.14 The side effects of treatment may impact adversely on work and social lives. The financial cost of treatment can also be high, placing further stress on hepatitis C sufferers:

> I took 12 months off work to have treatment, so did my mum. (26 y.o. single male).[13]

And:

> Whilst on treatment, the treatment for hepatitis C is about $2,500 a month and then there are additional costs to the person being treated for things like sleeping pills just to be able to get to sleep at night, because it is very difficult to sleep. There is a cost at work...I was very close to forgoing work myself. There is no guarantee as to whether or not your job is going to be maintained whilst you take time off to complete your treatment, and there is the likelihood that you might not respond successfully...[14]

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11 *Committee Hansard* 6.4.04, p.7 (Hepatitis C Council of NSW).

12 *Submission* 39, p.1.

13 *Submission* 82, p.22 (HFA).

14 *Committee Hansard* 5.4.04, p.21 (HFA).

3.15 However, the Hepatitis C Council of NSW noted that it was rare for people to come off the therapy because of the side effects. The Council stated that most of the side effects tend to lessen as the treatment progresses. Treatment lasts in cases of people with genotypes 2 and 3 for 24 weeks, and for 48 weeks for genotype 1.[15]

3.16 Unfortunately, not all those undergoing treatment successfully clear the virus. Witnesses informed the Committee that:

> I have watched many people go through the horrendous side effects of treatment to try and clear the hep C virus and I have seen, at the end of 48 weeks, that the treatment has failed. Like many of these people, I have genotype 1 of the hep C virus, the most resistant strain to treatment. To undertake treatment is a very difficult decision to make, knowing the side effects that could occur and knowing that you will go through 48 weeks of sheer hell and possibly find at the end of it all that it had not worked.[16]

And:

> I have had treatment twice, but it hasn't worked for me, so I really don't know what to expect in terms of my health in the future, I do worry about getting cancer because I have had hepatitis for so long (72 y.o. male)[17]

3.17 Another witness stated:

> I have undergone treatment for hepatitis C. It was the most horrendous experience imaginable. I almost had to give up work so that I would be able to complete treatment. I managed to keep going, with the support of others and an incredibly tolerant workplace. Treatment was completed four months ago when I had a negative PCR at the end of treatment. However, I have since tested positive again. Most people with haemophilia in Australia have genotype 1, which requires longer treatment times and does not respond to treatment as readily as genotypes 2 and 3 – a further complication for people with haemophilia.[18]

3.18 A significant number of people with hepatitis C acquired through blood transfusion had pre-existing conditions, such as haemophilia and cancer. These pre-existing conditions often become complex to manage as a result of hepatitis C infection. In addition, many haemophiliacs have HIV co-infection. The Australian Haemophilia Centre Directors Organisation (AHCDO) stated that co-infection with HIV increases the incidence of cirrhosis. It also increases the severity of complications and affects the time taken to develop them with deaths from hepatoma having occurred.[19] The Tainted Blood Product Action Group (TBPAG) noted

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15 *Committee Hansard* 6.4.04, p.8 (Hepatitis C Council of NSW).

16 *Committee Hansard* 5.4.04, p.6 (HFA).

17 *Submission* 82, p.22 (HFA).

18 *Committee Hansard* 5.4.04, p.7 (HFA).

19 *Committee Hansard* 6.4.04, p.49 (AHCDO).

'haemophiliacs who had previously acquired HIV/AIDS from blood products face uncertain treatment scenarios when co-infected with HCV. Co-infected individuals are less likely to respond to drug therapies used to combat hepatitis C'.[20]

3.19 The AHCDO also noted that 'it has been more difficult to assess the degree of disease associated with hepatitis C in haemophiliacs because the disorder makes liver biopsy, which is the trademark investigation technique, very difficult'.[21]

3.20 Many hepatitis C sufferers also seek out complementary and alternative therapies. One witness submitted that:

> Over the years I have tried the following at an unbelievable cost. Physiotherapy, iridology, alternative medicine, chinese herbs, lymphatic drainage, homeopathic & osteopathic treatment, diets, vitamins, herbs, live blood tests etc.[22]

However, these treatments may be expensive and further stretch limited budgets.

Psychological impact

3.21 The Committee heard that fear, apprehension, anxiety and depression are common responses to an initial diagnosis of hepatitis C infection. These feelings about hepatitis C infection may be exacerbated by anger as sufferers feel that they have been infected with a debilitating disease as a result of the standard medical procedure of receiving blood or blood products. These feelings are compounded by lack of knowledge about the virus, lack of specialised counselling services and negative attitudes of family, friends and health care professionals.

3.22 Having hepatitis C affects all aspects of life. One sufferer graphically described the impact of hepatitis C:

> There is a psychological thing happening here – I have developed fears – fear about what the future holds for me, fear about liver disease, fear of cancer, fear about what I would do if I don't respond to treatment sometime down the track if I need to have treatment. All this affects me now – its just having to live with knowing you have hepatitis C and knowing the doctors don't really know enough about it still. The counsellor is helpful but it is really hard living with something that could be a time bomb – no-one really knows.[23]

Another witness noted:

> Not one day passes in which I am able to forget that I am the carrier of an infectious disease. The psychological impact has been devastating.

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20 *Submission* 70, p.25 (TBPAG); see also *Committee Hansard* 5.4.04, p.7 (HFA).

21 *Committee Hansard* 6.4.04, p.50 (AHCDO).

22 *Submission* 45, p.5.

23 *Submission* 82, p.24 (HFA).

> Hepatitis C is an isolating disease; the fear of rejection prevents you from disclosing it to family or friends.[24]

3.23 Many witnesses also spoke of psychological symptoms, with depression arising from their hepatitis status being common. One witness stated:

> I was suicidal, to tell you the truth. I am not coping very well at all anymore. I cannot work, so I am living on $480 a fortnight. I have two children to support. I find it very hard to get the housework done and feed the children and cope with the utter fatigue that I suffer. I have clinical depression. I am not coping very well at all.[25]

And:

> ...depression through the virus has had him contemplating suicide, something that would not have ever been in him prior to getting this virus.[26]

3.24 The impact of both HIV and hepatitis C on the haemophiliac community has been particularly difficult. The AHCDO stated:

> Psychologically, the haemophilia community suffer greatly with hepatitis C. Many were relieved not to be infected with HIV in the early eighties, but were then devastated by their hepatitis C infection.[27]

3.25 Witnesses also pointed to the impact arising from the way in which they learned of their hepatitis C status. Some witnesses spoke of the anger they felt that they had not been contacted by the ARCBS about their infection. Rather they had learned from medical test results they had undertaken in an attempt to identify the cause of their health problems. Often a positive diagnosis had only occurred after many years of searching for a reason for their failing health. One witnesses stated:

> I have been diagnosed as suffering hepatitis C after many years of unexplained symptoms. My deteriorating condition has lead me to numerous consultations with a variety of doctors and specialists together with endless tests conducted to ascertain the causes behind the degenerating condition of my health.[28]

3.26 Other witnesses informed the Committee that they had been notified of their hepatitis C status by the Australian Red Cross Blood Service (ARCBS) by mail. For many, this means of notification added to their distress:

> It was evening when I opened the letter and I couldn't call Lookback until the next morning. I found it hard to believe this was something they would

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24 *Submission* 65, p.5.

25 *Committee Hansard* 7.4.04, p.4.

26 *Confidential Submission* 53, p.2.

27 *Committee Hansard* 6.4.04, p.50 (AHCDO).

28 *Confidential Submission* 25, p.1.

> tell you by mail, or that they would tell you by mail and not include some information about the virus.[29]

The ARCBS stated that it had changed the practice of notifying recipients by letter that they were HCV positive. Currently, the ARCBS uses a letter to contact patients or donors, who are likely to be infected with hepatitis C, for confirmation of identity and to invite them to contact the ARCBS. The ARCBS commented 'one of the things we have learnt through our management of lookback programs is that one of the initial means of contacting donors (i.e. by letter) was inappropriate and we are sorry for any distress this may have caused'.[30] The Hepatitis C Council of NSW noted that the ARCBS also notifies the recipient's medical practitioner who then contacts the recipient.[31]

Social and relationship issues

3.27 A diagnosis of hepatitis C brings with it many social consequences. Sufferers may lack the energy to undertake normal social activities and become fearful of how others will view their health status. This may lead to isolation and exacerbate depression and other psychological problems. Family and friends may also fear the infection due to lack of knowledge about how hepatitis C is transmitted.

3.28 The Committee was provided with examples of the social impact of hepatitis C:

> It has impacted very much on my social life as once again the tiredness is a problem and I fear 'getting close to people' as I may have to tell them.[32]

And:

> I found that my personal relationships deteriorated as my hepatitis C progressed to cirrhosis. I think this is because I couldn't keep up with people, and they didn't understand the illness. I didn't have the energy for others and they didn't seem to care about me and I was fairly depressed about it. (male 50 y.o).[33]

3.29 Family relationships often come under increased pressure with some family members being unable to cope with the infection. Witnesses stated:

> My brother and sisters who are Catholics have shut all doors on me, I am an outcast, they don't want to know...I can't keep up with people, I'm basically

29 *Confidential Submission* 38, p.1.

30 *Submission* 64, Submission prepared for hearing 7.4.04, p.39 (ARCBS).

31 *Committee Hansard* 6.4.04, p.10 (Hepatitis C Council of NSW).

32 *Submission* 19, p.1.

33 *Submission* 82, p.23 (HFA).

> friendless and get terribly lonely. I don't even enjoy the spirit of Christmas and yet I so much want to.[34]
>
> My sisters took the news in different ways, one was supportive and the other I now have no contact with as she fears the infection of herself and her children. The stigma of this disease stays with you always.[35]
>
> A member of our support group is in her 70s and has recently had a knee operation. She has not told her daughters that she has hepatitis C. She feels dirty. She will never tell her daughter, because she said her daughter would keep her grandchildren away from her.[36]

3.30 The breakdown of family relationships is often particularly difficult. As the Australian Hepatitis Council noted:

> Public life is one thing but, when you have trust in your family and friends, you think you have those relationships and that they will support you through thick and thin. People who end up with this diagnosis talk about family members not speaking to them; grandmothers talk about their children keeping their grandchildren away from them because they are worried about their grandchildren getting hep C.[37]

Another witness reported:

> I only have energy to work 3 days as my job is very demanding and my inability to have the energy to do daily housework, school events – life is very frustrating and hard on all my family. This in turn creates untold tensions and unhappiness.[38]

3.31 Submitters also reported the breakdown of relationships and marriages as tiredness, irritability and depression take their toll. Witnesses stated:

> A strong relationship, living together with my girlfriend of almost 3 years duration had been destroyed and therefore terminated due to the pressures of this condition.[39]
>
> I have no doubt that the diagnosis of hepatitis C destroyed the relationship I had been in at the time and had a significant effect on my partner, who bore the brunt of my anguish.[40]

3.32 Some witnesses indicated that they feared having hepatitis C would mean that they would not be able to find a partner in life:

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34 *Submission* 51 p.3.

35 *Submission* 70 p.1.

36 *Committee Hansard* 6.4.04, p.16 (Traids).

37 *Committee Hansard* 1.4.04, p.18 (AHC).

38 *Submission* 3, p.2.

39 *Confidential Submission* 33, p.2

40 *Committee Hansard* 5.4.04, p.7 (HFA).

> I am still, and pretty much always have been a single man and at 34 yrs I wonder if I will ever find myself a wife and have children now I have got a second virus to deal with. One might say it's become a much bigger ask of someone (prospective partner) to accept me as I am.[41]

And:

> Too tired for a relationship, have been on my own for 12 years, so gave up on men.[42]

3.33 The Committee also heard evidence of the impact of hepatitis C on parenting. Parents feared infecting their children. Mothers in particular feared the transmission of the disease to children conceived after infection. One mother stated:

> Following the initial HCV diagnosis my concern was for my family. Tests proved that none was infected. They were very fortunate in those 22 years, that I did not unwittingly infect them, particularly the breast fed baby.[43]

3.34 Others expressed anxiety of transmission through the day-to-day care of their children. Witnesses submitted:

> It is the little acts that occur within the family unit, that suddenly take on a more sinister meaning in the face of HCV infection. Sharing razors, accidentally using someone's toothbrush, your four year old putting a band-aid on your cut and kissing it better, the way you have done for him. You wonder at what point you may have compromised the safety and well being of those you care about the most.[44]

And:

> The constant fear of infecting my nearest and dearest is most confronting. I isolate myself by using personal crockery, cutlery, cooking utensils, toiletries, linen etc. This fear is magnified if a minor cut or abrasion occurs, during gardening or the like, causing me immense anxiety for the safety of others.[45]

3.35 Other problems raised in evidence were the impact of fatigue and general ill health on the ability of HCV positive parents to interact with, and raise, their children in the way they would like. In addition, with high health costs and restricted incomes, many parents felt that their partners and children were being cheated by the disease. One witness stated:

> My 16-year-old has gone to live with her father because of all the tension and the fact that sometimes I could not get up to cook a meal and do things

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41 *Submission* 47, p.1.

42 *Submission* 51, p.2.

43 *Submission* 10, p.1

44 *Submission* 65, p.5.

45 *Confidential Submission* 2, p.1.

> like that. She left to go and live with her father because I was not looking after her very well...My son is 31. He was 12 when I had the blood transfusion. Before that, I used to play soccer, basketball and netball. I would go training and take him to his football games. I came out of hospital and I expected to have a bit of time to get over it. I was in hospital for 2½ months when I had the blood transfusion. I came out...I was not the same mother after I came out of hospital. I was tired. I gave up all sport. I could not manage the sport. I was not doing the tuckshop for him anymore. I feel I have let him down. I feel that he has missed out a lot by me being sick.[46]

And:

> It has been hard on my family over the years. Instead of having a normal mum, they have had to put up with someone who is tired all the time, suffers from depression, and is always sick and sometimes unable to participate in planned activities.[47]

Impact on earnings and career

3.36 The impact of hepatitis C on earnings and career is two fold. First, the chronic fatigue and other symptoms of the disease often make it difficult for people with hepatitis C to work to their usual capacity or to continue their chosen careers. Secondly, the cost of treatment is sometimes very high.

3.37 Witnesses provided evidence of the impact of their employment:

> I could not perform a full days office work and always needed a "siesta" in the middle of the day to recharge my batteries. My income deteriorated substantially.[48]

And:

> I used to work full time but since contracting this condition I have not been able to work because of severe tiredness and pain...Trying to make ends meet is a daily battle for us because 1 salary is just not enough...It has stopped us from having children. It has turned our life inside out.[49]

Another witness indicated:

> I think employment is important because once you have used up your sick leave you start using leave without pay. If you are the sole provider for the family, that starts to affect your ability to support your family. Having odd days off here and there, you accumulate a large financial burden. You cannot get sickness benefits for that short term...If you are a mother, your partner is working and you have to attend appointments or you are unwell

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46 *Committee Hansard* 7.4.04, p.8.

47 *Submission* 7, p.1.

48 *Confidential Submission* 1, p.5.

49 *Confidential Submission* 12, p.1.

> you may have to use child-care services. There are a whole range of other things that you would normally not have to expend money on. This adds to the costs of people surviving with hepatitis C, or living with it.[50]

3.38 Other witnesses spoke of the long term impact of hepatitis C on retirement plans:

> I have tried to keep working over the years, but have had to give up a number of jobs because they became too strenuous and tiring. I am now earning less money than before because I cannot do the sort of work done previously. At the moment I am working full time, but cannot keep it up because of the stress and heavy work load. So instead of having reached the stage where my husband and I should be planning for retirement all I can manage is to take one day at a time, and because I will not be able to work much longer we are facing the prospect of not having enough money to retire on.[51]

3.39 Many witnesses indicated that having hepatitis C had resulted in them being unable to continue in their chosen field of work, this is particularly the case for those HCV positive people who are health care workers. The Committee received evidence from one nurse:

> I am a registered nurse in operating rooms...I was informed after the discovery of Hep C that I could no longer be involved in exposure prone procedures ie I could not 'scrub'...I therefore was forced to cease working night shift with a subsequent loss of income...and a loss of job satisfaction.[52]

Another witness submitted:

> ...I was an ambitious practitioner of my profession, looking forward to a developing career...I now find it necessary to retrain for a different, less physically arduous vocation.[53]

And:

> Prior to [contracting hepatitis C] I ran a successful building operation...for 30 years. I am now on disability pension and lost everything including friends.[54]

3.40 The cost of medication and treatment for chronic conditions such as hepatitis C can be very high. Witnesses submitted:

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50 *Committee Hansard* 6.4.04, p.15 (Traids).

51 *Submission* 7, p.1.

52 *Submission* 49, p.2.

53 *Submission* 4, p.1.

54 *Submission* 28, p.1.

> It has been a very expensive time since I have learnt I have the disease. Medicare covers part of doctors bills but specialists costs are way over the Medicare rebate, plus prescription costs for various treatment is also expensive.[55]

And:

> Accessing medical care also present a big drain on me. After a while you feel like you are on a cattle truck and a lab rat to boot. You try any sort of care that may be available just to get some normality in your life.[56]

3.41 Travel costs for those living outside metropolitan areas can also be substantial:

> I just live on a pension, this gives me little money each week. With the running of my car, house, my medicine is up to $100 per month. With the isolation from Tamworth and Newcastle to see a doctor or hospital in these centres you need at least $200 each visit for petrol and for doctor's account.[57]

Discrimination

3.42 Hepatitis C discrimination and stigmatism is well documented and has a profound impact on affected individuals.[58] Hepatitis C sufferers have reported discrimination in employment, education, health care, accommodation and insurance. The discrimination is often so distressing that people with hepatitis C have chosen to keep their health status private:

> I don't tell people I have hepatitis C, but then I feel guilty and avoid them.

And:

> I am an allied health professional and I don't tell people/colleagues of my hepatitis C status because so many are so judgemental about others with hepatitis C that I don't want them to know I have it.[59]

Health care settings

3.43 Many witnesses referred to discrimination and insensitivity while receiving medical treatment. This is particularly distressing for people who are already trying to

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55 *Confidential Submission* 10, p.1.

56 *Submission* 45, p.5.

57 *Submission* 40, p.2.

58 Parliament of NSW Legislative Council, Standing Committee on Social Issues, *Hepatitis C: The Neglected Epidemic Inquiry into Hepatitis C in NSW*, Report No 16, 1998; Anti-Discrimination Board of NSW, *C Change: Report of the Enquiry into Hepatitis C Related Discrimination*, 2001.

59 *Submission* 82, p.24 (HFA).

cope with a broad range of health problems. The discrimination ranges from refusal to provide services to breaches of confidentiality and disclosure issues.

3.44 The Committee was provided with examples of incidents of discrimination in health care settings. One witness reported that while in hospital signs had been place on her room door indicating that the room was occupied by a hepatitis patient and that she was asked to wear a red band in front of a full ward of patients which made other patients think the person was a drug addict.[60] Another witness stated that their loved one had 'been exposed to all manner of verbal and inferred discrimination when he has been required to have any procedures or medical testing; basically considered unclean, a risk, a danger'.[61]

3.45 The Tainted Blood Product Action Group submitted:

> Cancer patients who need to donate their own stem cells for possible autologous transplantation (self-donation) are denied tanks to store their stem cells, because they have HCV. Patients with chronic pain who have Hepatitis C frequently feel uncomfortable when asking for pain relief. There can on occasion be suggestions from medical practitioners that the patient may have used IV drugs in the past, because of incorrect assumptions that their HCV infection occurred as a result of sharing dirty needles, and that they should not be prescribed strong pain relief for fears that they are asking for medication under false pretences.[62]

3.46 Other witnesses cited instances of insensitivity, particularly when they were being informed of their HCV status. One witness stated:

> I found out through a routine pregnancy blood test in 1995 that I had hep C. I was unaware of the situation. The doctor really did not inform me; he told the medical student over my head, 'This patient has C antibodies and is also hep C positive,' at which point I sat up and said, 'Hepatitis C? I haven't got hepatitis C.' He just looked at me and said, 'Yes, you have,' but I was not informed.[63]

3.47 Unfortunately, experiences of discrimination may lead to fear of accessing services which may have a detrimental impact on health outcomes for sufferer of hepatitis C. The Australian Hepatitis Council stated:

> One of the big issues is that, if you have a negative experience within the hospital system or when you are first diagnosed by your GP, it actually discourages you from going back. So I guess an issue is that you may not actually seek treatment and you may not seek to have your condition monitored well, because you do not like being treated in that kind of negative way. I think that has quite an impact for a number of people,

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60 *Submission* 31, p.1.

61 *Confidential Submission* 17, p.1.

62 *Submission* 79, p.25 (TBPAG).

63 *Committee Hansard* 7.4.04, p.1.

> particularly people from marginalised groups who are affected by hepatitis C. They traditionally do not access health care services well, so again they do not access them around these issues too.[64]

3.48 People who have acquired hepatitis C through blood transfusion also reported people did not understand that hepatitis C could also be acquired through blood transfusion. The Committee was provided with many examples:

> I was made to feel dirty and constantly asked if I had been involved in drug use.[65]

> People with blood transfusion related hep C find it very difficult that they may also be judged to be an illegal drug user. Many face things like, 'I suppose you're going to tell us you got it through blood transfusion,'...As an excuse. It is not a condition that gets a sympathetic response in the wider community or within the health system.[66]

> There is a real stigma about having hepatitis C, when you say you have it you can see the look on people's faces and can almost hear them thinking "drug addict".[67]

The general community

3.49 Discrimination in the general community adds to the distress of hepatitis C sufferers. One witness stated:

> There is nothing more embarrassing than having someone not shake your hand, hug you, kiss you, touch something you've touched or pull a child away from you because you have Hepatitis "C" and they don't understand anything about the disease.[68]

Witnesses, having experienced negative attitudes to their health status, reported that they chose not to tell people that they were HCV positive. One witness states 'I keep this [HCV status] a close guarded secret fearing that people may think I am a drug user'.[69]

3.50 The Committee also heard of discrimination in the work place. One witness submitted:

> I informed my work colleagues that I had been infected with hepatitis. The staff were very wary. A few members of my working team were concerned of being infected by body sweat and contact with me. A staff meeting was called and the Railways called in a doctor specialist to reassure the staff of

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64 *Committee Hansard* 1.4.04, p.17 (AHC).

65 *Confidential Submission* 18, p.2

66 *Committee Hansard* 6.4.04, p.16 (Traids).

67 *Submission* 7, p.2.

68 *Submission* 8, p.6.

69 *Confidential Submission* 14, p.1

> the limited risk involved. Regardless of the meeting my fellow workers were still distant in many ways [and] isolated me.[70]

3.51 Other witnesses stated that they had been unable to obtain travel insurance, loss of income insurance or life insurance because of their hepatitis C and were distressed at the special arrangements that would have to be made for the funerals.[71]

3.52 Discrimination may also extend to the families of hepatitis C sufferers. One mother submitted:

> My children have suffered discrimination at school and we have already changed from another school...My children are told to get out of class when they are bleeding and no adult supervision is offered to help them when they are injured or have nose bleeds. Both my children are HEP C negative.[72]

3.53 The NSW Legislative Council Standing Committee on Social Issues reported in November 1998 on its inquiry into Hepatitis C. The report, *Hepatitis C: The Neglected Epidemic*, also detailed discrimination suffered by people with hepatitis C.[73] In 2001 the Anti-Discrimination Board of NSW, reported on its inquiry into hepatitis C related discrimination. This inquiry found that hepatitis C is a highly stigmatised condition and the discrimination against people with hepatitis C is rife. The discrimination takes many forms and is often motivated by stereotyped responses towards people on the basis of past, current or assumed injecting drug use.[74]

Conclusion

3.54 Those who have been infected with hepatitis C from blood transfusion and blood products include adults, children, haemophiliacs, accident victims, mothers post childbirth and those having surgery. While many received these blood or blood products as part of life-saving medical measures, they also received the hepatitis C virus.

3.55 The Committee heard that, although some of those infected cleared the virus, for those who did not, hepatitis C is a 'life-changing' disease. Fatigue, pain and depression are the most common symptoms of hepatitis C. While in most cases, liver and other major organs also break down. Hepatitis C affects all aspects of the infected person's life from their working life to their relationships with their spouse, children, family and friends.

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70 *Submission* 15, p.2.

71 *Submission* 31, p.3; *Committee Hansard* 5.4.04, p.14 (HFA).

72 *Confidential Submission* 32, p.1.

73 *Hepatitis C: The Neglected Epidemic*, pp.108-117.

74 *C Change: Report of the Enquiry into Hepatitis C Related Discrimination*, Executive Summary.

3.56 Many witnesses were distressed that they had lived with the symptoms of hepatitis C without it being diagnosed. Once diagnosed, sufferers face the prospect of undertaking treatment which may have distressing side effects or developing severe liver disease. The treatment of HCV positive people with other health conditions such as haemophilia and cancer may be more complex and co-infection with HIV increases the severity of complications.

3.57 People with hepatitis C also face ignorance, discrimination and stigma. The Committee heard many disturbing incidents of discrimination. Most distressing were those that had taken place in health care settings. As a result, people with hepatitis C often choose not to inform family or friends about their health status for fear of rejection and ostracism.

CHAPTER 4

THE KREVER REPORT

4.1 Terms of Reference (g) and (h) require the Committee to examine, respectively:

> The implications for Australia of the world's most extensive blood inquiry, Canada's Royal Commission (the Krever Report); and
>
> The implications for Australia of the recent criminal charges against the Canadian Red Cross for not implementing surrogate testing for hepatitis C in the 1980s.

4.2 This Chapter provides a summary of the findings of the Krever Report,[1] the subsequent criminal charges, and then comments on its applicability to the Australian situation.[2]

What did Krever say?

4.3 Justice Horace Krever was appointed in October 1993:

> [T]o review and report on the mandate, organization, management, operations, financing and regulation of all activities of the blood system in Canada, including the events surrounding the contamination of the blood system in Canada in the early 1980s, by examining, without limiting the generality of this inquiry:
>
> 1. The organization and effectiveness of past and current systems designed to supply blood and blood products in Canada;
>
> 2. The roles, views, and ideas of relevant interest groups; and
>
> 3. The structures and experiences of other countries, especially those with comparable federal systems.[3]

4.4 An Interim Report was released in February 1995 and the Final Report in November 1997.

4.5 The Canadian experience in relation to the implementation of surrogate testing reflected a similar lack of clarity and consensus to that which occurred in the United States, as outlined in Chapter 2. The difference, however, was that the discourse had not concluded by the time antibody testing became available in 1990, and hence, was largely obsolete upon completion.

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1 Krever H, *Commission of Inquiry on the Blood System in Canada*, 1997.

2 Much of Krever's discussion of the Canadian situation, particularly in relation to the evolution of opinion regarding surrogate testing, has been integrated into discussion in Chapter 2.

3 Krever Commission, Final Report, Volume 2, p.5.

4.6 It should be noted that Justice Krever's investigation concerned itself primarily with the Canadian response to HIV/AIDS. The Report is particularly critical of the delay in the introduction of HIV testing in Canada, which did not occur until March 1986. In contrast, Australia's comprehensive introduction of testing was complete by May 1985, placing it in the first few countries to do so.

4.7 With respect to surrogate testing for HCV, in the Canadian context, Krever concluded:

> Although, when used together, the tests were thought to reduce the incidence of non-A, non-B post-transfusion hepatitis by only 60 per cent, they were introduced because, in the United States, there were high rates of post-transfusion non-A, non-B hepatitis and because as many as 20 per cent of the persons infected were developing serious liver disease. During the years 1986 to 1989, the question of whether the two tests should be introduced in Canada was under active consideration. One of the reasons why the tests were not introduced is that, although data from U.S. studies showed that the introduction of the surrogate tests would probably reduce the rate of post-transfusion hepatitis significantly, they did not prove conclusively that the tests would have that effect. Instead of introducing the tests in Canada, a study was conducted to determine whether the tests would be effective in reducing the rate of post-transfusion hepatitis. Before the study could be completed, a specific test to detect the presence of hepatitis C (the most prevalent form of post-transfusion non-A, non-B hepatitis) was introduced in 1990. The study demonstrated that, before the hepatitis C test was introduced in 1990, the introduction of the surrogate tests would have greatly reduced the occurrence of post-transfusion non-A, non-B hepatitis. Rather than awaiting full scientific proof, the Red Cross could and should have accepted the estimates of the efficacy of the surrogate tests. If the Red Cross had introduced appropriate risk-reduction measures promptly, without awaiting full scientific proof, fewer persons would have been infected with HIV and hepatitis. In the words of a U.S. authority, public health has never clung to the principle that complete knowledge about a potential health hazard is a prerequisite for action.[4]

4.8 While Krever's findings implicitly recognise the role which surrogate testing may have played in reducing incidence of post transfusion hepatitis in Canada, it should be remembered that his findings were made in a context which could be contrasted with that of Australia in at least three key areas.

4.9 First, Krever was extremely critical of the time taken by Canadian authorities in deciding on, undertaking, reporting on, and then acting on, studies into the usefulness or otherwise of surrogate testing. This was in sharp contrast to Australia. For example, due to resource allocation and other bureaucratic delays, an authoritative

4 Krever Commission, Final Report, Volume 2, p.990.

study into surrogate testing was not undertaken in Canada until September 1989. In Australia, the equivalent study began a full two years earlier, in September 1987.[5]

4.10 Secondly, the epidemiological situation with which decision makers were presented varied substantially between the two countries. Throughout this inquiry, the Committee has been told of the importance of the rate of post transfusion hepatitis as a key factor in rating the usefulness of surrogate testing in a given blood supply, due to the incidence of false positive and false negative results.[6]

4.11 Krever's analysis of the culpability of the Canadian Red Cross was based on his acceptance that the American rate of hepatitis incidence could serve as the basis for estimating incidence in Canada. Krever's analysis was subsequently supported by a study of incidence in Toronto which arrived at a figure of 9.2 per cent, compared with an incidence of around 10 per cent in certain locations in the United States.[7] It was in this context that Krever found the inaction of the Canadian authorities to be wanting. He stated:

> In the absence of evidence that the rate [of incidence] was different in Canada, there was no sufficient reason to refrain from relying on the US data and introducing the surrogate tests.[8]

4.12 Professor Barraclough agreed that incidence rates were important, saying:

> The balance swings if the donor population has a high probability of having non-A, non-B or hep C. Those decisions become a little easier when the benefit is likely to be a little greater by excluding those. When the risk to the patient is a little over one percent, it becomes a doubtful proposition.[9]

4.13 The Australian situation was very different. In the study conducted by Professor Cossart in 1982, the incidence of post transfusion infection was reported at 1.7 per cent.[10] (This study is referred to in Chapter 2.) Krever observed that:

> In general, countries in which the incidence of post-transfusion Non-A, Non-B hepatitis was low were most likely to decide not to implement surrogate testing routinely.[11]

4.14 Thirdly, Krever found a series of systemic problems between the Canadian Federal and Provincial Governments, the Canadian Blood Transfusion Service, commercial fractionators and Boards of Governors charged with evaluating evidence

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5 *Submission* 64 p.53 (ARCBS). The importance of incidence of Post-transfusion hepatitis in the Canadian context is discussed in Krever Commission, Final Report, Volume 2, pp.650-651.

6 See, for example, *Committee Hansard* 6.4.04 p.65 (Prof Barraclough).

7 Feineman *et al*, as contained in *Submission* 64, p. 53 (ARCBS).

8 Krever Commission, Final Report, Volume 2, p.993.

9 *Committee Hansard* 6.4.04 p.65 (Prof Barraclough).

10 Cossart YE *et al*, Post-transfusion hepatitis in Australia, *Lancet* 1982, 1:208-13.

11 Krever Commission, Final Report, Volume 2, p.706.

and making decisions.[12] There is no compelling evidence before the Committee suggesting that such a situation was replicated in Australia. Indeed, the Committee received strong evidence that the decisions in relation to surrogate testing, and the manufacture of plasma products, were taken with due consideration of the evidence at hand, in a timely fashion and with the agreement of each jurisdiction except Queensland.[13]

Implications of criminal charges

4.15 While a number of Submissions called for the charging of the ARCBS following Krever's findings, the Committee received very little evidence going to the implications of the charges laid in Canada in the Australian context.

4.16 Consistent with its commentary with respect to the findings of the Krever Report itself, the ARCBS submitted that:

> It would be wrong to assume or infer that any of the identified systemic problems of the [Canadian Blood Transfusion Service] applied to the Australian Blood Transfusion Services in the eighties and indeed it would be submitted to the contrary. The Krever Report should be seen in its proper context. It was an inquiry relating only to the activities of the Canadian Health Services including Governments, commercial fractionators, and the CBTS.[14]

4.17 The ARCBS concluded that:

> The findings of the Krever Commission and the recent criminal charges against the Canadian Red Cross are not relevant in any way to the Australian situation.[15]

4.18 The Department of Health and Ageing also submitted that the charges raised in Canada had no implications for Australia.[16]

Conclusion

4.19 The Committee considers that although the Krever report provides a useful analysis of the state of knowledge at the time important decisions were being made in both Australia and Canada, those decisions were being made in markedly different contexts. In making this conclusion, the Committee is particularly mindful of Justice Krever's observation, as well as those from other experts during the inquiry, that the significant distinctions between the two scenarios were the basis for the different decisions made in each case.

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12 Krever Commission, Final Report, Volume 2, pp.985-1001.

13 See, for example, *Committee Hansard* 6.4.04 p.65 (Prof Barraclough); *Committee Hansard* 5.4.04 p.46 (Dr Maher).

14 *Submission* 64, p.50 (ARCBS).

15 *Submission* 64, p.50 (ARCBS).

16 *Submission* 54, p.10 (ARCBS).

CHAPTER 5

COMPENSATION ARRANGEMENTS

5.1 During the inquiry, there were many calls for compensation to be paid to those people who contracted hepatitis C through blood transfusion. Some compensation has been paid by various parties to those who have acquired hepatitis C. However, this is limited to a specific group of hepatitis C sufferers.

5.2 This chapter looks at the compensation arrangements already in place, including the Commonwealth's involvement, the calls to extend the coverage of compensation payments and compensation schemes overseas.

Provision of compensation

5.3 Compensation schemes exist in the States and Territories for those people who have acquired hepatitis C through the blood supply. Arrangements vary between the States and Territories, and the parties to the settlements can also vary. The parties, variously, are: the Australian Red Cross Blood Service (ARCBS), the State and Territory Governments, and the claimants' solicitors. The Committee was unable to ascertain the exact details of each scheme. However, the following information concerning arrangements in the ACT was provided in the ACT Legislative Assembly in answers to a question on notice, dated 23 March and 21 April 1999, by the then ACT Minister for Health.[1]

5.4 The compensation in the ACT is limited to persons infected between 1 January 1985 and February 1990.[2] The Minister stated that the decision regarding the time period and the need for financial assistance was based on the following considerations:

- in 1985, more information on non-A, non-B hepatitis and its relationship with blood transfusions was collected and blood banks in the US began using ALT testing to reduce the prevalence of hepatitis C in the donor pool;
- the Queensland Red Cross Blood Bank introduced screening and 'it is assumed that if the ACT Red Cross Blood Bank had introduced ALT testing at the same time as in Queensland, the risk of transmission of Hepatitis C may have been reduced'. Further, 'the failure of all Australian States, except Queensland, to introduce ALT testing for all blood donors may have created a situation where the Red Cross Blood Service in those states is legally liable to pay compensation'; and

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1 ACT Legislative Assembly, *Hansard*, 23.3.99, pp.685-88; 21.4.99, pp.1077-78.

2 In additional information provided to the Committee by the ACT Government, the cut off date for compensation eligibility was stated as 20 May 1991. Additional Information, 28.5.04, p.1.

- where a person who is now hepatitis C positive was transfused with blood from a hepatitis C donor between 1985 and 1990, and where it is more probable than not that the blood transfusion was the source of the infection, the person is eligible for financial assistance. Financial assistance should be based on the impact that the disease has had on the person's health and life; and that the cost of litigation over hepatitis C transmitted by blood transfusion, both to the Government, Red Cross and litigants be minimised.[3]

5.5 In answer to a further question on notice, the then Minister stated:

- the details of the compensation scheme are confidential;
- the scheme will include proof of infection, effects of the disease on the lifestyle and earnings of the individual concerned and the establishment of a link between the disease and the receipt of transfused blood from a donor who subsequently tested positive to hepatitis C;
- the ARCBS is the primary 'owner' of the Scheme and will need to agree to each proposed settlement as will the (then) Commonwealth Department of Health and Family Services; and
- no compensation is to be paid to the spouse of a deceased person as any individual who is deceased as a result of hepatitis C is likely to have contracted the virus at least two decades ago and outside of the compensable period.

5.6 The Minister added that 'the Commonwealth has made it clear that it will only contribute to the settlement of claims on the following basis:

- evidence of the liability of the ARCBS;
- agreement of the Commonwealth to the settlement offered on each individual case; and
- entry into a settlement scheme with all litigants'.[4]

5.7 The Commonwealth Department of Health and Ageing (DoHA) stated that during 1997 and 1998, the Department wrote to all jurisdictions outlining the conditions under which the Commonwealth would contribute to hepatitis C compensation settlements. DoHA stated:

> Any Australian Government funding of large scale legal costs or settlements was outside normal operational funding arrangements for the blood service and therefore not automatic. However, the Department agreed to pay 40% of any hepatitis C settlements and legal costs arising from settlements.[5]

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3 ACT Legislative Assembly, *Hansard*, 23.3.99, pp.685-88.

4 ACT Legislative Assembly, *Hansard,* 21.4.99, pp.1077-78.

5 *Submission* 54, Supplementary Submission, 21.5.04, p.4 (DoHA).

The 40 per cent contribution was not always provided. For example, in cases where a NSW Country Blood Bank was the service provider, the Commonwealth only contributes 20 per cent of the settlement. The basis on which the Commonwealth agreed to contribute a 40 per cent share was:

- the Australian Government funded 40 per cent of the general operating costs of the Australian Red Cross Society's blood transfusion service under cost-sharing arrangements between the Australian Government and the States and Territories during the period covered by the compensation schemes; and
- the fact that the Australian Government contributed 40 per cent of AIDS settlement costs under similar conditions.[6]

5.8 The Department also stated that it agreed to pay the contribution provided the following conditions were met:

- each claim was settled only after full assessment of its particular forensic risk;
- the State/Territory agreed to pay 60 per cent of the net cost;
- the Commonwealth was consulted and agreed in advance to any settlement;
- the Commonwealth contribution to legal costs and any damages payable as a result of a court decision, out-of-court agreement or settlement scheme was net of any contribution due or liable under a commercial or government insurance arrangement; and
- where a case proceeds to court, the Commonwealth's contribution was contingent on the Commonwealth having been consulted and agreeing in-principle to participate, at the time proceedings were initiated by a plaintiff.

5.9 DoHA pointed out that the Commonwealth is not a party to either the settlements or the settlement documents, including the confidentiality documents required by other parties. However, DoHA stated that its records 'indicate that between 1997 and 30 April 2004 the Australian Government has paid $6,999,882 for hepatitis C compensation settlements, including associated legal and administration costs'. The Commonwealth's contributions have been generally paid directly to the State and Territory health departments. The exceptions to this are: New South Wales, where the payment has been made to an insurance company and Victoria where a law firm has been paid.[7]

5.10 It was noted that the Commonwealth was 'not running the services but we were making a contribution from the national level'.[8] When the States and Territories entered into compensation arrangements, it was agreed that the Commonwealth would contribute to these arrangements to the same extent as it had contributed to funding of

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6 *Submission* 54, Supplementary Submission, 21.5.04, p.5 (DoHA).

7 *Submission* 54, Supplementary Submission, 21.5.04, p.1 (DoHA).

8 *Committee Hansard* 1.4.04, p.27 (DoHA).

services.[9] Each jurisdiction provides details of their settlement arrangements to the Department. There was no settlement scheme set up in Queensland.[10]

5.11 The Queensland Government informed the Committee that in 1985 Queensland Cabinet decided that Queensland would not introduce legislation for the purpose of limiting liability in respect to the transmission of HIV through the transfusion of blood. The Government stated that:

> The condition was that the ARCBS–Queensland would carry out all prescribed tests and that, in the event of any litigation against the ARCBS relating to the transfusion of HIV, the Queensland Government would accept the legal costs as part of the costs of operating the blood transfusion service. In September 1985, that decision was extended to include "other blood transmitted diseases".

5.12 The Government indicated that Queensland Health's most recent agreements with ARCBS–Queensland state that Queensland will honour its previous commitment to cover any liability. In conclusion, the Queensland Government stated that 'there is no evidence of any claim for compensation for transfusion-related hepatitis C being made against the Queensland ARCBS and therefore against the liability coverage provided by the Queensland Government'.[11]

5.13 The New South Wales Government stated that it indemnified the ARCBS for claims made against it in respect of those who have contracted hepatitis C from a transfusion of a fresh blood product. Where appropriate, claims have been settled in accordance with legal merit, and on a 'without admission of liability' basis. New South Wales also reported that such claims are handled within that State's self-insurance arrangements, and not by the ARCBS.[12]

Responses to compensation arrangements

5.14 Witnesses expressed concerns about aspects of the present compensation arrangements. Of particular concern were the confidentiality requirements and the criteria restricting payments to those who received transfusions between 1986 and 1990. For example, the Tainted Blood Product Action Group (TBPAG) argued that if the ARCBS 'had done no wrong', it was not reasonable for those receiving compensation to sign secrecy agreements. The TBPAG added:

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9 *Committee Hansard* 1.4.04, pp.27, 37 (DoHA).

10 *Submission* 54, Supplementary Submission, 21.5.04, p.4 (DoHA).

11 Queensland Government, Additional Information, 10.5.04, p.1.

12 New South Wales Government, Additional Information, 28.5.04, p.2.

16 *Committee Hansard* 6.4.04, pp.23, 32-33 (TBPAG).

> We have to console a lot of the members who have been compensated – and we are talking about only a few – because they also have to sign secrecy or confidentiality agreements in exchange for the cash. It is made clear that if they talk about the terms of the settlement or the scheme then they will be pursued by the Red Cross and other parties for that money.[16]

Another witness submitted:

> As to confidentiality clauses I feel that they are not right and are an infringement of people's right to speak out. No one should be threatened with legal action for discussing their personal affairs and it seems to me that these are just bullying tactics being employed by the ARC to cover up its mistakes.[17]

5.15 The ARCBS in responding to concerns about litigation stated:

> ...the ARCBS fully recognises the importance of transparency in all its activities. The question of litigation is therefore difficult and frustrating for us, due to the constraints of the legal process in Australia.
>
> It is on the public record – in our annual report – that there are legal proceedings in relation to hepatitis C. The society has denied liability in all these proceedings. Financial exposure to claims relating to events prior to 30 June 2000 are subject to commercial and government indemnities and are dealt with under a variety of arrangements. We are unable to comment on the specific situation or outcome of any individual case. There are sometimes confidentiality issues when litigation is resolved and, as you would understand, confidentiality clauses are standard practice in legal agreements.

5.16 The ARCBS went on to state that 'given the issues canvassed by this inquiry regarding discrimination, confidentiality agreements can also act to the benefit of plaintiffs'.[18]

5.17 In relation to confidentiality clauses, DoHA stated 'in no State or Territory is the Australian Government a party to either the settlements or the settlement documents, including the confidentiality documents required by other parties'.[19]

5.18 Many witnesses considered the financial compensation provided through current arrangements to be inequitable and that all people who have acquired hepatitis C through blood or blood products should receive compensation without regard to the time the infection occurred.

5.19 The TBPAG also questioned the grounds on which compensation has been paid. It argued that compensation could be paid either because of legal liability or on

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17 *Submission* 8, p.3.

18 *Committee Hansard* 7.4.04, pp.39-40 (ARCBS).

19 *Submission* 54, p.10 (DoHA).

humanitarian grounds. If compensation has been made on humanitarian grounds, it should be offered to all victims of tainted blood, not just those who contracted the virus in a certain time period.[20]

5.20 The Haemophilia Foundation Australia (HFA) pointed to the particular difficulties for haemophiliacs in gaining compensation. HFA noted that people who receive blood transfusions often had a single medical episode and were exposed to the blood of less than five people. The transfused blood can be dated and traced back to specific donors. In contrast, people with haemophilia are treated with products from pooled donations of many people. Those with severe haemophilia may be treated up to three times a week. As a result, they cannot establish a point at which transmission occurred so that compensation for negligence claims can be made.[21]

5.21 The HFA noted that people with haemophilia were infected at the same time as those who received blood transfusions and because of the use of products from pooled donors they were more at risk of infection. The HFA commented:

> It is unfair that those who were infected with hepatitis C from large pools have no redress when they were in fact at greater risk. The requirement of proof that a donation caused an infection is flawed. Common sense dictates that people with haemophilia became infected in the same way as those who did so through a blood transfusion.[22]

5.22 The HFA went on to argue that as government had recognised the 'moral case' for financial assistance for those infected with HIV, those infected with hepatitis C should be similarly offered assistance:

> People with haemophilia have an increased viral load, often more than one genotype, and a high proportion are known to develop liver disease. There is no way to compensate for the loss of a life or a life of a loved one, but surely there is evidence for a financial assistance package in recognition of the community's moral responsibility to people with haemophilia who have been infected by hepatitis C through the blood supply.[23]

5.23 The HFA recommended that each person with haemophilia infected with hepatitis C should receive a single payment in acknowledgement of the medical, social and economic impact on his or her life. All healthcare and medical treatment should be provided free of charge to all haemophiliacs infected with hepatitis C. Further, payments should be made available if and when each person's illness progresses, to assist with meeting the additional costs and to ensure financial assistance to relatives who provide care, or suffer hardship, because of the disease.[24]

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20 *Committee Hansard* 6.4.04, p.23 (TBPAG).

21 *Submission* 82, p.30; *Committee Hansard* 5.4.04, p.12 (HFA).

22 *Submission* 82, p.30 (HFA).

23 *Submission* 82, p.32 (HFA).

24 *Submission* 82, pp.31, 37-38 (HFA).

5.24 However, the Australian Hepatitis Council (AHC) and the Hepatitis C Council of NSW stated that they did not support the view that a particular group of people with hepatitis C should receive ex-gratia payments. They pointed to groups including health care and other workers who have acquired hepatitis C through needle stick injuries, children who have acquired hepatitis C from their mothers and those who contracted the disease through contaminated tattooing or body piercing equipment who would not receive recompense. It was considered that 'support, management treatment services for people with hepatitis C should be improved – but these need to apply to all people with hepatitis C'.[25]

5.25 The AHC also supported the comments of Professor McCaughan who had expressed concern that if financial recompense were to be paid to a particular group of people with post-transfusion hepatitis C, then:

> this might endanger the overall funding available, within current limited health budgets, which would enable the health care response for the broader group of all people with hepatitis C to be improved. We share his concerns that were recompense to be paid that consideration should be given to ensuring it does not affect ongoing (or future) funding for the current overall hepatitis C response.[26]

5.26 Some witnesses indicated that they believed that a greater amount of compensation should be offered with compensation for loss of earning, quality of life and to relieve the monetary stress on people living with hepatitis C. The HFA stated that such payments could be used both to target specific identified needs as well as to provide resources to allow infected individuals to regain some control over their lives.[27]

5.27 Many witnesses pointed to arrangements in other countries where significant payments have been made. In some countries payments are made as the disease progresses to assist with meeting the additional costs incurred and to ensure financial assistance to relatives who provide care or suffer hardship because of the disease. The schemes most often cited are those from Ireland, Canada and the United Kingdom.[28]

5.28 In Ireland, the Hepatitis C Compensation Tribunal deals with claims by those with hepatitis C caused by blood or blood components. A lump sum is paid in stages to take into account disease progression which may have occurred. Compensation is paid under a no-fault agreement, where there is no admission of liability by the National Blood Transfusion Service and claimants forgo their right to sue and are not

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25 *Submission* 81, p.5 (Hepatitis C Council of NSW); see also *Committee Hansard* 1.4.04, p.13 (AHC).

26 *Submission* 82, Supplementary Submission, 31.5.04, p.4 (AHC); *Committee Hansard* 6.4.04, p.97 (Prof McCaughan).

27 *Submission* 82, p.31 (HFA).

28 The following information is based on *Submissions* 75, pp.19-24 (AHC); 82, pp.33-36 (HFA).

required to prove negligence. Each claim is assessed individually in front of the Tribunal with payouts based on:

- general damage including pain and suffering, diminished quality of life and the need to be on treatment;
- health care costs; and
- loss of earnings.

Free medical care is also provided for any condition for any person infected with hepatitis C through blood and blood products.

5.29 Approximately 12,000 people in Canada became infected with hepatitis C through blood products, most prior to 1989. Following the release of the Krever Report, Federal and Provincial Ministers for Health announced in early 1998 that compensation would be paid to all people who contracted hepatitis C through blood products between 1 January 1986 and 1 July 1990 irrespective of the status of their health.

5.30 Compensation is provided depending on the degree of illness. In addition payments are made for:

- loss of income;
- costs of treatment and medication not covered by insurance schemes in public and private health insurance plans;
- monthly payments for those undergoing treatment in recognition of the strains involved with hepatitis therapy;
- costs of care;
- out of pocket expenses;
- compensation for people with HIV/hepatitis C co-infection;
- compensation for dependants and family members upon death;
- funeral expenses; and
- compensation for dependents and family members for loss of support, loss of services, and loss of guidance, care and companionship.

Compensation is conditional on people dismissing any further legal proceedings. People must also declare they haven't used 'illegal intravenous' drugs.

5.31 In 2003, the United Kingdom Government announced that a compensation scheme would be established for people infected with hepatitis C through blood or blood products before September 1991. Lump sum payments of £20,000 are provided, with an additional £25,000 for people with advanced liver disease. People who have recovered from the disease and those whose medical files had been lost are also eligible for payments. People who contracted hepatitis C through someone infected

with the disease also qualify for payment. Payments are also available for the relatives of those who die from the time of the instigation of the scheme.

5.32 Witnesses also pointed to the arrangements that had been put in place to compensate those who had acquired HIV through blood transfusion. In early 1990 the Mark Fitzpatrick Trust was established as a discretionary trust by the Commonwealth to provide special financial assistance to people with medically acquired HIV infection and AIDS. This special assistance did not represent compensation. Beneficiaries of the Trust were required to meet specified eligibility criteria including that they had medically acquired HIV or were a dependent, parent or guardian of a person who had medically acquired HIV; or were a dependent, parent or guardian of a person who had died from an HIV related illness as a result of medically acquired HIV.

5.33 The Commonwealth provided original seed funding of $13.2 million with a further grant of $1 million in 1999. The Trust was wound up in May 2001. Beneficiaries of the Trust received annual payments during the life of the Trust, with a final payment on the death of a beneficiary to assist with funeral and associated expenses. In total 423 beneficiaries received payments of $20.16 million.[29]

5.34 The TBPAG recommended that Australia establish a compensation tribunal for recipients of Hepatitis C contaminated blood or blood products, where each claim could be heard and accessed individually.[30]

5.35 However, not all witnesses sought compensation payments for their hepatitis C status. Rather, they saw coverage of health care costs as a priority. Given the chronic nature of the disease, health care costs can be high. One witness stated:

> The victims of this virus need financial compensation, as considerable costs have been incurred, travelling to doctors, medications, and in the future our homes will have to be altered to accommodate our disabilities.[31]

It was suggested that people with hepatitis C acquired through blood transfusion should be provided with health care cards irrespective of their level of income. This would help overcome the substantial financial burden of medications and treatment.[32]

National Managed Fund

5.36 The Commonwealth and the States and Territories have now established a fund to provide blood and blood products liability coverage for the Australian Red Cross Blood Service in Australia. The National Managed Fund replaces the previous State and Territory insurance arrangements and addresses problems the ARCBS had

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29 *Submission* 54, Additional Information, 26.5.04, pp.1-2 (DoHA).

30 *Submission* 79, p.26 (TBPAG).

31 *Submission* 21, p.1.

32 See for example, *Submissions* 7, p.2; 10, p.2.

experienced in obtaining commercial insurance in some States.[33] On the establishment of the fund on 1 July 2000, the ARCBS was indemnified for claims arising on or after that date.

5.37 The objectives of the National Managed Fund are to:

- provide the ARCBS with national, uniform, blood and blood products liability cover;
- identify and monitor liability risks; limit risk while balancing the requirement of an adequate blood supply;
- ensure national consistency in claims management; ensure accountability for risk management is devolved to those with control over risk; and
- provide a formal structure for monitoring risk management performance.

5.38 Under a Memorandum of Understanding (MoU) signed by the Commonwealth, States, Territories, and the ARCBS, the Commonwealth's responsibilities include contributing to the fund, the engagement of a fund manager and management of the contractual relationship with the fund manager. All parties to the MoU are to pay an annual contribution to the fund; this is intended to pay for any valid claims in respect of the ARCBS' defined blood-related activities and for the management of services (including claims management, risk management, reinsurance portfolio management, investment of fund monies and reporting and auditing). Under the MoU, the blood and blood products liability cover for the ARCBS remains in force until all parties agree to terminate the arrangements from an agreed date.[34]

Conclusion

5.39 The Committee has carefully considered the calls to increase and extend the compensation arrangements for those who have acquired hepatitis C through blood or blood products. The Committee notes that the current compensation arrangements are available only to those who have met certain criteria including the restriction to infection received during the years 1986 to 1990. This time frame precludes many people who have become infected with hepatitis C through blood transfusion from compensation.

5.40 The Committee is also aware that the criteria precludes many people suffering from haemophilia from accessing the compensation arrangements as it is difficult for those using blood products manufactured from many pooled donations to identify accurately the product which transmitted the infection.

5.41 Witnesses cited the compensation arrangements available overseas as possible models for an Australian scheme. Arrangements in countries such as Ireland, Canada

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33 Stephen, Sir N, *Review of the Australian Blood Banking and Plasma Product Sector*, Department of Health and Aged Care, Canberra, 2001, p.25.

34 Department of Health and Ageing, *Annual Report 2001-02*, p.165.

and the United Kingdom offer lump sum payments for people who have contracted hepatitis C through the blood supply. Some schemes offer addition payments for loss of earnings, cost of care and compensation to family.

5.42 The Committee is aware that some people infected with hepatitis C have chosen to pursue legal avenues for compensation. However, for many people with hepatitis C litigation is not always effective. It involves high costs, an adversarial environment, and outcomes are unpredictable.

5.43 The Committee considers that extending the current compensation arrangements is not in the best interests of those people who have acquired hepatitis C through blood and blood products. The Committee considers that the most effective way to assist this group of people with hepatitis C is to improve access to services, to improve education of medical personnel and to support research efforts to develop more effective treatments for hepatitis C.

5.44 The Committee considers that this is a practical, equitable and workable response to improve the long-term health outcomes of those people who have acquired hepatitis C through blood and blood products.

CHAPTER 6

SERVICES FOR PEOPLE WITH HEPATITIS C

> The thing is that I am sick. I have a liver that is not working properly any more. I do not want to blame anyone; I would just like some help.[1]

6.1 The Committee received much evidence from those who acquired hepatitis C through blood and blood products. This chapter outlines the services already provided by government, the Australian Red Cross Blood Service and support organisations. The chapter also considers what can be done to improve access to and the quality of these services.

Lookback program

6.2 For many people who have contracted hepatitis C through blood transfusion, identifying the event which led to their infection is an important step. The Australian Red Cross Blood Service (ARCBS), through its Lookback program, traces blood products which may have been contaminated.

6.3 The Lookback program was instituted by the ARCBS to identify recipients who may have been exposed to an infection via blood transfusion. The first Lookback program was undertaken for HIV. The ARCBS indicated that the process works in two ways:

- Donor triggered: if a blood donor is screened and found to be positive, prior recipients are traced by working sequentially backwards through the infected donor's prior donations and notifying recipients. These recipients are then tested to establish whether they are infected and referred to clinical and other services where appropriate.
- Recipient triggered: the process of attempting to identify an infected donor when a recipient develops a transmissible disease. This involves the recall and testing of all blood donors whose blood was transfused to the recipient.

6.4 The ARCBS indicated that it has identified 2,050 recipients of fresh blood products who have contracted hepatitis C. The ARCBS also estimated that, based on modelling[2] it had undertaken, that the number of people living with hepatitis C as a result of transfusion of blood and blood products was in the range of 3,500 to 8,000.[3]

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1 *Committee Hansard* 7.4.04, p.6.

2 The modelling took into account survival rates of people receiving transfusions and estimated the possible number of Australians alive today with transfusion acquired hepatitis C. The upper limit was reduced by the number expected to have cleared the virus. The number of people with haemophilia who have hepatitis C was also included.

3 *Submission* 64, Submission prepared for hearing, 7.4.04, p.39; *Committee Hansard* 7.4.04, p.39 (ARCBS).

6.5 In evidence, some witnesses reported positive experiences of the Lookback program.[4] However, other witnesses expressed concern about the program's effectiveness. Of major concern was that many recipients had discovered their hepatitis C (HCV) status through their failing health rather than through the Lookback program. The Tainted Blood Product Action Group (TBPAG) for example, stated that it had conducted its own survey of people who contracted HCV through blood transfusions. The TBPAG reported that 81 per cent of those surveyed had never been officially contacted nor offered any medical support by the ARCBS.[5]

6.6 Other areas of concern reported to the Committee included delays in notifying recipients of contaminated blood, with some witnesses reporting it was many years before they were contacted by the ARCBS. Witnesses also reported delays in the provision of information and provision of incomplete or incorrect information, for example, that they had not received a transfusion, once contact had been made with ARCBS. Of particular concern for some witnesses was the lack of accurate hospital records or the destruction of hospital records so that it was no longer possible to identify the blood or blood products they had received. Even when records were complete and donors could be identified, some witnesses reported that the ARCBS was unable to trace these donors to establish their HCV status.[6]

6.7 Suggestions were made in evidence that a form of universal lookback should be introduced. The TBPAG argued that all those who received blood transfusion in the high-risk blood transfusion era prior to the early 1990s should be traced. In particular, the TBPAG expressed concern at the number of mothers who received transfusions post childbirth and who may be unaware that they have hepatitis C.[7]

6.8 In evidence, the ARCBS voiced concern that, although it had identified 2,050 recipients of fresh products, there are others it cannot currently identify and who may never have been notified of their hepatitis C status.[8] ARCBS indicated that both donor and recipient triggered Lookback have limitations:

> I think the first important point to make is that Lookback, at its best, is an imperfect process. There is no form of Lookback available that will ever find all people who received or acquired non-A, non-B hepatitis or hepatitis C post transfusion. The Lookback that can achieve that does not exist. There are limitations with every form of Lookback that you undertake.[9]

6.9 The ARCBS identified a number of problems with the Lookback process. For instance, donor triggered Lookback may not be possible because:

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4 *Committee Hansard* 7.4.04, p.2.

5 *Committee Hansard* 6.4.04, p.31; *Submission* 79, Reference E, p.1 (TBPAG).

6 *Committee Hansard* 6.4.04, p.27 (TBPAG); *Submissions* 3, p.2; 33, p.2.

7 *Committee Hansard* 6.4.04, p.21 (TBPAG).

8 *Committee Hansard* 7.4.04, p.39 (ARCBS).

9 *Committee Hansard* 7.4.04, p.69 (ARCBS).

- a large proportion of blood comes from the 10 per cent of donors who only ever donate once and, as they have not re-presented for a donation and been retested by the ARCBS after the introduction of screening, their hepatitis C status is not known to ARCBS;
- even though the donation may be traced to a particular hospital, it may not be possible for the hospital to link the donation to a particular patient as records may have been lost or destroyed, or patients may have moved and be uncontactable; and
- doctors may choose not to contact or test patients particularly if they are very elderly or terminally ill.

From international experience, only about one third of infected recipients are located using donor triggered Lookback.

6.10 There are also limitations to recipient triggered Lookback:

- many cases are not reported to the ARCBS as notification to the ARCBS is not compulsory;
- as with finding recipients, donors may have moved and be uncontactable or may be now deceased and therefore unable to be tested; and
- in many cases the recipient has received hundreds of blood products, particularly in the case of cancer or trauma patients, and the task of finding and testing all the donors is enormous and often impossible.

The ARCBS stated:

> So clearly the lookback program can never be complete and there have been limitations to the programs in Australia. ARCBS is concerned that although in our submission we identified 2050 recipients, there are others who have not and cannot currently be found. ARCBS has however, pursued all cases as well as it has been able. That said, the lookback experience in Australia has the same difficulties as experienced in other countries and in fact, commenced well before many other countries, notably the USA which did not decide to commence lookback programs until 1998.[10]

6.11 The ARCBS emphasised that the Lookback process is 'a complex one and involves a number of key stakeholders. ARCBS must work together with these stakeholders (eg. hospitals for patient and transfusion records, tracing agencies) in order to ensure the process is successful'. In addition, the Lookback program varies in each State and Territory as Lookback was developed separately in each jurisdiction prior to the establishment of the ARCBS as a national organisation in 1996. As a result, the role of the Red Cross was and remains different in each program.[11]

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10 *Submission* 64, Submission prepared for hearing 7.4.04, p.17 (ARCBS).

11 *Submission* 64, p.88 (ARCBS).

6.12 The ARCBS also noted that the recommendation of a working party report to the Commonwealth Diseases Standing Committee on the National Health and Medical Research Council in 1991 was that only 'recipient (cases) triggered lookback' should be undertaken as other forms of lookback were too expensive and inefficient. The ARCBS indicated that it was not until a further application by the ARCBS that it was agreed by Health Ministers in December 1994 that donor triggered lookback would be undertaken. Funding for the program was only received from 1995 and the ARCBS stated that 'lookback programs were, by necessity, limited by resources available prior to this time'.[12]

6.13 The ARCBS concluded:

> I think it is very important to resolve any confusion there may be about our ability to quickly identify recipients of blood or blood products once we know the donor. We do not have that capacity. We can identify the unit. We can then notify the hospital, but the Australian Red Cross Blood Service does not have the ability to instantly or even quickly identify once we know of a possible infective donor unit who the recipients of that unit were.[13]

6.14 The ARCBS indicated that it is attempting to harmonise the activity of all stakeholders involved with the Lookback process, and it strongly supported the replacement of individual State and Territory Lookback programs with a single Australian Lookback system.[14]

6.15 In relation to the suggestions for contacting all those who received blood transfusions prior to 1990 (universal Lookback), the ARCBS pointed to an extract from a National Health and Medical Research Council (NHMRC) paper on the difficulties of Lookback, including universal Lookback.[15] The NHMRC paper considered the recommendations of the 1991 working paper report 'in the light of improved knowledge of the epidemiology of hepatitis C and developments in diagnostic technology since then'. It went on to state:

> Universal Lookback has not been conducted, ie, offering HCV screening to anyone who received a transfusion in the past. Although this may in principle provide a better indication of the number of people in the community with anti-HCV, it is unlikely that such a goal could be achieved. Based on experience in other settings, it is believed that it would be possible to contact only a proportion of those at risk, of which only a fraction will present for screening. Conversely, it is probable, especially if a publicity campaign is mounted, that many who are not at risk will present for testing. This would include, for example, people who had at some time been hospital inpatients. For these reasons, at this point in time, universal

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12 *Submission* 64, Submission prepared for hearing, 7.4.04, p.17 (ARCBS).

13 *Committee Hansard* 7.4.04, p.70 (ARCBS).

14 *Submission* 64, p.88 (ARCBS).

15 NHMRC, *Report on the Epidemiology, Natural History and Control of Hepatitis C*, Nov 1993, pp.18-20.

> lookback was regarded as ineffective as a public health measure in the control of hepatitis C.[16]

6.16 However, the ARCBS suggested to the Committee that if universal Lookback was to be further explored:

> it would be worth focusing on younger patients transfused in the 1980's, or to give consideration to patients who were under a certain age when they were transfused. Unlike the majority of transfusion patients who were quite elderly when transfused, younger patients would be much more likely to be alive today. They may have experienced the burden of (perhaps undiagnosed) disease for a considerable part of their life. They would be likely to both qualify for treatment and be able benefit from treatment once diagnosed.[17]

6.17 The ARCBS also suggested that consideration be given to mandatory reporting to the ARCBS by medical practitioners or health care professionals of suspected transfusion transmitted cases of hepatitis C to enable more timely tracing and adequate support of those affected.

Conclusion

6.18 The Committee considers that it is imperative that an effective Lookback program is in place. Early identification and notification of recipients of contaminated blood and blood products ensures that they can seek treatment at the earliest opportunity and in so doing gain the maximum benefit from that treatment. Those people infected, whether notified through donor or recipient triggered Lookback, also need to receive information about HCV so that those exposed to HCV can be advised on ways to minimise the risk of passing the virus on to others. Many witnesses to the inquiry were very distressed that, because they were not diagnosed with the virus for some time, they may have inadvertently passed the virus on to others. It is also important that affected recipients have access to counselling, as hepatitis C can have a devastating impact on lifestyle, relationships and employment.

6.19 The Lookback program has identified many of those who have received blood contaminated with the hepatitis C virus. The Committee has also noted the time and effort put into searching through records by the ARCBS and hospital staff, particularly where records are old and incomplete. The Committee considers that to undertake a universal Lookback program would be logistically very difficult and there are doubts about its effectiveness, and that a more effective mechanism would be through the more specifically targeted education campaign undertaken on a wider scale.

6.20 The Committee also considers that mandatory reporting to the ARCBS by medical practitioners or health care professionals of suspected transfusion transmitted

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16 *Submission* 64, Responses to questions, p.4 (ARCBS).

17 *Submission* 64, Submission prepared for hearing 7.4.04, p.21 (ARCBS).

cases of hepatitis C would improve tracing of contaminated blood and enable adequate support to be provided to those affected.

Recommendation 1

6.21 That the Australian Health Ministers' Advisory Council consider the introduction of mandatory reporting to the Australian Red Cross Blood Service by State and Territory health authorities of instances where a person is diagnosed with hepatitis C and it is judged that the infection was contracted through the blood supply.

Haemovigilance strategy

6.22 In order to ensure the safety and high quality of blood and blood products, the ARCBS recommended to the Committee that a national government sponsored haemovigilance system be established in Australia.[18] The Australian and New Zealand Society of Blood Transfusion also supported the introduction of a national program.[19]

6.23 A haemovigilance system would collect information on complications arising from blood transfusions. The ARCBS indicated that 'such a system linking all hospitals with ARCBS would provide valuable data to detect hepatitis C transmission, other emerging blood borne infectious diseases and other non-infectious complications of blood transfusion. This would ultimately enable us to maximise patient safety and care for the longer term.'[20]

6.24 The development of a haemovigilance system for Australia has been considered in a number of reviews. In 1997 a Haemovigilance Working Party was formed to advise on the development and implementation of a national haemovigilance system. The working party was composed of representatives from the ARCBS, the Australasian Society of Blood Transfusion, CSL Bioplasma and the National Centre for Epidemiology and Population Health.[21]

6.25 The 1999 review into the infection of a patient with HIV after a blood transfusion at Melbourne's Royal Children's Hospital by Professor Richard Smallwood also supported the establishment of a national haemovigilance system.[22] The Review of the Australian Blood Banking and Plasma Product Sector (Stephen Review) examined the role of haemovigilance. The Stephen Review recommended the

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18 *Submission* 64, Submission prepared for hearing 7.4.04, p.20 (ARCBS).

19 *Submission* 71, p.2 (ANZSBT).

20 *Committee Hansard* 7.4.04, pp.40,70 (ARCBS).

21 Stephen, Sir N, *Review of the Australian Blood Banking and Plasma Product Sector,* Department of Health and Aged Care, 2001, p.124.

22 Ministerial Inquiry conducted by Professor Richard Smallwood into the transmission of Human Immuno Deficiency Virus (HIV) to a recipient of a homologous blood donation at the Royal Children's Hospital, Melbourne in December 1998. Media release, Minster for Health, Mr J Thwaites, 9.12.99.

establishment of a national haemovigilance scheme to monitor untoward transfusion-related events and outcomes in hospitals, as a priority, with the purpose of identifying contributory factors; providing feedback to enable clinical practice and product improvement and providing data to place Australian transfusion risks in perspective. The Review further recommended that the scheme be developed as part of the national approach to improving patient safety led by the Australian Council for Safety and Quality in Health Care (ACSQHC). It was also recommended that the Council, with the National Blood Authority, provide Australian Health Ministers with a detailed plan for the scheme.[23]

6.26 The Department of Health and Ageing (DoHA) stated that the Jurisdictional Blood Committee had considered organised options for a national haemovigilance system. As a result:

> Given the on-going work by the Australian Council for Safety and Quality in Health Care (ACSQHC) and others to improve patient safety in the health care sector, the JBC [Jurisdictional Blood Committee] determined that there was further work to be done on drawing together the lessons to be learned from existing Australian safety and quality initiatives. Accordingly, work is under way with the ACSQHC to synthesise information from these initiatives...[24]

Conclusion

6.27 The Committee notes that the Stephen Review recommended in 2001 that a national haemovigilance system be established as a priority. Work toward a national haemovigilance system is presently being undertaken by the Australian Council for Safety and Quality in Health Care and the National Blood Authority. However, the Committee considers that there is an urgent need for a national haemovigilance system to be implemented. A national haemovigilance system would be an important component of the overall quality assurance strategy of the health sector, would improve patient safety and would ensure continued public confidence in the blood supply in Australia.

Recommendation 2

6.28 That, in order to ensure the safety of patients and continued confidence in the blood supply, the Australian Council for Safety and Quality in Health Care and the National Blood Authority implement, as a matter of priority, a national haemovigilance system.

Government services

6.29 The Commonwealth Department of Health and Ageing (DoHA) collaborates with State and Territory Governments and community-based organisations in a

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23 Stephen Review, pp.124-27.

24 *Submission* 54, Additional Information, 25.5.04 (DoHA).

national response to hepatitis C. This focuses on prevention of HCV transmission and increasing access by people living with hepatitis C to treatment, care and support services.

6.30 The delivery of health services through hospitals, health promotion, and care and support services provided by public and community-based organisations for people affected by hepatitis C are the responsibility of State and Territory Governments.

National Hepatitis C Strategy

6.31 By the mid 1990s the extent of hepatitis C infection in Australia was raising alarm. In response, the *National Hepatitis C Strategy 1999-2000 to 2003-2004* was launched in June 2000. The Strategy provides a comprehensive framework for national action to address hepatitis C. It is based on the approach taken to management and response to HIV/AIDS in Australia. The Strategy promotes and supports the health, safety and well-being of all Australians in relation to hepatitis C, both those infected and those affected. The two primary aims of the Strategy are to reduce transmission of hepatitis C in Australia and to minimise the personal and social impacts of hepatitis C infection. The four priority areas for action identified in the Strategy are:

- reducing hepatitis C transmission in the community;
- treatment of hepatitis C infection;
- health maintenance, care and support for people affected by hepatitis C; and
- preventing discrimination and reducing stigma and isolation.

6.32 The Strategy is based on six components that are considered fundamental to developing effective responses in the four priority areas. There components are:

- developing partnerships and involving affected communities;
- access and equity;
- harm reduction;
- health promotion;
- research and surveillance; and
- linked strategies and infrastructures.[25]

6.33 DoHA reported that the Strategy is not a funding initiative. It is a comprehensive framework to guide Australia's response to hepatitis C.[26]

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25 *Submission* 54, pp.20-21 (DoHA).

26 *Submission* 54, Additional Information, 26.5.04, p.3 (DoHA).

6.34 The National Strategy was independently reviewed in 2002.[27] The Department noted that the review acknowledged that the Strategy had established a good foundation for action and has contributed to an increased awareness of hepatitis C as a serious public health problem.[28]

6.35 However, the Australian Hepatitis Council (AHC) commented that no funding has been identified for the specific implementation of the strategy and resourcing for hepatitis C interventions from all levels of government is insufficient.[29]

6.36 In relation to the review of the Strategy, the Australian Hepatitis Council stated that the review also found that implementation was constrained.[30] The review pointed to serious constraints to implementation including:

- lack of resources for implementation;
- absence of an implementation plan and performance indicators for monitoring it;
- failure to grapple with the complexities of treatment and care;
- inadequate research; and
- rudimentary surveillance.

6.37 In relation to lack of resources, the review stated that:

> Commonwealth program funding for hepatitis C has been limited. The states and territories and the non-government and community sector are largely dependent on limited resources from the Commonwealth to contribute to the development of an effective national response to the epidemic.
>
> Hepatitis C is not one of the strategies or programs covered by the PHOFAs [Public Health Outcome Funding Agreements].[31] These Agreements contribute to the national population health effort by providing broadbanded Commonwealth funding to state and territory governments to support nominated population health strategies and programs.

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27 Levy M, Baum F & Thomas H, *Review of the National Hepatitis C Strategies: A Road Not Taken*, July 2002.

28 *Submission* 54, p.21 (DoHA).

29 *Submission* 75, p.1 (AHC).

30 *Committee Hansard* 1.4.04, p.14; *Submission* 75, p.9 (AHC).

31 The PHOFAs are bilateral funding agreements between the Commonwealth and each State and Territory which provide broadbanded and special purpose funding from the Commonwealth to the States and Territories for a range of public health programs. These programs include the National Drug Strategy; National HIV/AIDS Strategy; National Immunisation Program and BreastScreen Australia.

In relation to treatment and care, the review pointed to the stringent eligibility criteria of S100 arrangements (Highly Specialised Drugs Program) and limited models of care.[32]

6.38 Recommendations of the review included that:

- new governance structures be developed to support the national response to hepatitis C;
- equitable, sustained funding be provided to develop and implement an effective response to hepatitis C in Australia at all levels – federal, state and territory, local government and the non-government and community sector;
- the Commonwealth support a national hepatitis C public awareness campaign to increase knowledge of and reduce the stigma associated with hepatitis C infection;
- new research be commissioned including research into the treatment, care, support and costs for people affected by hepatitis C; and
- awareness of the availability and efficacy of hepatitis C treatments be increased by targeted information provision through primary care physicians, specialist liver clinics and needle and syringe programs.[33]

6.39 The review concluded:

> A second National Hepatitis C Strategy is essential for dealing with the hepatitis C epidemic in Australia.
>
> The Strategy must be supported by effective partnerships, strong governance structures, equitable resource allocation, legislative and regulatory reform, committed professional action, and community advocacy...With hepatitis C, Australia has an opportunity to seize international recognition for its strong political leadership and innovation – just as it did in a previous century with HIV/AIDS.[34]

6.40 ARCBS pointed to the review's finding that 'while Australia has had considerable success in tackling hepatitis C, there is a need for an invigorated and innovative approach to prevention of further cases and to counselling, treatment and care activities'.[35]

6.41 DoHA stated that following the review of the Strategy, the Commonwealth announced that a second National Hepatitis C Strategy would be developed in consultation with all stakeholders and under the guidance of a new ministerial advisory body. The second Strategy will take into account priority areas for action

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32 *Review of the National Hepatitis C Strategies,* p.85.

33 *Review of the National Hepatitis C Strategies,* pp.86-92.

34 *Review of the National Hepatitis C Strategies,* p.92.

35 *Submission* 64, p.72 (ARCBS).

identified through the review process and emerging needs identified in consultation with key stakeholders. The current Strategy expires in June 2004.[36]

Health maintenance, care and support services

6.42 The Commonwealth funds a range of services available to a wide range of service providers including general practitioners, haemophilia foundations, Aboriginal and Torres Strait Islander primary health care services and specialist health services for people from culturally and linguistically diverse backgrounds.[37]

6.43 For people with hepatitis C, making choices about antiviral therapy is assisted by targeted information and education resources produced with Commonwealth funding. The Department provided the following examples:

- *Contact 01: post-test information for hepatitis C* produced by the Australian Hepatitis Council. This booklet, designed for people who have been recently diagnosed with hepatitis C, provides important referral information. It has been distributed nationally through Hepatitis C Councils.
- The *National Hepatitis C Resource Manual*, produced by the Australian Institute for Primary Care at La Trobe University. The Manual is a concise source of standardised information for health care workers who provide services to people affected by hepatitis C.[38]

6.44 Funding of treatments and investigations is provided through the Pharmaceutical Benefits Scheme (PBS) and the Pathology Services Table of the Medicare Benefits Schedule (MBS). The hepatitis C antibody test may be reimbursed under the MBS. Qualitative nucleic acid testing which provides a measure of viral load can be reimbursed within certain criteria.

6.45 In 2002-03, the Commonwealth provided $16.7 million for the treatment of hepatitis C through the section 100 arrangements (Highly Specialised Drugs Program) under the PBS. In 2003-04, the cost of treatment for hepatitis C through the Program was estimated to increase to $24.6 million, following approval of S100 listing for pegylated interferon from 1 November 2003.[39] The two new Medicare safety nets introduced in 2004 may assist some people with out-of-pocket, out-of-hospital medical costs.

6.46 The Commonwealth also provides funding to increase access to a wider range of services for people with hepatitis C including funding for the Education and Prevention Initiative announced in the 1999-2000 Federal Budget. Of the $12.4 million over four years, $6.6 million was allocated to State and Territory Governments

36 *Submission* 54, p.21 (DoHA).

37 *Submission* 54, p.21 (DoHA).

38 *Submission* 54, p.22 (DoHA).

39 *Submission* 54, p.23 (DoHA).

to develop and implement hepatitis C education and prevention programs. The remaining $5.8 million was allocated to national hepatitis C education and prevention activities administered by DoHA. In the 2003-04 Federal Budget, the Government allocated funding to continue the Initiative. A total of $15.9 million was allocated over four years, of which $8.8 million will go to the State and Territory Governments and the remaining $7.1 million will be allocated to national activities to be administered by DoHA.[40]

6.47 Some national projects funded through this Initiative include:

- National Centre in HIV Epidemiology and Clinical Research (NCHECR) – *Surveillance of the long-term outcomes of chronic HCV infection.* These data will be used for research into the long-term outcomes of hepatitis C virus-related liver disease by using a longitudinal study of people with hepatitis C infection attending both primary care and hospital-based clinics.
- Australasian Society of HIV Medicine – *General Practitioner Education and Training* project, which aimed to provide training for GPs in relation to hepatitis C, as well as encourage medical training providers to expand their curricula to include hepatitis C and hepatitis C-related issues.
- Multicultural HIV/AIDS and Hepatitis Service – *Ethnic Media Campaign* which aimed to increase awareness of hepatitis C among people from culturally and linguistically diverse backgrounds.

6.48 Activities implemented by the States and Territories under the initiative include hepatitis C education for general practitioners (Victoria); rural/remote education and prevention pilot (South Australia) and hepatitis C information services (Tasmania).[41]

6.49 The Committee considers that many of the programs funded under the Budget Initiative appear to be used for the identification and management of hepatitis C rather than for education and prevention. The Committee considers that funding for such programs should be provided from the funding allocations provided to the professional medical organisations including the Divisions of General Practice and specialist colleges. The Committee further considers that public 'education and awareness' should be funded through this initiative and should be based on a broad campaign including the electronic and print media and a letter campaign to households. The implementation of an education and awareness campaign is discussed later in this chapter.

Organisations supporting those with hepatitis C

6.50 There are a number of support groups which provide assistance to those infected with hepatitis C. These groups provide a range of support services which

40 *Submission* 54, Additional Information, 26.5.04, p.3 (DoHA).

41 *Submission* 54, p.23; Additional Information, 1.6.04, p.2 (DoHA).

make a significant difference to the impact of hepatitis C on individuals. Services include counselling, information and advocacy.

Australian Hepatitis Council and State and Territory Councils

6.51 The Australian Hepatitis Council and the State and Territory Hepatitis Councils provide a range of services to people with hepatitis C including information, support, advocacy and representation. These organisations form a fundamental part of the national partnership response to hepatitis C.

6.52 The vision of the Australian Hepatitis Council is for:

- all people with hepatitis C and other chronic viral hepatitis reaching their potential;
- communities affected by hepatitis being valued and free from discrimination; and
- a society free from new infections of hepatitis C and other chronic viral hepatitis.

6.53 The Australian Hepatitis Council indicated that it and its members work in partnership with a range of agencies including community based agencies such as peer based injecting drug user groups, organisations representing people with haemophilia and Indigenous health services. In addition, the Council works with government at all levels, as well as research agencies such as the National Centre in HIV Epidemiology and Clinical Research, the National Centre in HIV Social Research and the Australasian Society of HIV Medicine.

6.54 The AHC considered that the hepatitis councils play a pivotal role in the provision of health maintenance and monitoring information to people with hepatitis C through a series of strategies. These include the development of resources, the provision of telephone information services, the facilitation of support and information groups, capacity building, particularly in the health care sector, and through websites and newsletters. However, it stated that the resources available to do this work are limited.[42]

Haemophilia Foundation Australia

6.55 The Haemophilia Foundation Australia (HFA) is the primary agency supporting those with haemophilia, von Willebrand Disorder and relating bleeding disorders. Most services and activities are funded by donations, however the secretariat is funded by DoHA. Its primary objectives are to represent people affected by bleeding disorders through advocacy, education and the promotion of research. HFA is governed by a Council of delegates from State/Territory Haemophilia Foundations.

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42 *Submission* 75, p.14 (AHC).

Traids

6.56 Traids is a NSW Health agency established in 1986 with a specific charter of providing support and advocacy for people with medically acquired HIV/AIDS and their families. Responsibility was subsequently extended to include people with medically acquired hepatitis C.

6.57 Traids services are available to residents across NSW. Services include counselling, information and support at its centre, by telephone, in homes and in hospital. The service facilitates support and information groups for people living with HIV and HCV. Traids also provides advocacy for its clients, liaison with medical practitioners and other health care workers for the benefit of clients and support to access travel and accommodation assistance for specialist and hospital treatment.[43]

Tainted Blood Product Action Group

6.58 The Tainted Blood Product Action Group is a voluntary organisation which advocates special assistance for people injured by faulty blood products and transfusions in Australia. The TBPAG encourages people affected by tainted blood products to support one another.[44]

Health services for those living with hepatitis C

Access to antiviral treatment

6.59 The Australian Hepatitis Council stated that 'Australia now has a world class standard of hepatitis C treatment, which unlike in many other countries, is fully funded by the Pharmaceutical Benefits Scheme subject to criteria'.[45] For those accessing treatment, combination therapy with pegylated interferon and ribavirin are now available. The Hepatitis C Council of NSW pointed to the benefits of combination therapy:

> Success is measured in terms of sustained viral response, which for many people is a cure for their hepatitis C infection. It is total viral clearance...people who have a sustained viral response, if they do not have cirrhosis to start with, are in fact cured. Those people who have cirrhosis and who have successful treatment can go on to develop liver cancer or liver failure, even though the virus is not present in their bloodstream, but that is in a small percentage of cases. So we are confident as a community organisation in talking about cure for people with hepatitis C in certain circumstances.[46]

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43 *Submission* 83, pp.1-2 (Traids).

44 www.taintedbloodnetwork.com

45 *Submission* 75, p.7 (AHC).

46 *Committee Hansard* 6.4.04, p.7 (Hepatitis C Council of NSW).

6.60 However, the widespread uptake of antiviral treatment has not been without problems. Some barriers to uptake include:

- meeting section 100 criteria;
- public hospital waiting lists;
- lack of treatment services in rural and remote areas;
- lack of knowledge about antiviral treatment amongst general practitioners and people with hepatitis C;
- concerns around treatment side effects, particularly depression;
- lack of personal resources to support a significant period of ill health;
- disclosure issues when side effects are visible or people need to negotiate considerations in their workplace; and
- lack of culturally appropriate support for Aboriginal and Torres Strait Islanders and people from culturally and linguistically diverse communities.[47]

6.61 In evidence, the AHC commented on the restrictive nature of the S100 criteria:

> Obviously, the government are trying to target those people who will go on to have serious liver disease and they are trying to target those quite expensive treatments to those people. Basically, S100 criteria mean that you have to have a fibrosis score of one or two on a scale of one to four before you can access those treatments. A lot of people would like to access treatment for reasons apart from liver disease. Also, if you are suffering debilitating symptoms you may not have a high fibrosis score but you are still suffering significant effects from having the virus.[48]

6.62 Witnesses stated that they were fearful of having a liver biopsy and that the procedure had its own morbidity and mortality.[49] The Review of the Hepatitis C Strategy also noted that many people are not eligible for treatment with some people not choosing to be treated.[50]

6.63 Other witnesses recommended the extension of treatment with the HFA stating that full and unhindered access to free hepatitis C treatment should be made available irrespective of genotype and previous treatment outcomes.[51] The Australian Haemophilia Centre Directors Organisation stated that while there have been recent changes which allow easier access to antiviral agents to treat hepatitis C, wider and

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47 *Submission* 75, pp.7-8 (AHC).

48 *Committee Hansard* 1.4.04, p.21 (AHC).

49 *Committee Hansard* 6.4.04, p.13 (Traids); *Committee Hansard* 6.4.04, p.90 (Prof McCaughan).

50 *Review of the National Hepatitis C Strategies* p.116.

51 *Submission* 82, p.37 (HFA).

easier access to these treatments should be made available.[52] The ARCBS also supported and recommended expediting consideration of, and access to, anti-hepatitis C drugs for Australian patients.[53]

6.64 The DoHA commented that:

> Improving treatments and widening their availability, as well as identifying the groups that are most suitable for treatment, are central to the response to hepatitis C infection in Australia. The primary goals of treatment are to eradicate the hepatitis C virus and prevent development of decompensated liver disease (scarring throughout the liver that gets progressively worse).[54]

6.65 The Committee considers that it is imperative that as many people as possible who are suffering with hepatitis C have access to S100 drugs as soon as clinical evidence indicates that such treatment would be beneficial. The evidence suggests that the present criteria for access to S100 drugs is too restrictive and the need to undertake a liver biopsy may be discouraging people from undertaking treatment.

Recommendation 3

6.66 That the Commonwealth review the criteria access to S100 drugs for those people suffering from hepatitis C to provide for greater access.

Service delivery

6.67 During the inquiry there were a number of comments concerning the adequacy of service delivery to those infected with hepatitis C. These comments ranged from the availability of specialist clinics to information available from general practitioners and poor co-ordination of services in the health sector.

6.68 Subsidised antiviral treatment of hepatitis has been restricted to specialists in hospital settings. DoHA indicated that people who have acquired hepatitis C through blood transfusion (together with those who have acquired the infection through other means) have good access to treatments through liver clinics.[55]

6.69 However, the Australian Hepatitis Council commented that 'the ability of healthcare infrastructures to provide the full range of treatment services to those who qualify for treatment is in doubt'. Extensive hospital waiting lists in some States mean that a person with hepatitis C may wait up to two years for assessment at a gastroenterology unit from the time of initial referral.[56]

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52 *Submission* 72, p.3 (AHDCO).

53 *Submission* 62, Submission prepared for hearing, 7.4.04, p.20 (ARCBS).

54 *Submission* 54, p.22 (DoHA).

55 *Submission* 54, p.22 (DoHA).

56 *Submission* 75, p.12 (AHC).

6.70 The AHC argued that an expansion of S100 prescribing into general practice would relieve some of the pressure on gastroenterology services to meet the demand for treatment, particularly in regional areas where no specialist gastroenterology services currently exist. This expanded framework would facilitate greater S100 availability, particularly in rural areas, and may encourage people who prefer to visit specific general practitioners to more fully consider their treatment options.[57]

6.71 In early 2003, a pilot program for general practitioner S100 prescribing commenced in NSW, Victoria and the ACT. The pilot is conducted by the Australasian Society for HIV Medicine, funded by NSW, Victorian and ACT Departments of Health and approved by the Highly Specialised Drug Working Party. The Australian Society for HIV Medicine indicated that to date approximately 100 general practitioners had been trained and had entered the program.[58]

6.72 Professor McCaughan pointed to shortages in the number of nurses required to manage patients with chronic hepatitis C. He noted that:

> Many of these patients in treatment assessment and management during the treatment with interferon, which has quite a lot of side-effects, require quite intensive nursing hours, and there is certainly a limitation on the number of nurses who are experienced in that area. Many of these patients also require mental health services, drug and alcohol services and access to those services in a multidisciplinary team, which we try to run at our hospital. It certainly puts a lot of pressure on those services. I know that across Australia there are significant deficiencies in access to those areas of care.[59]

6.73 Access to services for those living in rural and regional areas can also be difficult because of distance and expense involved.

6.74 Witnesses also pointed to the need to improve the co-ordination of services for those with hepatitis C. The Hepatitis C Council of NSW pointed to the lack of resources and disputes between the Commonwealth and States over funding for services on the ground – 'one blames the other, and it is community health and it is the public that suffers'.[60] The HFA was concerned about the lack of co-ordination of services between haemophilia treatment centres and those centres providing hepatitis C care. The HFA stated:

> In proactive centres, patients would be referred to liver clinics and their hepatitis C would be monitored and probably well cared for. People would be given good education and would know how to respond to things that might be happening to them, they would get good advice and counselling

57 *Submission* 75, p.12 (AHC).

58 Personal communication with the Committee, Australian Society for HIV Medicine.

59 *Committee Hansard* 6.4.04, p.92 (Prof McCaughan).

60 *Committee Hansard* 6.4.04, p.10 (Hepatitis C Council of NSW).

> about accessing treatments and when to have those treatments et cetera, but others would not. So there is some inconsistency in that respect.[61]

6.75 There was much comment in evidence concerning the adequacy of treatment provided by general practitioners. The AHC noted that general practitioners are often ill-equipped to offer appropriate information, support or referrals to people with hepatitis C.[62] The AHC stated that:

> ...there are a lot of doctors who did their training a long time ago. Doctors, like anyone, reflect community values, and there has been general misinformation about hepatitis C. Certainly, a lot of work on the Hepatitis Council phone lines is around correcting misinformation that people have. There are a number of horror stories about what people have been advised in terms of getting a diagnosis. So there are still very poor practices around pre and post test counselling for people with hepatitis C when they are diagnosed.[63]

6.76 Witnesses pointed out that for those receiving a diagnosis of hepatitis C, it is doubly traumatic if adequate information is not provided or the diagnosis is communicated poorly. However, the AHC noted that 'many people with hepatitis C report poor practices amongst general practitioners in providing a hepatitis C diagnosis'. There is a lack of knowledge, lack of communication skills and judgemental attitudes. This statement was borne out in evidence:

> The lack of knowledge with regards to this disease is appalling to say the least. Most Hep "C" sufferers know more about their disease then the Medical professionals who are treating them. This is because we research this disease constantly. The Internet is a vast source of information including the latest medical studies and treatments. It can supply facts on the disease, side effects of the latest treatments and can correct the miss-information, which the Australian Medical Profession is currently handing out as fact...All of the above shows to me a sad lack of knowledge of this disease in all of areas of the Medical profession, Blood bank operators and the Health Departments.[64]

Another witness stated:

> The virus was only identified then and there was not very much knowledge. I had the virus for 10 years and, with the virus, I saw the same doctor for 10 years. He gave me virtually no information. To be fair to my doctor, he is a very knowledgeable doctor but in the hep C field he did not know very much at all. So, for 10 years, I carried this alone and isolated. I did not tell anyone in my family about it – I did not know much to tell other people about it. Whenever I went to my doctor for information, I would have a

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61 *Committee Hansard* 5.4.05, p.16 (HFA).

62 *Submission* 75, p.5 (AHC).

63 *Committee Hansard* 1.4.04, p.15 (AHC).

64 *Submission* 8, pp.1-2.

> liver function test – once a year – which was close to normal. He would say, 'If it gets any worse, we'll look at treatment; if not, you're right.' I had symptoms during those 10 years, and often I would say to my doctor, 'Could it be the hep C virus?' and he would just dismiss it and invalidate it.[65]

6.77 Organisations noted that knowledge within general practice has improved but 'they have a long way to go yet'. [66] The Review of the National Hepatitis C Strategy stated that:

> Levels of professional education and training being undertaken at the national and state and territory levels are inadequate. Undergraduate training for medical and nursing students needs to be strengthened. Given the projected burden of hepatitis-C related disease, and the identified need to expand service delivery and models of care, it is critical that more resources are allocated to professional education and training at all levels.[67]

6.78 One problem is the amount of information that general practitioners receive and as noted by Traids, if the professional is not dealing with the particular problem on a regular basis, it is difficult to retain adequate information levels.[68] In order to ensure that hepatitis C sufferers can obtain adequate care, hepatitis councils keep GP-friendly lists so they try to have available those doctors who have a good knowledge about hepatitis C and who are willing to see people with hepatitis C.[69]

6.79 The Commonwealth also provides funds to the Australasian Society for HIV Medicine which provides education programs specifically for medical personnel, including general practitioners.[70]

Support services for those with hepatitis C

6.80 Those suffering from hepatitis C require personal and medical support to manage their condition. Support is particularly important when undertaking treatment as the side effects, including depression, can be particularly debilitating. Support services can be particularly valuable in providing information. Australian Hepatitis Council stated in evidence:

> People with hepatitis C need: access to correct current information so that they can make informed choices about their health; access to supportive, non-judgmental health care services to assist them to manage the physical and psychological impacts of hepatitis C; and access to the best available

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65 *Committee Hansard* 6.4.04, p.12 (Traids).

66 *Committee Hansard* 6.4.05, p.10 (Hepatitis C Council of NSW).

67 *Review of the National Hepatitis C Strategies*, p.103.

68 *Committee Hansard* 6.4.04, p.14 (Traids).

69 *Committee Hansard* 1.4.04, p.15 (AHC).

70 *Committee Hansard* 1.4.04, p.32 (DoHA).

> treatments to give them the optimal chance of clearing the virus, as well as a society that is much better informed and less fearful about hepatitis C. Obviously, there are many challenges in achieving these outcomes.[71]

6.81 Support is provided through specialist support groups including the hepatitis councils, the HFA and Traids. One witness indicated the benefits of support groups:

> The support group is very important to me, because since mixing with other people with the virus I have found that all these symptoms that I had for a long time before I was treated for it were very real. Lack of information, invalidation, dismissal, carrying it alone and not telling my family – it would have been very nice to have had the information.[72]

6.82 Unfortunately, support services are not always accessed by those who need them. Traids stated that people outside the health care system were not always aware that services that are available.[73]

6.83 The Hepatitis C Council of NSW suggested that one problem is the lack of compulsory pre-and post test counselling. Counselling would provide people with information and assist them in relation to their diagnosis.[74] Counselling is also beneficial to those suffering depression and those undergoing treatment. The Triads Support Group stated:

> Some patients experience significant depression. Counselling is possibly the only course of treatment, if they can't tolerate the combination therapy available to date. This type of support is very expensive if sought privately, and of very limited duration through Community Health Centres.[75]

One witness undergoing treatment stated that she needed counselling and saw a psychologist on a weekly basis.[76]

6.84 Many witnesses pointed to the cost of undertaking treatment and suggested the need for additional support. One witness indicated that whilst on treatment, the costs were about $2,500 per month. This included visits to doctors and medication such as sleeping tablets.[77] The Traids Support Group stated that the cost of services associated with the disease can be exorbitant and 'some people just give up because they can't afford it'.[78] Many people with hepatitis C find alternative medicines of benefit. Traids stated:

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71 *Committee Hansard* 1.4.04, p.14 (Australian Hepatitis Council).

72 *Committee Hansard* 6.4.04, p.12 (Traids).

73 *Committee Hansard* 6.4.04, p.12 (Traids).

74 *Committee Hansard* 6.4.04, p.10 (Hepatitis C Council of NSW).

75 *Submission* 84, p.1 (Traids Support Group).

76 *Committee Hansard* 6.4.04, p.12.

77 *Committee Hansard* 5.4.04, p.21 (HFA).

78 *Submission* 84, p.3 (Traids Support Group).

> Some of the herbs have been found to ease some of the symptoms. Increasingly, when people find that the treatment is not going to work for them they seek alternatives to orthodox medicine.[79]

This can add significantly to the costs of people with hepatitis C.

6.85 Witnesses noted that it was not only the cost of treatment but the impact on earning capacity. Those undergoing treatment may have to decrease their workload or give up work completely. The HFA stated:

> An example is that at the moment some people who are having hepatitis C treatment are paying for scripts. They are actually having to take time off work and lose pay to have their treatment, but they are also having to pay for some of their medications. That is just one example of why it is difficult and why we are asking for free and universal treatment.[80]

And:

> There is a great need for support. Our people suffer in many ways: reduced wage earning capacity, dependency upon pensions and benefits, increased health care costs – even a health care card would be some help to some people – reduced capacity to complete education, complex treatments and side effects, and difficulties with social relationships and discrimination. There is a great need for financial assistance. People were infected with hepatitis C in the same way as those infected with HIV. A government trust was set up for people with HIV, but there has been no such financial assistance for people with hepatitis C. Governments and others have a moral responsibility to address the widespread financial impact on people with haemophilia who were let down by the very blood system which was meant to improve their health. For many, the system has caused them great harm. For some, it has resulted in death.[81]

6.86 In other evidence, witnesses suggested a range of other services that would be useful to those suffering from hepatitis C acquired through blood transfusion. As those with hepatitis C often suffer from debilitating fatigue, many pointed to the need for help within the home. Others also supported access to home nursing services and out-reach home visiting services. Help in the home was of particular concern for single people who did not always have other family members on hand to assist them.

6.87 Assistance with travel costs was also highlighted. As specialist liver clinics and haemophilia centres are located in capital cities and major centres, people in regional areas must travel to access services. Those on treatment with S100 drugs

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79 *Committee Hansard* 6.4.04, p.15 (Traids).

80 *Committee Hansard* 5.4.05, pp.12-13 (HFA).

81 *Committee Hansard* 5.4.04, p.8 (HFA).

generally can only access specialists in larger centres. This adds to treatment costs. If accommodation costs are added the total cost may be substantially higher.[82]

Need for further research

6.88 Witnesses to the inquiry stressed the need for further research to be undertaken in the area of hepatitis C. One witness commented that 'research is needed to find better treatments and a possible cure to give the sufferers of Hep "C" hope for a future free of pain and illness'. [83]

6.89 Suggestions ranged from more funding for research already being undertaken to the establishment of a dedicated foundation targeting hepatitis C research.

Special needs of haemophiliacs

Haemophilia Treatment Centres

6.90 People with haemophilia and other related bleeding disorders have their condition managed by one of 16 comprehensive Haemophilia Treatment Centres (HTC). The HTCs offers medical services and a range of other professional services including counselling; advocacy and social work, and physiotherapy. The Australian Haemophilia Centre Directors' Organisation (AHCDO) stated that 'the holistic approach to the welfare of patients taken at the HTCs is greatly beneficial and the federal government should be encouraged to ensure that adequate funding is available to ensure provision of all the services provided'.[84] As HTCs are located in capital cities and major centres, some people with haemophilia must travel to their nearest centre and this may cause problems with access.

Recombinant products

6.91 As has already been noted in chapter 2, the high infection rate of hepatitis C in people suffering from haemophilia is related largely to the amount of Factor VIII or IX concentrates used in treatment. The amounts of Factor VIII or IX used by an individual is proportional to the severity of haemophilia and the frequency of bleeding. These Factors are manufactured from pools of thousands of donations of plasma.

6.92 The HFA noted that there have been problems with the supply of plasma derived Factor VIII with CSL being unable to produce sufficient quantities at various times.[85] ARCBS noted that every possible plasma donation currently has Factor VIII

82 See for example, *Submission* 79, p.26 (TBPAG).

83 *Submission* 8, p.2.

84 *Submission* 72, p.2 (AHCDO).

85 *Submission* 82, p.15 (HFA); see also *Committee Hansard* 6.4.04, p.49 (AHCDO).

manufactured from it, while Factor IX production is not limited by the supply of plasma and CSL is able to manufacture the amount required.[86]

6.93 Factor concentrates manufactured using genetically engineered cells became available in Australia in 1994 when recombinant Factor VIII was imported. In 2001 recombinant Factor IX became available. People with von Willebrand disorder are unable to use recombinant Factor VIII as it does not contain von Willebrand factor.

6.94 Organisations expressed concern about the availability of recombinant products. HFA stated that recombinant Factor VIII and Factor IX has been restricted to children who were not already infected with hepatitis C and/or HIV and that 'government policy means that most people in Australia still must use plasma derived products even though safer alternatives are available'.[87] This is despite the recommendations of the Factor VIII and Factor IX Working Party of the AHMAC Blood and Blood Products Committee. The Working Party recommended that current restrictions on access to recombinant Factors VIII and IX be removed as rapidly as possible, and that these products be used whenever clinically indicated in order improve patient safety. The Working Party also recommended that a target of 85 per cent recombinant use be reached by 2004.[88] The Barraclough Report supported this recommendation. HFA concluded:

> Despite the recommendations of these government agencies and committees, patients continue to be placed at risk by being forced to use plasma derived treatment products which are more likely to expose them to blood borne viruses and agents, known and as yet unknown...Countries with similar health care standards and expectations have accelerated programs to do this in recent years and now Australia falls well below international standards...If an alternative safer product can be supplied, it is reasonable and prudent to supply it and the government, doctors, hospitals and other bodies may be exposing themselves to potential claims for negligence if a new illness or infectious agent did emerge.[89]

The HFA also stated that the policy was 'clearly discriminatory and unacceptable'.[90]

6.95 The AHCDO noted that funding had been made available in 2003 for the importation of greater quantities of recombinant Factor VIII when CSL had not been able to produce sufficient supplies of plasma derived Factor VIII. However, AHCDO's policy on Factor VIII and IX concentrates expressed a preference for recombinant products as the treatment of choice for all patients.

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86 *Committee Hansard* 7.4.04, p.47 (ARCBS).

87 *Submission* 82, p.15 (HFA).

88 Australian Health Ministers' Advisory Council Blood and Blood Products Committee, *Report on the Working Party on the Supply and use of Factor VIII and Factor IX in Australia*, April 2003, p.6.

89 *Submission* 82, p.16 (HFA).

90 *Committee Hansard* 5.4.04, p.4 (HFA).

6.96 The AHCDO added that many people, even those not infected with hepatitis C, are not able to access recombinant products. AHCDO stated that patients who have, for one reason or another, cleared the hepatitis C virus and are considered to be 'virally free' are often required, for lack of availability of recombinant products, to use plasma derived products to treat their bleeding disorders, thus subjecting themselves to the psychological distress of possibly acquiring another, as yet unknown, blood borne infection. This distress could be alleviated by improving access to recombinant treatment products.[91]

6.97 Witnesses argued that the availability of recombinant Factor VIII and IX is limited because of the cost to government and the policy of self-sufficiency in blood products.[92] Witnesses were unable to provide an exact comparison of costs for plasma derived and recombinant products. However, HFA stated that it considered them to be close, while ARCBS noted that in international markets the price of recombinant product generally runs at $A1 or more per international unit, whereas the price for plasma derived Factor VIII products generally runs at around A40c per unit.[93] Another witness indicated that the premium paid in the Netherlands for recombinant Factor VIII is 15 per cent (factor containing human albumin) and 24 per cent (factor without human albumin) above plasma derived Factor VIII and for recombinant Factor IX it is 21 per cent.[94]

6.98 The ARCBS recommended that governments facilitate access to recombinant Factors VIII and IX as recommended by the Commonwealth Working Party and by HFA.

6.99 In response to concerns about the safety of plasma derived Factor VIII and IX, CSL stated that:

> The current plasma derived factor VIII and factor IX both have excellent safety records. We have no evidence of transmission of any of these nasty viruses by those products – in fact, no evidence of transmission since the introduction of the 80-degree dry heat treatment in the late eighties or early nineties. Over the last eight years or so, with the introduction of recombinant factor VIII in Australia, we have seen a steady growth in demand and use of factor VIII in Australia.

6.100 CSL went on to state that very few countries had made the decision to use only recombinant Factor VIII. It was viewed that 'the the haemophiliac community would be best served by increasing the availability of factor VIII rather than just focusing on recombinant factor VIII'.[95]

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91 *Submission* 72, p.2 (AHCDO).

92 See for example, *Committee Hansard* 5.4.04, p.7 (HFA).

93 *Committee Hansard* 5.4.04, p.4 (HFA); *Committee Hansard* 7.4.04, p.47 (ARCBS).

94 Additional Information, Mr G Volk.

95 *Committee Hansard* 5.4.04, p.53 (CSL).

Conclusion

6.101 The Committee considers that the haemophilia community should have the choice of using either plasma derived products or recombinant products. The Committee also notes that the AHMAC Blood and Blood Products Working Party on the Supply and Use of Factor VIII and Factor IX recommend the increased use recombinant products by 2004 and that the Expert Advisory Group on Hepatitis C and Plasma supported the recommendations of the Working Party.

Recommendation 4

6.102 That the recommendations relating to the use of recombinant Factor VIII and Factor IX contained in the Report of the Working Party on the Supply and Use of Factor VIII and Factor IX in Australia be implemented as a matter of priority.

Education of the general community

6.103 Many witnesses emphasised the need to improve community awareness of hepatitis C.[96] Traids stated:

> I think there has to be a wider media campaign and more awareness on a broader level. That role could be done in conjunction with someone like the Hepatitis C Council, who are very knowledgeable about awareness and how to raise it on a broader level. It needs to get out of the health system and into the general population so that people are much more aware. People who work in the area and share the knowledge know where to refer on, but when you are not in the health system—and clients are not—you do not know where to get support and information that would help you understand.[97]

6.104 The lack of awareness in the community was seen as contributing to discrimination and stigma of those suffering from hepatitis C. This causes personal hardship for sufferers who may become isolated or fearful disclosing their condition. It can also mean loss of employment and promotion opportunities, denial of accommodation and difficulties in obtaining goods and services including dental and medical care. The AHC noted that 'the underlying causes of such discrimination are varied but are often the result of either a usually irrational fear of infection or the close link hepatitis C has with injecting drug use – an illegal and highly stigmatised behaviour'.[98]

6.105 With hepatitis C infection in the general population on the increase, education is also vitally important to reduce the spread of hepatitis C in the community. An effective education campaign would alert those at risk of contracting hepatitis C about

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96 See for example, *Committee Hansard* 6.4.04, p.98 (Prof McCaughan).

97 *Committee Hansard* 6.4.04, p.17 (Traids).

98 *Submission* 75, p.14 (AHC).

current dangers. It would also inform those who may have, in the past, undertaken activities leading to hepatitis C infection and encourage them to be tested. A public education campaign would also raise the profile of the disease and put it on the public agenda.

6.106 The review of the National Hepatitis C Strategy had recommended a national hepatitis C public awareness campaign. However, the AHC stated that the Commonwealth's response indicated support for 'education and prevention activities for hepatitis C' from within existing funding levels. The AHC commented that 'given the level of funding available to hepatitis C, this response indicated a lack of genuine support'.[99]

Conclusion

6.107 The Committee considers that there is a great need for a community information campaign to raise awareness of hepatitis C. Hepatitis C can be acquired through a number of means and may remain undiagnosed for a long period of time. There are thus, potentially, many people in Australia who have hepatitis C and who are unaware of their condition. The Committee considers that an education campaign should emphasise the various ways in which hepatitis C is or was contracted including through blood transfusion. This would alert those people who may have contracted hepatitis C through the blood supply to have their HCV status investigated.

6.108 As noted earlier in this chapter, the Commonwealth provides funding for certain programs through its Hepatitis C Education and Prevention Initiative. The Committee considers that this funding would be more effectively allocated to a broad public awareness campaign including through the electronic media.

Recommendation 5

6.109 That the Commonwealth fund a national hepatitis C awareness campaign to increase the public's knowledge of hepatitis C and that such a campaign emphasise all the means by which the infection may be acquired and the need for early testing and treatment.

Apology

6.110 Many witnesses called for an apology to be made to those who have acquired hepatitis C through blood and blood products. An apology was seen as an acknowledgement by those involved in blood services – governments and the ARCBS – of the serious nature of the infection that had been acquired through their services and the devastating impact on many individuals. Witnesses stated:

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99 *Submission* 75, p.8 (AHC). See also, *Australian Government Response to the 2002 Review of the National HIV/AIDS and Hepatitis C Strategies and Strategic Research*, p.15.

> We feel we deserve an apology. All victims of contracting hepatitis C through tainted blood deserve an apology. No one asked to have this lifestyle passed to them.[100]

And:

> ...many of the people I work with in the haemophilia community have said, 'If only some of the agencies' – so not just government – 'or the people involved in the blood system actually said sorry and said, yes, this did happen.' Hepatitis C has been very much underestimated. Even though people are suffering in the ways you have heard today and have been for some years, there has not been any acknowledgement of that.[101]

6.111 Some other witnesses argued that the apology should also admit responsibility and liability for the impact of hepatitis C on their lives:

> That the Australian Red Cross admits responsibility and liability and publicly apologise to the victims and their families and that the Australian Government do the same.[102]

6.112 Other witnesses suggested that an apology be accompanied by measures to address the needs of hepatitis C sufferers:

> I think it is up to someone, the Red Cross or whomever, to put their hand up and say, 'Yes, we made a mistake. We're sorry' – of course, that has never been mentioned anyway – 'and we think you deserve some sort of compensation and help.' I am not really interested in blaming anyone.[103]

6.113 On 27 May 2004, a meeting convened by the ARCBS and chaired by Sir Laurence Street was held at the NSW Parliament and involved representatives of organisations who had appeared before the Committee to speak on behalf of those affected with hepatitis C. Members of the Committee attended as observers.

6.114 At the meeting, the ARCBS indicated that it had 'listened carefully to the concerns of those who had made submissions to the inquiry and reflected upon what was said'. They had instigated the face to face meeting to express 'our sorrow at what had occurred', to establish a dialogue and 'to seek your input in terms of how best to move forward to support those affected by hepatitis C'. In a statement made on behalf of the ARCBS, Dr Brenton Wylie said:

> The Red Cross has recognised that, in the past, some blood-transfusion recipients contracted hepatitis C virus from blood transfusions.
>
> This is a terrible fact and we are sorry that this occurred.

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100 *Submission* 16, p.2.

101 *Committee Hansard* 5.4.04, p.11 (HFA).

102 *Submission* 8, p.6.

103 *Committee Hansard* 7.4.04, p.6.

> We are sorry that for some of those recipients contracting hepatitis C has resulted in often debilitating physical symptoms of this disease, and in some cases, unfair discrimination. We as individuals at the ARCBS have been distressed to hear of people's particular situations

6.115 The ARCBS acknowledged that 'it is clear that we have not always met the expectations of the people with hepatitis C in terms of how we have interacted with them' and hoped that 'we have learned from our experiences and intend to implement improved systems wherever practicable in our day to day dealings with those affected by hepatitis C'. The ARCBS maintained that it had 'acted and took decisions responsibly and in accordance with the best available scientific knowledge at the time and, accordingly we do not accept liability'.

6.116 The full text of Dr Wylie's statement is reproduced at Appendix 3.

6.117 As a result of the meeting, the ARCBS proposed that it would:

> ...establish a steering committee to review donor- and recipient-triggered Lookback programs with a view to making improvements in communication and engagement with blood donors and recipients. As a result of today's meeting, we will seek the participation of stakeholders representing groups such as those who appeared before the inquiry.[104]

6.118 The Hepatitis C Council of NSW stated that it 'strongly welcomed the position taken and apology given by the ARCBS'. The Council concluded:

> We believe this is a genuine attempt by the ARCBS to convey its sympathy to representatives of people who acquired hepatitis C from blood transfusions, and to address some of their concerns.
>
> We consider that this is an honest and heartfelt gesture that will help us all move forward in the current debate.[105]

Conclusion

> Nobody can return our lost years or our good health, but, whatever help given would surely lighten our load.[106]

6.119 For those who have hepatitis C, the impact is multifaceted. There are significant health issues; family and social lives are disrupted; and employment and career opportunities may be limited. It is therefore imperative that those suffering from hepatitis C receive optimal personal, medical and social support.

6.120 From the evidence received by the Committee it is clear that hepatitis C sufferers have found it difficult to access adequate medical support and access effective treatments. There was evidence that the services provided lack co-ordination

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104 *Submission* 64, Supplementary Submission, 27.5.04, pp.1-2 (ARCBS).

105 *Submission* 81, Supplementary Submission, 31.5.04, p.5 (Hepatitis C Council of NSW).

106 *Submission* 27, p.2.

across the health sector. This is particularly a problem for haemophiliacs who attend both specialist haemophiliac clinics and liver clinics. Hepatitis C sufferers living in rural and regional areas also have problems in accessing specialist services and also face higher travel costs.

6.121 Many people who have acquired hepatitis C through blood transfusions indicated that they had problems with receiving services from general liver clinics and required services tailored to their particular problems. Many witnesses spoke of their distress when it was assumed, wrongly, that they had acquired hepatitis C through intravenous drug use or sexual activity. (This is discussed further in Chapter 3.)

6.122 Associated with this is the evidence of the discrimination and stigma related to hepatitis C status and the detrimental impact on those who have acquired it through blood transfusion. Many witnesses recommended a public education campaign to reduce discrimination and stigma.

6.123 The Committee has also found that there is a great need for counselling and referral services. Some of these services are currently available but many people do not access them. Wider circulation of information about the services as well as an increase in resources for services was recommended.

6.124 The Committee considers that further assistance should be provided to those people who have acquired hepatitis C through blood and blood products. The Committee has already stated in Chapter 5 of this report that it does not support an extension of existing compensation payments for those who have been infected with hepatitis C through blood and blood products. The Committee considers compensation schemes are not the best option when improved services would prove a more direct, efficient and beneficial vehicle to support a greater number of people.

6.125 The Committee therefore supports the establishment of a post-transfusion hepatitis C committee specifically tasked to improve the provision of services to those who have acquired hepatitis C through blood transfusion. Such a committee would be made up of representatives of the Commonwealth, State and Territory Governments, the ARCBS, representatives of organisations which supporting people with hepatitis C and individuals who have acquired hepatitis C through the blood supply. The Committee considers that the funding for the operation of the committee and the work it undertakes should be provided by the Commonwealth and State and Territory Governments. The Committee also believes that the ARCBS should consider contributing financial support to the proposed committee, to any extent it is able to do so.

6.126 The Committee considers that the post-transfusion hepatitis C committee should be established as a priority for the purpose of:

- formulating, coordinating and delivering an apology to be made to those who have acquired hepatitis C through the blood supply;
- establishing an effective Lookback program;

- improving service delivery to victims;
- establishing and managing a fund to provide financial assistance for certain services; and
- establishing criteria for accessing the fund.

6.127 The Committee acknowledges that a statement has recently been made by the ARCBS to those who acquired hepatitis C through the blood system. However, the Committee considers that an apology should also be made by governments as a further means of acknowledging the grave consequences of hepatitis C infection. The Committee, in supporting such a move, does not consider that an apology indicates guilt or liability on the part of government, or any other party.

6.128 The Lookback program currently in place, has identified some of those who have received blood contaminated with hepatitis C. However, a more effective program and greater resources are required to identify further victims. The Committee also considers that current Lookback programs are undertaken with goodwill and dedication but that the ARCBS should not be solely responsible for the program. Rather, increased coordination across the whole health sector is required.

6.129 Improved service delivery is fundamental to good health outcomes for hepatitis C sufferers. The Committee considers that the post-transfusion hepatitis C committee should formulate and implement strategies to improve service delivery to those with post-transfusion hepatitis C through case management. In this way, there would be greater liaison across various services and agencies to ensure those who have acquired hepatitis C through blood products receive appropriate and optimal medical, counselling and support services, including Home and Community Care services.

6.130 The Committee has carefully considered calls for financial assistance for the provision of services not normally covered by government. These include travel expenses for those sufferers living in rural and remote areas; psychology and counselling costs; the costs of medication not covered by the Pharmaceutical Benefits Scheme and recompense for lost income while undergoing treatment and as a result of curtailed employment due to symptoms.

6.131 The Committee recognises that these costs can be substantial and impose financial hardship on hepatitis C sufferers and their families. The Committee considers that the post-transfusion hepatitis C committee should be tasked with establishing a fund to provide financial assistance to cover the costs not covered through existing services. The proposed committee may wish to consider costs which are often not covered or fully covered including visits and transport to general practitioners; prescribed medication and surgical aids; dental, aural, optical, physiotherapy and chiropody treatments; home care and/or home help; and alternative medical treatments.

6.132 The Committee believes that the post-transfusion hepatitis C committee should be funded by the Commonwealth and the State and Territory Governments.

Access to the fund should be based on criteria established by the committee but it is the strong view of this Committee that access should be open to any person who is HCV positive and who can show that they received blood or blood products prior to the introduction of third generation tests. The Committee does not believe it should be necessary for a person to prove beyond a reasonable doubt that they have received hepatitis C through a blood transfusion. For example, the Committee received evidence that for some, records no longer exist which would prove that they had received a blood transfusion. For these people, the lack of records should not preclude them from accessing assistance. The Committee considers the committee should err on the side of compassion rather than require people who have acquired hepatitis C through blood products to undertake an exhaustive process to prove the means of their hepatitis C infection. In this way, many of the concerns of the haemophilia community would be addressed as well as those from people who became infected with hepatitis C in the 1970s and early 1980s.

6.133 The Committee considers the establishment of a post-transfusion hepatitis C committee tasked with improving services and providing some financial support will relieve some of the major concerns of people who have acquired hepatitis C through blood and blood products.

Recommendation 6

6.134 That a national post-transfusion hepatitis C committee be established as a priority with the purpose of:

- **formulating, coordinating and delivering an apology to those who have acquired hepatitis C through the blood supply;**
- **establishing an effective Lookback program; and**
- **improving service delivery through a case management approach that ensures that appropriate medical, counselling and welfare services are provided, sensitive to the needs of people who have acquired hepatitis C through blood and blood products.**

That membership of the committee include representatives of the Commonwealth, State and Territory Governments, the Australian Red Cross Blood Service, representatives of organisations which support people with hepatitis C acquired through the blood supply and individuals who have acquired hepatitis C through the blood supply.

That the committee establish and manage a fund to provide financial assistance for costs not covered through existing services, which could include the costs of visits and transport to general practitioners, prescribed medication and surgical aids, dental, aural, optical, physiotherapy and chiropody treatments, home care and/or home help, and alternative medical treatments, to the people who have acquired hepatitis C through blood and blood products.

That the committee, and the fund it establishes, be jointly funded by the Commonwealth and State and Territory Governments.

That the committee develop criteria for people to access the fund.

Senator Jan McLucas
Chair

ADDITIONAL COMMENTS BY SENATOR STEVE HUTCHINS

The Decision to Not Introduce Surrogate Testing for Hepatitis C in Australia

There are thousands of Australians who have acquired hepatitis C as a result of a blood transfusion or receiving a blood product. Each of those people have at least suffered terrible hardship and pain, while some face the possibility of death as a result of their illness. In weighing up the evidence presented to the committee, the effect this illness has had on the individuals concerned must be at the heart of any conclusions drawn.

In deciding whether the relevant authorities made appropriate decisions with regard to the introduction of surrogate testing for hepatitis C in donated blood, the following issues must be considered:

- when the seriousness of non-A, non-B hepatitis was generally accepted by the medical profession;
- how effective surrogate testing is in excluding non-A, non-B hepatitis; and
- whether the deliberative processes of the relevant authorities regarding the implementation of ALT testing were carried out in a comprehensive and expeditious manner.

Concerns have been raised that the inquiry, by its very nature, threatened the quantity of blood available because negative publicity for the Australian Red Cross discourages donors from providing blood. As the Tainted Blood Action Group stated at the hearing in Sydney, the two years (2002 and 2003) when the issue of tainted blood received the greatest media attention coincided with record levels of donations of blood[1] . In other words, fear that findings of this committee would impact upon the future viability of the blood supply are unfounded.

At the heart of any decisions made regarding the implementation of surrogate testing is what appears to have been the ethical balancing act at the time: whether excluding hepatitis C infected blood was worth the exclusion of a certain amount of blood which was actually uninfected.

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[1] Committee Hansard, 6 April 2004, CA 44.

Understanding of hepatitis C

In determining whether the actions of the Australian Red Cross and CSL Ltd were appropriate, it is essential to consider the knowledge of the seriousness of hepatitis C (or non-A, non-B hepatitis). Clearly, one would expect any organisation to introduce measures to prevent the transmission of an illness which was known to be harmful, and which could potentially be life-threatening. As a result, the knowledge of hepatitis C and its impact upon the lives of its victims should be essential to the conclusions of this inquiry.

Professor Burrell, the very first witness to give evidence to the Committee, informed us that in 1974-75 'two key publications identified a percentage of cases of hepatitis after blood transfusion not caused by hepatitis A or hepatitis B'. At the same hearing Professor Burrell gave evidence that the following was known about the infection:

> 'unless the blood recipients were tested for liver function, it would not be evident that they had become infected. It was known that chronic infection occurred in a percentage of these, though the exact rate was not known. It was also known that some of these people remained infectious for a long time. It was also known that there was a link to chronic active hepatitis and to cirrhosis. The proportion of individuals was not known and the time frame was not known.'[2]

So, it was clear from as early as the mid-1970's that an unidentified type of hepatitis was in the blood supply, and that it was detectable through testing for liver function (also known as surrogate or ALT testing). The seriousness of the illness, at least in terms of its longevity and its link to cirrhosis of the liver, were known at the same time. There is no doubt that blood authorities across the world were aware of the same information to which Professor Burrell referred.

Further evidence to the Committee from the Australian Association of Pathology Practices stated that 'by 1987, the problem of hepatitis C was well known. International strategies to reduce the incidence of post transfusion hepatitis caused by NANB in donated blood had been in place internationally since 1984'[3]. By 1986, the threat of hepatitis C was deemed serious enough for the United States Food and Drug Administration to implement mandatory anti-NANB hepatitis strategies. Not until February 1990 did Australia routinely test for hepatitis C in donated blood when the first licensed testing kits became available.

There was clear evidence more than a decade before the introduction of hepatitis C testing in Australia that thousands of Australians were being

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[2] Committee Hansard, 1 April 2004, CA 1.

[3] Australian Association of Pathology Practices, Submission 61, p. 3.

regularly exposed to an illness which can have long-lasting and terrible effects.

The Effectiveness of Surrogate Testing

The evidence presented to the inquiry undoubtedly agreed that, if surrogate testing for hepatitis C had been implemented, the following results, on the balance of probability, would have occurred: a certain amount of hepatitis C infected blood would have been excluded from the blood supply; and a certain amount of hepatitis C free blood would have been mistakenly excluded. In other words, the organisations and governments involved in the National Blood Transfusion Advisory Committee knew that the decision not to implement testing for hepatitis C would result in blood recipients acquiring hepatitis C. That is the essence of this inquiry: whether it was right to keep blood which was known to be infected to preserve the availability of blood which most likely was not infected.

Prior to 1990, the Australian Red Cross Blood Service estimates that the likelihood of risk of hepatitis C, per unit of blood, was 1 in 333. That figure has, thankfully, fallen to less than 1 in 3 million. When ALT testing and anti-Hbc testing was introduced in the United States of America, the risk profile of infection reduced from 5.5% to 4.1% from a transfusion[4]. While the arguments made concerning the higher incidence of hepatitis among donors in the United States are compelling, it would have been foreseeable that the implementation of the same tests in Australia would have reduced the incidence of blood transfused hepatitis C by the same ratio. This is because surrogate testing removes a fixed percentage of infected blood despite the overall level of infected blood in the blood supply. As such, whilst Australia has a safer population and hence a lower overall risk, this means that that overall risk would have been reduced by a similar ratio to a much smaller overall rate of infections.

That means that the 1 in 333 likelihood could have been reduced to 1 in 500 at the higher limit of ALT effectiveness.[5] While, in statistical terms, this may seem insignificant, it would have undoubtedly saved some lives and would have improved the quality of life of hundreds, if not thousands, of people. This would have also meant a net saving by up to 1/3 in the total costs of health care, running possibly into the hundreds of millions, of persons now unfortunately infected with hepatitis C through the blood supply.

The Department of Health and Ageing's submission dismisses the usefulness

[4] Australian Red Cross Blood Service, Submission 64, p. 45.

[5] Australian Red Cross Blood Service, Submission 64, p. 37.

of surrogate testing by stating that it is only as effective in ruling out hepatitis C as using a 'random marker' such as a person's initials[6]. This assertion does not take the cumulative nature of risk associated with exposure to infected blood, as is highlighted in the Australian Red Cross Blood Service's submission, 'For instance, if the risk for a single unit is 1 in 1 million, then receiving a second unit means the cumulative risk to the recipient is 2 in 1 million'[7]. One of the Department's most significant justifications of the decision not to implement surrogate testing is based upon the false premise that each patient only receives one unit of blood. The conclusions based on those calculations are misleading because they fail to focus upon the victims of hepatitis C infection.

The Australian Red Cross Blood Service estimates that 1.5% of all donations would have tested positive using surrogate testing (based on findings in the United States), and that 70% of blood excluded would have, in fact, been the result of a false positive[8]. It is undeniable that the Commonwealth, the States and Territories, the Australian Red Cross Blood Service and CSL were placed in an unenviable position. They were compelled to choose between the quantity of the blood supply and its quality.

The fact that the Queensland Red Cross Blood Transfusion Service, under leadership of Dr Catherine Hyland, chose to implement surrogate testing and that no other Red Cross Blood Transfusion Service chose to demonstrates the difficulty of the question. But it also shows that a blood supply could be maintained and function without the 1.5% of false positive donations. The lesson from Queensland is that other Australian blood services may have been unnecessarily cautious in their protection of the quantity of blood available.

Deliberative Processes

The role of various governments and organisations in providing direction for the collection of and transfusion of blood, prior to 1996, were undoubtedly complex. As far as the Department of Health and Ageing could advise in hearings in Canberra, the Australian Red Cross regularly convened meetings of a national blood transfusion advisory committee, and that committee had representatives from the Red Cross, the Commonwealth and State and Territory governments. Each state Red Cross blood authority made its own decision regarding the implementation of surrogate testing for hepatitis C, but was advised by the national committee. At no stage did the national committee advise that surrogate testing should be implemented, although

[6] Department of Health and Ageing, Submission 54, p.8.

[7] Australian Red Cross Blood Service, Submission 64, p. 94.

[8] Australian Red Cross Blood Service, Submission 64, p. 30.

Queensland later decided to introduce surrogate testing of its own accord.

The Red Cross commenced a study of the effectiveness of surrogate testing in 1987 (a study into the transfusion rate of hepatitis C was conducted in 1979). So, significantly after knowing the seriousness of the illness and years after the test became available, an Australian study was first instigated. By the time the study was concluded, the first generation test for hepatitis C was on the verge of being widely available.

By international standards, Australia was slow in studying the prospective effectiveness of surrogate testing. In fact, Australia did so at the recommendation of 'experts from the US and Europe'[9]. It would appear that, up until the establishment of that study, Australia relied upon information from overseas, much of which was seen as irrelevant because of differences in the way blood was collected.

Without timely and relevant domestic studies, the true impact of surrogate testing could not have been adequately ascertained.

Conclusions

It is undeniable that thousands of Australians have acquired hepatitis C as a result of receiving a blood transfusion. The seriousness of hepatitis C (or non-A, non-B hepatitis) was known in the early 1980's. By 1978, according to Professor James Mosley, it was well-known that surrogate testing could reduce the incidence of hepatitis C[10]. In fact, he delivered a lecture in Melbourne on this matter, a lecture which representatives of the Australian Red Cross Blood Service attended[11]. Yet Australian blood authorities chose not to recommend that surrogate testing be implemented because its effectiveness was not deemed great enough to justify the exclusion of some blood which returned 'false positive' results to surrogate testing.

A decision had to be made, and no amount of retrospection can replicate the difficulties faced by those people at that time. Nonetheless, it remains that many Australians today suffer from what can become a debilitating illness as a result of the decision not to implement surrogate testing outside Queensland.

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[9] Committee Hansard, 7 April 2004, CA 38.

[10] Professor James W Mosley, Submission 89, p. 1.

[11] Ibid.

If surrogate testing had been introduced, the incidence of post-transfusion hepatitis C would most probably have been reduced from 1 in 333 to 1 in 500. As a statistic the difference is negligible. But the negligible difference has had a profound and sad effect on the lives of thousands of Australians.

The decision not to introduce surrogate testing was what created that effect.

Senator Steve Hutchins
Australian Labor Party, New South Wales

APPENDIX 1

LIST OF PUBLIC SUBMISSIONS, TABLED DOCUMENTS AND OTHER ADDITIONAL INFORMATION AUTHORISED FOR PUBLICATION BY THE COMMITTEE

1 Poile, Ms Diane
2 Bell, Mr Robert (NSW)
3 Jacobson, Ms Jacinta (NSW)
4 Callard, Mr David Arthur (NSW)
5 Fennell, Ms Vicki (NSW)
6 Name withheld (NSW)
7 Day, Ms Heather (QLD)
8 Harris, Ms Vickie (QLD)
9 Pyatt, Mrs Carmel (QLD)
10 Name withheld (QLD)
11 Johnston, Mr Glenn (NSW)
12 Pollack, Mr Michael (NSW)
13 Pollack, Mr Ron & Mrs Robyn (NSW)
14 Pollack, Ms Bernadette (NSW)
15 Crust, Mr Graham (QLD)
16 Crust, Mrs Rae (QLD)
17 Stevens, Mr David and Mrs Rosalie (NSW)
18 Smith, Ms Bronwyn (QLD)
19 May, Ms Susie (QLD)
20 Hughes, Mr Peter (QLD)
21 Hastedt, Mr Neville Raymond (NSW)
22 Hastedt, Mrs Patricia (NSW)
23 d'Alessandra, Ms Teresa (NSW)
24 Barraclough, Professor Bruce
Chair, Australian Council for Safety and Quality in Health Care (NSW)
25 Herrmann, Mrs E (NSW)
26 Name withheld (NSW)
27 Borowsky, Mr Alan (NSW)
28 Wilkinson, Mr Norman (QLD)
29 Frainey, Ms Michelle (QLD)
30 Name withheld
31 Vladimirov, Mrs Ellen (NSW)

32 Rootham, Mr Danny (NSW)
33 Morgan, Ms Maxine (NSW)
34 Simcoe, Ms Barbara (NSW)
35 Meredith, Mr Michael (NSW)
36 Name withheld
37 Howell, Mr Ronald (NSW)
38 McDermott, Mr Brad (WA)
39 Borowsky, Ms Mayne (NSW)
40 Shanley, Ms Beverley Anne (NSW)
41 Newman, Mrs Robin (NSW)
Supplementary information
- Additional information dated 10.6.04

42 Waddell, Mr John Malcolm (NSW)
43 Hibbert, Ms Enid (NSW)
44 Wilson, Mr Alan (NSW)
45 Graham, Ms Julie (NSW)
46 Carroll, Mr Shelton (NSW)
47 Jeffs, Mr Craig (VIC)
48 Palombi, Mr Luigi (NSW)
Supplementary information
- Supplementary submission provided following hearing 7.4.04, dated 14.4.04

49 Name withheld (NSW)
50 Franklin, Ms Bertha (VIC)
51 Forrest, Ms Mary (NEW ZEALAND)
52 Harcourt, Ms Andrea (NSW)
53 Hickey, Mr Raymond (NSW)
54 Commonwealth Department of Health and Ageing (ACT)
Supplementary information
- Additional information following hearing 1.4.04, dated 3.5.04
- Supplementary submission, responses to questions from hearing 1.4.04, dated 21.5.04
- Additional information dated 25.5.04; 26.5.04; 1.6.04 and 3.6.04

55 Skidzevicius, Ms Helen Marija (SA)
56 Dunn, Mr Scott (VIC)
57 Batey, Professor Robert G (NSW)
58 Giacca, Ms Barbara Eleanor (NSW)
59 Land, Mr Gordon (NSW)
60 Turner Freeman Solicitors (NSW)
61 Australian Association of Pathology Practices Inc (AAPP) (ACT)
62 Ross, Ms Elva (NSW)

63 No submission

64 Australian Red Cross Blood Service (NSW)
Supplementary information
- Documents provided at visit to Garran, ACT on 24.3.04

Provided at hearing 7.4.04
- Correction to submission
- Submission prepared for oral hearing

Provided following hearing
- Responses to questions from hearing 7.4.04, dated 18.5.04
- Supplementary submission dated 27.5.04
- Statement dated 27.5.04

65 Name withheld

66 Lewis, Ms Maureen (NSW)

67 National Serology Reference Laboratory, Australia (VIC)

68 Day, Mr Kevin (QLD)

69 Royal College of Pathologists of Australasia (NSW)

70 Bollmeyer, Mrs Suzanne (SA)

71 Australian and New Zealand Society of Blood Transfusion (NSW)

72 Australian Haemophilia Centre Directors' Organisation (VIC)

73 Medical Error Action Group (NSW)
Supplementary information
- Addendum to submission provided at hearing 6.4.04

74 McCaughan, Professor Geoff (NSW)

75 Australian Hepatitis Council (ACT)

76 Williams, Ms Nikki (NSW)

77 Holt, Ms Suzanne (NSW)

78 Hanrahan, Ms Therese (NSW)

79 Tainted Blood Product Action Group (NSW)
Supplementary information
- Additional information following hearing 6.4.04, received 19.4.04

80 Australian Centre for Hepatitis Virology Inc (SA)
Supplementary information
- Additional information following hearing 1.4.04, received 10.5.04

81 Hepatitis C Council of NSW (NSW)
Supplementary information
- Supplementary submission dated 31.5.04

82 Haemophilia Foundation Australia (HFA) (VIC)
Supplementary information
- Information folder provided at hearing 5.4.04
- Responses to questions following hearing 5.4.04, dated 7.6.04

83 Traids (NSW)

84 Traids Support Group (NSW)

85 People with Disability Australia Incorporated (PWD) NSW
86 Cooksley, Dr W G E
87 Bell, Ms Sue (VIC)
88 Deleacy, Dr D (VIC)
89 Mosley, Professor James W (USA)
90 Name withheld
91 Brereton, Mr Graeme (WA)
92 Haag, Mr David (NSW)
93 Laver, Mr Colin (QLD)

Additional information

Correspondence authorised for publication by the Committee relating to the hearing on 7 April 2004

Tainted Blood Product Action Group, dated 22.4.04
Australian Red Cross Blood Service, dated 10.5.04

Responses by State and Territory Governments to questions concerning the regulation of blood transfusion services and compensation arrangements, if any:

Queensland Government, dated 10.5.04
Victorian Government, dated 7.5.04
NSW Government, dated 25.5.04
ACT Government, dated 21.5.04

Volk, Mr Gerard T

Additional information following hearing dated 19.4.04

APPENDIX 2

WITNESSES WHO APPEARED BEFORE THE COMMITTEE AT PUBLIC HEARINGS

Thursday, 1 April 2004
Parliament House, Canberra

Australian Centre for Hepatitis Virology Inc
Professor CJ Burrell, Chairman

Australian Hepatitis Council
Ms Kerry Paterson, A/g Executive Officer

Department of Health and Ageing
Mr Philip Davies, Deputy Secretary
Professor John Horvath, Chief Medical Officer
Mr Terry Slater, National Manager, TGA
Dr Louise Morauta, First Assistant Secretary, Acute Care Division
Mr Andrew Stuart, First Assistant Secretary, Population Health Division
Ms Nola Witchard, A/g Assistant Secretary, Acute Care Development Branch

Monday, 5 April 2004
St James Court Conference & Function Centre, West Melbourne

Haemophilia Foundation Australia
Ms Ann Roberts, President
Ms Sharon Caris, Executive Director
Mr Peter Mathews, Vice President
Mr Gavin Finkelstein, Treasurer

National Serology Reference Laboratory
Associate Professor Elizabeth Dax, Director

Australian Association of Pathology Practices
Dr Graeme Swinton, Past President & Executive Member
Dr Robert Baird, Observer

CSL Limited
Dr Daryl Maher, Medical and Research Director

Tuesday, 6 April 2004
Jubilee Room, NSW Parliament House, Sydney

Hepatitis C Council of NSW
Mr Stuart Loveday, Executive Officer

TRAIDS
Ms Maria Romaniw, Coordinator
Ms Miriam Vellscek, Client

Tainted Blood Product Action Group
Mr Charles MacKenzie, Administrator
Rev. Bill Crews, Member
Mr Michael Pollack, Member
Ms Jacinta Jacobsen, Member
Ms Suzanne Bollmeyer, Member

Australian Haemophilia Centre Directors' Organisation
Dr John Rowell, Chairman

Professor Bruce Barraclough
Chair, Australian Council for Safety and Quality in Health Care

Medical Error Action Group
Ms Lorraine Long, Founder

Professor Geoff McCaughan

Wednesday, 7 April 2004
All Seasons Menzies Hotel, Sydney

Ms Maureen Lewis

Mr Shelton Carroll

Mr Luigi Palombi

Australian Red Cross Blood Service
Dr Brenton Wylie, Spokesperson
Dr Paul Holland, International expert
Dr David Rosenfeld, Haemotologist
Mr Brian Pepper, Donor
Mrs Carole Tozer, Recipient

APPENDIX 3

Australian Red Cross
BLOOD SERVICE

ARCBS NATIONAL

153 Clarence Street Sydney NSW 2000 Australia
Telephone: +61 2 9229 4005 Facsimile: +61 2 9229 4497
E-mail: macadmin@arcbs.redcross.org.au

Statement by Dr Brenton Wylie at meeting convened by ARCBS
Jubilee Room, Parliament House, Sydney
10:00 am Thursday 27th May, 2004

"Firstly, on behalf of the Australian Red Cross Blood Service (ARCBS) I would like to thank you all for your time today and say that we are extremely pleased that you have agreed to meet with us in this forum.

This meeting is really a result of the hearings that took place as part of the Senate Community Affairs Reference Committee inquiry into Hepatitis C and the blood supply. At those hearings, we listened carefully to the concerns of those who made submissions to the inquiry and reflected upon what was said.

A number of things have become clear to us as a result of the hearings and we felt that it would be beneficial to instigate a face to face forum today. Primarily we are here today to express to you, as representatives of organisations who act on behalf of those affected by hepatitis C, our sorrow at what has occurred.

We are also here today because we understand the importance of establishing a dialogue with you, and would like to seek your input in terms of how best to move forward to support those affected by hepatitis C.

The Red Cross has recognised that, in the past, some blood-transfusion recipients contracted hepatitis C virus from blood transfusions.

This is a terrible fact and we are sorry that this occurred.

We are sorry that for some of those recipients contracting hepatitis C has resulted in often debilitating physical symptoms of this disease, and in some cases, unfair discrimination. We as individuals at the ARCBS have been distressed to hear of people's particular situations.

As we have stated before, we extend our sympathy to each Australian who has acquired hepatitis C, including those who have contracted it through blood transfusions. We recognise the impact that this disease can have on the person and their family.

However, as we said at the Inquiry, we maintain that we acted and took decisions responsibly and in accordance with the best available scientific knowledge at the time and, accordingly, we do not accept liability.

As part of this forum, we would also like to say that there have been specific circumstances mentioned in the hearings when it is clear that we have not always met the expectations of the people with hepatitis C in terms of how we have interacted with them.

We would like to make it clear that this was not deliberate or through lack of compassion. All those within the ARCBS are human beings and have the very best of intentions at all times.

We hope that we have learned from our experiences and intend to implement improved systems wherever practicable in our day to day dealings with those affected by hepatitis C.

As a humanitarian organisation and charity, which is dependent on the goodwill of the Australian public, ARCBS fully recognises the importance of transparency in its activities and we acknowledge that there has been frustration about our inability to discuss issues in relation to the legal process.

The fact is that because of our obligations of confidentiality, we cannot discuss issues relating to this, however we are here today because we, at ARCBS, believe that there is some common ground between all the organisations represented at this table.

We share a common concern for those affected by transfused hepatitis C. We are committed to continuing to provide services such as Lookback, counselling and referral services to those affected both as a result of a transfusion, and those identified through the donation program. Importantly we are committed to continuing to improve these services in consultation with the Australian and State and Territory governments.

What we would now like to focus on is the present and the future and we would like to discuss with you today how we are able to move forward beyond the senate inquiry. We are keen to hear your thoughts on constructive ways to improve our existing services and dealings with those who have hepatitis C as we move forward.

Again I'd like to say that the circumstances that bring us together today are very sad ones.

That anyone ever received hepatitis C through a blood transfusion is a terrible fact.

We are very sorry that this ever occurred. We would like to listen to you today and hope that we can find a positive outcome from this process together with you all."

HAEMOPHILIA FOUNDATION AUSTRALIA

THE IMPACT OF HEPATITIS C UPON PEOPLE WITH HAEMOPHILIA AND RELATED BLEEDING DISORDERS

1. INTRODUCTION

Haemophilia Foundation Australia (HFA) will confine its submission to the *Committee of Inquiry into Hepatitis C and the Blood Supply in Australia (the Committee)* to a discussion about the impact of hepatitis C upon the haemophilia community. All references to haemophilia in this submission should also be read to include references to von Willebrand disorder (vWD) and related bleeding disorders unless express reference is made specifically to any of these. The submission relates to hepatitis C which has been medically acquired through the use of blood and blood products for the treatment of haemophilia and related bleeding disorders. Unless specified this submission does not extend to other modes of medically acquired hepatitis C transmission such as transfusion.

HFA expects that the Committee will have sought submissions from relevant experts to provide expert scientific, clinical and epidemiological data. HFA does not have the resources to conduct medico legal, scientific or epidemiological research, but must rely upon the integrity of such data from external sources. The strength of this submission will be that it will contribute relevant and valuable Australian and international experience about the impact of hepatitis C upon the haemophilia community.

In the submission HFA will address several of the questions of interest to the Committee of Inquiry, particularly the impact of hepatitis C upon the haemophilia community, the safety and supply of treatment products, the relevance of overseas experience and approaches to hepatitis C contamination in the blood supply, and the need for redress for people with haemophilia and von Willebrand disorder in Australia who have become infected by hepatitis C through blood products.

2. HAEMOPHILIA FOUNDATION AUSTRALIA (HFA)

HFA is the national peak body which advocates for the treatment and care needs for people with haemophilia and related bleeding disorders, including von Willebrand disorder and other rare factor deficiencies. Most services and activities are funded by donations, however the secretariat is funded by Commonwealth Department of Ageing. Its primary objectives are to represent people affected by bleeding disorders through advocacy, education and the promotion of research. HFA is governed by a Council of delegates from State/Territory Haemophilia Foundations.

The vast majority of people with haemophilia or vWD are treated at specialist centres located at major public hospitals throughout Australia. Haemophilia Foundations work closely with clinicians and health care professionals at these designated centres.

HFA has strong links with specialist health professionals groups, and auspicesand financially supports Australian Haemophilia Counsellors' and Social Workers' Group, HFA Nurses' Association and Australia New Zealand Haemophilia Physiotherapists' Group to enable them to develop specialist clinical expertise.

The HFA Medical Advisory Panel (MAP), whose members are haemophilia specialist clinicians from haemophilia treatment centres throughout Australia was auspiced and financially supported for many years by HFA. In 2001 MAP commenced operating as the Australian Haemophilia Centre Directors' Organisation (AHCDO) and this independent body is recognised as the peak clinical body that provides expert clinical advice and recommendations for the treatment and care of bleeding disorders in this country.

HFA hosts biennial national haemophilia conferences attended by people with haemophilia and other bleeding disorders, haematologists, infectious diseases specialists, liver specialists and other health care professionals, manufacturers, government regulators and policy makers. HFA is an active affiliate member of the World Federation of Hemophilia. Through its membership and work with this international body, HFA maintains up-to-date knowledge of the treatment of bleeding disorders and the complications of treatment including the management and care of blood borne viruses, blood product safety, and issues relating to the sustainability and supply of treatment products in both developed and emerging health care economies. HFA and its individual members are therefore very well informed about bleeding disorders and the complications caused by treatments, including blood safety and treatment product safety.

3. WHAT IS HAEMOPHILIA?

Haemophilia is a genetic disorder, which is usually inherited. The haemophilia gene is passed down from a parent to a child. Men with haemophilia pass the gene on to their daughters, but not to their sons.

Women do not usually have haemophilia, but they can be carriers of the gene. Women who are carriers have a 50 percent chance of having a boy with haemophilia and a 50 percent chance of having a girl who is a carrier. About one third of new cases are caused by a spontaneous mutation of the gene, which means that there was no history of haemophilia in the family before.

Haemophilia A or Classical Haemophilia, is the most common form of haemophilia and is due to the deficiency of factor VIII. Haemophilia B or Christmas disease is due to the deficiency of factor IX. The severity of haemophilia is determined by the level of clotting activity of factor VIII or factor IX in the blood. There are three levels of severity: mild, moderate, and severe.

The incidence of haemophilia is 1 in 6000 -10000 people. Prevalence is harder to determine as many people with haemophilia in developing countries are not diagnosed and without treatment die from haemophilia at an early age.

People with severe haemophilia bleed frequently into their muscles or joints. They may bleed one to two times per week. Bleeding is often spontaneous, which means the bleeding just happens with no obvious cause. People with severe haemophilia will have used large amounts of clotting concentrates for their treatment throughout their life

People with moderate haemophilia bleed less frequently, usually after an injury, perhaps once a month. Cases of haemophilia vary however, and a person with moderate haemophilia may also bleed spontaneously.

People with mild haemophilia usually bleed only as a result of surgery or major injury. They may never have a major bleeding problem.

4. WHAT IS VON WILLEBRAND DISORDER?

von Willebrand disorder (vWD) is an inherited bleeding disorder. It is the most common inherited clotting disorder, affecting both men and women. It has been estimated that vWD affects up to one percent of the whole population. However, it is generally the least severe of the clotting disorders.

vWD is caused by a deficiency or defect of a blood clotting protein called von Willebrand factor (vWF). This glue-like protein that helps platelets in the blood stick together and seal off tears in injured blood vessels. This is called a platelet plug. If a person does not have enough von Willebrand factor or it does not work properly, no platelet plug will form and bleeding will continue for a longer period of time.

Most people with vWD will have few, if any, symptoms and most will not require treatment unless having dental work or surgery. The main symptoms are easy bruising, frequent or prolonged nosebleeds, heavy or prolonged menstrual bleeding, and prolonged bleeding following injury, surgery, dental work, or childbirth. Treatment will be required for more severe forms of vWD with desmopressin (DDAVP) or with infusions of a clotting factor concentrate that contains vW factor. People with severe forms of vWD will have used large amounts of clotting concentrates for their treatment throughout their life.

5. TREATMENT

Haemophilia is treated by replacing the missing clotting factor in the blood. The necessary clotting factor must be injected into a vein. Bleeding stops when sufficient clotting factor reaches the bleeding site. When bleeding is into a joint it is very important that treatment is given as quickly as possible to prevent long-term damage.

Haemophilia is a lifelong or chronic condition, however the development of clotting factor concentrates has meant in most cases, that haemophilia can be managed effectively with proper treatment.

A small number of people with haemophilia develop inhibitors to clotting factors and bleeding continues unabated resulting in significant disability, particularly in adult haemophilia patients who have not had the benefit of sufficient quantities of inhibitor treatment products. Whilst children with inhibitors are more likely to be treated optimally in this country, adults with inhibitors still do not have access to the best product for this, (recombinant factor VIIa) except in the event of a life or limb threatening bleed. These people suffer from terrible ongoing pain and disability.

Today most people treat themselves at home. Timely treatment to stop bleeds enhances self care and independence, and helps reduce major joint damage/atrophy. Most people have normal life expectancy unless complications occur. Children are treated prophylactically, usually 2-3 times per week to prevent bleeds from occurring or to reduce their severity. In Australia, government policy has restricted preventive or prophylaxis to children on the grounds of cost. Nevertheless, there is strong argument that adults should also have access to prophylaxis.

Factor concentrates have revolutionised haemophilia treatment. They can be made from human blood (called plasma-derived products) or manufactured using genetically engineered cells that carry a human factor gene (called recombinant products). There are several levels of purity (the concentration of factor) ranging from intermediate to very high depending on the manufacturing process.

Synthetic or recombinant factor VIII does not contain von Willebrand factor and is not effective for the management of von Willebrand disorder, so this group of patients must use plasma derived concentrates which contain von Willebrand factor.

In the past, bleeding has been treated with unrefined blood plasma in the form of fresh frozen plasma or cryoprecipitate. Whilst generally effective to stop bleeds, and with the advantage of being made from small pools of blood they meant exposure to less donors which was an advantage. These products were sometimes used in preference to large pool products when it became known that blood borne viruses were infecting these products. This in fact did protect some people who were treated in this way in the lead up to viral inactivation techniques.

Concentrates by definition are preparations made by pooling blood plasma of many blood donations. Large pools increase the risk of infectious agents. Measures must be taken to reduce the risk inherent in the collection and viral inactivation processes used.

The therapeutic safety of plasma derived products depends on the methods used to prevent, remove, or inactivate viruses that may be present in the source plasma. The safety of plasma derived clotting concentrates is dependent upon donor selection, plasma pool size and the fractionation procedure and the associated viral inactivation processes.

Viral inactivation processes are based on heat, solvent detergent or filtration. Heat inactivates viral proteins and nucleic acids and prevents replication and can be used in dry preparation or in liquid (pasteurisation). Solvent detergent inactivates enveloped viruses such as HIV, hepatitis B and hepatitis C and makes them non infectious, but it is unsuccessful against non enveloped viruses such as hepatitis A and parvovirus B19. [1]For this reason plasma derived products with two effective viral inactivation steps, including one that is effective against non enveloped viruses are considered safest.

There is great reliance on the scientific and regulatory community to ensure current viral inactivation procedures used in the fractionation of products are sufficient to eliminate the risk of transmission of known viruses. Regulators are quick to point out that it is impossible to achieve zero risk, and there is always the potential for an unknown agent for which screening and blood testing may be ineffective or for human or manufacturing error to occur.

6. CHRONICITY OF HAEMOPHILIA AND DISABILITY

There is no cure for haemophilia. Gene therapy promises hope for the future, however experts consider it will be at least 20 years before the scientific, clinical, ethical and other barriers will have been removed to enable safe, effective and accessible treatments to overcome the burden of haemophilia. A recombinant clotting treatment product for the management of inhibitors is available to children in Australia, however product access for adults is only available to adults if they are experiencing life or limb threatening bleeds. HFA considers that inhibitor treatment in Australia is sub - optimal currently for adults.

Medical and technological progress in recent decades means it is now possible to manage and prevent the complications of haemophilia. Clotting factor can be made safer than ever before. The quality and safety requirements of key regulatory authorities continue to strengthen standards. Today, improved treatment knowledge with new modes of treatment, including prophylaxis as standard treatment are proven to be extremely effective and prevent long term joint damage and disability.

However people with haemophilia nevertheless live with the legacy of past treatments and the effectiveness and safety of those treatments. Many are crippled with disabling and painful arthritis. Even with current treatment, many adults have to struggle to maintain an adequate

quality of life. Many suffer as a result of inadequate treatments. Haemophilia continues to be a challenge as it requires treatment for life and it presents complex medical and psychosocial issues for the individuals affected and their families. The memory of past experiences of poor treatment, inadequate treatment products, and the tragedy of HIV/AIDS followed by hepatitis C and the perception that blood borne viruses could have been prevented results in distrust, pain, grief and fear for many. [2]

Inadequate supply of safe clotting factor treatments puts people with bleeding disorders at risk of life or limb threatening consequences. In a health care economy such as Australia, mortality or morbidity due to inadequate treatment is unlikely and is unacceptable, however without appropriate measures in place to ensure an adequate supply of the safest treatment products people with bleeding disorders will continue to risk unnecessary iatrogenic consequences of their treatment.

.....canaries in the mineshaft.....

People with bleeding disorders requiring blood clotting agents to stop their bleeding, throughout the world, have always been amongst the first to be affected when a virus or pathogen has entered the blood supply because of the lack of, or inadequate blood screening measures or viral inactivation processes.

Australia is no exception to this and the hereditary nature of bleeding disorders is such that most families with haemophilia have one or a number of members infected with either HIV and or hepatitis C. Many of their relatives have died, whilst others must live with the health, psychosocial and financial consequences of the use of unsafe blood products prescribed for their treatment. They continue to live with physical disability and pain of chronic arthritis caused by prolonged bleeding into joints and muscles.

Despite the various risk management approaches implemented over the years to make the blood supply safer, including donor screening, donor deferral, NAT testing, and viral inactivation procedures to treat fractionated products, it is only a matter of time that those who are dependent upon these clotting concentrates for their treatment will again be failed.

7. HEPATITIS C IN THE HAEMOPHILIA COMMUNITY

Following treatment with contaminated blood clotting factor concentrates given as part of their treatment provided by the Australian Health Service, 85-90% of people with haemophilia have been infected with hepatitis C. It is likely that up to 90% of people with haemophilia A and haemophilia B developed non A non B hepatitis (NANB hepatitis) with their first treatments of non heat treated clotting factor.[3] More than 250 people with haemophilia were also infected with HIV and many of these people also have hepatitis C.

8. HOW MANY PEOPLE IN AUSTRALIA ARE INFECTED WITH HEPATITIS C IN AUSTRALIA?[4]

It is unfortunate that there is no comprehensive data available on haemophilia, vWD and hepatitis C in Australia. AHCDO collects data for the Australian Bleeding Disorder Registry (ABDR), however this does not contain data for NSW. HFA has access to limited unpublished ABDR data and the Senate Community Affairs Legislation Committee published Questions on Notice Question

ABDR (all States except NSW)

446 people with haemophilia have hepatitis C (79 also have HIV)

82 people with haemophilia B have hepatitis C (5 also have HIV)

64 people with vWD have hepatitis C (3 also have HIV)

Total number of people on the registry = 1769

However a further 395 have no hepatitis C status recorded. Assume 50% have hepatitis C, a further 197 = 789

NSW

225 people out of a total of 748 reported to have hepatitis C, however as this may exclude vWD,add a further 3.6% in line with proportion of vWD patients with hepatitis C in ABDR (8 patients) = Total of 233 in NSW with hepatitis C

APPROXIMATELY 1022 WITH HEPATITIS C

9. BLOOD SAFETY

"Safety of the blood supply system is paramount. The goal of the blood supply system must be to supply safe therapies to persons who need them. The principle of safety must transcend other principles and policies.

The costs of promoting safety may well be high – for example when new pathogens appear and new tests are required, when newer and more sensitive tests are developed to identify known pathogens, or when blood products must be withdrawn or recalled and be replaced because they are or may be unsafe, the promotion of safety may well require that substantial sums of money be spent. When enhanced donor screening measures are needed to identify a new pathogen, the cost to the blood supply system may be a reduction in the number of donors.

The safest blood supply is an aspect of public health philosophy, which rejects the view that complete knowledge of a potential health hazard is a prerequisite for action. *The balancing of risks and benefits of taking action should be dependent not only on the likelihood of the risk materialising but also on the severity of the effect if the risk does materialise, on the number of persons who could be affected and on the ease of implementing protective or preventive measures. The more severe the potential effect, the lower the threshold should be for taking action.*

Preventive action should be taken when there is evidence that a potential disease causing agent is or may be affected. ***If harm can occur, it should be assumed it will occur.*** *If there are no measures that will entirely prevent the harm, measures that may only partially prevent transmission should be taken".*

(Krever) [5]

HOW DID IT HAPPEN?

10. TESTING OF BLOOD

Hepatitis has been known for many years. The link between jaundice and liver problems was known despite there being no identified causative agent which could be tested for and the problem of post transfusion hepatitis was also well known. The hepatitis B surface antigen (HBsAg) was identified as part of the hepatitis B virus and allowed for tests to be developed to screen blood for hepatitis B in the 1960s. A test also became available for hepatitis A antibodies in 1973. Despite the expectation that these tests would identify most cases of serum hepatitis (hepatitis B) and infectious hepatitis (hepatitis A), they did not. However, significant numbers of cases of hepatitis were caused by neither hepatitis A and hepatitis B. This was called non A non B hepatitis (NANB). There was no test for this until 1990, after the hepatitis C virus was cloned by Chiron in 1989. This antibody testing showed that hepatitis C had been the cause of NANB hepatitis and liver disease. In the mid – to – late 1970s it was accepted that transfusion of blood could cause NANB hepatitis in recipients.

By the early 1980s it was apparent that most people infected with NANB hepatitis were carriers and could transmit the disease by exposing others to their blood. People at risk were recipients of blood transfusion, people who had used intravenous drugs (shared needles) and

people who engaged in behaviours where blood contamination was possible (tattooing) and people with previous episodes of jaundice or liver problems.

NANB hepatitis was recognised as a cause of long term health effects by the early to mid 1980s, even though in most cases identified there were no symptoms associated with initial infection.

Many people with haemophilia in Australia have been aware of their "funny liver levels" since the 1970's and were known to have NANB hepatitis from the use of blood products and any symptoms they had "were lived with". Many did not experience any serious symptoms. The risks inherent in plasma pooling were balanced against the benefit of the utility of concentrates. Hepatitis was seen as an unfortunate consequence, but an acceptable risk of blood products.[6] Some patients were spared through the use of cryoprecipitate which they continued to use until testing. Nevertheless for many, it is likely that hepatitis C antibody positive donations have been a part of every plasma fractionation pool since 1952 when the process commenced.[7] After the first generation antibody test became available many haemophilia patients received letters from their clinicians to inform them that they had tested positive for hepatitis C soon after the test became available , but they were advised that they did not need to worry about it as "hepatitis is a benign infection".

In reality, people with haemophilia had no choice of whether or not to use plasma products. When they have severely painful joint or a life threatening bleeding episode, the decision is clear to use the available treatment products, even if the treatment may have associated risks. Living with recurrent and chronic pain is very difficult.

There was great trust placed in products that were developed to treat bleeds, but little was known about their safety risks until HIV came through the blood supply. Parents continue to live with the guilt of having treated their children with these infected products.

A key issue is whether adequate screening of blood donors was undertaken to identify donors for risk factors of infection with NANB hepatitis and whether blood which showed elevated ALT levels (a possible sign of NANB hepatitis) or anti-HBc (indication of past infection with hepatitis B) should have been discarded (surrogate testing). Most people with haemophilia were exposed to many donors, and have an increased likelihood of having been exposed to more than one infected donor.

11. SURROGATE TESTING

The use of surrogate testing to reduce transmission risk has always been controversial in Australia as it was in the USA and elsewhere between 1981 and 1983.

Testing clearly reduced the risk of transfusion transmitted NANB hepatitis in some donor populations before hepatitis C tests were available and these markers had been helpful in reducing the risk of transmitting NANB hepatitis via some donor populations.[8] In Australia surrogate markers were only adopted to screen blood in Queensland, however it is unclear whether studies of comparable donor populations to measure the effects of this factor were undertaken.

The benefit of surrogate testing appears to have been balanced against other issues. Despite the international debate, there was local concern that NANB hepatitis was less prevalent in Australia and that surrogate testing would jeopardise the local blood supply. We understand the Australian Red Cross Society (ARCS) decided not to introduce surrogate testing pending a study into the incidence of post transfusion NANB hepatitis in Australia and the effectiveness of surrogate testing in Australia. An exception was the Queensland Division of the ARCS, which introduced ALT testing in mid 1987, but not anti-HBc testing. There is

debate about the actual efficacy of surrogate testing to detect NANB hepatitis. It is unclear just how many people may have been unnecessarily infected with hepatitis C through blood transfusions because of a failure to implement surrogate testing.

The Krever Commission was critical of Canadian blood services for long delays relating to screening. The Canadian investigators concluded that "although ALT screening lacks the sensitivity to detect all infectious units and lacks the specificity to detect only infectious units, the high correlation between an elevated ALT level and infectivity of transfused blood provides a compelling argument that such screening should be instituted". [9]

Krever wrote "the Red Cross (Canada) had said until the mid to late 1980's NANB hepatitis was believed to be a mild disease, yet by 1980 some studies had shown that between 25 -50 per cent of persons infected with NANB hepatitis had prolonged abnormal levels of ALT, and that of this group the majority showed evidence of chronic active hepatitis and 10-12 % showed evidence of cirrhosis. However little attention was given to the data demonstrating the serious consequences of NANB hepatitis until 1984 when a study at the US NIH found that as many as 20 %of patients with chronic NANB hepatitis developed cirrhosis. By the mid to late 1980's, NANB hepatitis was known to cause serious disease, including cirrhosis and liver cancer in a significant proportion of infected individuals. The seriousness of NANB hepatitis was one of the reasons that surrogate testing was implemented in the US". [10]

Krever was scathing about the lack of follow up and action in Canada despite the debate (p635) and the failure to resolve this issue "whilst some USA blood centres did implement ALT testing, in Canada the recommendation that a study of the incidence of post transfusion hepatitis or the desirability of surrogate testing for NANB hepatitis does not appear to have been followed up". Surrogate testing was rejected in Canada in favour of a multi centre study which was delayed for several years, but which showed on completion (by which time a test for hepatitis C was being used), that surrogate testing would have reduced post transfusion NANB hepatitis.[11]

In 1986 a blood products advisory committee of the United States FDA decided that both ALT and anti-HBc testing should be implemented, and although several blood banks in the US moved to adopt the tests in late 1986/87, the FDA did not issue a regulation requiring anti-HBc testing of donated blood until 1 March 1991 for the purpose of identifying units contaminated with HBV, and never issued a regulation requiring testing for ALT levels. Nevertheless by the end of 1987 all plasma intended for fractionation was being routinely tested for ALT levels in the USA.[12]

Other international responses to the question of surrogate testing were varied. For example, the German regulatory agency required ALT testing of all plasma used in clotting factor concentrates and would only accept plasma with ALT levels of less than twice the upper limit of normal. US companies that supplied concentrates to Germany therefore tested some plasma to German standards and used any that tested between 2-5 times the upper limit of normal for manufacture of products to be used elsewhere. Any plasma greater than 5 times the upper limit of normal was discarded and donors were deferred until ALT levels fell to below two times the upper limit of normal. Krever notes this was "clear acknowledgement of the risk, but they were still only testing a proportion of the plasma they were fractionating. Canada which was supplied from the USA, opted for plasma which was unscreened for ALT rather than the remaining plasma from that which was sent to West Germany". [13]

Krever reported, that "German blood centres began the ALT testing of donations as early as 1968. In July 1985 ALT testing was required of all plasma used in the manufacture of imported blood products. Germany did not require anti-HBc testing, but its efficacy was demonstrated in at least one study and some blood centres conducted anti-HBc testing voluntarily. ALT testing was also required by regulation or conducted routinely in Japan,

Switzerland, Spain, Italy, Portugal, Finland and Malta. ALT testing was conducted voluntarily in some blood centres in Australia, Belgium and Luxembourg".[14] It was not adopted in the UK on the grounds of the low incidence of NANB and cost effectiveness.[15] Barraclough refers to the UK which also did not implement surrogate testing because of the low risk of transmission of post transfusion hepatitis. Astoundingly, the UK blood bankers also questioned the need for antibody screening when it became available. ALT and anti-HBc screening was introduced in 1987 in USA.

Surrogate testing was not conducted routinely in Australia. Barraclough does not make an assessment of whether this was an appropriate strategy or not .[16] He does however refer to conflicting advice about the best course of action. The Ismay et al study (1995) suggested surrogate testing of donations by ALT or anti- HBc offered no advantage, however the Hyland et al study (1988) in Queensland concluded that the chronic effects of NANB hepatitis outweighed the argument against implementation of surrogate testing. Surrogate testing was adopted in Queensland.

Surrogate testing was introduced in Queensland in 1987, but not in other States. The debate was that whilst they reduced hepatitis transmissions, surrogate tests lacked sensitivity and specificity and would identify many false positives. Instead, the low incidence of post transfusion hepatitis and donor screening which had already been introduced to identify those at risk of transmitting HIV was relied upon elsewhere in Australia.

In 2001, Wood, Coghlan and Boyce[17] suggested that surrogate tests had been shown to be helpful in reducing the risk of transfusion transmitted NANB hepatitis in some donor populations before(sic) assays became available , but "their continued value in donor screening in the setting of current hepatitis C testing schedules is unclear. Many feel they provide some extra measure of safety, reflecting past risk behaviours of donors that may not otherwise be identified, although there is scant evidence to support this view. Others believe that surrogate tests are now unhelpful – deferring many donors for no defined medical reason, compromising the sufficient supply of blood products and creating significant anxiety and uncertainty in unnecessarily deferred donors. Furthermore substantial financial and human resources are devoted to initial surrogate screening, retesting and counselling donors with positive results on such tests, both by the blood service and during their consequent medical investigations and evaluations. Many would argue that these resources could be better spent ".This might well be a suitable argument in the presence of well developed antibody tests and other tests such as NAT testing, however such opinion which might also have been prevalent in the mid to late 1980's in the absence of antibody testing, may well have compromised the safety of patients at the time when it could have been avoided. If any kind of testing was available that could have potentially saved people from a life threatening virus, efforts should have been taken to implement these. Decisions based on cost effectiveness do not stand the test of time.

The adoption of surrogate testing by authorities in Australia prior to hepatitis C antibody testing would have been of concern at the time because of the cost of implementation, the impact on donors, a possible loss of public confidence in the blood system and the impact a loss of donors would have had on the supply of blood products, perhaps less of an issue if there were more blood donors. Krever said that the Canadian Red Cross was "convinced the cost of surrogate testing outweighed the benefits of testing despite contrary published evidence. ....it did not take into account the medical and social costs..... and therefore the savings that could be achieved through testing." [18]

It is a widely held view that the majority of people with haemophilia who became infected did so in their earliest treatments with pooled plasma derivatives and that ALT testing alone would not reduce the risk of NANB transmission, but combined with the viral inactivation procedures, including solvent detergent and heat treatment the risk may have been reduced.

Because of the large pool size used for the manufacture of fractionated products the viral inactivation steps are relied upon to eliminate the risk of viruses. Nevertheless, it is possible that if NANB hepatitis had not been considered such a benign disease by researchers, clinicians and policy makers, and if surrogate testing had been implemented universally some infections might have been prevented. If not in users of fractionated products, most certainly in those who had transfusions. People with haemophilia who had become newly infected with hepatitis C during the period of debate may well have avoided that infection had surrogate testing been implemented.

As patient records are likely to be poor it is difficult to know how many people became transmitted NANB hepatitis in the period when surrogate testing was being debated and thus the consequence of hepatitis C might have been avoided for a small group. [19]

12. TREATMENT PRODUCT SAFETY HISTORY

There have been several instances where Australian haemophilia treatment product safety has been at risk. HFA can only refer to specific events of which it is aware to demonstrate this problem. Barraclough was charged with the responsibility to investigate whether hepatitis C positive plasma was used in the manufacture of plasma products for several months in 1990.[20]

In his Executive Summary pp 1 – 4 he writes that:

Australia was one of the first countries in the world to introduce the first generation hepatitis C antibody test for donation of blood and plasma in order to increase the safety of the national blood supply.....

In 1988–89, before the introduction of the first generation hepatitis C antibody test, the overall risk of post-transfusion hepatitis was approximately 1 per cent. This was almost half that of a decade earlier, an improvement attributable to changes in donor screening and transfusion practices and in the donor population in the wake of the HIV pandemic.

The first generation hepatitis C antibody test identified about 85 per cent of potentially infective donations. However, it was also known to give a high level of false positive results. It has subsequently been estimated that only approximately 30 per cent of donations of blood or plasma that tested repeatedly positive to the first generation hepatitis C antibody test would actually confer risk of transmitting virus to the recipients.

There was significant divergence of scientific opinion and debate internationally during the early part of 1990 about the relative safety of immunoglobulin manufactured from plasma that did not contain hepatitis C antibody as compared to plasma containing anti-hepatitis C antibody.

Based on the incomplete scientific knowledge of the time, and after wide consultation and detailed discussion on the conflicting evidence by committees of experts, the decision was taken to allow plasma that tested positive to the first generation hepatitis C antibody test to be sent to the Commonwealth Serum Laboratories from February 1990 and further decisions were taken in July 1990 that stopped its use.

This plasma was available to be used in the manufacture of plasma proteins that were known to be safe and not to transmit hepatitis C, provided proscribed viricidal manufacturing processes were followed. It was not to be used for the manufacture of Prothrombinex (Factors IX and X) and Factor VII, where the viricidal processes were

necessarily less rigorous and therefore less effective.

It is probable, but not certain, that some of the anti-hepatitis C positive plasma sent to the Commonwealth Serum Laboratories was actually used in the routine manufacture of albumin and immunoglobulins, but it is less certain that this plasma was used in the manufacture of Factor VIII product.

Donors whose blood repeatedly tested positive to hepatitis C screening tests were told they could continue to donate blood for the manufacture of plasma fractionation products only until July 1990, after which blood banks were advised that this practice was to stop. Donors were not finally deferred from donation until tests that could confirm their hepatitis C status became available. Such tests became available from September 1990.

From July 1990 until July 1991, some plasma testing hepatitis C positive was sent to the Commonwealth Serum Laboratories for segregated storage with a view to future use in the development of a new hyperimmune anti-hepatitis C immunoglobulin, but with clear instruction for it not to be used in manufacture of other products. This program was never initiated and the plasma sat in safe storage. Any remaining stored hepatitis C positive plasma was destroyed by May 1994.

Decisions to exclude donations of plasma that tested positive for hepatitis C from the manufacturing process for fractionated plasma products were taken in June and July 1990. They were taken after international and local scientific debate and in recognition that safety was likely to be enhanced if the possibility of human errors in labelling, transport, storage and manufacture were reduced by excluding these donations. The science relating to the decision was still not clear, but arguments against the use of anti-hepatitis C positive plasma had been enunciated more clearly during the first half of 1990 and following what is now called 'the precautionary principle', the decision to forward anti-hepatitis C positive plasma to the Commonwealth Serum Laboratories was changed. This decision would, even in 2003, be regarded as complying with the highest contemporary international standards of safety.

The Australian Red Cross Society has not received any reports through either the Commonwealth Serum Laboratories, hospitals, medical practitioners or their patients, of acquisition of hepatitis C infection through immunoglobulin, SPPS, NSA or AHF1 produced from anti-hepatitis C repeat-reactive plasma. To date, the Expert Advisory Group has not been informed of any cases of hepatitis C that can be reasonably ascribed to the transfusion of plasma-derived blood products since February 1990.

Manufactured (fractionated) plasma products from this period have not been implicated in the transmission of hepatitis C. However, in NSW there were a number of cases of transmission of hepatitis C from the use of whole blood or blood components (packed cells, fresh plasma and platelets) in 1990. These cases followed errors in interpretation of complex and confusing technical advice in the introductory phase of hepatitis C testing at one blood collection centre. Some hepatitis C positive plasma from this episode was sent to the Commonwealth Serum Laboratories for manufacture into VIII plasma products. As it was not labelled 'hepatitis C positive', the Commonwealth Serum Laboratories used it as though it were tested, hepatitis C negative plasma. Because this particular problem was first identified in 1992, the Commonwealth Serum Laboratories were not informed of the error until 1992. However, there was a very low viral transmission risk as a result of this incident, due to the known viricidal effects of the immunoglobulin manufacturing process. CSL Limited is not aware of any reports of infection related to this incident. Recall of unused product from these donations by the Therapeutic Goods Administration, Commonwealth Serum

Laboratories with the assistance of the Australian Red Cross followed in 1992.

The Australian Red Cross Blood Service does not say and did not say during 1990 that blood and blood products are free from risk of transmission. It has always drawn attention to the window period, that short period of time between infection and the development of antibody when antibody screening cannot detect infection.

A question HFA is unable to answer is whether the delays in improvement of heat treatment of Prothrombinex (PTX) and lack of ALT testing may have resulted in the transmission of hepatitis which would otherwise not have occurred. HFA continues to seek a full analysis of all reports of the timing of transmissions of hepatitis through haemophilia blood products from TGA, CSL, ARCBS and all governments to ascertain whether any could have been prevented.

The example of the 1992 recall of the CSL product for the treatment of haemophilia B - Prothrombinex (PTX) demonstrates the difficulties for consumers in understanding past decisions and the impact alternative decisions might have had upon their health. Review of questionable bureaucratic processes which are hidden from open and transparent scrutiny cause patients to loose faith in the very systems that are there to protect them. There was a considerable delay before Prothrombinex, heat treated to 80° C, was introduced in mid 1993. This caused frustration and anxiety for clinicians and patients. Some clinicians kept their patients on cryoprecipitate to minimise the risk of larger plasma pools. PTX heat treated to 60° was insufficient to inactivate hepatitis C.

HFA has experienced considerable bureaucratic barriers since May 2003 when it sought information about the1992 recall of PTX. The recall occurred after it was reported that plasma that had not been correctly tested for antibody to hepatitis C might have been used in the manufacture of treatment products. Only PTX was recalled in this situation because the heat treatment to 60°C was known not to be effective against hepatitis C. The delay in the introduction of the higher heat when it was known that users were not safe from hepatitis C was in itself unacceptable, as was the decision not to recall factor VIII and other products that may also have been manufactured from contaminated plasma on the grounds that viral inactivation processes would not fail. Despite assurances from TGA that CSL stated it had not had any reports of hepatitis C transmission by PTX in the years preceding this incident, HFA is not satisfied that the recall was managed appropriately, whether patients were advised of this recall and that there were no transmissions of hepatitis C resulting from this incident. It is unclear whether any patients were advised of this recall, how much of the product had been used in treatment, and what happened to the product that was not returned to CSL following the recall. Further analysis of this particular incident is required.

It is clear from HFA investigations through discussions and correspondence with CSL, TGA and ARCBS that the recall occurred almost 2 years after the product was distributed and that very little of the product was returned following the recall. Presumably it was indeed used by patients. However, to date, no agency or authority has been able to assure HFA that patients were 1) advised of the recall and 2) whether patients who may have used the affected product were identified and if so, 3) whether they received proper advice and timely testing. This is not known, however some patients would have been tested earlier as the Chiron test became available. HFA now awaits a response from State/Territory Health Ministers as to how each jurisdiction dealt with this issue. The fragmented system at the time, now reported in many documents including the Review of the Australian Blood Banking and Plasma Product Sector (the 2001 Stephen Review), the 2003 report of the Expert Advisory Group on Hepatitis C and Plasma in 1990 (Barraclough Report) and several preceding reports each point to inadequacies in the blood supply system and accountability.

Reliance upon the absence of hepatitis C transmission reports is little comfort in the circumstances, and failure to provide detailed data leads HFA to fear bureaucratic cover up of some sort or an admission that data is so inadequate as to provide meaningful information. Informal discussions with clinicians suggests that many who were in the field at the time do not recall the incident, which would have been quite unusual at the time and therefore of interest, and some acknowledge their records may be scant in regard to these issues, although one would expect testing would have been prudent if patients had been at risk.

There was clearly a view that the Australian blood supply was freer of at risk donors than the USA blood supply which used paid blood donors and was therefore more likely to include donors with at risk behaviours. Further false positives were found to represent 63% of donors in blood bank data in 1990-91 and would undoubtedly have lead people to believe a large number of anti hepatitis C positive donations were not infected with hepatitis C.

Hepatitis C antibody testing was available and used in Australia from February 1990, however donations of plasma which had tested positive to hepatitis C were supplied to CSL for the manufacture of products by the Red Cross until 29 June 1990 when an agreement between ARCS and CSL agreed that antibody positive plasma would not be used in manufactured products. Factor VIII and albumin had been considered to be safe because of their dedicated viral inactivation processes, but there was concern about the impact of removing anti –hepatitis C antibodies from the IVIg and therefore compromise the safety of immunoglobulin. As discussed above, anti- hepatitis C positive plasma was not to be used for Prothrombinex and factor VII, as it was heat-treated to only to 60° at the time which did not inactivate hepatitis C. The debate about the issue in Europe and USA lead to the change in Australia, however Barraclough reports that CSL has not been able to "confirm or deny" whether antibody positive plasma had been used in production processes after June 1990, although internal CSL communications suggest hepatitis C positive donations may have been used in the manufacture of Factor VIII, albumin and immunoglobulins.[21]

By November 1984 CSL was heat treating blood products successfully to eliminate HIV (p45) However, factor VIII which had been heat treated to 80° C for 72 hours was known to inactivate hepatitis B, HIV and NANB hepatitis. The Elstree Blood Products Laboratory in the UK had used this method and there had been no cases of NANB hepatitis found in patients since 1985. [22]Its introduction in Australia was delayed for several years until it was used in 1989 in Australia. Presumably this provided reassurance that the 1990 decisions to use blood that had tested positive for hepatitis C antibodies were acceptable. At the same time however, France introduced hepatitis C testing of blood donations and extended testing to plasma for fractionation.

Barraclough concluded following his investigation of a relatively small period of time in 1990 that "we are also able to conclude with a very high degree of confidence, that those decisions did not result in any user of blood plasma products becoming infected with hepatitis C". Barraclough went on to say the cardinal principles underlying current concepts of the safety of blood derived therapeutics from infection by pathogenic organisms are:

- The selection of donors from populations at low risk of carrying transfusion transmitted pathogens
- The screening of such donors using appropriate laboratory tests
- The treatment of the products using measures that eliminate any residual risks.[23]

The fact that authorities continued to use donations from those who had tested positive in the manufacture of factor VIII and other products is a risk that HFA believes, even with the benefit of hindsight, is one that should not have been taken.

In Australia there has not always been a timely introduction of new viral inactivation procedures on the grounds that product yield will decrease or the cost is too high. For example, the introduction of the double virally inactivated plasma derived factor VIII product, Biostate in April, 2003, had previously been subjected to considerable delays. Biostate was introduced many years after other countries had introduced such a product with its additional inactivation steps, thus exposing the Australian haemophilia A community to unnecessary risk (see below). Heat treatment of Prothrombinex to 80° C for the treatment of haemophilia B was delayed until 1993 is another example of unacceptable delays.

13. CURRENT TREATMENT PRODUCT SAFETY

Recombinant treatment products have been available in Australia to relatively few people. They were first imported here in 1994 when CSL had been unable to produce sufficient supplies of plasma derived factor VIII. Recombinant factor VIII has been restricted to children who were not already infected with hepatitis C and/or HIV. In 2001 recombinant factor IX became available and this too was provided only to children who did not have blood borne viruses in all State/Territories except SA where it was not available at all until August 2003.

Government policy means that most people in Australia still must use plasma derived products even though safer alternatives are available and despite the recommendations of the Factor VIII and Factor IX Working Party of the AHMAC Blood and Blood Products Committee. The Working Party last met in November 2000, but its report was only tabled in June 2003. It contains several relevant recommendations affecting safety and quality, the most significant is a recommendation to switch people with haemophilia A and B to recombinant concentrates by 2004. Despite consideration of this issue at each of the July and November Australian Health Ministers' Conference, these recommendations have still not been adopted.

In May 2003 the Expert Advisory Committee on Hepatitis C and Plasma in 1990 (Barraclough) recommended the implementation of the Factor VIII and Factor IX Working Party recommendations following its retrospective review of the impact and risk of hepatitis C transmission through the blood supply.

In March 2003, the intermediate purity CSL plasma derived factor VIII AHF (HP) was removed from the Australian Register of Therapeutic Goods because it was not considered safe enough and was to replaced by Biostate that is a high purity factor VIII with double viral inactivation steps. CSL was later in releasing product than other countries also using this technology because it was having difficulty in achieving desired yields. Astoundingly, all stocks of the soon to be de-registered product were issued by CSL to ARCBS immediately prior to that date and the product continued to be prescribed to patients until the stocks were exhausted. HFA lobbied unsuccessfully to governments and clinicians that this was poor practice and imprudent in view of past experiences and subjected patients to unnecessary risks when an alternative safer plasma derived factor VIII was available, albeit in short supply, and when further supplies of recombinant factor VIII could be purchased to meet clinical need. As anticipated, the yield from the source plasma was lower and CSL has been unable to generate a sufficient supply of this safer blood product. The shortage is not expected to pass until well into 2004. After considerable discussion at State/Territory jurisdictions and the Jurisdictional Blood Committee, agreement was reached in late 2003 so that recombinant factor VIII could be purchased to top up this shortfall. HFA believes that several jurisdictions went to get lengths to avoid the additional cost of recombinant product which each would need to share under the National Blood Agreement, in contrast to using plasma derived product which would be supplied freely under the Plasma Fractionation Agreement. This resulted in unnecessary and unfair anxiety and fear for some patients whose home therapy supply was rationed.

Despite the recommendations of these government agencies and committees, patients continue to be placed at risk by being forced to use plasma derived treatment products which are more likely to expose them to blood borne viruses and agents, known and as yet unknown. The Commonwealth, and State/Territory governments have been considering the recommended switch to recombinant products for several years. Countries with similar health care standards and expectations have accelerated programs to do this in recent years and now Australia falls well below international standards. HFA has lobbied strenuously for this, and is at a loss to know why health ministers fail to accept the advice of their own expert committees and increase the safety of this vulnerable group of patients. The AHMAC Factor VIII and Factor IX Working Party Working Party Report, completed in late 2000, was not tabled until June 2003. HFA fears the recommendations of this Working Party will continue to be ignored, not withstanding further committee work having been initiated. The delays should be of concern to all given the history of litigation and criminal action taken in other countries that failed to provide safe products when they could have done so.

By the early 1980's procedures were in place to inactivate hepatitis. Heat treatment of clotting factor concentrates to inactivate HIV was possible in late 1984 and in 1985 several studies were published to confirm this. Unfortunately if more work had been done to eliminate hepatitis in concentrates, more HIV and hepatitis would have been prevented, but hepatitis was seen as a manageable complication of effective haemophilia treatment. (Krever p757) . In Australia, the dry heat treatment of factor VIII to 80° C that was introduced in 1989, and for factor IX in 1993, has been effective against hepatitis C.

The experience of people with haemophilia through the HIV and hepatitis C epidemics is evidence of their reliance on the safety of the blood pool and their extreme vulnerability to any emerging infectious disease or agent. In each epidemic those in charge of blood collection acted with good faith, even if negligently to try to prevent infections. In each epidemic most people with haemophilia were infected. The assurance that all reasonable steps are being taken to safeguard the blood supply, "based on current knowledge" provides little comfort to people with haemophilia given their experiences. If an alternative safer product can be supplied, it is reasonable and prudent to supply it and the government, doctors, hospitals and other bodies may be exposing themselves to potential claims for negligence if a new illness or infectious agent did emerge.

14. THE NATURAL HISTORY OF HEPATITIS C

Even though the existence of NANB hepatitis has been known for many years little has been known of the natural history of the disease until the last few years. Many people who acquire hepatitis C clear the virus spontaneously and unless re-infected will not develop chronic hepatitis. They will be antibody positive, but RNA negative on PCR testing. Once chronic hepatitis C is established by persisting viraemia, the course of the disease will be highly variable, but protracted. Although there is a clear relationship between chronic hepatitis C and cirrhosis, liver failure and hepato-cellular carcinoma (HCC), there is uncertainty about the rate of progression to advanced liver disease, the proportion of people who will develop these complications, and predictors of disease progression.

Dore estimates that based on current data, 70-80%of people initially infected will appear to progress to chronic infection. [24] Many people have impaired quality of life prior to the development of advanced liver disease, however the major morbidity is associated with progression to cirrhosis and liver failure and/or HCC.

Dore refers to several studies of post transfusion hepatitis C following antibody testing which confirmed NANB hepatitis as the cause of about 90% of prior cases of post transfusion NANB hepatitis. Several studies which have followed disease progression in people with post

transfusion hepatitis for 10 -15 years indicate a cirrhosis prevalence of 10-20%. The Seef study found no greater mortality among people with NANB hepatitis Compared to controls after 18 years of follow up. Dore goes on to note that despite post transfusion hepatitis C appearing to have no effect on survival over the initial 20 years of infection, more than 20% develop cirrhosis over this period and would be at high risk of progression to liver failure and/or HCC over subsequent decades. Studies of two groups of women in Ireland and Germany who were infected with hepatitis C through contaminated immunoglobulin indicate low rates of cirrhosis and in the Irish group 80%of women had little or no fibrosis. It is difficult to know what other factors may have impacted on these findings, such as low virulence of hepatitis C strain, gender, low alcohol use. They were all infected with genotype 1b, which has been associated with more rapid progression. Heavy alcohol intake was linked to those with cirrhosis suggesting that was a major co factor for that sub set. Rodger reported 8% cirrhosis after 24 years of infection. Dore notes there is conflicting evidence about whether mode of transmission and/or dose of hepatitis C is related to disease progression. In some studies of people who have been infected through blood products there is a suggestion of a more rapid progression, however the key issues could be older age at infection or other chronic diseases processes. Dore notes the conflicting evidence about the link between high viral load and progression compared with HIV where viral load and progression are linked to advanced HIV. The role of genotype is also uncertain, however some genotypes are known to have a poorer response to antiviral therapies.[25]

In summary, Dore concluded that the influence of viral load is not fully assessed on disease progression to advance liver disease, but there is strong evidence for genotype, mode of acquisition and gender, and there is strong evidence of the impact of alcohol, stage of fibrosis, age at infection, duration of infection, co-infection with HIV, and/or HBV (p95). The estimated prevalence of cirrhosis among people with chronic hepatitis C is 5 - 10% after 20 years and 15 - 20% after 40 years duration of infection. The risk of HCC, liver failure and death are 2, 5, and 4% respectively.[26]

Dore developed an algorithm for the natural history of hepatitis C. Of 100 people with antibodies to hepatitis C, 20-30% will clear the virus, and 30-40% of the remaining PCR positive group will have consistently normal ALT levels and 60- 70% will have consistently or intermittently abnormal ALT levels and 5- 10% will go on to cirrhosis after 20 years of infection
(3-5% of this group will go on to liver failure and/or cancer) Thus most people with chronic hepatitis C will not progress to advanced liver disease, but may have impaired quality of life.[27]

15. WHAT DO WE KNOW ABOUT PEOPLE WITH HAEMOPHILIA AND HEPATITIS C?

Before the heat treatment of clotting factor concentrates in the mid 1980's almost between 85-90% of people with haemophilia who were exposed to clotting factor concentrate developed NANB hepatitis, which was subsequently identified as hepatitis C. Lee reports that in countries which virally inactivated products, there has been virtually no transmission of hepatitis C since 1996, but it nevertheless remains a high risk factor in countries where single donor, unsterilised preparations such as cryoprecipitate may still be used. [28]Most people who used Australian manufactured concentrates prior to 1990 have been uninfected. There has been no known infection since additional heat treatment of factor VIII concentrates in 1989 and factor IX in 1993.

This exposure to NANB hepatitis with concentrates means that many people in the haemophilia community have a history of more than 20 years of infection and would have received a high viral burden. Many who were young at the time of infection may have cleared the virus, however those who were older at the time of infection and after receiving many doses of infected product may well have a different health outcome. In the questionnaire

completed by many HFA members in late 2003 many people indicated that they are experiencing more problems due to hepatitis C.

It is not known to HFA how many people have progressed to cirrhosis and/or advanced liver disease or who has been diagnosed with HCC, or died from hepatitis C. Anecdotally we have heard of several deaths due to hepatitis C, however this will need to be confirmed with surveillance authorities and AHCDO.

Lee related the results of two studies of people with haemophilia who had received large pool concentrates and infected with hepatitis C. [29] The1994 Tefer et al study found at 20 years duration progression to liver failure was 11%. (p133) However this study was updated in 1999 and it was reported that 30 out of the 305 (10%) had cleared hepatitis C on the basis of repeated PCR testing. Most of these patients however, did not have severe haemophilia and would have been exposed to less frequent clotting factor treatment. Those that cleared were also younger at first exposure and their immune response may have been more effective. At 25 years post exposure 19% progressed to liver disease. Both studies showed that people with HIV and hepatitis C co-infection had an 18 times higher risk of death than those with only hepatitis C (p133). However Lee also noted that there were reports of people with co-infection who cleared hepatitis C nevertheless. The later Tefer study showed that people in the study with hepatitis C only progressed very slowly, with 3% progressing to liver failure and that 76% of those who died were co- infected with HIV. Alcohol use was associated with deaths in people who only had hepatitis C to liver failure (3%). Lee noted that co factors affecting the outcome of hepatitis C are age at infection (younger people have a greater chance of responding to treatment), co-infection with HIV, excessive alcohol use because alcohol increases hepatitis C viraemia, HIV co-infection and genotype. [30]

Lee referred to a study reported in 2001 that involved three centres, the researches concluded there was slow progression of hepatitis C infection in a group of hepatitis C infected people with haemophilia. 14% of the patients with a 15-34 year history of hepatitis C cleared the virus spontaneously. 86% were hepatitis C RNA positive and of these, 69% had non progressive liver disease and 7% had cirrhosis. Lee described an UK 1997 study that showed mortality from liver disease was 16.7 times higher than for the general population, however cumulative risks for those infected with hepatitis C only were relatively lower than those infected with HIV also. However, a Sheffield study showed a high incidence of cirrhosis in people with haemophilia and hepatitis C alone. [31]

16. TREATMENT FOR HEPATITIS

Many people with haemophilia report to HFA that hepatitis C mono - therapy was unsuccessful for them and they fear undergoing combination therapy. This was evident in the HFA 2003 questionnaire respondents who were clearly struggling with the decision or not to undergo treatment. Makris et al in 2001 reported that although interferon was of value in chronic liver disease, sustained remissions were only achieved in 20% of non haemophilia patients after treatment for 12 months. In individuals with haemophilia, the sustained response rate appeared to be even lower due to genotype, high hepatitis C viral load and the presence of cirrhosis. However with combination therapy with alpha - interferon and ribavirin there had been significantly improved responses which he thought promising for people with haemophilia. Makris et al referred to a study by Shields in which 71% of people with haemophilia had remained in remission following combination therapy.[32]

Lee concluded that antiviral treatment is important and that treatment results appear to be similar for people with haemophilia as for the general population, although patients with non genotype 1 respond better to those with type 1, and younger patients without cirrhosis may have improved response rates.[33]

Because little is known about the optimal treatment for people with haemophilia and chronic hepatitis C who were treated with pooled plasma products Schulman et al undertook a study of 61 patients with haemophilia A, haemophilia B and vWD who were undergoing either 6 or 12 months combination therapy. Overall sustained viral response was achieved in 41% (22% in genotype 1 and 80% in other genotypes, including all who were genotype 2 and there was no difference in the treatment duration of 6 or 12 months. The study was stopped sooner than planned because of changed treatment regimens, however the researchers concluded that the efficacy and safety of combination therapy was equal to other populations.[34]

Hepatitis C treatments have a limited success rate of about 40% for people with genotype 1, which is the most common strain of the virus affecting people with haemophilia and they are unpleasant to take with important side effects. About 1 in 10 people have to stop treatment which usually takes a year, because of the side effects. Many are unable to work during treatment.

17. HEPATITIS C AND HIV CO-INFECTION

The clinical management of people with hepatitis C and HIV is difficult and complex. People who are co-infected progress more quickly to liver failure and are often recommended to have anti hepatitis therapy, however this is difficult if they are already having antiviral therapy.[35]

Between 80 -90%of people with HIV and haemophilia will also have hepatitis C.
HIV co-infection has important affects on hepatitis C disease process, including rapid progression to progressive liver disease in some. A 1989 study reported in1999, showed that in people with haemophilia who had hepatitis C, those with HIV co-infection had higher hepatitis C RNA levels and a greater risk of liver failure. Mortality was higher in people with haemophilia and hepatitis C/HIV co-infection than those with only hepatitis C. Hepatitis C genotype 1 has been reported to be more prevalent in people with HIV than those without HIV and shifts in genotype have been reported in people with haemophilia who are co-infected with hepatitis C and HIV as immune deficiency increases. Morbidity and mortality as a result of liver disease is increased in people with HIV/hepatitis C co-infection. The Sabin study in 1997 showed higher mortality in people with haemophilia and HCV/HIV co-infection with hepatitis C genotype 1. [36]

Treatment of hepatitis C in co-infected people is important as there is a higher risk of advanced HIV disease compared to hepatitis C but concerns about toxicity and tolerability of hepatitis C therapy in HIV patients has been a disincentive to therapy. With increased HIV survival, treatment for hepatitis C is increasingly recommended. A number of people who are co-infected with HIV and hepatitis C are now in a situation where HIV treatments have ceased and are in a position to consider antiviral therapy for hepatitis C in an attempt to avoid further liver damage, improve quality of life and extend life expectancy.

18. THE IMPACT OF HEPATITIS C ON THE LIVES OF PEOPLE WITH HAEMOPHILIA AND VWD IN AUSTRALIA

Early results from a recent Queensland study looking at Quality of Life among people living with chronic hepatitis C infection confirm the clinical impression that individuals with HCV experience a variety of symptoms, and that these symptoms are frequently perceived as being of at least moderate intensity. In particular they highlight the potential importance of physical tiredness, irritability, depression, mental tiredness and abdominal pain as symptoms in people living with hepatitis C. A subset of the participants in the study have haemophilia. Preliminary analysis of the data suggests the group with bleeding disorders may have different prevalence and severity of symptoms. This will require further analysis, however it

suggests host factors such as haemophilia influence the impact of chronic hepatitis C on symptom profile and quality of life.[37]

THE HFA SURVEY - 2003

HFA requested members to complete an anonymous survey in late 2003 about the impact of hepatitis C and their bleeding disorder upon their lives. Responses from those who did not have hepatitis C were discarded. Over 250 responses were received from people who identified themselves as having hepatitis C and/or HIV. HFA had sent the survey to everyone on its database, as it does not keep personal health data on its records and therefore has no way of accurately quantifying how many of its members have a bleeding disorder nor how many are infected with blood borne viruses. Assumptions made over the years suggest that each family affected by haemophilia in this country are represented in our database.

The significant response rate highlighted the seriousness of hepatitis C for them and indicated a strong desire for participation in discussion and decision making about it. Furthermore, many respondents identified themselves and/or made personal contact with HFA because they wished to provide further details or add emphasis to some of their concerns. The responses represented a range of views, and many respondents followed up with phone calls, personal approaches and or/letters to disclose their personal experiences with a passion not previously observed by HFA.

In 2000 HFA conducted a Needs Survey of members, and although this only included very general questions about service needs related to hepatitis C and/or HIV, respondents at the time were clearly worried about future impact of blood borne viruses upon their lives, and a fear that they would become ill from chronic liver disease.

The 2003 survey specifically addressed hepatitis C issues and therefore provided an opportunity for members to be more direct if they had been constrained previously. 226 questionnaires were analysed. Issues raised regarding hepatitis C in the 2003 survey were considerably stronger and expressed with greater passion than in the 2000 survey that might be explained by a number of factors, including greater community awareness, evidence of further disease progression and the personal impact of symptoms – health, psychosocial and economic.

Clearly, a factor for many is the inability to distance themselves from an ongoing fear of other viruses entering the blood supply upon which most people are still dependent for their treatment. The ongoing fear of new and as yet unknown viruses and agents adds a dimension which is impossible to overlook as people who have hepatitis C are forced to receive less safe plasma derived haemophilia treatment products because of government policy. In fact, the criterion for access to safer recombinant products in Australia is that a person does not already have a blood borne virus. Further, there remains an overwhelming personal anger about the discrimination experienced because of hepatitis C and/or HIV, particularly as they have become infected through contaminated blood products. For many, there is a strong belief that infections should or could have been prevented, that the blood sector has again betrayed them and most feel aggrieved that the impact of hepatitis C has not been officially recognized, apologized for or compensated in any way.

Because of the chronic nature of haemophilia and the added problems caused by blood borne viruses, many people are unable to separate the effects of each. The 2003 questionnaire confirmed anecdotal reports from our members that the complications of blood borne viruses has increased the burden of chronic illness and in many cases is a greater problem for them than their haemophilia, whilst for others hepatitis C has been put on the "backburner' as they try to manage the physical, psychosocial and economic consequences of their bleeding disorder.

Overall, however, the responses to the questionnaire painted a picture of three main groups of people – one which held great fears of future morbidity and mortality due to hepatitis C and a second which was already experiencing major effects of hepatitis C upon their health and capacity to live active and fulfilling lives, some of whom had undergone treatment unsuccessfully, and a third, but very much smaller cohort of people who had hepatitis C but who have not experienced any serious symptoms or illness from it and are not bothered at all at the present time and a sub set of people who are most concerned about the impact of their bleeding disorder than hepatitis C. There was a concerning number of people who were unable to indicate the extent of their liver disease, how far their disease had progressed and had little clinical monitoring. This indicates the need for regular testing, education and monitoring.

For many respondents there was great difficulty (and often no point) in separating out the impact of hepatitis C given the already difficult social, economic and emotional impacts associated with having haemophilia. For many people, in particular those with severe haemophilia and those who also have HIV, the hepatitis C was of lesser consequence.

19. WHAT IS THE ECONOMIC IMPACT OF HEPATITIS C?

A significant proportion of respondents indicated they were unable to work without the threat of disruption due to the need for treatment for hepatitis C or treatment of bleeds. There was a high incidence of casual, part time and intermittent work. Many people were concerned about their future financial status in the event of disease progression. People with severe bleeding disorders are more likely to be unable to work, and carers and family members had to give up work to provide care. Many were in receipt of income support, and many reported that partners/spouses needed to work part-time and/or seek other forms of financial assistance such as rent assistance, parenting payments and family tax benefits.

Very few surveys were completed by individuals in high income earning occupations. Those who worked were often in clerical, trades or unskilled positions. This may reflect the difficulty not only in obtaining work continuity, but also in the difficulty in gaining tertiary education.

20. WHAT IS THE LEVEL OF UNDERSTANDING ABOUT HEPATITIS C TREATMENTS AVAILABLE?

It was difficult to assess the level of understanding about hepatitis C from the survey. High numbers of people who are unsure/unaware of their hepatitis C status may indicate the need to provide information about hepatitis C, or it may indicate that people are aware, but that it is not relevant to them in their own particular circumstances. Presumably people with haemophilia have frequent contact with health professionals, and are provided with hepatitis C education opportunities as required. There was a general trend that people needed education and information about treatments.

21. IS THERE A DIFFERENCE BETWEEN PEOPLE WITH HIV/HCV CO-INFECTION?

There was only one co-infected person with haemophilia B, one with Von Willebrand disorder and 22 with Haemophilia A . For this population group, the seriousness of hepatitis C was far outweighed by their HIV status. Most knew they had hepatitis C, but didn't know the current status of their infection. One respondent said life would be different had he not had hepatitis C, but for most, the social and financial consequences could not be separated out from those already encountered as a consequence of their haemophilia and HIV status.

22. MAJOR THEMES OF RESPONDENTS

- side effects of interferon treatment
- uncertainty of treatment outcomes
- uncertainty about disease progression
- inability to access combination treatment
- concern about discrimination, prejudice, and the association with drug abuse
- avoidance of intimacy
- fear of the consequences of disclosing hepatitis C status
- inability to obtain insurance
- social/relationship difficulties
- depression and anxiety
- fatigue is debilitating
- privacy issues, disclosure
- school students with haemophilia and associated conditions encounter difficulty with school based activities and with social interactions

23. COMMENTS OF THE RESPONDENTS

The following list is a fair representation of the range and breadth of the comments made by members when they completed the questionnaire or contacted HFA for further discussion. Comments are verbatim and have not been modified in any way.

24. HEALTH/TREATMENT ISSUES

I took 12 months off work to have treatment, so did my Mum (26 y.o single male)

At times I have had to cut down my workload because of depression)and that causes all sorts of other problems. It becomes a vicious circle in the end – I feel a bit better, so I do more, then I do too much and become depressed again. The worst thing is cannot see any end in sight either *(34 y.o female)*

My doctor said I should have treatment, but I am worried about whether I would cope – they say its pretty bad and I live on my own – besides I am not sure that I could cope with work as well – and I couldn't afford not to work – I already use most of my sick leave and recreation leave on time off because of bleeds

It's the lethargy and fatigue, its hard to cope with and others don't seem to understand – even my family – and the guys at work get fed up with me because I don't pull my weight

I have had treatment twice, but it hasn't worked for me, so I really don't know what to expect in terms of my health in the future, I do worry about getting cancer because I have had hepatitis for so long (72 y.o male)

One of the hardest things is wondering if/when it will flare up

I do worry about how hepatitis C will affect me in another 20 years

I have mild haemophilia, it is well controlled these day. My greatest concern is about the possible impact hepatitis C might have on my liver in the future

Surgery has been delayed and put off. I know it is because of my hepatitis C, but when I ask the doctors they say that's not the problem and that everyone has to wait. In the meantime my knee has got really bad

My husband has died. Hepatitis C and HIV was listed as a contributing factor on the death certificate.

I didn't know until a year ago that I have hepatitis C. It was a shock the way I found out after all these years. I haven't needed treatment for vWD for many years. If I had been tested before, no one has told me, and I would remember that. It is really hard to deal with it, I think of all the times I cleaned up blood spills with my grandchildren, and of my husband and children. When you find something like this at my age it is really hard. I didn't know where to turn. I only used blood products a few times, it is just not fair (62 y.o female with vWD).

I have chosen not to have treatment because it will impact so much on my earning potential and lifestyle. Besides, I would not have enough to live on if I could not work during treatment. I have elected to go this way because my genotype is not the best one for treatment success, but this might be a bad decision in the long run.

I have haemophilia A with inhibitors to factor VIII. I also have hepatitis C and feel very unwell at times. My life is pretty shithouse actually. I live with pain because I have gone without treatment for so long and the hepatitis is flaring up all the time now. I am not a candidate for treatment so the future doesn't look too bright for me (42 y.o male)

25. SOCIAL CONSEQUENCES

My husband and I have a farm, we are about to retire, and we wont have a lot to live on. I am beginning to spend more time at doctors. I had a biopsy recently and found out I have cirrhosis and will need much more monitoring which means lots of travel. In some ways I feel better knowing, but I am resentful that I have to bear all the costs. I shouldn't have to pay. There should be some compensation for this. Our son lives overseas and we would like to visit him. I cant get travel insurance. I haven't been able to look after my aged parents because of the hepatitis C and even my own children have been "over the top" about infection control issues. It was years before my husband would kiss me after we found out I had hepatitis C. (70 y.o.female with vWD)

Fatigue often means I don't go out with my family. They get sick of that, especially my partner, she feels like she is always making excuses for me (49 y.o male)

I never tell anyone that I have hepatitis C. I am only 15 now and I am not sure if it will affect me in the future. I am well now though. (male 15)

I am a lawyer and sometimes have to take time off work because of fatigue and lethargy associated with hepatitis and occasionally end up in hospital at times for haemophilia bleeds. What is the most painful thing for me though is the discrimination I experience because of hepatitis C in personal relationships. After all these years and after so much attention to community education I cannot understand why there remains so little compassion and sensitivity towards people who have hepatitis C issues.

I found that my personal relationships deteriorated as my hepatitis C progressed to cirrhosis. I think this is because I couldn't keep up with people, and they didn't understand the illness. I didn't have the energy for others and they didn't seem to care about me and I was fairly depressed about it. (male 50 y.o).

I haven't told anyone I have hepatitis C. I won't tell anyone. I don't have to and I don't think it is their business. I don't expect it to affect my earning capacity in future.

26. PSYCHOLOGICAL ISSUES

There is a psychological thing happening here – I have developed fears – fear about what the future holds for me, fear about live disease, fear of cancer, fear about what I would do if I don't respond to treatment sometime down the track if I need to have treatment. All this affects me now – its just having to live with knowing you have hepatitis C and knowing the doctors don't really know enough about it still. The counsellor is helpful but it is really hard living with something that could be a time bomb – no-one really knows

Its all about quality of life. Ours is really poor now. I am self employed with a wife and 2 kids – I had two lots of unsuccessful interferon treatment for hepatitis C. Not sure if I can face combination therapy. We had to sell the house because of financial problems because I couldn't work a couple of years ago. I worry that I may not be able to look after my family. Hepatitis C has destroyed my quality of life and now endangers my family. My family has had to endure our decline from a normal lifestyle with security to not knowing what tomorrow will bring and living from day to day. I have the disease, but the others are the ones suffering

Career and employment issues are now secondary thoughts for me. Now I have a two year old son, I am more concerned about how long I will be here for him

This is no fault of mine, but I have to live with this monster, and I do think the government should provide more support and financial assistance to people like me

I have no family. Hepatitis C broke up marriage.

27. DISCRIMINATION

I still feel like an outcast – some of my teachers and friends discriminated against me when I was at school because of my haemophilia and then when my parents were told I had hepatitis some teachers were pretty bad about it - so now I don't tell very many people at work about the hepatitis if I can get away with it, and luckily I am not sick, but they can see my haemophilia (35 y.o male office worker)

I encounter people who think I am lazy. They don't understand fatigue of hepatitis C

My parish priest doesn't want me taking communion

We are discriminated against, probably because hepatitis C is associated with drug use.

I was recently made redundant after being in the same senior position for 13 years. It is great because I recently cleared hepatitis C after having treatment. But when I was undergoing my treatment I told the company CEO and a few others at work. I am still not sure if this was the reason they made my position redundant (55 y.o male)

Health professionals treat me most differently and even the people who do my blood tests often ask me how I got hepatitis C

I don't tell people I have hepatitis C, but then I feel guilty and avoid them.

I am an allied health professional and I don't tell people/colleagues of my hepatitis C status because so many are so judgmental about others with hepatitis C that I don't want them to know I have it.

I live in a small country town. It is really difficult to have any privacy here. Everyone knows your business. I live in fear of the doctors' receptionist telling my neighbor I have hepatitis C. I

go to swimming classes for gentle exercise as I have arthritis and pain from my bleeding and one day the women were all talking about what they would do if someone came to their house with HIV or hepatitis C. I was terrified and I didn't go back. I won't contemplate treatment as I would have to travel so far – it just wouldn't be possible locally (female, 74 with vWD)

I can't get work because of both my haemophilia and hepatitis C. The bleeds and hepatitis C fatigue stop me from working. I lost the last job because I had to take hours off for treatment. It effects relationships also. But I reckon hepatitis is worse than haemophilia because the discrimination is worse. The dentist steers clear of me, leaves me to the last patient and it always looks like he has cleared the room the surgery before I arrive (male 22)

28. RELATIONSHIP ISSUES

For the first few years of my marriage there was constant friction and tension with my wife because of my constant tiredness and sickness (45 y.o male with mild haemophilia and chronic hepatitis C).

It was all I could do to keep up at work – I couldn't do anything around the house, I didn't pull my weight – I let her down in our marriage (54y.o male)

I have no doubt that hepatitis C caused the failure of my first marriage (43 y.o male)

Our sexual relationship has been quite restricted because of the fatigue

I stopped having sex with my partner because I was scared I would give her hepatitis even though doctors told me this would be unlikely – she already had to cope with my haemophilia (49 yo male)

It is a real strain on our marriage. Often I am not well enough to go out and I feel unwell. I can't do my share with the kids. She has to do it all and she is working part time as well (47 y.o male with son 20 at university and daughter 17 at school)

I am 17 and I haven't had a girlfriend yet. Most of the girls I know now know about my haemophilia and they understand I won't die from a cut, but they don't know I have hepatitis C
Hepatitis puts a lot of stress on my family. I only have mild haemophilia and I am pretty much OK most of the time from that point of view because I don't have many bleeds, but I am often too tired to be a dad and do my share. (34 y.o male with 3 children under 12)

It's really hard, I don't let myself get close to people, and I haven't had a girlfriend either. How could I tell her my story – I feel like I have no future, no health, no money, and lots of anger. It's not a good look (25 y.o male)

For years my wife and I couldn't understand why I was coming home tired and exhausted. My wife thought I was rejecting her sexually. I always went to bed early leaving her alone or to deal with the household issues that needed to be taken care of. Often I spent the weekends sleeping just so I could get through the next week. In the early days of our marriage we didn't know why I was like this, but after a few years I was diagnosed with hepatitis C. It all started to make sense after that, but by then we had already distanced from each other emotionally – it has been really hard -

Relationships and marriage are a big problem for people with hepatitis C. The biggest issue for me is that my wife's family is really scared of it and that causes a lot of tension (55 y.o male).

I gave up sex out of consideration for my wife. This hepatitis C is mine, and I have no intention of sharing it (71 y.o male)

29. CAREER LIMITATIONS/RESTRICTIONS

Several male and female medical, nursing and allied health professionals have indicated they have avoided specialties in their disciplines which involve procedural interventions and/or the need for disclosure of their viral status

I am careful about what work I do, and which of my professional colleagues I tell, because I have found health professionals to be the most judgmental about hepatitis C (32y.o female)

It's not the present that makes hepatitis C a problem. It is the potential for the future - it could become a major problem for my work (28 y.o male)

I am only a student, but I am worried that when I have to do shift work in hospitals I won't be able to keep up with my peers because of fatigue. It is already a problem and I am only just a student (20 y.o male)

I am an engineer. I had to cut back my hours and pass up opportunities for promotion because I knew I wouldn't cope with too much stress and long hours of work. It's not my haemophilia that is the problem, it's the hepatitis (59 y.o male)

I have mild haemophilia, but that is not a problem, as I rarely have bleeds any more. Recently I had the choice of 2 jobs – one with a salary of $60,000 p.a and another at $130,000 p.a. The higher paid one fits well with my competence, tertiary education, career goals and interest, however I accepted the lower paid position with less responsibility as I knew I would struggle to manage the additional hours and sophisticated input required as my health is too unreliable these days. My wife and I have decided not to have any children because of the health problems I have because of my hepatitis C, but we have a mortgage and I remain concerned that I will leave her with financial commitments that she cannot meet (36 y.o male)

Hepatitis C influenced my early retirement from my position as a university academic. I needed treatment and had interferon early on. It was not successful and the side effects had affected my confidence so much that I really did not feel able to continue at the level I was previously operating. Now I live with a permanent anxiety that the liver disease will progress.

30. INCOME/ECONOMIC ISSUES/CAREER CHOICES

I have just been told I have cirrhosis and my health has been deteriorating. I work for myself, and expect my income will reduce by 50% this year.

I only have mild haemophilia, but I have a lot of hepatitis C! I am on and off work all the time and will be starting treatment soon. My parents encouraged me to be independent, capable, and ambitious. I manage my haemophilia really well, but I get really angry when I think that it is not my haemophilia that restricts me, but the hepatitis C. Hepatitis C has limited my choices and stopped me going into the career I wanted. I won't have the money for further education after that, so I am not sure what I will do, even if the treatment is successful (22.y.o.male)

My income has decreased over the years. I have had to reduce the amount of work I do – especially while I was waiting to get my knee replacement and even now I still have to take time off because of bleeds, and when my hepatitis C got bad and I started treatment I had

even more time off work because I was tired all the time, and I really suffered from the side effects. My hepatitis didn't clear with treatment so I am back to square one now

I had to find a safe, secure job with flexible work hours so I can take time off if I have bad bleeds or in case I have a hepatitis flare up (32 y.o female with vWD)

Hepatitis C has affected my ability to study and get on in my job. The stress of worrying about it makes it harder. I had to overlook more senior positions because I knew I couldn't cope (44 y.o male)

My son is 17 and still at school. I am worried for his future, and his income potential, whether he will be able to work full time. His haemophilia is fine, he is on prophylaxis and he doesn't have very much joint damage, but I worry most that hepatitis C will interfere with his life. His genotype is the least likely to respond to treatment - what would he do then – he is only 17 – he wants to go to university next year

My income decreased by 40% in 10 years. I had a good career ahead of me, but I decided to leave that and work from home. My wife works so we can keep up our mortgage payments and the kids' school expenses but it's pretty hard on her

I have used all my sick leave with hepatitis C and now when I have to take time off, it has to be unpaid leave

I have reduced my hours to save energy, but I still get really tired and find it hard to keep up with work and have some sort of social life

I would like to see government financial support. What if my hepatitis C takes a turn for the worse? I am self employed with three children and a wife to support. I am self employed and I can't get loss of income or disability insurance because of my haemophilia and hepatitis C (34 y.o with 3 children aged 8, 5 and 3)

I wasn't really well enough to manage a full working week, especially as I would become tired and lethargic in the afternoons, so I negotiated to work reduced hours. This meant a reduced income as well, but I thought I could adjust to that. But the problem is somehow I am expected to do more work in less hours and now I suffer from stress. I am not sure that it is any better, in fact I think it is worse for me now -

I used to be a teacher. My wife can only work part time because she has to help look after me. I am on a pension. Hepatitis C is a greater problem for my health now than my haemophilia 48 y.o male)

I am an experienced IT professional and now find that C has affected my work performance. The tiredness and depression has affected promotion. It's difficult to compete in this day and age when you are not feeling as good as the people you are competing against. They have an immediate advantage over you. (38 y.o male)

I have given up my work in the bank because of hepatitis C

Shift work became impossible for me when I was having treatment because I was tired all the time and could not operate the equipment safety.

We are talking about selling our house and moving to a lower cost area.

I have moderate haemophilia, but that doesn't cause any problems with my work, but because of hepatitis C I have been afraid to take on a higher management position thatg has

been offered to me. I feel it is more important to try and lead a stress-free life and manage my health and well being carefully (male 44)

Uncertainty about my health is the reason I didn't pursue career advancement and seek higher paid positions. I have had treatment for hepatitis C but it was not successful so I am not sure what my future will be. I didn't finish my university studies, and now that I look back on it and don't like to admit failure I know it was because I just wasn't well enough to do all the work. I couldn't concentrate and I was sick fairly often and I became depressed at one time

THE NEED FOR FINANCIAL ASSISTANCE

31. HISTORY OF FINANCIAL SUPPORT FOR PEOPLE WITH HIV

More than 250 people with haemophilia were infected with HIV through their treatment with contaminated blood clotting concentrates prior to the introduction of viral inactivation procedures in 1984. In 1989, the Federal Government accepted the principle of providing financial support for those infected, establishing the Mark Fitzpatrick Trust. Payments from the Trust have been a combination of lump sum and regular payments. Subsequently, between 1991 and 1994 all State Governments provided financial assistance packages to people with haemophilia and HIV. Governments established the Mark Fitzpatrick Trust, and made State settlements not on the basis of accepting legal responsibility, but rather as a "moral responsibility" to provide financial help to those infected with HIV through products provided as part of their health treatment. Those eligible received an initial payment, and subsequent annual payments determined upon the level of severity of physical impairment. Claims could only be made if infection transmission occurred before May 1985. Payments were made to 425 beneficiaries. The Trust was wound up in 2001 when the remaining funds were distributed.

When the trust wound up, many people were healthy and had lived longer than expected when the Trust had been established. Many continued to experience financial hardship. The issues for people who are co-infected with hepatitis C are complex, and at the time the Trust was established the health problems of this group of people who also had liver disease was not anticipated (see below under co-infection).

Those who believed they could prove a case of negligence took separate legal action against blood transfusion services, CSL, hospitals and clinicians. Court action focussed on delays of transfusion services to acknowledge the risk of AIDS through blood products, the failure to implement donor declarations to exclude at risk donations, delay in introduction of surrogate testing, delay in heat treatment of products etc. Many people could not identify when they had become infected and thus it would be difficult to be successful. HFA lobbied further for compensation rather than the need for establishing negligence and threatening relationships with treaters, and discrimination by the health system. The successful PQ case against a hospital succeeded on the grounds that the patient should have been informed of the risks of factor VIII concentrate in September 1984 when treatment was changed from cryoprecipitate

to AHF. After huge costs of litigation in this and another case, State governments (except NSW) agreed upon out of court settlements with governments with payments ranging from $100000 - $650000. In NSW people with haemophilia refused to sign away rights to sue when amounts up to only $50000 were offered by way of a settlement offer. [38]

32. FINANCIAL SUPPORT FOR PEOPLE WITH HEPATITIS

People with haemophilia infected with hepatitis C were infected in the same way as those who became infected with HIV through contaminated blood products given as part of their health treatment prior to 1989. No financial help has been made available to the people infected with hepatitis C who are not co-infected with HIV. There is clearly a great need for this. For people with haemophilia, the added health and psychosocial consequences of hepatitis C upon an already potentially debilitating chronic disorder warrants special consideration.

33. MORAL RESPONSIBILITY

The many recent personal stories related to HFA for the purposes of this submission have highlighted the increasing concern for the community about hepatitis C. Many people feel betrayed by the blood system they had been encouraged by the authorities to trust. They had no choice but to use the products which caused them harm, and even death.

Haemophilia is a significant life challenge in itself, however the complication of hepatitis C illness and progression of liver disease with increasing years of infection, leads many to fear and anxiety about their future health and treatment needs, and creates doubts for the security of their social and economic future, and that of their family and loved ones.

That the hepatitis C infection has occurred through the blood supply leads to a greater sense of betrayal – first HIV and now hepatitis C,and .....what next? The haemophilia speaks openly and with strong feeling about TNV, The Next Virus. For people with haemophilia there is the ongoing fear that unknown viruses and agents such as vCJD could slip through the blood supply. As new experiences of blood borne viruses and infections occur the fears are exacerbated. The theoretical risk of transmission of vCJD through the blood supply was realised in December 2003 when a person in the United Kingdom who had received a blood transfusion from someone who had later developed vCJD, also developed vCJD. New, and as yet unknown viruses are likely because of the time lags between when new viruses are identified and when testing methods are developed and implemented.

People with haemophilia who live with the consequences of contaminated blood products are supported by competent virologists, immunologists, blood transfusionists and regulatory officials who share their concerns about the possibility that a virus or agent is a real risk, hence their advocacy for risk reduction strategies.

Concerns about blood supply safety in the media suggests many people in the broader community are also worried about the blood supply, and how decisions have been made in the past and now, but for the haemophilia community which must live with the consequences of the past and hold real fears for the future, it is even more difficult.

Many feel they have been betrayed by the blood system in the past and feel this even more so now because they are forced to use plasma derived haemophilia treatment products, even when safer alternatives are available, because of direct government policy not to provide them. It is a further insult that the main criterion for rationing these safer recombinant treatment products in Australia is blood borne viral status and age.

34. THE CASE FOR FINANCIAL ASSISTANCE

"The compassion of a society can be judged by the measures it takes to reduce the impact of tragedy on its members. Although the risks to the users of blood components and blood products today may be low, serious disease and some deaths will continue to occur as a result of the therapeutic use of blood.

There is, moreover, always the likelihood that a new and mysterious blood-borne pathogen may strike. .... it is of little consolation or even relevance to those unfortunate members of our society who suffer from infection caused by blood transfusions or blood products that the blood supply now is adjudged relatively safe. A system that knows that these consequences will occur and what brings them about has, at the very least, a moral obligation to give some thought to the question of appropriate relief for those affected by the inevitable events".

Krever Ch 39

The legal grounds of negligence upon which settlements have been made for many people with medically acquired hepatitis C are not applicable to the majority of people with haemophilia.

People receiving a blood transfusion had a single medical episode, and exposure to the blood of less than five people. It can be dated and traced back to specific donors. People with haemophilia were, and continue to be exposed, to the blood of tens of thousands of people, often twice per week. We now know that before blood products were treated sufficiently that all people with haemophilia who used those concentrates between 1985 and 1990 were being infected and re-infected.

People with haemophilia were infected at the same time as those who received blood transfusions. In fact, the risk for infection is increased for people with haemophilia because of the huge number of donors they are exposed to. It is unfair that those who were infected with hepatitis C from large pools have no redress when they were in fact at greater risk. The requirement of proof that a donation caused an infection is flawed. Common sense dictates that people with haemophilia became infected in the same way as those who did so through a blood transfusion.

The full impact of hepatitis C as well as haemophilia on people's lives is very hard to appreciate. Apart from the various physical symptoms experienced, there is also the extreme anxiety of living with multiple health issues, each of which is potentially life threatening.

People with haemophilia infected with hepatitis C were infected in the same way as those who were infected with HIV and those problems were recognised. On "moral grounds" they should, therefore, be similarly offered financial help. Government has already recognised the moral case for financial assistance for those infected with HIV. Haemophilia Foundation Australia would like to see the principle extended to those infected with hepatitis C on grounds of equity and social justice.

35. THE FINANCIAL NEED

Financial support would at least help alleviate some monetary stress for infected people. Financial support is essential to enable this group of people to deal with the day to day and long term consequences of hepatitis C obtained through the blood supply through no fault of

their own. Payments could be used both to target specific identified needs as well as to provide resources to allow infected individuals to regain some control over their lives. In the absence of a cure or a preventative vaccine for hepatitis C, education and prevention strategies remain the most important mechanism for controlling the disease in the Australian community. Different forms of payment could be used to meet the complex and changing needs of those infected.

HFA considers that each person with haemophilia infected with hepatitis C should receive a single payment in acknowledgement of the medical, social and economic impact on his or her lives. All healthcare and medical treatment should be provided free of charge to all people infected with hepatitis C. Further payments should be made available if and when each person progresses in hepatitis C illness, to assist with meeting the additional costs and to ensure financial assistance to relatives who provide care, or suffer hardship because of the disease.

In many other countries just as in Australia government financial assistance for blood-transmitted disease was initially restricted to people with HIV or AIDS. However, because of the high loss of life through HIV there are now more people who are actually affected through blood with hepatitis C than HIV and many of these people experience poor health outcomes and suffer financial hardships through loss of income and high health care costs as a result. Some countries have taken steps to redress this anomaly.

At the XXVI General Assembly of the World Federation of Hemophilia in Seville, Spain, on May 24, 2002 the 77 National Member Organisations present, including Haemophilia Foundation Australia, unanimously agreed on the following resolution:

"The WFH recognizes the pain and suffering caused to people with hemophilia and related bleeding disorders by iatrogenic infection with the hepatitis C virus. The WFH calls on all governments to make available suitable recompense to all those infected and their families

The Krever Commission recommended the Canadian Compensation schemes which has become a model for other countries as they have taken steps to acknowledge and attempt to compensate for the losses associated with hepatitis C. Krever recommended compensation instead of actions for negligence because of the difficulties in establishing fault of an individual or organisation in the case of hepatitis C. Common law is not an effective remedy for many who are injured through no fault of their own. It involves drawn out legal argument in an adversarial environment, high costs of litigation and unpredictable outcomes, none of which is helpful if you are sick, or already financially disadvantaged because of chronic illness, undergoing toxic antiviral treatment and/or necessarily forced into litigation against the same people who continue to provide your treatment – as was the case for many people with haemophilia with HIV litigation and would be the case for individuals now if they mounted action in respect of their hepatitis C infection.

The significance of hepatitis was disputed until the HIV era, therefore the production of virally inactivated concentrates was a low priority until 1984/85.The failure of litigation on the basis of "current knowledge at a point in time" remains a frustration for people with haemophilia who have been affected by contaminated blood products when they had no alternative but to rely on clinicians, researchers, policy makers and regulators to ensure the blood supply and therefore their treatments safe.

Hepatitis C is not unlike the HIV experience for many people with haemophilia. Most people with haemophilia have hepatitis C. More than one person in each family affected by haemophilia is likely to be affected by hepatitis C and/or HIV. The risk of NANB hepatitis has been known since the 1970's. The possible delays in the introduction of screening tests or viral inactivation procedures may have infected more people unnecessarily. People with haemophilia have an increased viral load, often more than one genotype, and a high proportion are known to develop liver disease. There is no way to compensate for the loss of a life or a life of a loved one, but surely there is evidence for a financial assistance package in recognition of the community's moral responsibility to people with haemophilia who have been infected by hepatitis C through the blood supply.

There are various precedents around the world for compensation and financial assistance for people who have been infected by hepatitis C through the blood supply, and in some cases, for their families. Each situation is slightly different in respect of blood safety record and standards, viral inactivation technologies adopted, time/date restrictions, burden of proof and /or the need to establish fault, eligibility criteria, and type of assistance provided and for whom.

The Australian situation may well be unique in some respects, and share similarities with other jurisdictions in other respects, however for people with haemophilia, the background is the same, the pain and suffering is the same and the special needs of this group of people are the same. The effect of hepatitis C on people with haemophilia is significant and perhaps quite different from others who became infected through other modes of transmission. HFA makes no judgement about the validity of other claims for or against compensation or financial assistance, but seeks the acknowledgement of the Senate Committee that the special circumstances of the haemophilia community justifies the provision of a financial assistance package to ease their difficulties.

Further, HFA seeks the Senate Committee's support for a range of other recommendations to help overcome or manage some of the disadvantages affecting the part of the haemophilia community which is so adversely people affected by hepatitis C.

We seek an outcome that reflects a greater sense of justice having been afforded to people with haemophilia, rather than revenge for the failure of individuals or the blood supply system to make them safe. We seek recommendations that strengthen the blood sector in Australia and that optimises the safety and supply of haemophilia treatment products.

HFA supports the principle of self sufficiency, in general terms, as it relates to blood products, however, it must be ensured that sufficiency of required treatment products for any indication is not compromised at the expense of national self sufficiency. It is recommended that Australia adopts systems which allow it to meet the treatment of people who require plasma products and blood components made from blood given freely by Australians. We recognise this is a proud tradition and one that is valued by most sectors of the community, including governments. However, such a principle must never be allowed to continue for political and/or financial reasons and decisions must be based upon evidence, solid data and a sound regulatory framework. A principle of national self sufficiency in this country for some blood products should not be adopted at the expense of best practice for the treatment of haemophilia in this country. Australia needs to retain the capacity to manufacture high quality, well regulated, blood products required by the Australian community to the highest degree of safety possible as well as fund the importation of the safest, gold standard treatment products which, in the case of haemophilia products, are currently those made from synthetic, recombinant technologies in Europe and USA. Policy decisions should be made on the grounds of clinical best practice and safety rather than political, economic and commercial

considerations. There are several examples in the history of haemophilia treatment products in this country where the latter principles have been adopted at the expense of the former, some of which have been mentioned above. This is not acceptable. A policy of self sufficiency must not come at the expense of best practice. All policies should be based upon evidence based medicine, a strong regulatory framework, robust haemo-vigilance and pharmaco-vigilance programs. Guidelines for the clinical use of products should be confined to clinical recommendations rather than non clinical matters such as supply or financial considerations. Furthermore, there should be a clear delineation between policy and the commercial interests of stakeholders which could impact on decision making relating to the clinical use of the products which are the subject of the Plasma Fractionation Agreement.

36. OTHER COMPENSATION SCHEMES/ INTERNATIONAL EXPERIENCE[39]

CANADA

Approximately 1400 people with haemophilia were hepatitis C positive. The Krever Commission recommended compensation for all those who were infected with hepatitis C via blood or blood products. In Canada like in Australia, most people became infected through use of blood products before 1989. Surrogate testing for NANB hepatitis was rejected by the authorities in 1977 and heat treated products were rejected in 1982. In 1986, Canadian authorities refused to introduce hepatitis C antibody testing and opted for a study instead in which half the subjects received screened blood and the other half unscreened blood to find out the efficacy of the test. In 1998 compensation was awarded to all those infected between 1 January 1986 and 1 July 1990 irrespective of the status of their health. The scheme also includes secondarily infected family members or partners. Compensation was also awarded to the partners of those infected, and to dependents of those who had died. The total cost of this program to the government was $1,118,000,000 Canadian dollars plus interest derived after April1998. [40]

The Payment Schedule	
First payment if hepatitis C antibody positive	$10,000 (AUD$9900)
Second payment if PCR positive	$20,000 (AUD$19800)
Third payment with fibrosis or needing interferon therapy	$30,000 (AUD$29700)
Fourth payment for cirrhosis	$65,000 (AUD$64350)
Fifth payment for liver decompensation/HCC or after a liver transplant	$100,000 (AUD$99000)

Those who had previously received HIV compensation received a one off payment of $50,000 only (AUD$49500).

Additional payments under the Settlement Agreement are made for:

- monthly payments of $1000 are made for people undergoing treatment in recognition of the strains involved with hepatitis C therapy. The third payment can be waived in favour of a loss of earnings payment and payment for students under the age of 18.
- payments may be made for treatment and medication not covered by insurance schemes in public and private health insurance plans
- compensation is paid for costs of care up to CAN$50,000 per year (AUD$49500)
- compensation for out of pocket expenses related to seeking medical advice, treatment as well as medical expenses for a claim, including travel, accommodation, meals and telephone etc

- compensation for people with HIV/Hepatitis C co-infection
- compensation for deceased persons' relatives, if person died after 1 January 1999, in which case they will receive all payments to which that person would have been entitled for the period up to his death. If person died before 1January1999 the survivor will receive between CAN$50000 - $120000 (AUD$49500 - $118000)
- up to $5000 will be paid for funeral expenses (AUD$4950).
- compensation for dependents and family members for loss of support, loss of services, loss of guidance, care and companionship

UNITED KINGDOM

Approximately 4800 people with haemophilia infected with hepatitis C, representing 47% of haemophilia community. The UK Haemophilia Society has been campaigning since 1995 for compensation on the grounds that hepatitis C is similar to HIV, which has been compensated for by the government, and that there were moral grounds for granting compensation for hepatitis C as well. Between 1996 and 1998 different governments refused to provide compensation.

In 1999, when it became known that non virally inactivated treatment products had been used in Scotland until 1987, a separate inquiry was launched in Scotland. In 2002 the Scottish House of Parliament granted compensation of a minimum of GBP 50,000 . (AUD$119000)

The UK Haemophilia Society's 2002 proposal to government for a scheme based on the Canadian scheme, sought average payments of GBP140,000 per person (AUD$333200) The proposed scheme would pay according to the stage of liver disease reached to allow for individual circumstances and made provision for additional payments for dependents and family, inconvenience of long term therapy, out of pocket expenses and costs of care. It also took into account loss of earnings using research findings demonstrating the financial impact of hepatitis C infection.

Payment level 1	Antibody positive, PCR negative	GBP7500
Payment level 2	Antibody positive, PCR positive	10000
Payment level 3	Fibrosis or having drug therapy	20000
Payment level 4	Cirrhosis (proof may be other than liver biopsy)	40000
Payment level 5	Decompensated liver disease or liver cancer (AUD$333200)	60000 GBP 137500

In August 2003 the UK government made an unexpected decision in 2003 to grant a compensation package for the UK.

In January 2004 the UK Health Secretary John Reid announced a scheme that makes people who were infected with hepatitis C from NHS blood or blood products eligible to receive ex-gratia payments from the Department of Health.

"I'm pleased to be able to announce the details of this scheme today. I felt it was important that English Hepatitis C patients should receive these payments on compassionate grounds. It's clear that providing assistance is the right thing to do"

UK Health Secretary John Reid January 2004

Everyone whose hepatitis C is attributable to NHS treatment with blood or blood products before September 1991 will be eligible for the payments (including those who have cleared hepatitis C). The ex-gratia payment scheme means that people infected with Hepatitis C will receive initial lump sum payments of GBP20,000 (AUD$47600) and those developing more advanced stages of the illness - such as cirrhosis or liver cancer - will get a further GBP25,000 (AUD$59500) and people who contracted hepatitis C through someone infected with the disease will also qualify for payment. People with HIV will also be eligible if they have hepatitis C, however the surviving relatives of those who have died from hepatitis C are excluded. The ex-gratia payments will not affect social security entitlements. The payments are considerably less per person than the proposal of the UK Haemophilia Society and time will tell whether this is accepted by the UK haemophilia community.

IRELAND

The Irish Haemophilia Society (IHS) has been involved in many years of negotiations for financial support for people infected with hepatitis C through blood products, including many women who had been infected by hepatitis C through immunoglobulin- Anti D.

In 1994 IHS asked for free medical treatment for people with hepatitis C and in 1995 commenced discussions for compensation for hepatitis C. In 1996, the Hepatitis C Compensation Tribunal was set up and claims were dealt with on a case by case basis. Applicants had to prove on the balance of probabilities that the infection was caused by blood or blood components. Applicants had to agree not to initiate civil action. (Krever Ch).

This scheme was legislated for in 1997. Free medical care for any condition for any person who had been infected with hepatitis C through blood and blood products was also provided for in the Health Amendment Act in 1996. A lump sum was paid in stages to take into account disease progression which may have occurred. Claims from 240 people have been heard, including people with haemophilia, their partners and relatives of those who have died. Payments have ranged from 50,000 Euro to 2.5 million Euro. (AUD$81,500 - $4,077,900)

The payments for hepatitis C infection are made in accordance with the following categories;

- General Damages – pain and suffering, diminished quality of life, the need to be on treatment, higher viral load in people with haemophilia, multiple genotypes and the underlying effects of haemophilia are considered under this category.
- Health Care Costs – covered under the Health Amendment Act (1996)
- Loss of earnings – different test for children and adults, includes actual loss of earning and superannuation entitlements, loss of earning through loss of opportunity. Payments can be tailored to the individual needs of applicants.

In 2003 the Hepatitis C legislation was amended to include people infected with HIV. This was in addition to the payments made under the 1991 HIV compensation scheme where the payments ranged from 100,000 – 130,000 Euro (AUD$163000-$21900). This new scheme covers general damages, healthcare costs and loss of earnings (paid retrospectively with interest at an annual rate of 8%) and the following new areas:

- Loss of consortium (in the case of relationships for 3 years or more, impairment of sexual relations, fear of transmission of hepatitis C, loss of love care and attention due to a spouse being unwell, fatigued or incapable of undertaking normal social activities, loss of ability to communicate, aggressive behaviour would be included under this category).
- Loss of society
- Post traumatic stress Disorder for survivors and dependents
- Solatium – 28,000 Euro (AUD$45700) paid to next of kin and those who died (AUD$45700)

ITALY

In Italy, as early as 1992 the government provided a government funded program of financial assistance for people with haemophilia and HIV/AIDS and legislation was amended to cover people who suffered irreversible liver damage from hepatitis A, B and C. Whilst this program was not without its problems it set up 8 categories of entitlement based upon the severity of damage etc. The amount paid varied up to CAN$43850. (AUD$43425)

NEW ZEALAND

In New Zealand 70% of people with haemophilia were estimated to have been infected with hepatitis C. Most infections are believed to have occurred before 1989. The hepatitis C antibody test was not introduced until July 1992, far later than many other countries, and it is understood that unscreened blood products were used after this date. Under the Accident Compensation Act (1982) HIV had been recognised as an accident due to medical misadventure. Hepatitis C was also recognised as a medical misadventure so that claims could be made, however, the deadline for making claims was sudden and many of those affected missed this. Hence some people were compensated with a lump sum of up to NZ$27000, plus health costs, which were not covered by the government medical insurance scheme. The legislation was amended in 1992 and required an applicant to establish a physical injury resulting from medical error or medical mishap rather than misadventure. A medical mishap is defined as a rare and severe adverse consequence of treatment provided by a health professional, resulting in significant disability. The amendments made hepatitis C claims under this legislation unfeasible which has resulted in much anguish for people with haemophilia who have been treated quite differently in relation to compensation for hepatitis C. (AUD$23700)

37. GOVERNMENT INQUIRIES

There have been several inquiries into hepatitis C transmission, the most notable being the Krever Commission in Canada that after a comprehensive review resulted in compensation for people with haemophilia and hepatitis C. In Ireland there has been two inquiries – the first, the 1996 Finlay Inquiry did not deal adequately with the issues of people with haemophilia, and after IHS negotiations it was followed by the Lindsay inquiry of 2000-2001 which lead to the establishment of the National Haemophilia Council and a product Selection and Monitoring Advisory Group with IHS representation. This gives people with haemophilia a statutory authority right to decision making about their treatment products and services and allocation of funding resources in the future.

38. A PROPOSAL FOR RECOMPENSE FOR PEOPLE WITH HAEMOPHILIA AND vWD IN AUSTRALIA

AN APPROPRIATE MODEL INCLUDES:

- Recognition and apology that contaminated blood caused infections
- No fault financial recompense for all people with haemophilia and vWD who have hepatitis C
- Full and unhindered access to free hepatitis C treatment irrespective of genotype and previous treatment outcome
- Full and free access to all medical treatment for any condition
- Recompense as well as government income support for people whilst having treatment for hepatitis C
- Education on treatment and services available for people with hepatitis C
- Access to free and comprehensive education to alternative therapy and complementary medicine
- Adequate resources for haemophilia treatment centres and co-ordinated access to hepatology and liver clinics to care for people with bleeding disorders
- Comprehensive health care for people with haemophilia who have hepatitis C and /or HIV
- Coordinated, national standards for delivery of hepatitis C services
- Full access to liver transplantation program
- Strengthened bleeding disorder data collection and analysis
- Access to recombinant products for all people with haemophilia immediately
- HFA participation in decision making about the selection of haemophilia treatment products and resource allocation
- Prophylaxis for the treatment of haemophilia in children and adults
- Adequate supplies of the safest treatments for vWD

39. COST OF FINANCIAL ASSISTANCE

In the UK proposal a computer model which simulated the progress of hepatitis C was used to predict the number at different levels of severity of hepatitis C over 10 years into the future. The UK model proposes payment determined by the level of injury at the time the compensation is determined, compared to the Canadian system which stages the payment. In the UK system the compensated person can return for a further payment if they move onto another level taking into account the previous payment. The UK computer modelling is used below as a basis to estimate costs of a similar scheme in Australia the following costs are suggested. It is important that full actuarial calculations on the basis of expected disease progression are made for the Australian situation, taking into account a range of local factors including healthcare costs, common law payment history etc, and that future dollar values are factored into the progressive payments proposed.

On the basis of the estimated number of people with haemophilia, vWD and hepatitis C described above we assume there are approximately 1022 people with hepatitis C.

Payment level		Hypothetical number at 1 Jan 2000	Payment amount per person AUD$	Total payments for level AUD$
1	AB+, PCR-	153	18000	2,754,000
2	AB+,PCR+	130	24000	3,120,000
3	Fibrosis, drug therapy	565	47800	27,007,000
4	cirrhosis	129	95500	12,319,500
5	Advanced liver disease/HCC, transplant	42	143300	6,018,600
Total		1022	328600	51,219,100

The Australian model assumes free and comprehensive medical care irrespective of condition. That is everyone with haemophilia and hepatitis C will be eligible for free health care throughout their life. Further costs should be factored in for additional expenses, such as care, HIV in addition, out of pocket expenses, those who died before the payments were available, dependents and family members.

This model will only be successful if it is supported by strong hepatitis C health, medical and counselling services that are provided to all people with haemophilia and vWD who have been infected with hepatitis C and relevant financial and other support services for their families and carers.

4 February 2004

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[1] UKHCDO in Haemophilia(2003), 9, 1, pp1-23
[2] Ponce, M in Haemophilia (2000), 6, Supplement, 2, 35-52 at p 52
[3] Leslie, D.E et al. (1992) Medical Journal of Australia 156:789-792
[4] HFA has made a best guess estimate based upon unconfirmed data from Australian Bleeding Disorders Registry and data provided by DHA to Senate Community Affairs Legislation Committee, Question EO3-130, June 2003.
[5] Krever at p1048
[6] Report of Krever Commission at p687
[7] Report of the Expert Advisory Group on Hepatitis C and Plasma in 1990 (2003) Referred to elsewhere in this submission as the Barraclough Report, at p61
[8] Wood, Boyce et al in Hepatitis C- An Australian Perspective (Crofts,Dore,Locarnini - Eds) at p249.
[9] Krever at p632
[10] Krever at p696
[11] Krever at p696
[12] Krever at p647 and Barraclough at p41
[13] Krever at p646
[14] Krever at p707
[15] Barraclough at p40
[16] Barraclough at p40
[17] Wood,Coghlan and Boyce in Crofts et al (eds) 2001 at p248
[18] Krever at p695
[19] Wood, Coghlan and Boyce (2001) at p246ff

[20] Barraclough Report (2003) at p 1-4
[21] Barraclough Report (2003) at p12
[22] Barraclough Report(2003) at p78
[23] Barraclough Report (2003) at p81
[24] Dore, G in The natural history of hepatitis C virus infection in Crofts et al (eds) 2001, at p83
[25] Dore, G (2001) at pp 89-96
[26] Dore, G (2001) at p96
[27] Dore, G (2001) at p96
[28] Lee in Haemophilia (2000), 6, Suppl, 133-137.
[29] Lee, C (2000) at p133
[30] Lee, C (2000) at p135
[31] Lee,C (2000) at p323
[32] Makris, Dusheiko et al, Haemophilia (2001),7, 339-345 at p340
[33] Lee, C at p325
[34] Schulman et al, (2002) Haemophilia, 8,129-135
[35] Makris et al, (2001) p 341
[36] Mijch, A in Crofts et al (eds) (2001) at 117-125
[37] MacDonald,G, Uni of Queensland, informal discussions with HFA 2003
[38] Material from several HFA documents and from Sendziuk,P Learning to Trust - Australia's responses to AIDS (2003)
[39] HFA has drawn material from several sources in this section including UK Haemophilia Society publications, Brian O'Mahony , President, World Federation of Hemophilia, report of the Krever Commission, and the 2000 World Federation of Hemophilia Report (Status of Financial Assistance for HCV Infected Persons with Haemophilia in WFH Countries, Update Spring 2000)
[40] The full text of the Agreement can be downloaded from the website www.hepc8690.com

(C) Post-Transfusion Hepatitis Study

A final draft report on the Post-Transfusion Study carried out in N.S.W had been circulated. Dr. Cossart intended submitting it to the Lancet for publication. It was decided that Dr.Archer should draw Dr.Cossart's attention to sections of the text which contained errors of where amendments appeared desirable. There was discussion on the proposal in the report for the adoption of core antibody screening. It was the Sub-Committee's view that this would in fact impose considerable expense on the Blood Transfusion Service because of the high price of commercial testing kits. Nor would it be possible to cease screening for HB AG. Dr. Archer was asked to advise Dr. Cossart of these views and to seek her co-operation in qualifying the remarks on core antibody screening. It was also decided that with the agreement of Dr.Cossart copies of the report should be forwarded to members of the Project Committee who were not members of the B.T.S. Executive Sub-committee.