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# Review of health services available for persons who contracted Hepatitis C through the administration within the state of blood or blood products

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# Review of Health Services Available for Persons who Contracted Hepatitis C through the Administration within the State of Blood or Blood Products



Consultative Council on Hepatitis C

March 2000



Review of Health Services  
Available for Persons who  
Contracted Hepatitis C through  
the Administration within the  
State of Blood or Blood Products

Review conducted by:

Professor Hannah McGee  
Dr. Anne Hickey  
Ms. Mary Smith  
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Health Services Research Centre  
Department of Psychology  
Royal College of Surgeons in Ireland

March 2000



## Consultative Council on Hepatitis C

### List of Members

Ms. Paula Kealy	(Positive Action)
Ms. Josephine Mahony	(Positive Action)
Ms. Aideen Connolly	(Transfusion Positive)
Mr. Colm O'Toole	(Transfusion Positive) – resigned April 1998
Mr. Gerry Hogan	(Transfusion Positive) – from June 1998
Ms. Rosemary Daly	(Irish Haemophilia Society)
Ms. Patricia Doherty	(Irish Kidney Association) – resigned November 1998
Mr. Gerard Sweeney	(Irish Kidney Association) – from November 1998
Ms. Ann Broekhoven	
Ms. Mary Healy	
Dr. John Hegarty	
Ms. Mary Hogan	
Ms. Leonie Lunny (Chair)	
Mr. Dermot Morris	
Mr. John Murphy	
Dr. Cliona O'Farrelly	
Dr. Vivian O'Gorman	
Dr. Angela Savage	



## Forward

The proposal of a major review of the health services available to those people infected with Hepatitis C through the administration of blood and blood products was first suggested by Positive Action. Services had been evolving since 1994 and it was considered timely to examine the current provision and to plan for the future service needs.

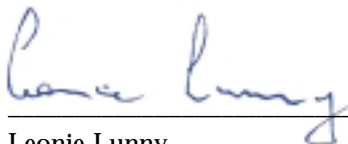
The Consultative Council on Hepatitis C was pleased to be asked by the then Minister for Health and Children, Mr. Brian Cowen, T.D., to direct, co-ordinate and oversee such a review. The term of office of the first Consultative Council is drawing to a close, and the completion of this review counts as one of the main achievements of our three-year term of office.

The four support groups, Positive Action, Transfusion Positive, the Irish Haemophilia Society and the Irish Kidney Association, all of which are represented on the Consultative Council, are to be commended for their invaluable input, particularly in encouraging their members to participate in the review. The report will assist health service providers, the Department of Health and Children and the support groups to continue their working relationship to ensure that the future service needs of this Hepatitis C group are met.

The individual representative groups will play a significant part in ensuring that where necessary, the services will be customised to suit the particular clinical, psychological and social needs of their members. The Council recognises that this review is not an end in itself but part of an on-going process which will continue to examine and evaluate the available services.

On behalf of the Council, I would like to thank the authors of the report, Professor Hannah McGee and Dr. Anne Hickey and their research team, Ms Mary Smith and Ms Molly Bryne. I also want to thank all the members of the Consultative Council who gave the benefit of their expertise throughout the conduct of the review. I particularly want to thank the chair of the review sub-committee, Dr Vivian O’Gorman, and the members of the committee.

On behalf of the Council, I am pleased to present this report to the Minister for Health and Children, Mr Michéal Martin, T.D. I believe that the incoming Council will have an important role in the implementation process and will provide support and guidance as required.



Leonie Lunny  
Chair, Consultative Council on Hepatitis C

March 2000



## Preface

This review was commissioned by the Consultative Council on Hepatitis C of the Department of Health and Children. The Health Services Research Centre (HSRC) at the Department of Psychology, Royal College of Surgeons in Ireland conducted the review. The HSRC is a multidisciplinary centre established in 1997 to promote quality health care delivery in Ireland. The review was directed by Professor Hannah McGee and Dr Anne Hickey. Professor McGee is a health psychologist and HSRC director. Dr Hickey is a health psychologist and grant-holder on another hepatitis C research project since 1997. Two researchers complete the research team: Ms Mary Smith, research nurse and project co-ordinator, and Ms Molly Byrne, health psychologist. The review was completed between July 1998 and June 1999.

The completion of the review depended on the co-operation of many individuals and organisations. Those consulted in their working roles for the review are acknowledged by name in Appendix 1 and others are listed on the following page.

We have produced the review on the basis of the information provided to us and have endeavoured to represent both the broad view on issues and the range of views where there is a discrepancy of opinion. The account and the inferences drawn are those of the Health Services Research Centre.

## Acknowledgements

Our first and most important acknowledgements go to those infected by hepatitis C who shared their experiences with us. As well as being an emotionally difficult process for many, people gave generously of their time and travelled long distances to contribute to this project. We hope that their efforts will have benefits for their own care and that of others in similar circumstances in the future.

We extend our thanks to many people; especially professional and administrative health care staff, who gave generously of their time and experience to make this project possible. The Review Steering Committee of the Council on Hepatitis C, and in particular, Ms Mary Hogan of the Department of Health and Children, provided valuable information and clarification throughout the conduct of this review.

In addition, we thank the following people who provided professional support, advice, and assistance:

Department of Psychology, Royal College of Surgeons in Ireland: all of the staff but particularly Ms Eileen Walsh, Ms Fidelma Fearon, Ms Kathryn McCarthy, and Professor Ciaran O'Boyle (research); Ms Rose Minihane; and Ms Linda O'Connell (secretarial).

Also:

Dr Colette Barry, registrar, and Ms Elsie Beggs, clerical officer, Hepatology Unit, Beaumont Hospital, Dublin; Ms Kate Frazer, research nurse, and Ms Noreen Kelly, secretary, St Vincent's Hospital, Dublin; Ms Lily Heuston, acting section officer, Mid-Western Health Board; and Dr Ruth Pilkington, registrar, Hepatology Unit, St James's Hospital, Dublin; Dr Emer Feeley, specialist in public health and Ms Ella Lovett, clinical psychologist, Eastern Health Board.



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## Executive summary

### Background

- ◆ Following the discovery in 1994 that anti-D immunoglobulin manufactured by the Irish Blood Transfusion Services Board (BTSB) was infected with hepatitis C, testing, identified approximately 1,600 people infected with hepatitis C through administration within the State of blood or blood products.
- ◆ Specialist hepatology services were established in six designated hospitals nationwide to provide services for this group. A seventh centre has since been established.
- ◆ The Health (Amendment) Act, 1996, provided statutory entitlements to a range of primary health care services to persons with hepatitis C following receipt of blood or blood products.
- ◆ In 1996, a Consultative Council on Hepatitis C was established by the Minister for Health to advise and make recommendations to the Minister on all aspects of care of this hepatitis C group. It commissioned this review.
- ◆ The review documents use of, and views on, service quality and future service needs from hospital chart reviews and from individual interviews with infected persons, relevant professionals and administrators from hospitals, health boards, disease-specific support organisations, and relevant national agencies.

### Review methodology

- ◆ Medical chart review: Twenty-five percent of randomly selected hospital charts were surveyed for service use in each of the seven centres nationally (N=388; 99% of charts were available for review).
- ◆ Interviews with hepatitis C-infected individuals: Focus group sessions with representatives from four patient representative organisations informed development of a structured interview schedule. A random sample of patients was invited from each centre to provide a nationally representative sample of each infection group (that is, anti-D, haemophilia, renal, transfusion, and 'recall') (N=132; 37% response).
- ◆ GP survey: Randomly selected GPs who had billed for services under the Health (Amendment) Act in the previous year were surveyed by post regarding care provided for patients with hepatitis C (N=150; 57% response).
- ◆ Health services personnel interviews: Sixty-four individuals were consulted or interviewed as part of this review including staff from hospitals (medical and administrative staff), health boards, the Irish College of General Practitioners, support groups, the BTSB, the Department of Health and Children, and the Health Research Board. Private and health board employed counsellors were also interviewed.

## Secondary care

### *Liver biopsy*

- ◆ Sixty-three percent had undergone at least one biopsy; most (77%) were satisfied with the overall experience.
- ◆ Medical consultants provide qualitative rather than numerical test results. Most patients (77%) reported satisfaction with biopsy result communication while one support organisation strongly argued for the value of providing numerical test results.

### *Interferon*

- ◆ Eighteen percent had undergone interferon therapy. Most (77%) were satisfied with medical assistance but fewer (40%) with general counselling and support while on interferon.
- ◆ Interviews with secondary care providers reflected a general view that interferon services are operating quite successfully. This discrepancy of opinion (between patients and support groups on one side and secondary care providers on the other) is cause for concern.

*Recommendation 1: That a committee be established to agree treatment protocols (including liver biopsy procedures and scoring, and administration of anti-viral therapy) for this particular group. The committee should comprise the medical consultants with primary responsibility for this group of patients and be chaired on a rotating basis.*

- ◆ The non-hepatology service to which the highest number of referrals was made was rheumatology (9%), followed by gynaecology and ophthalmology (5% each). Staff expressed concern over the availability of physiotherapy services. Problems were also identified in implementation of the two-week referral system.

*Recommendation 2: That the system whereby patients are referred by their consultant hepatologist to another specialty be regularised to facilitate Hepatology Unit staff in making priority referrals in accordance with the 'two-week' rule. A comprehensive system for physiotherapy should be established to ensure that it is available to all who require it.*

- ◆ There was seen to be confusion regarding regulations concerning management of the person with hepatitis C following death, with the potential to cause considerable anxiety and possible inappropriate and insensitive management of individuals concerned and for their families.

*Recommendation 3: That guidelines be developed for the management of death, including funeral arrangements, so that the necessary safe practices are understood and accepted by all concerned.*

### Primary care services

- ◆ These services are coordinated by a liaison officer in each of the eight health boards to ensure efficient delivery of primary care services. This role is seen to operate very effectively. The continuing contribution of this group was seen as important.

*Recommendation 4: That health board liaison officers meet on a regular basis to ensure uniformity and continuity in the provision of primary health care services.*

### Counselling and home help services

- ◆ Half (51%) of the group had availed of counselling at some time since diagnosis with three-quarters of this group intending to use services again. Satisfaction with services was high (82% rating or 'good' or higher) despite significant initial reluctance by 57% of users.

*Recommendation 5: That health board liaison officers ensure choice of counsellors and counselling locations in all health board areas.*

- ◆ A quarter (24%) of the group currently use home support services, averaging about 10 hours service weekly; current satisfaction with service provision for users was high (88%).
- ◆ Sixty-two percent of those availing of home support services have nominated their own home support, an option unique to this patient group. Use of home support raises challenges for patients regarding confidentiality and for health boards regarding training and health and safety.

*Recommendation 6: That a general training programme for all home support providers be available. This programme must have as a basis an agreed strategy regarding the balance to be achieved between duty of care to the provider and the right to confidentiality of health information of the recipient.*

- ◆ Difficulties in relation to differential rates of pay between health boards and ongoing recruitment of providers of home support services were identified.

*Recommendation 7: That the issues surrounding the difficulty in recruitment of home support providers, including remuneration issues, be reviewed to ensure availability of the service to all who require it.*

### General practice services

- ◆ Almost all patients (95%) have a GP whom they regularly attend. A significant minority (19%) had changed GP since hepatitis C diagnosis (19% also reporting having difficulty with a GP since diagnosis); satisfaction with current GP services was very high (89%) and similar across groups with different routes of infection. (This level is somewhat higher than found in a recent large general practice survey (81%) across two health boards.)

### Other primary care services

- ◆ Difficulties were noted by interviewed patients with dental service provision concerning eligibility and infectivity; 75% of users were satisfied with services.



- ◆ Pharmacy services were seen as generally of high quality including attending to confidentiality; 83% of users reported satisfaction with services.

*Recommendation 8: That staff in all primary care disciplines dealing with this patient group (including general practitioners, dentists, and pharmacists) be adequately informed about both the actual risk of transmission of hepatitis C and the guidelines on universal precautions against transmission of infection; this is to ensure that such patients are treated in a sensitive manner.*

#### *Complementary therapy*

- ◆ A quarter (24%) of the interviewed group had tried complementary therapies for hepatitis C; over half (62%) of their consultants were aware of their use of such therapies.
- ◆ Medical consultants were neutral regarding use of therapies excepting those involving needles or herbal remedies likely to spread infection or damage an already weakened liver respectively. Most neither objected to nor referred for other therapies.
- ◆ Resources for complementary therapies differed across health boards and hospitals.

*Recommendation 9: That the role of complementary or alternative therapies in the management of hepatitis C be reviewed as part of a wider framework of evaluation of the use of such therapies in the Irish health system.*

#### *Research on hepatitis C in Ireland*

- ◆ There was consensus that a unique opportunity exists for internationally significant research which can inform both treatment and understanding of the nature of the hepatitis C process.
- ◆ There was also agreement that hepatitis C research in Ireland would be greatly advanced by the availability of a national independent database of those affected by the virus.

*Recommendation 10: That a national database be established for research purposes; this to be located at an independent coordinating agency and run in association with relevant groupings.*

#### *Hepatitis C: current status and service needs in the future*

##### *Current clinical status*

- ◆ Thirty-nine percent of patients in the chart review group were PCR negative. Of PCR positive patients, classification of disease severity was possible for 70%: 20% of these had chronic hepatitis C with normal ALT; 50% had chronic mild disease and 30% had chronic moderate/severe disease.
- ◆ It is likely that the longer-term prognosis in these patients, even those classified with moderate/severe disease, is good, with only a small number showing evidence of serious liver disease.

##### *Current psychological well-being*

- ◆ High levels of both depression and anxiety were identified by standardised assessment, with 26% and 35% of the group showing clinical levels of depression and anxiety respectively. These levels did not vary significantly according to route of infection.

- ◆ Those who had attended the Compensation Tribunal had a more serious depression profile than those who had not (with 32% versus 7% in the clinical depression score range). A trend was evident for anxiety scores, where scores for both groups were uniformly high (22% and 39%).

#### *Disclosure, stigma, and confidentiality*

- ◆ A third of those interviewed reported feeling stigmatised by their diagnosis of hepatitis C.
- ◆ Patients were generally satisfied with confidentiality of personal information and identity in a range of health services (86% satisfied/very satisfied).

#### *Recall patients*

- ◆ Twenty-three 'recall' patients, that is those initially tested negative for hepatitis C and recently asked to return for further testing, were included in this study; most (81%) reported alarm on being asked to retest.
- ◆ Many were unclear about the reasons for retesting, over half stating that they did not have adequate understanding of why they were being retested. Even though all had tested negative in the second series of tests, 48% still remained fearful about diagnosis of hepatitis C.
- ◆ General health and psychological well-being for this group did not differ significantly from other groups interviewed.

#### *Future service needs and concerns*

- ◆ The major concerns for all groups were for increased understanding of the course and management of hepatitis C and for guarantees regarding long-term commitment for the funding necessary to provide optimum care.

*Recommendation 11: That assurances be given that adequate funding and resources will continue to be provided to ensure a quality health care service for this patient group.*

#### **General conclusions and recommendations**

- ◆ The constituents necessary for effective service delivery including staff, facilities, protected funding, and a perceived willingness of professionals, patients, and representative organisations, appear to be in place for those infected by hepatitis C through State-provided blood products. Implementation of the recommendations of this Review should serve to promote a coordinated, comprehensive service which will optimize patient care into the future.

*Recommendation 12: That progress on the recommendations of this Review be monitored on an annual basis for three years with a report summarising progress to be completed at the end of this period. Progress to be monitored by a sub-committee of the Consultative Council on Hepatitis C.*



## REVIEW RECOMMENDATIONS

- ◆ That a committee be established to agree treatment protocols (including liver biopsy procedures and scoring, and administration of anti-viral therapy) for this particular group. The committee should comprise the medical consultants with primary responsibility for this group of patients and be chaired on a rotating basis.
- ◆ That the system whereby patients are referred by their consultant hepatologist to another specialty be regularised to facilitate Hepatology Unit staff in making priority referrals in accordance with the 'two-week' rule. A comprehensive referral system for physiotherapy should be established to ensure that it is available to all who require it.
- ◆ That guidelines be developed for the management of death, including funeral arrangements, so that the necessary safe practices are understood and accepted by all concerned.
- ◆ That health board liaison officers meet on a regular basis to ensure uniformity and continuity in the provision of primary health care services.
- ◆ That health board liaison officers ensure choice of counsellors and counselling locations in all health board areas.
- ◆ That a general training programme for all home support providers be available. This programme must have as a basis an agreed strategy regarding the balance to be achieved between duty of care to the provider and the right to confidentiality of health information of the recipient.
- ◆ That the issues surrounding the difficulty in recruitment of home support providers, including remuneration issues, be reviewed to ensure availability of the service to all who require it.
- ◆ That staff in all primary care disciplines dealing with this patient group (including general practitioners, dentists, and pharmacists) be adequately informed about both the actual risk of transmission of hepatitis C and the guidelines on universal precautions against transmission of infection; this is to ensure that such patients are treated in a sensitive manner.
- ◆ That the role of complementary or alternative therapies in the management of hepatitis C be reviewed as part of a wider framework of evaluation of the use of such therapies in the Irish health system.
- ◆ That a national database be established for research purposes; this to be located at an independent coordinating agency and run in association with relevant groupings.
- ◆ That assurances be given that adequate funding and resources will continue to be provided to ensure a quality health care service for this patient group.
- ◆ That progress on the recommendations of this Review be monitored on an annual basis for three years with a report summarising progress to be completed at the end of this period. Progress to be monitored by a sub-committee of the Consultative Council on Hepatitis C.



## Chapter 1

### INTRODUCTION AND TERMS OF REFERENCE

#### BACKGROUND

Hepatitis C is a relatively common blood-borne infectious disease. It has been estimated that 3% of the world's population is infected. Hepatitis C accounts for about 20% of cases of acute hepatitis and 70% of cases of chronic hepatitis. Its importance is that it is a major cause of cirrhosis and hepatocellular cancer<sup>1</sup>. End-stage liver disease secondary to hepatitis C virus infection is main reason for liver transplantation.

Following the discovery in February 1994 that anti-D immunoglobulin manufactured by the Irish Blood Transfusion Service Board was infected with hepatitis C, a number of screening programmes were put in place to identify those persons who had been infected, either directly or indirectly. It is estimated that about 1,600 persons have been infected with hepatitis C through the administration of blood and blood products in the Republic of Ireland.

Acute hospital services for persons diagnosed positive for hepatitis C were put in place in 1994 in specialist hepatology (liver) units at six designated hospitals: Beaumont Hospital, the Mater Hospital, St Vincent's Hospital, Elm Park, and St James's Hospital in Dublin, Cork University Hospital, and University College Hospital in Galway. More recently, St Luke's Hospital in Kilkenny has been included in the list of hospitals funded to provide specialist hepatology services. These services, provided under the Health Act (1970), are free of charge and include access to both in-patient and out-patient treatment as required.

On 23 September 1996, the Health (Amendment) Act (1996) came into effect. This legislation provided statutory entitlement to a range of primary health care services, free of charge, to persons who have contracted hepatitis C from the receipt of a blood product or blood transfusion. The services provided include general practitioner services, medicines, home nursing services, home support services, dental, ophthalmic, and aural services, as well as counselling services. At the request of the then Minister for Health, each health board appointed a liaison officer to ensure the efficient delivery of services under the Act, and to serve as a contact point for individuals and various interest groups whose members can avail of services under the Act. A Health Care Package for secondary services was also agreed between Positive Action and the Department of Health and Children in 1995. This covered entitlements to hospital treatments and sought to ensure sufficient funding, staffing, and facilities to provide high quality and appropriate secondary care services to those requiring them as a consequence of hepatitis C.

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<sup>1</sup> Marcellin P. The clinical spectrum of the disease. International consensus conference on hepatitis C (1) 1999; 1: 1-6.

## CONSULTATIVE COUNCIL ON HEPATITIS C

The Consultative Council on Hepatitis C was established by the Minister for Health in November 1996 to advise and make recommendations to the Minister on all aspects of hepatitis C, including the organisation, delivery, and on-going review of services for persons with hepatitis C. The Council may advise and make recommendations on its own initiative, or at the request of the Minister.

## REVIEW OF THE HEALTH SERVICES FOR PERSONS WITH HEPATITIS C

In 1998, the Council was requested by the Minister to oversee a major review of the health services - both secondary and primary - available to persons who contracted hepatitis C through the administration within the State of blood and blood products. The Health Services Research Centre, Department of Psychology, Royal College of Surgeons in Ireland was commissioned to conduct the review on the Council's behalf.

### **Review framework**

The Council was concerned to ensure that the health services respond efficiently and effectively to the changing needs of persons with hepatitis C. In this regard, the current review involved:

- ◆ analysis of the services currently available, including their delivery;
- ◆ recommendations on how these services could be improved (with particular regard to the need for consistency of approach across the various hospitals and health boards); and
- ◆ recommendations on services which should be provided to persons with hepatitis C.

The review involved consulting with a wide range of groups, including persons iatrogenically<sup>2</sup> infected with hepatitis C, support groups, primary and secondary care providers, and State institutions. It assessed the structures, processes, and outcomes of current health services as perceived by these groups and developed recommendations, where appropriate, aimed at providing an effective and efficient service to meet evolving needs of persons with hepatitis C. Information was collected using a variety of methodologies in the following sequence: hospital chart review; focus groups of persons infected by different routes of infection; interviews with disease-specific support organisations; an interview-based survey of specialist unit registered patients<sup>3</sup>; interviews and postal surveys with health professionals; and interviews with national policy organisations.

The review aimed to provide a first national profile of:

- ◆ the population base and health service management of persons who contracted hepatitis C through State-provided blood products;
- ◆ the view of interested parties, as specified by the Consultative Council on Hepatitis C, on current service adequacy and future service needs.

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<sup>2</sup> 'iatrogenic': where medical problems are induced by medical treatment of another condition. The term 'iatrogenic' here distinguishes those infected through State-provided blood products from persons infected through other means such as injecting illicit drugs.

<sup>3</sup> the term 'person with hepatitis c' and 'patient' are used interchangeably. As much of the discussion is about individuals' use of and views on services in the medical or health setting, the term 'patient' was considered appropriate.

Table 1.1 outlines those consulted for the review.  
Appendix 1 acknowledges the personnel consulted.

Table 1.1: Consultation process for hepatitis C services review: those interviewed/consulted for review

Location/group	Personnel consulted
<p><b>Hospitals</b> Staff of specialist units in the seven hospitals: Beaumont Hospital, Dublin Cork University Hospital Mater Hospital, Dublin St James's Hospital, Dublin St Luke's Hospital, Kilkenny St Vincent's Hospital, Dublin University College Hospital, Galway</p>	<ul style="list-style-type: none"> <li>❖ Relevant consultants</li> <li>❖ Nurses or nurse counsellors</li> <li>❖ Secretaries</li> </ul>
<p><b>Health boards</b></p>	<ul style="list-style-type: none"> <li>❖ Hepatitis C liaison officers</li> </ul>
<p><b>Primary care</b></p>	<ul style="list-style-type: none"> <li>❖ Irish College of General Practitioners</li> <li>❖ 150 randomly selected general practitioners who provided services under the Health (Amendment) Act, July 1997-June 1998 (N=86; 57% response)<sup>4</sup></li> <li>❖ Counsellors</li> </ul>
<p><b>Support groups</b> For those infected with hepatitis C through State-provided blood products – executive committees or representatives of same</p>	<ul style="list-style-type: none"> <li>❖ Irish Haemophilia Society</li> <li>❖ Irish Kidney Association</li> <li>❖ Positive Action</li> <li>❖ Transfusion Positive</li> </ul>
<p><b>Persons with hepatitis C</b></p>	<ul style="list-style-type: none"> <li>❖ Four focus groups of persons identified by national support organisations (N=28)</li> <li>❖ 373 persons invited to participate in interview (37% accepted)<sup>5</sup>; 132 persons completed interviews across seven hospitals<sup>6</sup></li> <li>❖ Review of 388 relevant hospital medical charts (99% of overall; 25% national review achieved)<sup>7</sup></li> </ul>
<p><b>Relevant national agencies</b></p>	<ul style="list-style-type: none"> <li>❖ Blood Transfusion Service Board</li> <li>❖ Expert Committee on Hepatitis C, Department of Health and Children</li> <li>❖ Health Research Board</li> </ul>
<p><b>Others</b></p>	<ul style="list-style-type: none"> <li>❖ Pathologist – specialist in hepatitis C</li> <li>❖ Epidemiological and general practice advice</li> </ul>

From these consultations, recommendations were developed to promote a coordinated, comprehensive, and accountable service ensuring the best achievable service for this unique group within the Irish health system in the coming years.

<sup>4</sup> 150 GPs contact by postal questionnaire

<sup>5</sup> interview acceptance rate: letter followed by researcher telephone contact (five hospitals) - 61%; letter with patient returning envelope to indicate consent (two hospitals) - 25%

<sup>6</sup> small proportion agreed to telephone rather than face-to-face interview because of distance to travel to centre.

<sup>7</sup> hospital-based chart review





## Chapter 2

### REVIEW METHODOLOGY

The methodology to address the areas identified in the Review Framework can be described under four main headings:

- ◆ information relating directly to the patient population, in terms of current medical status, levels of service use, and patient views on services;
- ◆ information from the secondary care (hospital) units, including interviews with unit staff;
- ◆ information from primary care services, including interviews with health board personnel; and
- ◆ information from specific individuals representing State institutions that have direct involvement with the hepatitis C issue.

### PATIENT INFORMATION

Information on patients focussed both on their clinical status (from a review of patients' hospital charts) and on patient experiences and views on services (from interviews with patients). Chart review took place in each of the seven hepatology units. Patients invited for interview were also identified through these units. Ethical approval for the study was obtained from the Research Ethics Committee of each hospital.

#### Hospital chart review

##### *Aim*

To obtain a detailed profile of the current clinical status and health service use of the hepatitis C patient cohort.

##### *Procedure*

**Hospital chart review:** Information was anonymously recorded on demographic profile, PCR<sup>8</sup> status, date(s) of liver biopsy(s), liver biopsy results, details of number of blood test and blood test results, attendance at other hospital specialties, and details of hospital admissions. A review of 25% of relevant hospital charts in each of the seven centres was conducted. Charts were randomly selected from clinic listings.

**Patient interviews:** Patient lists in the hepatology units were used to identify those invited to take part in interviews. The selection criterion used was route of infection. This was to allow for adequate representation of the views of the different groupings within the hepatitis C cohort.

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<sup>8</sup> PCR: the Polymerase Chain Reaction (PCR) test is used to find out if hepatitis C virus is in blood. It checks for generic material of the virus. A positive PCR result means that the hepatitis C virus is present in blood while a negative test means the virus is not present (although, antibodies, identified by other tests, may be present).

The aim was to interview a total of 150 individuals; 30 randomly selected people who had contracted hepatitis C through each of the following routes:

- ◆ anti-D administration ('anti-D')
- ◆ anti-D administration – those recalled following initially negative results ('recall')<sup>9</sup>
- ◆ blood transfusion for reasons other than above ('transfusion')
- ◆ treatment for renal disease ('renal')
- ◆ treatment for haemophilia ('haemophilia')

The sampling strategy was to interview a sample nationally representative of the different routes of infection so that similarities and differences across groups and the clinical implications of this could be ascertained. Patients were written to by their consultant and invited to participate in the study. Following telephone contact, those agreeing to participate were interviewed at the hospital providing their hepatitis C care. Travel expenses were paid for participation. Because of small numbers in some groups and somewhat different approaches to invitation at each centre, all identified haemophilia and renal patients nationally were invited to participate.

Interview questions were developed from separate focus group sessions held with representatives from the four patient representative organisations; the Irish Haemophilia Society, the Irish Kidney Association, Positive Action, and Transfusion Positive. In all, 28 people participated in four focus groups. Analysis of this information aimed to ensure that the concerns of each group would be reflected in interviews.

## Response rates

### *Hospital chart review*

Two hospitals required patient written consent for anonymised chart review. Forty-six percent of those invited gave permission. In other centres, 25% of all charts were randomly selected. The system of reviewing charts operated very successfully with 99% of identified charts available for review.

### *Demographic profile*

The demographic profile of chart review patients is summarised in **Table 2.1**. A total of 388 charts were reviewed across seven centres; a majority (75%) were patients who had contracted hepatitis C from anti-D, followed by transfusion (18%), haemophilia (5%), and renal patients (2%). Most were female (87%) and married (83%). Almost half (49%) worked in the home while others worked full-time outside the home (26% of the anti-D group, 50% each of the haemophilia and renal groups, and 34% of the transfusion group).

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<sup>9</sup> The 'recall' group of approximately 150 women who had tested hepatitis C positive using the ELISA test, but negative on confirmatory testing using the more sensitive RIBA test. they were recalled in Summer 1998 on the recommendation of the Expert Committee on Hepatitis C.

**Table 2.1: Demographic profile of hospital chart review patients**

	ROUTE OF INFECTION				Total N=388
	Anti-D N=289	Haemophilia N=21	Renal N=7	Transfusion N=71	
Age - median <sup>10</sup> (range)	48(26-66)	40(19-74)	47(30-72)	55(20-83)	49(19-83)
Sex (%) - male: female	0:100	81:19	71:29	61:39	13:87
Number of children -(median (range))	3(0-15)	0(0-4)	1(0-6)	2(0-14)	3(0-15)
Distance (miles) from hospital - median (range)	20(1-190)	50(5-180)	50(1-180)	30(2-180)	20(1-190)

***Patient interviews***

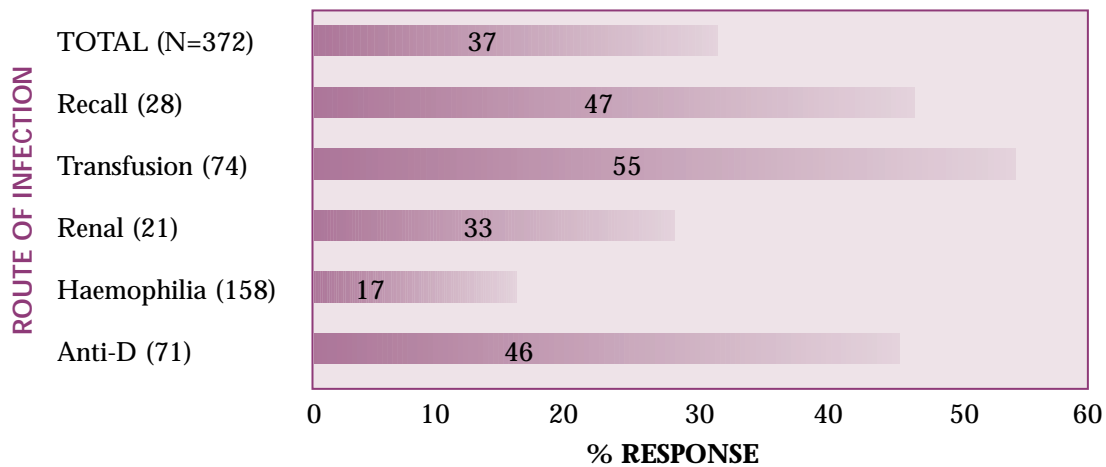
Of 373 individuals invited for interview, 139 agreed to participate, of whom 132 were interviewed during the study<sup>11</sup> (response rate: 37%). In hospitals where it was possible to telephone patients, the response rate was considerably higher than where consent to participate had to be indicated by post (61% versus 25%). Response rates are shown by group in Figure 2.1.

It was intended that interviews would be carried out with 30 people in each of the five patient groups described earlier. However, in most hepatology units, patients with renal disease were recorded as “transfusion” patients and were not identifiable as a distinct patient group. It was only possible to identify 21 individuals in the renal subgroup to whom invitations could be extended<sup>12</sup>. The result was a very small group of renal patients (N=7; 33% response rate). It was thus regrettably not possible to make reasonable comment on or statistical comparisons with the renal group, given the small numbers involved. For this reason, in much of the discussion to follow, information on the renal subgroup is combined with that of the transfusion group.

<sup>10</sup> the median is a statistical score which divides the group into halves so that half the group’s scores are on or below and half are on or above the median. Where there are very unequal balances of scores, it provides a more informative description of the group than mean (or average) scores.

<sup>11</sup> in two cases parents were interviewed on behalf of patients; a 15 year old male haemophilia patient and a 28 year old male haemophilia patient with a learning disability.

<sup>12</sup> estimates of the total numbers of renal failure patients with hepatitis C were obtained from the Irish Kidney Association; the counsellor has met with 26 patients in the course of her work while the chief executive estimated there were 34 renal patients at maximum with at least 6 others having died since diagnosis. Thus over 60% of relevant patients nationally were invited to take part in this review.



**Figure 2.1: Interview response rate by route of infection**

The demographic profile of patients who participated in interviews was statistically compared to that of the chart review. In terms of patient age, sex, marital status, number of children, and distance from hospital, there were no significant differences between groups. As the charts were randomly selected, with selection bias possible at only two centres (where patients were asked to grant permission), the similarity of the chart and interview group demographic profiles is very reassuring since it suggests that particular types of patient (for example, older patients or those living longer distances from hospitals) are adequately represented in the interview study. In short, the interview group appears to adequately represent the underlying population.

The 'recall' group is quite distinct from others in their relatively recent classification as being positive for hepatitis C and since they have had an initially positive health evaluation followed by later revision of this diagnosis. Thus they are expected to have fewer and different service interactions to date. For these reasons, this group is not included in general descriptions of primary and secondary care services in the following chapters. They are considered in comparison to other groups regarding clinical and psychological status in Chapter 6.

## SECONDARY CARE: HEPATOLOGY UNITS

In each unit, interviews were conducted with the consultant gastroenterologist/hepatologist, the clinic nurse/nurse counsellor, the clinic secretary, and the clinic counsellor, where applicable. Semi-structured interviews addressed experiences of, and views on, current service use and future need for services.

## PRIMARY CARE

Interviews were conducted with health board liaison officers, counsellors and general practitioner (GP) representatives. A nationwide survey of randomly selected GPs was completed.

### **Liaison officers**

Interviews were conducted with the liaison officer appointed to coordinate hepatitis C services in each of the eight health boards. Interviews focussed on patient numbers; requests for specific services including dental, ophthalmic, aural, home support, and counselling services; confidentiality; and views about current and future needs for hepatitis C services. Detailed information was provided on numbers registered by route of infection; numbers of children and partners registered; and the pattern of billing for counselling and home support services.

### **Counselling**

Counsellors interviewed were those employed by a hepatology unit or patient support organisation to provide counselling services to the hepatitis C blood product positive group (N=4). Interviews focussed on demand for counselling services; nature of services; number of sessions per week allocated to the counsellor; counselling needs of the hepatitis C group and their families and whether these needs have changed over time; and estimates regarding future needs of the group.

### **General practitioners**

When hepatitis C was first publically announced in 1994, GPs became the first point of contact with health services for the majority of patients who suspected they were at risk from hepatitis C. Most GPs had little experience of hepatitis C and were not briefed to deal with the demand for testing and counselling services. Two representatives of the Irish College of General Practitioners (ICGP) were interviewed regarding needs of GPs in relation to hepatitis C; communication between the secondary care hepatology units and GPs; experiences in relation to the Health Services Card; and expectations for the future in relation to service needs and the role of the GP. Following this a national GP survey was developed.

### ***Aim***

The aim of the survey was to record GP experiences with this hepatitis C patient group, focusing on current service adequacy, and future needs and concerns.

### ***Sample***

The listing of GPs who had billed for services under the Health (Amendment) Act (1 July 1997 - 30 June 1998) was obtained from the Department of Health and Children (N=548). One hundred and fifty doctors were surveyed at random from this listing.

### ***Procedure***

A self-report questionnaire was developed and piloted following consultation with GP representatives. A postal survey was conducted with written and telephone reminders. Eighty-five replies (a 57% response) were received.

## INTERVIEWS AT SPECIFIC RELEVANT NATIONAL AGENCIES

### Blood Transfusion Service Board

This interview with the chief executive officer and consultant haematologist focussed on numbers and geographic location of people infected. Effects of the hepatitis C outbreak on the routine work of the BTSB, specifically in relation to the rates of blood and organ donation since 1994, were also examined.

### Expert Group on Hepatitis C, Department of Health and Children

The chief medical officer at the Department of Health and Children was interviewed in his capacity as Chairperson of the Expert Group on Hepatitis C. This group's remit was related to recall of persons whose test for hepatitis C (as part of the 1994 screening programme) had been positive on the initial ELISA test, but proved negative on confirmatory RIBA testing. The interview focused on present and future management of recall situations in the context of hepatitis C.

### Health Research Board

The nature of infection of the Irish hepatitis C blood product positive cohort is unique in that for many individuals the date of their infection is known, and challenges to their pattern of illness progression are not complicated by other health problems such as intravenous drug use. Thus, this patient group is highly suited to studies on the natural history and course of the infection. It is also the case that those who received contaminated blood products but did not seroconvert to hepatitis C positive can be identified, as can the date of their inoculation with infected blood products. In short, Ireland has a unique opportunity to conduct research into hepatitis C that is of significant international importance. The interview with the Health Research Board chief executive and accountant focussed on HRB's currently funded research and on their perspective on the coordination of information relating to hepatitis C in the form of a national database. Views on how best to disseminate research information to both patients and professionals were also considered.

### Other professionals: consultant pathologist

A consultant pathologist was consulted regarding diagnostic services for hepatitis C. This interview focussed on the types and adequacy of tests used for hepatitis C, and on training needs for pathologists. Demands on pathology services resulting from hepatitis C to date and for the next five years were examined.

## Chapter 3

### SECONDARY CARE SERVICES

This chapter describes services in the hepatology units and other hospital-based services. Service use was estimated from hospital chart review while patient views on professional service providers and support organisations were considered from interviews.

#### POPULATION SIZE

The first issue to consider in relation to service use is the size of the population being served. Numbers registered with the seven hepatology units are presented by route of infection in Figure 3.1. The hospital numbers are likely to be an over-estimate since some patients will have attended more than one clinic. Figure 3.2 outlines the distribution of patients across health boards. The figures of patients registered with the health board liaison officers are an under-representation of numbers infected since an indeterminate number of people choose not to register for free services. Blood Transfusion Services Board numbers are lower still (N=1089) with incomplete listing, for instance, of the haemophilia group.

Differences in estimates of the population requiring services point to the need for a single agency to have responsibility for maintaining a complete count of patients in this iatrogenic hepatitis C group. This list will need to be updated through the coming years when, for instance, a large group of recall patients will be re-tested. A national register of patient names is one method of achieving this but one which may raise concerns about confidentiality. More complete information about patient numbers may assist financial planning in both current allocation of funds and in estimates of future service demand. It is to be expected that some of those patients not currently registered or using health board and GP funded services will come in to this system in the future as, for instance, their health needs increase or the stigma associated with the disorder decreases.

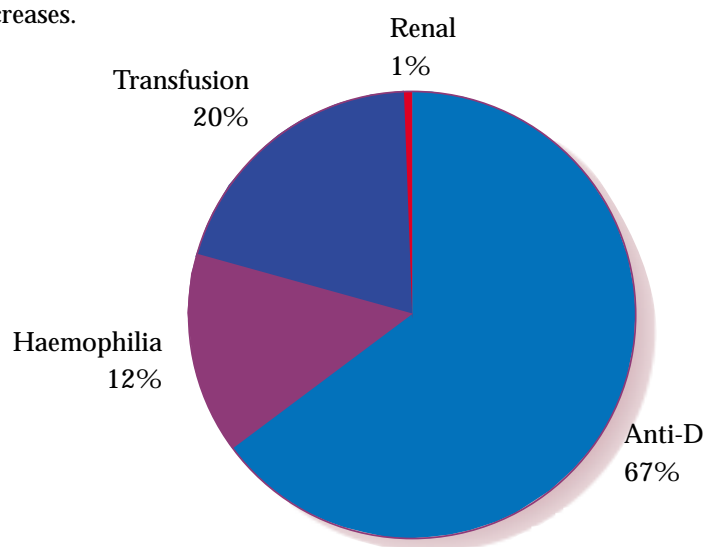


Figure 3.1: Numbers of patients with iatrogenic hepatitis C infection registered with the seven hepatology units by route of infection (N=1645)



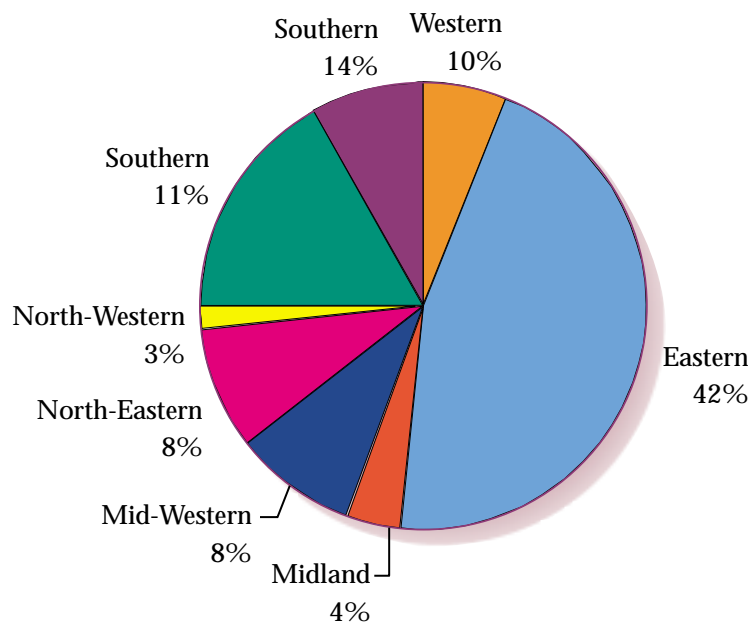


Figure 3.2: Numbers of patients with hepatitis C infection registered with health boards (N=1268)

## HEPATOLOGY UNITS: SERVICE USE AND SATISFACTION

### *Medical chart review*

The median number of visits to specialist hepatology clinics in the previous year was two with no significant difference in the numbers of visits made by the different subgroups. As expected, patients who were PCR positive had significantly more visits to the hepatology clinics<sup>13</sup>.

### *Interview study*

Patients participating in interviews were asked about the number of visits made to a hepatology clinic and about their satisfaction with the frequency of visits and with the specific hepatology unit services more generally. Two-thirds of the patients (67%) had attended the clinic for 2 or more visits in the 12-month period under consideration with about one-fifth (21%) not attending the clinic in the same period. Satisfaction with frequency of clinic visits was high (87%).

The specialist services provided are considered next.

## LIVER BIOPSY

Liver biopsy is described as the 'gold standard' test for the assessment of patients with chronic hepatitis by the US National Institute of Health (NIH) (USA)<sup>14</sup>. Disease progression has been monitored by conducting liver biopsy every two years for those considered at risk. However, repeat liver biopsies at two years have shown little histological change compared to the first results.

<sup>13</sup> PCR positive: mean number of visits: 3.04 (S.D.: 2.72). PCR negative: mean number of visits: 1.59 (S.D.: 1.72) (t=6.43, p<0.0001)

<sup>14</sup> NIH. Management of Hepatitis C. Consensus Development Conference Statement, March 24-26, 1997.

For this reason, and because of the health risks associated with the procedure, it is now considered that liver biopsies should be conducted at five year intervals. This recommendation is in accordance with the most recent (February 1999) consensus statement of the European Association for the Study of the Liver (EASL)<sup>15</sup>.

For this review, liver biopsy information was recorded as part of the chart review process and interviewed patients were asked about their experiences of liver biopsy. Liver biopsy was also addressed in interviews with health professionals and patient support organisations. Of 388 charts reviewed, there were 368 biopsies with 243 individuals (63%) having undergone at least one biopsy. More than one-quarter (27%) had undergone more than one biopsy, 22% having a second and 4% a third biopsy. Twenty-five percent of those who were PCR negative, compared with 88% of those who were PCR positive, underwent liver biopsy.

The majority (73%) of biopsies have been carried out on the anti-D group, with only 5 individuals in the haemophilia group (24%) undergoing one biopsy each. For many patients, their initial biopsy will also be their most recent. Results of the most recent biopsies are presented in **Table 3.1**. Hospital pathologists, when compiling biopsy reports, provided the disease severity classification. It is important to note that percentages relate to the percentage of the population indicated who had biopsies and not to percentages of that population as a whole. It is not possible to conclude from the information available that evidence of liver disease documented relates only to Hepatitis C<sup>16</sup>. Proportions of patients at different stages of severity of liver dysfunction do not change from first to latest biopsy.

**Table 3.1: Result of most recent biopsy by infection route and PCR status**

PCR status by route of infection (N)	BIOPSY RESULTS – SEVERITY CLASSIFICATION				
	Normal %	Mild/mild-moderate %	Moderate/moderate-severe %	Severe %	Other %
Anti-D					
PCR positive (162)	<1	80	17	1	2a, b
PCR negative (32)	22	59	6	0	13
Haemophilia					
PCR positive (5)		40	20	20	20c
PCR negative (0)					
Transfusion					
PCR positive (39)		72	15	5	8a
PCR negative (5)	20	60	0	0	20d
Total (243)	4	70	18	3	5

<sup>a</sup>no information, results not stated (N=8); <sup>b</sup>inadequate specimen (N=2); <sup>c</sup>report missing (N=1); <sup>d</sup>results not available at time of review (N=1).

<sup>15</sup> European Association for the Study of the Liver (EASL) Consensus Statement, EASL International Consensus Conference on Hepatitis c. *Journal of Hepatology* 1999; 30:956-961.

<sup>16</sup> Kay E, O'Dowd J, Thomas R et al. Mild abnormality in liver histology associated with chronic hepatitis: distinction from normal liver histology. *Journal of Clinical Pathology* 1997; 50:929-931

Outcome of liver biopsy by disease status is outlined in **Table 3.2**. Test results from both the haemophilia and transfusion groups have evidence of more advanced liver disease; 20% and 21% respectively have evidence of cirrhosis when compared with 6% for the anti-D patient group. However, as detailed previously, there are differences in the proportions in each patient group who have had a biopsy. The small percentage of biopsies for haemophilia patients, given the particular difficulties of risk of bleeding associated with undergoing liver biopsy for the haemophilia group, mean that it is more likely that those who undergo the procedure have strong clinical indicators for biopsy, in terms of more advanced disease. If it was assumed that those not tested have no evidence of disease, then proportions with evidence of cirrhosis would be quite different at 4% (anti-D), 5% (haemophilia), and 10% (transfusion).

**Table 3.2: Evidence of disease status in biopsy reports, by route of infection and PCR status**

PCR status by route of infection(N)	Numbers having biopsies	EVIDENCE OF DISEASE				
		Hepatitis	Necrosis	Fibrosis	Cirrhosis	Cancer
Anti-D						
PCR positive (164)	162	99	61	43	4	0
PCR negative (125)	32	69	30	27	2	3
All anti-D	194 (67%)				6	
Haemophilia						
PCR positive (14)	5	80	60	60	20	0
PCR negative (7)	0					
All haemophilia	5 (24%)				20	
Transfusion						
PCR positive (57)	39	100	49	46	21	0
PCR negative (21)	5	60	40	20	0	0
All transfusion	44 (56%)				21	
Total (N=388)	(243)	(231)	(131)	(99)	(18)	(1)
%	63	95	54	41	7	0.4

Conclusions about overall disease status and disease progression are discussed further in Chapter 6.

### ***Liver biopsy: patient interview information***

Liver biopsy is considered a stressful medical procedure both because of the invasive nature of the procedure and because of the possibility of negative long-term implications of test results. This section reviews patient experiences of biopsies including satisfaction with treatment.

### ***Overall satisfaction with management of liver biopsy***

Most patients (77%) were satisfied with their overall experience of biopsy. This finding did not differ significantly across patient groups. However, 17% expressed dissatisfaction.

### ***Opportunity to prepare for, and recover after, biopsy***

The Health Care Package (1995) allows for inpatient stay before and /or after biopsy tests to facilitate patient preparation for, and recovery from, the procedure. In this group, the largest proportion (45%) spent only the night after biopsy in hospital, closely followed by the number of patients spending overnight the night before and after in hospital (32%). All haemophilia patients had at least two nights in hospital for the procedure.

The majority of patients (84%) were satisfied with the length of time spent in hospital for biopsy, with no significant differences across patient groups. Satisfaction with liver biopsy management did not vary significantly according to length of time spent in hospital.

### ***Location in hospital for biopsy admissions***

The Health Care Package (1995) specifies that hepatology units should have a designated ward area for patients admitted for testing, treatment, or biopsy. In five hospitals one bed is protected for this group. Another hospital has two beds reserved, if required, while the remaining hospital is still in the process of establishing services. Half of the group interviewed here (51%) were admitted to a designated hepatology ward area; however, a large proportion of patients (41%) were admitted to a general day ward.

The majority of patients (76%) were satisfied with the area to which they were admitted for biopsy. This did not vary significantly across patient groups. General satisfaction ratings did not vary significantly according to type of ward. However, extreme dissatisfaction was expressed by a much higher proportion of those staying in a general day ward compared to a designated hepatology ward (30% versus 3%).

High levels of satisfaction were also indicated regarding communication aspects of the patient experience of liver biopsy. A majority of patients were satisfied with the knowledge and expertise of staff associated with their biopsy (94%), information received regarding biopsy results (78%), and the manner in which results were communicated (83%).

### ***Patient proposals about improving liver biopsy procedure***

When patients were asked about how the experience of liver biopsy could have been improved, a preference for more privacy was the most commonly quoted suggestion (19%). Nine patients (14%) wanted more information about the procedure and 11% wanted more support from staff while in hospital for biopsy.

## Interviews with Professionals

### Consultant hepatologists

Discussion with consultant hepatologists in relation to liver biopsy focussed on their approach to communicating biopsy results to patients. Without exception, consultants said they communicated biopsy information to their patients with verbal descriptors rather than scores. Consultants reported being subjected to considerable pressure from legal counsel involved in the Compensation Tribunal to provide scores from biopsies since information in the form of a score was seen to have greater meaning in the Tribunal context than a verbal description. However, in the clinical context, the consensus was that there is a considerable margin of error in current biopsy scoring techniques. The concern was about providing biopsy score information to patients, such that patients may perceive a change in liver status based on test scores, when in fact the pathologist and hepatologist are satisfied that the patient's status is stable. Biopsies taken from different parts of the liver at the same time may yield different test scores. For this reason, all hepatologists stated that they give biopsy results to patients in terms of 'mild', 'moderate', or 'severe', and then outline the significance of the result in terms of current status and prognosis. Information is subsequently sent GPs in the same way.

### Consultant pathologist

Irish pathologists involved in the examination of hepatitis C-related tests met regularly for some time following the 1994 announcements to determine protocol and procedures for the monitoring of hepatitis C infection. It was agreed at these meetings that liver biopsy scores should not be provided by pathologists in routine reporting of biopsy results.

It is interesting to note the high levels of patient satisfaction with information on biopsy results (78%) in a context where consultants uniformly do not provide numerical results. This occurs alongside very differing opinions about the necessity for communication of numerical biopsy results across support organisations.

## Patient Support Organisations

Representatives noted differences between units in how biopsy procedures are managed. For instance, in some hospitals, patients are admitted fasting, have the biopsy, and are released the following day; in others, patients are admitted the night before and discharged the next day. There was concern that patients may be discharged too quickly<sup>17</sup>. A number of issues were raised regarding communication. A booklet about the procedure was recommended as necessary to fully inform patients.

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<sup>17</sup> Recently published recommendations advise that patients can be discharged home after six hours if there are no complications and if the patient has a 'responsible person' to stay with on the first post-biopsy night and is able to return to hospital within 30 minutes if necessary (Grant a. and Neuberger J. Guidelines on the use of the liver biopsy in clinical practise. Gut 1999; Suppl. IV: IVi-IVxi.

## TREATMENT WITH INTERFERON

Treatment of active hepatitis C has been with interferon. Information on combination therapy with ribavarin is less common than treatment with interferon alone to date.

### Interferon: chart review information

Of 388 charts reviewed, 18% had records of treatment with interferon therapy; two patients had combination therapy. Of those receiving interferon, 31% continued treatment for 3–6 months, 44% for 7–12 months, and 13% for more than 12 months. Two percent of patients were unable to tolerate treatment for the minimum recommended three months and discontinued.

The outcome of interferon treatment is presented in **Table 3.3**. For 47%, hepatitis C status did not change following treatment and for a further 25%, initial response to treatment was not sustained. Thus, sustained benefit from interferon therapy was present in 26% of patients undergoing treatment.

**Table 3.3: Outcome of interferon treatment**

	Treatment not tolerated (%)	No change (%)	PCR negative status maintained (%)	PCR negative status achieved but relapsed (%)	No information %
Route of infection (N)					
Anti D (38)	0	40	32	28	4
Haemophilia (6)	0	100	0	0	0
Transfusion (16)	6	44	25	25	0
Total (60)	2	47	26	25	0

### Interferon: patient interview information

The majority of patients (70%) for whom anti-viral therapy was an option felt they had been offered a choice as to whether or not to undergo treatment. However, 18% did not agree. Where lack of choice was reported, it involved both patients feeling a requirement to participate in treatment as well as patients feeling they had not been offered treatment.

Provision is made for a stay in hospital of up to five nights when interferon is initiated under the terms of the Health Care Package (1995). Thirty-eight percent of those who had undergone interferon treatment reported being offered the opportunity to stay in hospital while 62% had not. Most patients (66%) did not spend a night in hospital; 13% stayed one night with 12% staying five or more nights.



For those who underwent interferon treatment, a majority of patients (63%) felt that they had been fully informed about the process of undergoing interferon therapy. Somewhat fewer (55%) felt that they had been adequately informed about the side-effects of treatment. Twenty-three percent felt that they had been given conflicting advice about receiving interferon from health professionals. Approximately 20% of those interviewed were ambivalent about the information and advice they were given in relation to interferon, with 20% dissatisfied with the information and advice given. A majority of the group (77%) reported being satisfied with medical care while on treatment. However, satisfaction levels were considerably lower (40%) in relation to counselling support available from the medical team while on treatment.

Twenty interviewed patients had declined interferon treatment. Patients who had declined treatment were asked to indicate their satisfaction with the knowledge and expertise of the medical staff and the medical and counselling support available to them following their decision. There was little reported dissatisfaction (5-9% respectively) but a majority (52-58%) were ambivalent about support received.

### **Patient Support Organisations**

Patient difficulties in choosing and fully understanding what is involved in interferon therapy were reiterated in support organisation interviews. Representatives felt that individuals were not being fully informed of the side-effects and potential long-term effects of treatment for hepatitis C. Written information was seen as a useful component of overall care for patients undergoing interferon. The need for adequate support during commencement of therapy was stressed. Regular contact at home, particularly to assist regarding side-effects, was seen as important for continuity of care. Support organisation interviews highlighted a sense of pressure being brought to bear on people to undergo treatment. This was seen to emanate in part from a belief that patient response to interferon treatment could be an important consideration in deciding financial settlement in the Tribunal of Compensation.

### **Interviews with Professionals: Secondary Care Providers**

Centres reported offering patients the option of admission to hospital when commencing treatment. However, their experience was that most patients opted not to stay overnight. Therefore, the majority of patients commenced on interferon as out-patients.

Overall, the perception of clinic staff was that the current service in relation to interferon was operating satisfactorily. Concern was expressed, however, about the anticipated demand on clinics by increasing numbers commencing treatment, particularly as use of combination therapy becomes more widespread. Unless resources are made available to cater for this increased demand, clinic staff anticipated difficulties in maintaining a quality service. The mismatch in perceptions of service adequacy between patient and advocate groups and those of professionals is cause for concern, particularly given the challenging course of interferon therapy for the patient involved. This may become more critical given that the upcoming treatment choice – combination therapy with ribavirin – can be even more difficult to tolerate. It is therefore

important that challenges facing those on anti-viral therapy, in particular management of side-effects, be monitored on an ongoing basis.

Biopsy and anti-viral therapy are two key aspects of the management of this patient group and as such require ongoing evaluation.

*Recommendation 1: That a committee be established to agree treatment protocols (including liver biopsy procedures and scoring, and administration of anti-viral therapy) for this particular group. The committee should comprise the medical consultants with primary responsibility for this group of patients and be chaired on a rotating basis.*

## OTHER HOSPITAL AND SPECIALIST SERVICES

Thirty-six percent of interviewed patients had another chronic illness besides hepatitis C (and their index condition, i.e. haemophilia or renal disease). A profile of use of other hospital specialties was documented from the review of charts. The service to which the highest number of referrals was made was rheumatology; 9% of the group having had a referral to this specialist area. Referrals to specialist gynaecology and ophthalmic services followed rheumatology (5% to each). Overall use of specialist services by this patient group was low especially considering the prevalence of other chronic illness.

Valid quantification of patient satisfaction with specialist services aside from specialist hepatology services was not possible since such a wide variety of services was used.

### Hospital admissions

Fifty-four people had one admission to hospital in the 12 month period examined in the chart review. A further seven had two or more admissions (16% of admissions in total). Of those having hospital admissions in the year, 57% were anti-D, 33% were transfusion and 10% were haemophilia patients. Thirty-one hospital admissions were for liver biopsy and two for commencement of interferon therapy. The remainder were primarily short-term admissions for investigations.

Staff at all centres were concerned about the availability of physiotherapy services, particularly into the future. Current scarcity of physiotherapy services in hospitals was seen as particularly problematic for rheumatology services as the most used other specialty by the hepatology units. Regular access to physiotherapy where needed was also seen as problematic if available only at hepatology unit locations. Allowance for provision of physiotherapy services at community level, including use of services of chartered physiotherapists in private practice, could increase access to services both in number and proximity.

Priority access to other specialist services is via the 'two-week rule'. The 'two-week rule' refers to the specification in the Health Care Package (1995) that individuals infected with Hepatitis C via State-provided blood products "will be given a priority appointment within two weeks for the first consultation". Details of the regulations have been circulated to medical consultants by



some health boards and hospitals. There were problems with the implementation of this recommendation in most hospitals. Most problems were reported as relating to the fundamental principle of operating a different system for this group of patients. When referral worked well, this often depended on good working relationships, for instance among secretarial staff, in these services. Thus there can be a reliance on relationships rather than on systems.

*Recommendation 2: That the system whereby patients are referred by their consultant hepatologist to another specialty be regularised to facilitate Hepatology Unit staff in making priority referrals in accordance with the 'two-week rule'. A comprehensive referral system for physiotherapy should be established to ensure that it is available to all who require it.*

## MANAGEMENT OF DEATH

The management of death and of the remains of the deceased person was raised by professionals and support organisations since there was seen to be confusion regarding regulations concerning management of persons with hepatitis C following death. There was concern to ensure that hospital and funeral practices should be guided by clearly stated and evidence-based protocols rather than by individual preference or custom. Such a protocol should serve to reduce anxiety, where this might be a concern, for funeral workers and should also serve to prevent inappropriate and insensitive management of this particularly difficult issue for the individuals concerned and/or for their families.

*Recommendation 3: That guidelines be developed for the management of death, including funeral arrangements, so that the necessary safe practices are understood and accepted by all concerned.*

## Chapter 4

### PRIMARY CARE SERVICES

Primary care services for this group are coordinated by health board liaison officers. These liaison officers, one in each health board, were specifically appointed to oversee the implementation of the Health Care Package (1995).

#### The liaison officer role

This role was established to enable efficient delivery of many primary care services including access to Health (Amendment) Act (1996) services. The positions have required a dual educational role of informing health board associated personnel of entitlements under the Health (Amendment) Act (1996) and of developing literature and clarifying requests from those eligible for services under the Act. It appears to have worked well from the perspective of liaison officers themselves. The view from health professionals and support organisations has been extremely positive with liaison officers seen as ‘brokering’ a link between anxious individuals and an unwieldy system. Indeed the liaison officer role was seen as one of the strengths of the system developed to support this particular group of patients following from their iatrogenic infection. The continuing contribution of this group was seen as important.

*Recommendation 4: That health board liaison officers meet on a regular basis to ensure uniformity and continuity in the provision of primary health care services.*

### COUNSELLING SERVICES

#### The role of counselling services

Counselling is a key concern regarding services for hepatitis C. International research has shown high levels of psychological distress among patients with hepatitis C. Counselling has been seen as an appropriate service to make available in Ireland given the psychological demands of coping with the health consequences of infection with the virus, combined with the effects of being iatrogenically infected and discovering about one’s infection in the highly-charged environment of significant media and political attention. The importance of this service is emphasised by its specification in detail in the Health (Amendment) Act (1996) documentation.

#### Counselling service provision by hepatology units

Patients needing psychosocial services over and above the support provided by medical and nursing staff were served by a varied arrangement of options across units. As with other medical patients, patient files for psychiatric referrals are recorded and stored separately from general medical records. It was not possible to ascertain the number of psychiatric or clinical psychology appointments availed of as part of service use by this group. Of 388 medical charts reviewed, there was some mention of counselling in 15% but even here it was not clear if counselling was simply considered, was discussed with the patient or was scheduled. For the future, availability of this information, especially regarding decisions to refer and use more specialist psychological and psychiatric services, will be important if patterns of serious psychological or neuropsychological problems are to be monitored.

### Counselling service provision in primary care

Service provision on a health board basis is organised by boards identifying lists of qualified counsellors and reimbursing patients for services availed of through them. Uptake of these services across health boards is reimbursed by liaison officers and is presented in **Figure 4.1**.

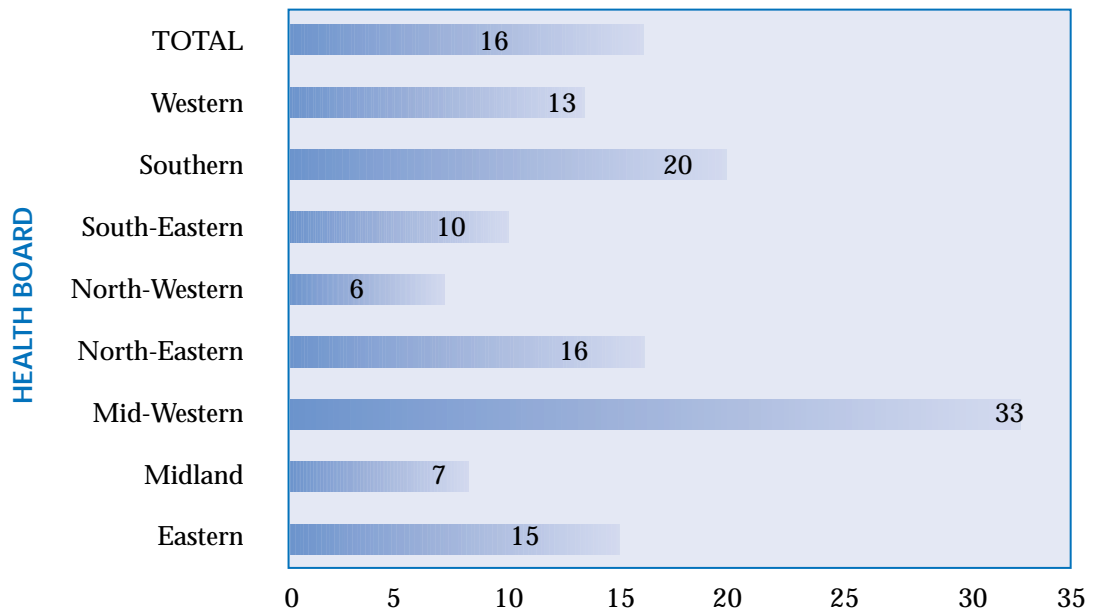


Figure 4.1: Counselling services funded by health board through the liaison officer system

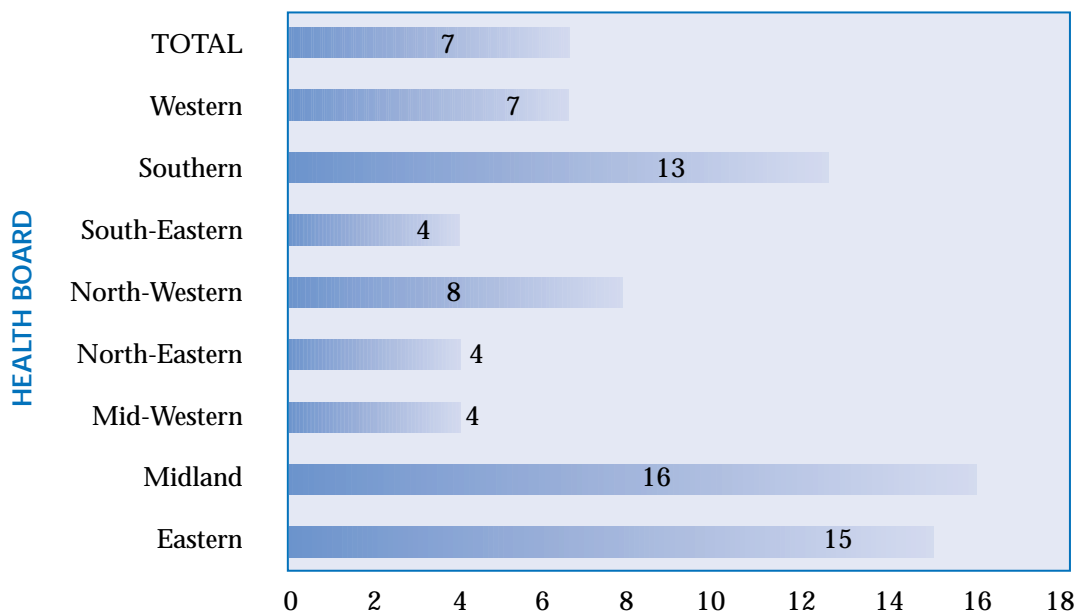


Figure 4.2: Average number of counselling sessions provided by health boards

Two-hundred and four patients (16%) availed of 1,457 counselling sessions in the year with 20 relatives availing of an additional 38 sessions (July 1997-June 1998). A total of 44 counsellors provided services across the health boards. **Figure 4.2** outlines session use across boards. General practitioners may provide counselling as part of their broad service provision for patients. Twenty-three percent of visits to surveyed GPs were for general counselling by the GP while another 8% of consultations were to provide administrative support for patients availing of specialist counselling services.

Three of four support organisations had specific organisational resources for counselling. Counsellors were already employed by the Irish Haemophilia Society and Irish Kidney Association; organisations which had been in existence for up to three decades before the announcement of this hepatitis C issue. Apart from formal counselling, a number of informal groups and activities exist which provide support to individuals. These were hospital or support organisation based. Counselling services were available and accessible from a number of health settings: hepatology centres, health boards and general practitioners, as well as patient support groups who could recommend counselling services.

#### Perspectives on and experiences of counselling services

Explicit access to, and provision for, counselling services in the context of a physical disorder is a departure from the usual experience of most Irish health professionals and administrators. This is especially so on the scale allowed for in this situation. The views of health professionals and those facilitating access to the services are all the more interesting in this context. The general view of health professionals and support organisations was that counselling as a service was working well. Regarding the functioning of counsellor lists, they were seen to work well in most settings with general agreement that the services provided and the staff providing them were of high standard. In some health board regions, coverage was seen to be available but with

little or no choice of counsellor or location of service. The psychiatric setting was seen as an inappropriate location for service by some patients and support organisations.

*Recommendation 5: That health board liaison officers ensure choice of counsellors and counselling locations in all health board areas.*

#### Acceptability of counselling and associated services

Patients were often seen as reluctant to avail of counselling but the general experience of staff was that patients who did seek counselling were glad in retrospect that they had. A view widely expressed was that counselling service independence from the Blood Transfusion Services Board has made for a more acceptable counselling service in recent years.

In total, 51% of the sample availed of counselling at some time since diagnosis. There were no significant gender differences in proportions of those availing of counselling services; 53% of women and 45% of men availed of services.

Of those who had availed of counselling services, a majority (75%) also intended to use these services in the future. This is noteworthy since it might be perceived that individuals not otherwise requiring or desiring counselling may have attended previously as part of their Compensation Tribunal preparation and would not wish to continue with service attendance in the future.

Most of those who used services rated them as being of high quality (82%). A significant minority however were dissatisfied (18%) (see **Table 4.1**).

**Table 4.1: Problems encountered regarding counselling for those availing of services**

Problem	Major problem (%)	Minor problem (%)	No problem (%)
Initial reluctance to attend counselling	26	31	43
Distance required to travel to the service	22	20	58
Actual location of the service	15	11	74
Waiting time to get an appointment	18	7	75

The most common problem in attending counselling; reluctance, was evident in similar percentages (57%) across patient groups<sup>18</sup>. Reasons for not attending counselling included patients feeling they had no need for the service (68%), that the services were inconvenient for them (10%), that services were not offered (13%), and a belief that the

<sup>18</sup> ( $\chi^2=1.13$ ,  $df=4$ ,  $p=0.89$ , i.e. no significant difference across groups).

not of high quality (9%). Thus most people not using services did not wish to do so despite availability.

In conclusion, counselling services were generally seen as working well by both providers and users.

## HOME SUPPORT SERVICES

The Health (Amendment) Act (1996) provides for “home help services within the meaning of Section 61 of the Health Act (1970) to be provided free of charge to persons who contracted the hepatitis C virus through State-provided blood products. This enables people to avail of home support<sup>19</sup> services. Although no limit on service use is specified, there exists a working definition of a maximum of 20 hours per week. The views of professionals, support organisations, and patients on this service are outlined.

Home support services are generally managed through the health board liaison officers. The issue of who provides home support is unique to this patient group. In all other circumstances, home support is provided by individuals employed by the health board. However, those holding a Health Services Card have the option of appointing their own home help. At present, 62% of those availing of home help services have nominated their own home support. Availing of home support raised challenges for patients regarding confidentiality of their diagnosis of hepatitis C, and health board challenges regarding training, safety, and direct employment of those providing the service.

There is a strong argument that the home support provider does not need to know the health details of the person concerned as firstly, it does not impinge on the service required, and secondly, the person availing of the service is entitled to confidentiality regarding health matters. On the other hand, health boards have a duty of care both to the patient and to the person providing home support. Health and safety may not be an issue if proper training for infectious disease control is provided to people working as home supports. Very little training is currently given to home support providers; at minimum training should be provided in universal precautions regarding infectious diseases.

*Recommendation 6: That a general training programme for all home support providers be available. This programme must have as a basis an agreed strategy regarding the balance to be achieved between duty of care to the provider and the right to confidentiality of health information of the recipient.*

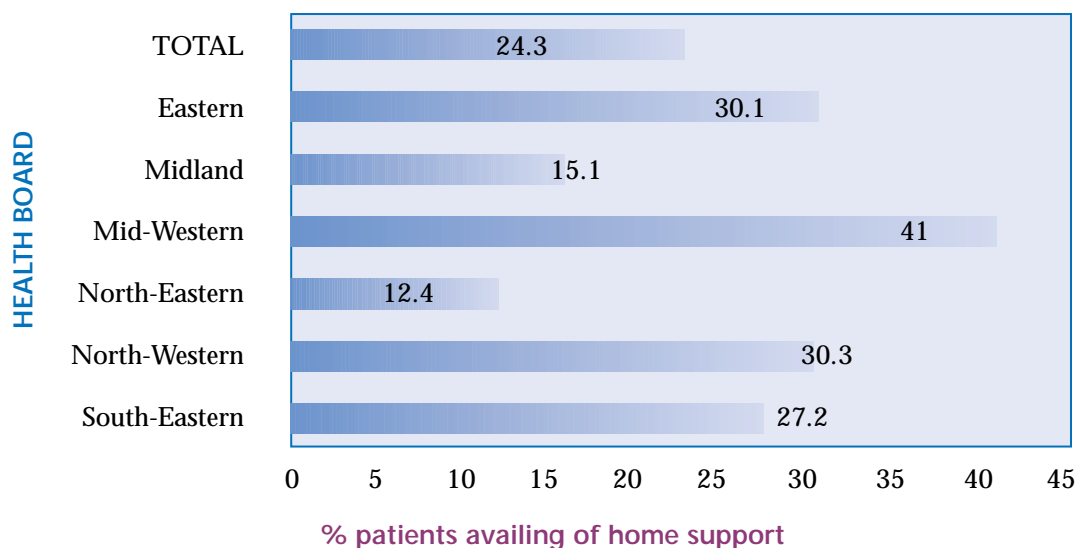
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<sup>19</sup> use of the term ‘home support’ was advised to distinguish this service and its different conditions of operation from the general ‘home help’ service.

Different rates of pay across health boards have created difficulties<sup>20</sup>. In situations where the person has chosen to pay the home support provider directly, they adopt the role of employer and, as such, become liable for PRSI payments and also for insurance liability for the individual.

*Recommendation 7: That the issues surrounding the difficulty in recruitment of home support providers, including remuneration issues, be reviewed to ensure availability of the service to all who require it.*

Liaison officers provided detailed information to the Review on use of home support services in their health board area for the 12 month period from 1 July 1997 to 30 June 1998 (this is summarised in **Figure 4.3**). In total, 24% of this patient population availed of home support services. Of those, the average time per week availed of was 9.7 hours (see **Figure 4.4** for use across boards). If these figures were applied across the overall population of people with iatrogenic hepatitis C infection, home support requirements at present amount to an average weekly requirement of 1.5 hours per person. The potential for an increase in demand for home support in the future is substantial (18.5 hours per person infected per week or more than twelve times the current level of use if a working upper limit of 20 hours per week is considered). Liaison officers endorsed the view that there is likely to be a significant increase in demand for home support services in the future, based on people becoming older and/or ill. What is most striking about these figures is the very low uptake of a discretionary service some four years after it was made available.



**Figure 4.3: Patients availing of home support services by health board (July 1997 - June 1998)**

<sup>20</sup> a national system of payment of £4.40 per hour for home support providers was announced by the Government in November 1999.



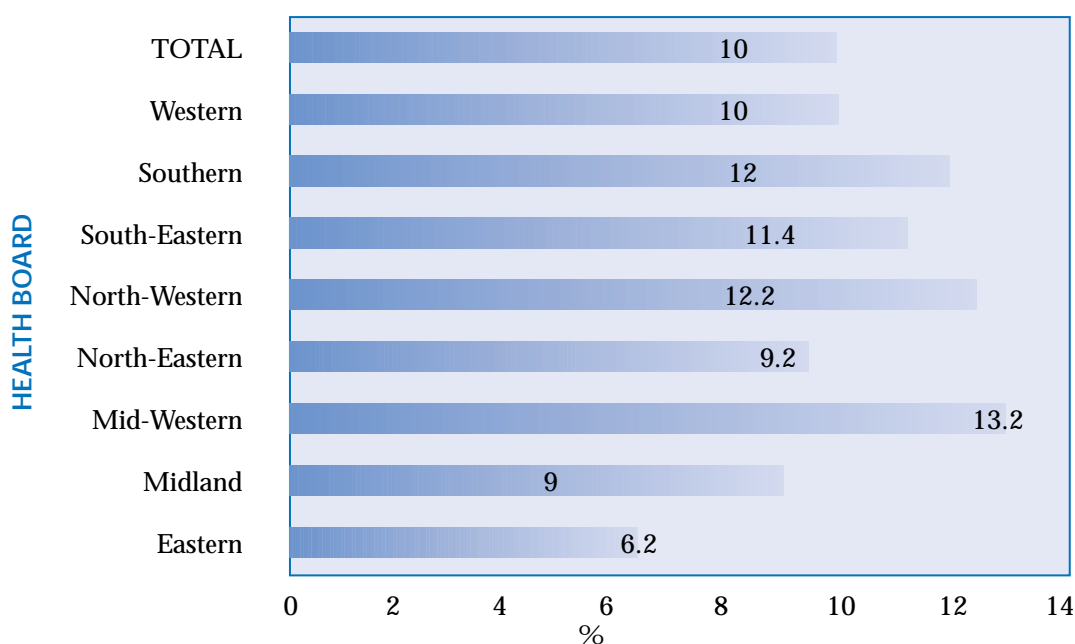


Figure 4.4: Average hours of home support availed of by patients per week by health board (July 1997 - June 1998)

Overall, 20% of the population surveyed had been offered home support services. Somewhat more than that (25%) had availed of the service at some time, with a further 16% stating that they would like to avail of the service in the near future, but were not currently doing so. It is noteworthy that 59% neither use nor intend to use these services in the near future (see **Figure 4.5** overleaf). Of those not availing of home support, a majority (76%) said they were not accessing the service because they had no need for it. A further 12% said they lacked information about the service, while 3% had encountered difficulties with health boards. Nine percent of patients interviewed said they saw the service as a threat to their privacy. Most of those who had availed of home support reported a high level of satisfaction with the service (87%). Nonetheless, a sizeable minority (18%) reported being quite/extremely dissatisfied.

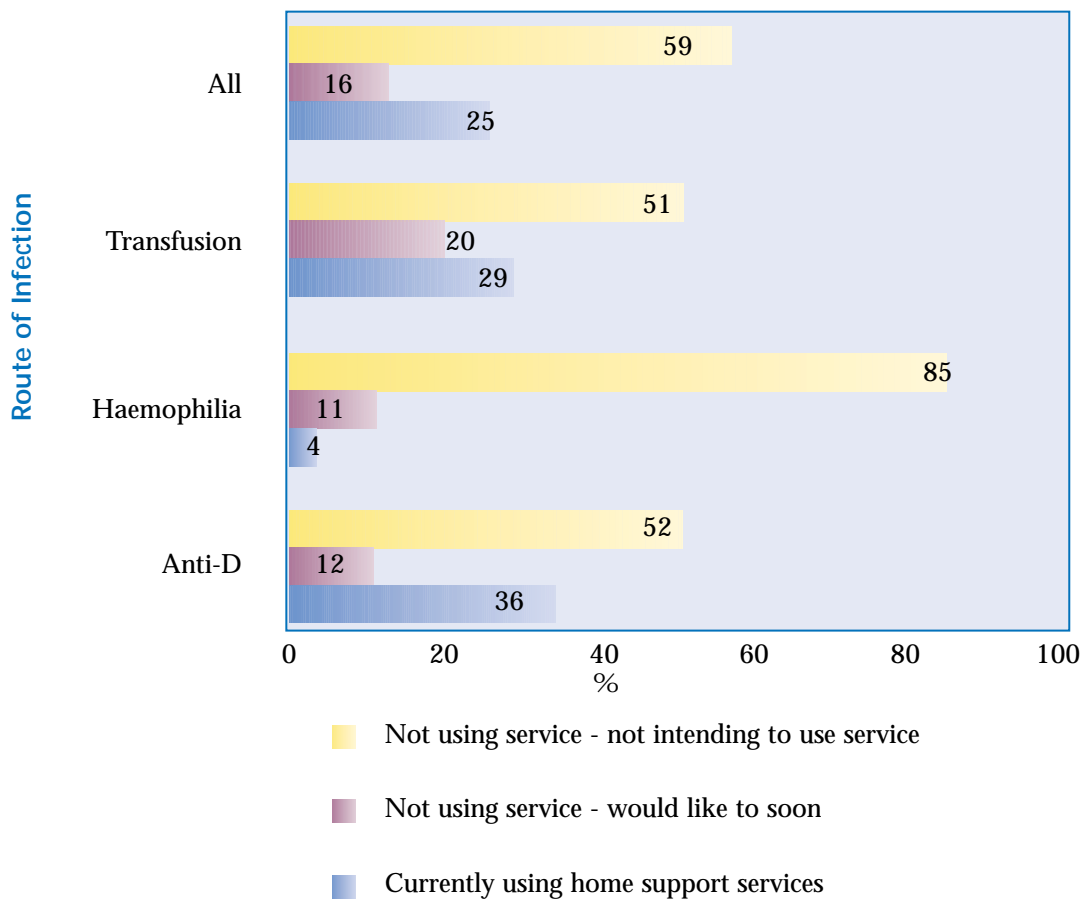
## GENERAL PRACTITIONER SERVICES

### Background

There was wide acknowledgment of the difficult position that GPs were placed in following the sudden announcement of the hepatitis C issue in 1994. The dilemma facing the Department of Health and Children and the implications of the decisions taken have already been addressed in the Report of the Expert Group on the Blood Transfusion Service Board (1995)<sup>21</sup>. Its relevance here relates to its impact on current GP service provision and the perception of same by GPs and others. The GP-patient relationship was seen to have been exposed to potential damage

<sup>21</sup> This will provide an estimate but there are an indeterminate number of cases (see section concerning liaison officers) where eligible patients have not applied for a Health Services Card, either paying directly by themselves or perhaps availing of a pre-existing medical card eligibility.





**Figure 4.5: Current and Estimated future use of home support services by route of infection**

following the hepatitis C announcement in 1994 when GPs were not provided with up-to-date advice for some days after the news release – days in which they may have found it difficult to inform anxious patients in a manner they would have desired. Subsequent GP visits could, it was felt, be seen by GPs, patients, and others as an attempt by those affected to increase their cases for compensation in the Tribunal. Thus there were ongoing challenges to maintaining or developing a good relationship with a GP which were outside the control of both patient and GP.

#### GP provision of and views of services

There were very differing views on current GP interest in involvement with this group of hepatitis C patients. On the one hand, it was believed that GPs feel ‘out of their depth’ and would prefer to leave care to specialists while patients ‘want to see the consultant’; on the other hand, hepatitis C was seen as one of many relatively rare conditions managed by GPs who can avail of specialist information while providing care in the wider context of the patient’s family, background and aspirations.

The level of service provision by GPs to this group was considered by examining the number of medical consultations billed to the General Medical Services (Payments) Board within the provisions of the Health Services (Amendment) Act through the Health Services Card<sup>22</sup>. Between

1 July 1997 and 30 June 1998, 576 doctors billed for services provided. A total of 7308 consultations were billed for (average: 12.7 [SD 14.3] per doctor; median 8 [range 1-103]).

From the national GP survey, 73 GPs currently cared for 152 patients with iatrogenic hepatitis C infection with 19 having a total of 104 patients infected with hepatitis C through other routes. Most clinical contact was for routine care (30%), GP counselling (23%), and administrative support to access specialist services (15%). The majority of GPs (86%) had experienced no difficulties with their patients' use of the Health Services Card.

### Patient views of GP services

Almost all patients interviewed (95%) had a GP whom they attended regularly. Most patients (72%) used the GP service for all health problems, whereas others visited their GPs only with non-hepatitis C related concerns. Difficulties with GPs were reported by 19% of patients, with 19% having changed GPs since diagnosis. Current GPs were seen as adequately informed about hepatitis C by 62% of patients. Levels of general satisfaction with GPs were high with 89% reporting being quite or very satisfied and with little variation across routes of infection. This level is somewhat higher than reported in a large recent study of public satisfaction with GP services in two health boards (81%)<sup>23</sup>. It illustrates a satisfactory match between patient expectation and GP service provision at present despite earlier difficulties for this hepatitis C group.

## DENTAL SERVICES

There has been confusion about dental service eligibility for this group in the past. The situation is now viewed as much improved with information provision through the principal dental surgeon network to colleagues clarifying eligibility criteria.

Most patients interviewed (83%) reported experiencing difficulties with dental services since diagnosis, with many (28%) changing dentists. Sixty-four percent felt their current dentist was adequately informed about hepatitis C. Support groups were concerned that dental decay resulting from medications taken for related conditions is not currently covered in the services provided. Because of this, they felt that service coverage should be at least the same as that available through PRSI<sup>24</sup> eligibility.

A small number of dentists have been reported as unwilling to treat this group. This has been managed at health board level by the creation of lists of dentists actively participating in the scheme. This was seen as a source of stigma for patients. Most stigmatising for patients was being seen 'last on the list'. This applied in a number of settings including dental care. While some individuals found this practice acceptable - provided there was adequate and sensitive explanation - there was a sense that it was a measure over and above the necessary, which again

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<sup>22</sup> this will provide an estimate but there are an indeterminate number of cases (see section concerning liaison officers) where eligible patients have not applied for a Health Service card, either paying directly by themselves or perhaps availing of a pre-existing medical card eligibility.

<sup>23</sup> Millar M. Patient satisfaction with general practice in Ireland. Irish Medical Journal (in press).

<sup>24</sup> PRSI: Pay related State-funded service to those paying insurance in employment.

people found stigmatising. Nine percent of patients reported extreme dissatisfaction with their dental services while another 10% were quite dissatisfied - a high level of overall dissatisfaction compared with GPs (9%).

## OPHTHALMIC AND AURAL SERVICES

Eye testing is covered under the Health Services Card with a contribution of £30 towards frames. While there is no waiting time for the Sight Test Scheme, essential in-hospital treatment (although unusual to date) was associated with long delays. Most patients interviewed for the study (72%) had visited an optician since diagnosis of hepatitis C. Few had difficulties with these services. General levels of satisfaction with these services were high (only 7% dissatisfied).

There have been very few requests for funding of aural services. However, the cost of hearing aid provision has been noted as considerable should demand increase.

For all of the above (dental, ophthalmic and aural services), health board liaison officers felt that services were being used in proportion to need.

## PHARMACY SERVICES

The majority of patients interviewed (91%) regularly used a local pharmacy. Nine percent however used a pharmacy at a distance from their homes, mostly for the purpose of protecting their privacy. When asked about the possibility of being identified as a Health Services Card holder on a nationwide computer database, 50% of patients said that they would find this either 'very helpful' or 'helpful'; another 46% had 'no opinion' on this issue. In general, pharmacy services were seen as discreet in their service provision (11% having concerns). Somewhat more were concerned about being seen using the Health Services Card (30%). Levels of satisfaction with service provision were very high with 7% reporting dissatisfaction.

*Recommendation 8: That staff in all primary care disciplines dealing with this patient group (including general practitioners, dentists, and pharmacists) be adequately informed about both the actual risk of transmission of hepatitis C and the guidelines on universal precautions against transmission of infection; this is to ensure that such patients are treated in a sensitive manner.*

## COMPLEMENTARY THERAPIES

The use of complementary therapies is part of a wider development in health service use. Although national Irish data is unavailable, about one-third of all American adults are reported as using unconventional or complementary medicine in any given year<sup>25</sup>. Users are typically younger, more educated, and in higher income categories. Of those visiting doctors for medical conditions in a national US survey, 28% also used some complementary treatment with most of these (72%) not reporting this to their doctors. The use of alternative or complementary therapies was of considerable interest to this Review. Such therapies can be used both for their direct effects on ill-health and for management of symptoms. In the hepatitis C setting, complementary therapies are not funded by the Health Services Card and there are differing views regarding both the appropriateness of such services and their funding.

Twenty-two percent of the interviewed group had tried complementary therapies. No single form of complementary therapy was particularly predominant (e.g. 7% had used aromatherapy, 6% massage, and 6% Chinese herbal medicine). Most consultants (consultants of 62% of all those who had tried complementary therapies) were aware of their patients' use of complementary therapies and most consultants were seen by their patients as being supportive of the practice.

Consultants were agreed in their serious concerns about the use of acupuncture (because of concerns regarding needle use and spreading infection) and of ingested remedies such as homeopathy, herbal remedies, and supplements (because of their inadequately investigated and possibly toxic effects on already compromised liver function). Most health board liaison officers have had only a small number of enquiries about complementary therapies. A small proportion (3%) of GP contacts with patients in the previous year were classified as providing complementary therapies. Support organisations were very favourably disposed to complementary therapies and were very anxious to have them reimbursed.

Complementary therapies appear to have reached a pivotal point where some professionals and locations provide endorsement of facilities and others do not. Debate about the role of complementary medicine in national health systems is currently taking place in a number of European Union Member States and in North America (Belgium has just legitimised the provision of a number of alternative therapies in general health settings, for instance). This matter needs to be dealt with as part of a wider debate on funding evidence-based health services and, as with recent consideration of funding should call on information about decision-making strategies and evolving practices in countries similar to Ireland. In this evolving situation, official inaction is likely to result in widespread coverage of practices already funded in some settings on the basis of maintaining equity of service access across regions rather than on considered advice about the relative merits of a variety of State-fundable services.

*Recommendation 9: That the role of complementary or alternative therapies in the management of hepatitis C be reviewed as part of a wider framework of evaluation of the use of such therapies in the Irish health system.*

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<sup>25</sup> Campion E.W. Why unconventional medicine? New England Journal of Medicine 1993; 328: 282-283.



## Chapter 5

### RESEARCH ON HEPATITIS C IN IRELAND

Research is an essential aspect of management of a little-understood disease such as hepatitis C; a disease formally known to the medical research community for only a decade. Many aspects of the disease and its treatment remain to be investigated. About one-third of the group interviewed had previously been involved in research with all but two of those involved in other hepatitis C research projects. Their experience of research was typically positive (73%) with only two individuals finding the experience negative.

A positive approach to research in Ireland was one shared by the support organisations. Their view was that as a unique clinical group, they themselves might not directly benefit from some of the findings of such work but that “someone should”, as a way for them to gain some sense of a lasting benefit from a personal and national health crisis. The hospital consultant group were uniformly agreed about the imperative for research in this area and most were actively involved in programmes of research; primarily clinical (laboratory) research, and research on changing clinical profiles of the patient group and on psychological well-being. A listing of current Irish research projects on hepatitis C is included in Appendix 2. The major funding source for hepatitis C research is the Health Research Board. Projects have been funded on a peer review basis both through the general annual call for applications to their grant award system and through provision of additional dedicated funding of £1,000,000 from the Department of Health and Children in 1996. The Department of Health and Children, as part of the Health Care Package (1995), are committed to providing dedicated funding to the Health Research Board beyond the period of current projects.

A key constituent of coordinated national research on hepatitis C is a national database of patients. The Cork University Hospital group has developed a national database from within their own funding resources. There was enthusiastic support for the concept of a national database from clinicians at all centres. The view of the majority was that a national database should be managed independently with most clinicians themselves proposing the Health Research Board as a national independent organisation to maintain such a database.

Discussions with Health Research Board officials clarified that they already operate national databases in a number of sectors and that they could provide a coordinating role for such a database, in association with hospital consultants and relevant others who would have responsibility for developing the database framework and providing and updating information from their centres.

*Recommendation 10: That a national database be established for research purposes; this to be located at an independent coordinating agency and run in association with relevant groupings.*



## Chapter 6

### HEPATITIS C: CURRENT STATUS AND SERVICE NEEDS IN THE FUTURE

The current state of knowledge on the natural history of hepatitis C is scant, with available data confounded by factors such as other health conditions (for example, haemophilia) or lifestyle (for example, intravenous drug use). The hospital chart review of almost 400 randomly selected patient records nationally provided an opportunity to examine current disease status and information relating to disease progression.

#### CURRENT CLINICAL STATUS: LIVER BIOPSY

Hepatitis C follows a highly variable disease course. Ideally, the progress of hepatitis C requires monitoring at a level at which liver pathology can be assessed. The only satisfactory method of doing this is taking a biopsy. Since liver biopsy is an invasive procedure, biopsies are only done when needed to inform clinical management of disease.

Data was available for 388 patients, of whom 70% were women. Thirty-nine percent were PCR negative; that is, they showed evidence of acute hepatitis C without having developed chronic disease. Of the remaining 61% of patients (N=235), 179 could be classified according to severity of disease. Of these, one-fifth had chronic hepatitis C with normal serum ALT<sup>26</sup>, half had chronic mild disease (26% of all test results), and the remaining three-tenths had chronic moderate/severe disease (16% of all test results).

#### Changes in disease over time

Liver biopsy results from this patient cohort underline two important factors: the first is that a single biopsy is not a definitive statement about the severity of disease: many patients had repeat biopsies whose results were better than the initial biopsies. Some of these may represent a reduction in disease activity, but others may simply reflect the fact that a liver biopsy is carried out by extracting a very small piece of a very large body organ; it cannot be expected to give a definitive picture. The second important feature is that the rate of deterioration visible in the biopsy data is too slight to quantify with any degree of reliability.

No biopsy data from the time of diagnosis were available on almost 40% of patients. In terms of conclusions about prognosis, the first important point is that 39% of patients were PCR negative; that is, they had no evidence of active hepatitis C virus. The prognosis for such patients is good; long-term follow-up in other studies indicates that the great majority will have cleared the virus permanently<sup>27</sup>.

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<sup>26</sup> Serum ALT is a non-specific (general) indicator of liver disease.

<sup>27</sup> Giuberti T, Marin MG, Marchelli S, Schianchi C, Degli Antoni AM, Pizzocolo G, Fiaccadori F. Hepatitis C virus viremia following clinical resolution of acute hepatitis C. *Journal of Hepatology* 1994, 20: 666-671.



Approximately 20% of those who developed chronic hepatitis had normal ALT on first follow-up. The prognosis of hepatitis C infection is favourable in patients who have consistently normal ALT.

The final diagnostic groups are the mild and moderate/severe groups with chronic hepatitis C. The term 'moderate/severe' is used to indicate that it is not possible to distinguish between patients within this group on the basis of the data available. Only six patients, in the moderate to severe groups, had severe disease on initial biopsy. One person had this confirmed by a subsequent biopsy.

Pooling all of those with active disease (mild and moderate/severe), there was no discernable change in disease status in the patient subgroup on whom biopsies were repeated (N=69). Nor was it possible to identify any poor prognostic sub-group based on information available. Routine biopsies at regular intervals would seem unnecessary, therefore, to monitor disease activity. Patients with repeat biopsies tended to be those whose disease status might have given greatest cause for concern. With this in mind, information available over the time period of patient monitoring indicated no evident progression in the disease of those with repeat biopsies.

## CURRENT PSYCHOLOGICAL WELL-BEING

Information from patient interviews on current evaluations of health and psychological well-being and their association with service use and financial compensation was considered. Patient views and experiences regarding stigma and confidentiality were also evaluated. The experience of the group who were initially deemed negative for hepatitis C, but who were recalled for testing in the past year ('recall' patients), is also outlined here.

Over half of the group described their health as fair or poor, with little difference in patterns across groups (**Figure 6.1**). Mood disorders of depression and anxiety were measured across groups in the present review with a view to identifying need for counselling services. Those participating in interviews completed the Hospital Anxiety and Depression Scale (HADS) <sup>28</sup>.

Proportions of patients with clinical levels of psychological distress were similar across patient groups. Thirty-five percent of the group had anxiety scores of clinical concern with 26% having clinical levels of depression (see **Figures 6.2** and **6.3**).

These proportions indicate high levels of psychological distress in these patient groups. The uncertain nature of hepatitis C consequences may account for the particularly high levels of anxiety reported. HADS figures for the general population in Ireland and the UK are not available for comparison. To provide some comparison, a German general population sample

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<sup>28</sup> The HADS is a brief (14 questions) well-validated screening measure which indicates levels of depression and anxiety in the general medical setting. This scale provides separate measures of depression and anxiety, each with scores in the 'normal', 'borderline' and 'clinical' range. Scores from 8 - 10 are 'borderline', serving to identify most possible cases of the relevant psychological problem with score of 11+ are in the 'clinical' range meaning there is a high probability of problems needing professional mental health services. Questions are asked about feelings 'in the past week'.

had clinical levels of depression in 5% of the group with 7% at clinical anxiety levels<sup>29</sup>. A group diagnosed with cardiological illnesses reported clinical depression (17%) and clinical anxiety (19%) while back pain patients reported clinical depression (29%) and clinical anxiety (36%). These figures provide some perspective on the group studied here and indicate that their levels of psychological distress are high for a medical population.

There is evidence that counselling services were used significantly more by those with higher levels of both depression and anxiety. For instance, 71% of those rated as clinically depressed attended counselling, whereas rates of attendance for counselling for non-depressed individuals was 27%.

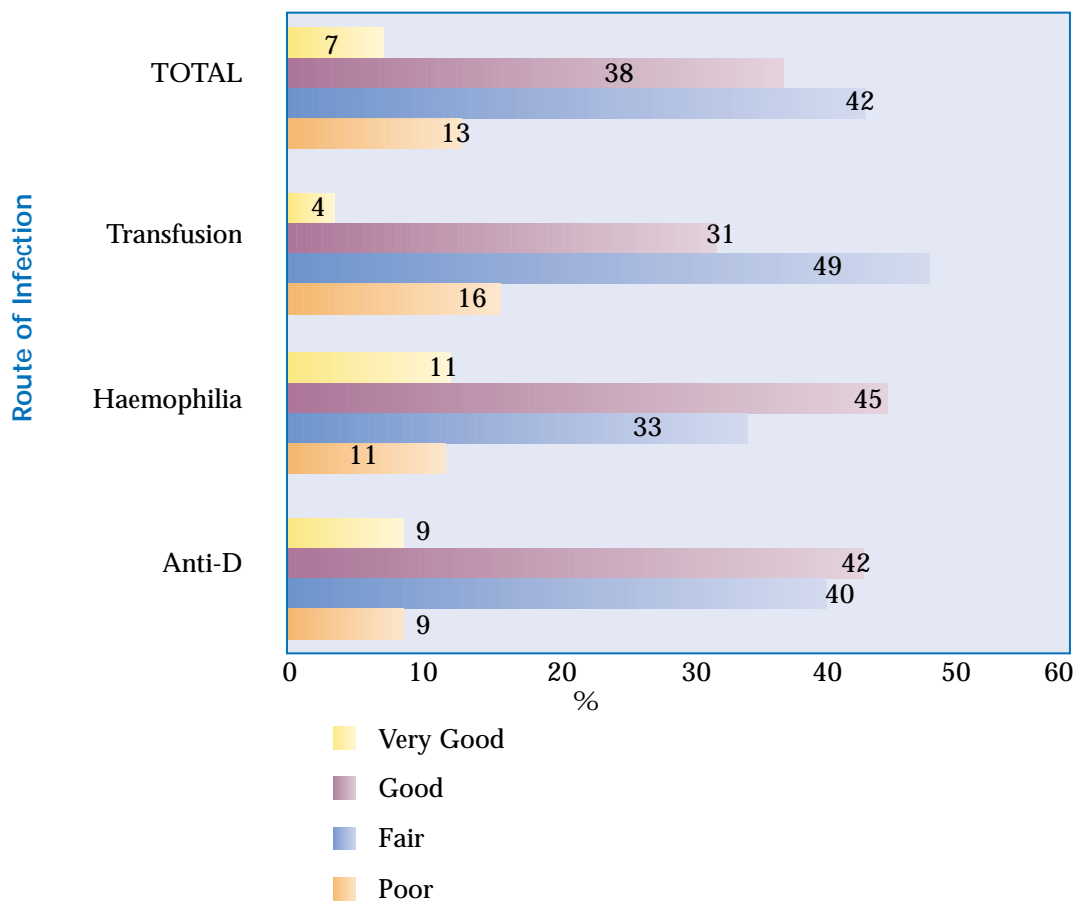


Figure 6.1: Current self-rated health by route of infection

<sup>29</sup> Hermann C. (1997) International experiences with the Hospital Anxiety and Depression Scale - a review of validation date and clinical results. Journal of Psychosomatic Research, 1997; 42: 14-41

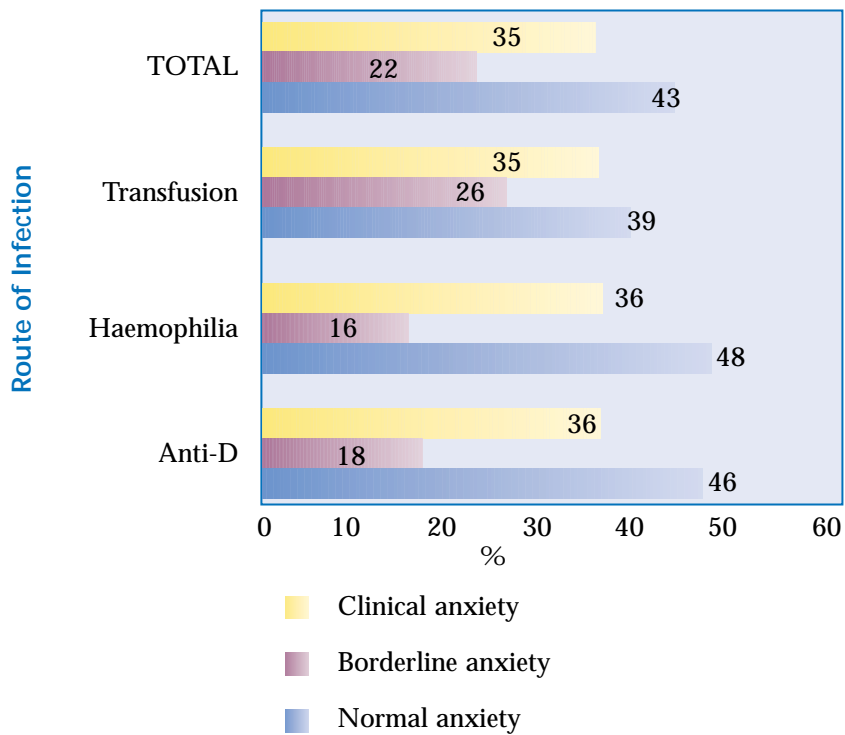


Figure 6.2: Patient anxiety score categories as measured by the HADS

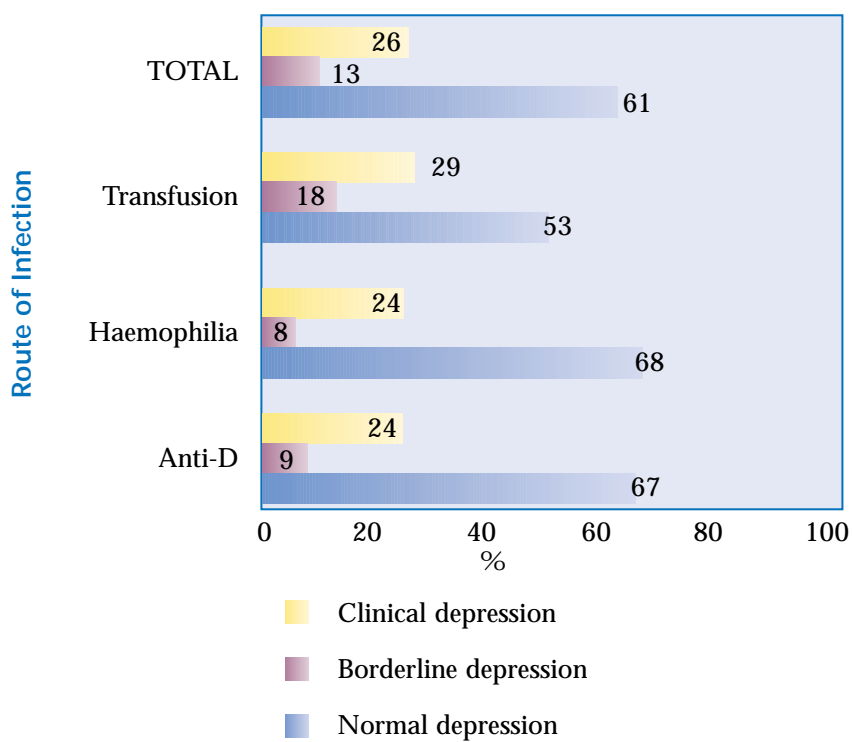


Figure 6.3: Patient depression score categories as measured by the HADS

### Compensation Tribunal attendance and psychological well-being

Sixty-three percent of those interviewed had attended the Compensation Tribunal by the time of interview with no difference in attendance across groups.

One issue which elicited very disparate views in discussion for the review was whether psychological well-being is improved or disaproved following attendance at the Tribunal. On the one hand, there was a view that there would be a great sense of relief for individuals post-Tribunal, with a corresponding improvement in levels of psychological distress. The other perspective was that the Tribunal is the focus of life for patients for a long time. When the Tribunal is completed, patients would then find themselves with the rest of their lives and their health uncertainty regarding hepatitis C to face. In this view, the post-Tribunal period would be associated with greater distress for patients.

Data on psychological well-being from the HADS was evaluated by Tribunal status. The post-Tribunal group were found to have a significantly more serious depression profile, with 32% (versus 7% pre-Tribunal) scoring as clinically depressed<sup>30</sup>. There was a trend but no significant differences in anxiety levels for those pre- and post-Tribunal<sup>31</sup> (22% and 39% respectively). Thus proportions of those scoring in the clinical level of depression were greater for those who have already attended the Tribunal. While levels of anxiety were not statistically different across groups, the actual level of anxiety displayed was high in both groups and therefore also cause for concern.

## DISCLOSURE, STIGMA, AND CONFIDENTIALITY

The stigma associated with hepatitis C was acknowledged by all groups (see **Figure 6.4**). Associations of one's hepatitis C with personal ill-health (for example, liver failure) and risk to public health (infectivity) were seen as relevant alongside associations with inappropriate personal behaviour (high alcohol use leading to liver disease), risky sexual conduct and illicit and intravenous drug use (acquiring infectious diseases). The similarities in abbreviations of the words human immunodeficiency virus (HIV) and hepatitis C virus (HCV) appears to have added to a sense of stigmatisation with a small number of people reporting that they initially believed they were infected with HIV.

Stigma is of particular concern because of its possible association with poor psychological well-being and with inadvisable health practices which arise from feeling stigmatised (for example, not seeking appropriate help; not disclosing one's infection in a health setting). It is difficult to quantify the latter. However, psychological well-being has been considered in relation to stigma (see **Figure 6.4**). Feeling stigmatised was strongly associated with high levels of both depression<sup>32</sup> and anxiety<sup>33</sup>.

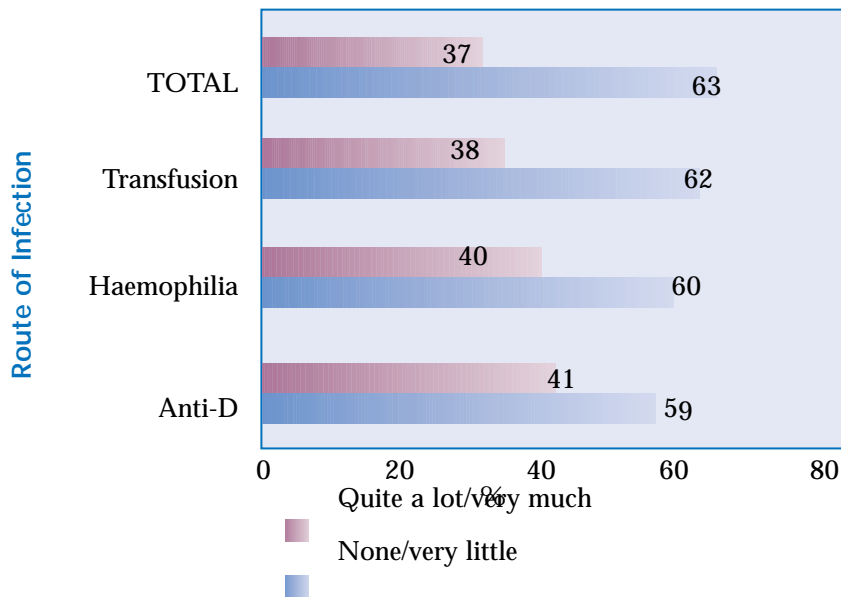
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<sup>30</sup> ( $\chi^2=7.71$ ;  $df=2$ ;  $p=0.02$ ).

<sup>31</sup> ( $\chi^2=5.29$ ;  $df=2$ ;  $p=0.07$ ).

<sup>32</sup> ( $\chi^2=27.9$ ;  $df=6$ ;  $p=0.0003$ ).

<sup>33</sup> ( $\chi^2=25.1$ ;  $df=6$ ;  $p=0.0003$ ).



**Figure 6.4: Levels of stigma experience as a result of having hepatitis C by route of infection**

One of the ways in which health or other problems can be seen as less stigmatising is by increasing contact with individuals in a similar situation. When asked their views, most people perceived direct personal contact with others to be unhelpful while support organisation contact was considered helpful or very helpful by a majority.

#### Disclosure of hepatitis C to others

Disclosure of conditions deemed stigmatising involves both a decision to tell others and the act of disclosure itself. One person interviewed had told no-one to date about his hepatitis C. Some had told just a few individuals while others reported that ‘everyone knows’. Confidentiality in dealing with hepatitis C services is a key concern for both professionals and service users. Patient satisfaction with confidentiality in various aspects of service provision is outlined in **Figure 6.5**.

Levels of satisfaction with confidentiality were uniformly high across health services from hospital to community. These satisfaction ratings contrasted with lower reported levels of satisfaction with confidentiality in employment settings. Given high feelings of stigmatisation and related concerns, the achievement of this level of confidence across a range of health systems, locations, and personnel is highly reassuring and to be commended.

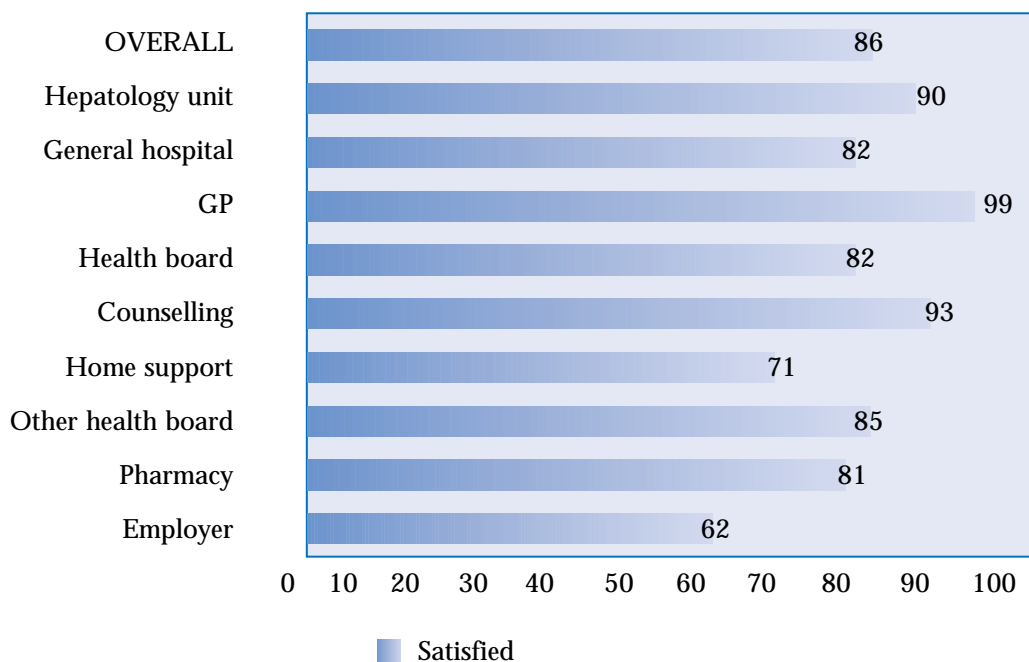


Figure 6.5. Patient satisfaction with confidentiality regarding hepatitis C in various health and related services

## RECALL PATIENTS

A distinct group interviewed as part of this study were those who, having initially tested negative for hepatitis C, were asked to return for further testing at a later date. Most of these individuals had been called for re-testing within the previous year. Satisfaction ratings with staff during retesting were adequate (74% satisfied) as were satisfaction ratings with experience of the hepatology unit (74%).

Over half of those interviewed (52%) felt they did not have an adequate understanding of why they were being retested at the time and 50% remain confused about the reason for re-testing. A significant proportion of these individuals (48%) report still feeling fearful about the diagnosis of hepatitis C. Regarding current status, self-rated health was similar to other groups (poor 14%; fair 57%; good 29%; very good 0%). Recall group depression and anxiety scores (as measured by the HADS) did not differ significantly from those of the interview population as a whole. The scores of 14% of individuals indicated clinical levels of depression; the scores of 29% of individuals indicated clinical levels of anxiety. Only one recall patient had been to the Tribunal.

## **FUTURE NEED FOR SECONDARY CARE SERVICES**

The need for clinical services over and above those of an ageing population, some already with chronic disease such as haemophilia, was seen as difficult to estimate by professionals. The view was that only a minority of patients would ever develop serious, end-stage liver failure. Services more likely to be in demand were seen to be those associated with general symptoms of fatigue and rheumatoid difficulties. Hence rheumatology (including physiotherapy) services were expected to be in increasing demand.

### **Anti-viral treatment**

The main increase in demand for secondary care services in the short-term is expected to be in the provision of anti-viral treatment for hepatitis C. Recent clinical trials indicating that interferon and ribavarin as combination therapy are beneficial, and more effective than interferon alone, will result in increased numbers availing of this treatment with associated hospital stays, laboratory tests, and other clinical procedures and staff time associated with such procedures.

### **Liver transplantation**

For those small numbers requiring liver transplantation, ongoing support for the National Liver Transplant Centre at St Vincent's Hospital, Dublin, was seen as important. Because of the needs of this and other hepatitis C groups, an additional transplant surgeon specialising in infectious hepatology was seen to be necessary. Support organisations felt strongly that liver transplantation should be facilitated, including international travel for transplantation where necessary. Others cautioned, however, that efforts to ensure an active programme of donation to complement transplantation in this country are a more feasible focus for service provision since the process of organ transplantation and recovery has sufficient challenges for patient and family without the additional burden of travel and geographical separation from extended family and friends.

## **FUTURE NEED FOR PRIMARY CARE SERVICES**

The general view of professionals was that demand for counselling will increase in the next few years. This was the majority view of consultants, nursing staff, GPs, health board liaison officers, counsellors, and support organisations. Where increases are expected, they are seen to relate to coping with increased illness over the lifetime and with undergoing interferon therapy.

### **General practitioner**

There was strong endorsement of the importance of the primary care role (with GPs at the centre of this and with practice nurses playing an important role) in the ongoing care of this group.

Professionals expressed concern that general health promotion and screening activities relevant to this group (such as hormone replacement therapy for the anti-D group), which are normally conducted through general practice, could be relatively neglected where the person's primary medical contact was a hospital specialist. However, support groups were conscious of the need for ongoing specialist contact; this was most evident in those groups who already had pre-



existing medical conditions when exposed to hepatitis C infection. Here, a significant move to redirect patient care from secondary to primary care would not be uniformly welcomed.

GPs were seen as having a role in identifying individuals at risk who have not come forward for testing to date either through fear, or through lack of contact from Blood Transfusion Service Board records. GPs are also clearly seen as having an important role in plans for the future where additional patients will be recalled for testing. The Department of Health and Children's Expert Group has identified GPs as the first point of contact for this group and, in consultation with the Irish College of General Practitioners, plan to provide GPs with educational material so that they can make contact with relevant patients. A need was identified to develop and regularly update a comprehensive national GP listing (as recommended in the Expert Group Report, 1995) to facilitate this process.

There was general agreement that the demand for the home support service will increase over the next few years. No dramatic changes in other service lists were expected in the short term. Use of home nursing services was expected to be a significant resource demand for a small number of individuals in the longer term.

#### **Management of public health crises**

There was seen to be a need for national planning for public health crises such as the 1994 hepatitis C issue, so that a system can be established to guide management of future, unpredictable but probably inevitable incidents. Expertise is available within the health and associated services to develop a blueprint for such a system<sup>34</sup>. Those producing critical incident strategies for hospitals, public health and public venue settings could combine to plan a generic system.

## **FUTURE CHALLENGES**

Continuing challenges include making explicit best practice guidelines for biopsy and anti-viral therapies such that patients are confident that individual treatment variation across centres is part of a flexibility to suit patients in delivering what is otherwise a basically similar and high quality service to all. Ensuring that access to additional specialist services is as outlined in the 'two-week rule', and managing home support services with safety and confidentiality were also seen as continuing challenges. It was felt that the focus should be on 'managed wellness' rather than on 'patient' or 'illness' status with health promotion advice becoming important for long-term well-being, now that the initial challenges of diagnosis and assessment are completed. It was also felt that specific health promotion guidance, including in particular advice about diet and management of fatigue, should be developed and disseminated to this group of individuals with hepatitis C.

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<sup>34</sup> O'Riordan PA. Emergency planning in Ireland. Dublin: Institute of Public Administration, 1992.



Apart from their health status, the major concern for the future, as expressed by both service providers and users, was that funding would continue to be made available to this group in the demand-led manner in which it was committed and is provided at present. Official reassurances on this continue to be necessary in order to allay fears that at a future time, recall about commitments following the 1994 contamination announcements will have faded and be overtaken by budgetary or other considerations. It is difficult to overstate the level of this concern and its pervasiveness across the individuals interviewed at every level of the system. Means of acknowledging these fears and reaffirming the commitments made should be considered to reassure those infected.

*Recommendation 11: That assurances be given that adequate funding and resources will continue to be provided to ensure a quality health care service for this patient group.*

Input to this Review was broad-ranging, with representation from patient support organisations, patients and professionals. Recommendations provided throughout the report are based on the evidence collected from these different sources. Implementation of these recommendations should serve to underpin quality patient care into the future.

*Recommendation 12: That progress on the recommendations of this Review be monitored on an annual basis for three years with a report summarising progress to be completed at the end of this period. Progress to be monitored by a sub-committee of the Consultative Council on Hepatitis C.*

## Chapter 7

### CONCLUSIONS

The hepatitis C contamination of blood products on the scale announced in Ireland in 1994 was unique both in the Irish and international setting. The wide distribution of a very large number of mostly women (because the intermediary for infection was anti-D immunoglobulin) meant that the impact of the contamination was experienced by individuals, families, and professionals throughout the country. The anger and hurt felt at the time appears to have resolved considerably. As summarised in previous chapters, it appears that the constituents necessary for effective service delivery are broadly in place and that both specialist units and primary care services are working to agreed standards.

#### Challenges for the future

A new level of negotiation of service use has been brokered by the nature in which the hepatitis C contamination issue arose and was managed over time. The development of good working relationships by groups with the Department of Health and Children over time was also acknowledged, with current relationships seen as having evolved from an initially adversarial stance, to a partnership approach with the liaison personnel at present.

#### Principles and standards

A level of mutual trust appears to have been established between professionals and service users. The major concern of all concerned is to maintain this equilibrium and the resources associated with it in the future. This summary appraisal is not to say that problems do not continue to emerge in the delivery of care. These problems focus mainly on communication – between professionals and service users, and among professionals. However, a level of acceptance that these problems need to continue to be resolved in this setting is more reflective of a partnership approach than is probably available elsewhere within the health delivery system. In itself, this reflects a significant move forward in the relationship between providers and users of care that is aspired to more generally; for instance, in the Department of Health's 1994 health strategy document which seeks to foster a more consumer-oriented approach to health service delivery.

In conclusion, the hepatitis C issue has proved to be one of the major challenges to face our current health services. We hope that this Review, as part of a broader strategic approach to managing hepatitis C, will ensure optimal management into the future.

## APPENDICES

### Appendix 1: Consultation process for hepatitis C services review: those interviewed/consulted for review

Organisation	Personnel
	<b>HOSPITALS</b>
Beaumont Hospital, Dublin	<ul style="list-style-type: none"><li>■ Dr Frank Murray, Consultant Gastroenterologist</li><li>■ S/N Marie Wilson</li><li>■ Ms Sinead Purcell, Secretary</li></ul>
Cork University Hospital	<ul style="list-style-type: none"><li>■ Dr Elizabeth Kenny, Locum Consultant Gastroenterologist</li><li>■ Dr Michael Whelton, Consultant Gastroenterologist</li><li>■ Sr Susan Corbett</li><li>■ Ms Nora O'Connor, Secretary</li><li>■ Mr Tony McNamara, Hospital Manager</li><li>■ Mr Michael Crowley, Statistician</li><li>■ Ms Claire Devereaux, Statistical Support</li></ul>
Mater Hospital, Dublin	<ul style="list-style-type: none"><li>■ Dr John Crowe, Consultant Gastroenterologist</li><li>■ Sr Alice Cockram</li><li>■ Ms Margaret McAndrews, Secretary</li><li>■ Ms Barbara Coughlan, Counsellor</li></ul>
St James's Hospital, Dublin	<ul style="list-style-type: none"><li>■ Professor Dermot Kelleher, Consultant Gastroenterologist</li><li>■ Sr Helena Irish</li><li>■ S/N Breda Jordan (Job-sharing)</li><li>■ Ms Sylvia Mathews, Secretary</li></ul>
St Luke's Hospital, Kilkenny	<ul style="list-style-type: none"><li>■ Dr Gary Courtney, Consultant Physician and Gastroenterologist</li><li>■ Sr Catherine Whitely</li><li>■ Sr Pauline Carroll</li><li>■ Ms Ann Marie McDonald, Secretary</li></ul>
St Vincent's Hospital, Dublin	<ul style="list-style-type: none"><li>■ Dr. John Hegarty, Consultant Gastroenterologist</li><li>■ Sr (acting) Deirdre O'Sullivan</li><li>■ Ms Sarah Lynch, Secretary</li></ul>
University College Hospital, Galway	<ul style="list-style-type: none"><li>■ Professor Ciaran McCarthy, professor of Medicine and Consultant Gastroenterologist</li><li>■ Dr John McWeeney, Locum Consultant Physician</li><li>■ S/N Mary Keane-Bowhan, Locum Clinic Nurse</li><li>■ Ms Sheena Laverty, Secretary (Part-time)</li></ul>
	<b>HEALTH BOARDS: HEPATITIS C LIAISON OFFICERS</b>
Eastern Health Board (Dublin)	<ul style="list-style-type: none"><li>■ Ms Sheila Marshall, Hepatitis C Liaison Officer, Community Care</li></ul>
Midland Health Board (Tullamore)	<ul style="list-style-type: none"><li>■ Mr Pat O'Dowd, Administrator, GP Unit</li></ul>
Mid-Western Health Board (Limerick)	<ul style="list-style-type: none"><li>■ Ms. Mary Healy, Senior Executive Officer, Community Care</li></ul>
North Eastern Health Board (Dundalk)	<ul style="list-style-type: none"><li>■ Ms Ann Coyle, Senior Executive officer, Community Care</li><li>■ Ms Rosemary Mulligan, Secretary to Ms Coyle</li></ul>
North Western Health Board (Manorhamilton)	<ul style="list-style-type: none"><li>■ Mrs Val O'Kelly, Acting Child Care Development Officer</li></ul>
South-Eastern Health Board (Kilkenny)	<ul style="list-style-type: none"><li>■ Ms. Anne Marie Lanigan, GP Unit Manager</li></ul>
Southern Health Board (Cork)	<ul style="list-style-type: none"><li>■ Ms Cathy Falvey (Newly Appointed)</li><li>■ Mr Donal Murphy (Outgoing)</li></ul>
Western Health Board	<ul style="list-style-type: none"><li>■ Mr Matt Hurley (Newly Appointed)</li><li>■ Mr Brian O'Donnell (Outgoing)</li></ul>

(Continued on next page)

## Appendix 1: continued

<b>Organisation</b>	<b>Personnel</b>
	<b>PRIMARY CARE</b>
Irish College of General Practitioners (ICGP)	<ul style="list-style-type: none"><li>■ Dr Michael Dunne (Cork)</li><li>■ Dr Michael Coughlan (Galway)</li><li>■ [ICGP designated specialists re. Hepatitis C]</li></ul>
Counsellors	<ul style="list-style-type: none"><li>■ Ms Pauline Beegan (Positive Action; Irish Kidney Association)</li><li>■ Ms Jo Campion (Independent Practice)</li><li>■ Ms Anne Ryan (Beaumont Hospital)</li><li>■ Ms Siobhan Sciascia (University College Hospital Galway)</li></ul>
	<b>SUPPORT GROUPS</b>
Irish Haemophilia Society	<ul style="list-style-type: none"><li>■ Ms Margaret King, Counsellor</li><li>■ Ms Rosemary Daly, Administrator</li></ul>
Irish Kidney Association	<ul style="list-style-type: none"><li>■ Mrs Patricia Doherty, Chief Executive</li></ul>
Positive Action	<ul style="list-style-type: none"><li>■ Ms Jane O'Brien, Chairperson</li><li>■ Ms Mary O'Connor, CEO, and Committee Member</li><li>■ Ms Pauline Beegan, Psychologist (also works for Irish Kidney Association)</li></ul>
Transfusion Positive	<ul style="list-style-type: none"><li>■ Ms Maura Long, Chairperson &amp; Committee Member</li></ul>
Support group members nominated by groups and invited to take part in two hour focus group in Dublin	<ul style="list-style-type: none"><li>■ 28 individuals divided across four focus groups – one for each infection route – names not published to protect confidentiality</li></ul>
	<b>INDIVIDUAL INTERVIEWS WITH PERSONS INFECTED WITH HEPATITIS C</b>
	<ul style="list-style-type: none"><li>■ 132 interviews of between one and two hour duration<ul style="list-style-type: none"><li>- 115 face-to-face interviews (87%)</li><li>- 17 telephone interviews (13%)</li></ul></li></ul>
	<b>RELEVANT NATIONAL AGENCIES</b>
Blood Transfusion Services Board	<ul style="list-style-type: none"><li>■ Mr Martin Hynes, Chief Executive</li><li>■ Dr Emer Lawlor, Consultant Haematologist</li></ul>
Department of Health and Children	<ul style="list-style-type: none"><li>■ Dr Jim Kiely, Chief Medical Officer and Chairman of Expert Group on hepatitis C</li><li>■ Ms Mary Hogan and Mr Gerry Coffey, Blood Policy Division</li></ul>
Health Research Board	<ul style="list-style-type: none"><li>■ Dr Ruth Barrington, Chief Executive Officer</li><li>■ Ms Carol Cronin, Accountant</li></ul>
	<b>OTHER SOURCES OF EXPERTISE</b>
Beaumont Hospital	<ul style="list-style-type: none"><li>■ Dr Elaine Kay, Consultant Pathologist and Senior Lecturer, Department of Pathology (RCSI)</li></ul>
Royal College of Surgeons in Ireland (RCSI)	<ul style="list-style-type: none"><li>■ Mr Ronan Conroy, biostatistician, Department of Epidemiology and Public Health Medicine</li><li>■ Professor William Shannon, Department of General Practice</li></ul>

**Appendix 2(A): Hepatitis C research projects funded by the Health Research Board (1996-1998 grant awards) and other major research funding agencies**

Title	Grant holders/ institutions	Project duration	Total funding* £	Additional funded personnel
Chronic HCV Infection: Clearance and persistence – the underlying mechanisms	L Fanning, J Collins, F Shanahan (Cork University Hospital)	1996-1999	33,000	
Extrahepatic reservoirs of HCV	L Fanning, J Collins, F Shanahan	1996-1999	47,000	postgraduate student
Human reproduction and hepatitis C The role of human leucocyte antigens in the persistence of hepatitis C infection	M Whelton (Cork University Hospital) E Lawlor, J. Power, D Kelleher (BTSB St James's Hospital Dublin)	1997-2000 1997-1998	44,620 25,000	MSc. research assistant
To correlate HLA-DR allele status with outcome in women with proven exposure to HCV contaminated anti-D immunoglobulin in 1977	J Crowe (Mater Hospital Dublin)	1997-2000	35,450	postdoctoral fellow
An investigation of the pathogenesis and severity of chronic disease in anti-D treated patients with hepatitis C virus	E Kay, M Leader, C O'Keane (Beaumont Hospital Dublin and RCSI)	1997-1999	57,582	postgraduate student, medical laboratory technician
Groups infected or tested as at risk for the hepatitis C virus in Ireland: psychological functioning and lessons for communications of health risk information in the future	A Hickey, C O'Boyle (Royal College of Surgeons in Ireland)	1997-2000	42,674	Research nurse
Detection of intrahepatic hepatitis C viral RNA in RIBA positive, PCR negative anti-D recipients	S Barrett, J Crowe (Mater Hospital Dublin)	1997-1998	8,500	
Virus variants and host immune responses in the resolution and progression of chronic liver disease following hepatitis C virus infection	J Hegarty (St Vincent's Hospital), D Kelleher (St James's Hospital), K Mills (NUI Maynooth), B Hall (Virus Reference Laboratory)	1997-2002	741,972	two senior postdoctoral fellows; two postdoctoral fellows
An exploration of the psychological impact of an accidental diagnosis of hepatitis C infection on a previously healthy female population	J Crowe, J Sheehan, B Coughlan (Mater Hospital Dublin)	1998-2000	36,000	postgraduate researcher
Correlation of HLA-DR status with outcome in women with proven exposure to hepatitis C virus contaminated anti-D immunoglobulin in 1977	J Crowe, E Ryan (Mater Hospital Dublin)	1996-1998	20,000	
Pathogenesis of hepatitis C (St James's Hospital),	D Kelleher C Ferran (Pharma)	1998-2000 (pharmaceutical company funds)	70,000	postdoctoral fellow
Biomedical effects of interferon (EU funds)	D Kelleher (St James's Hospital)	1997-1999	50,000	medical fellow

\* HRB-funded unless otherwise indicated

Appendix 2(B): Hepatitis C research projects conducted by or for health services organisations or support organisations

<i>Study details</i>	<b>Funding source</b>	<b>Contact</b>
<p><b>Cork University Hospital (CUH)</b></p> <ul style="list-style-type: none"> <li>■ Hepatitis C comprehensive database template development from 1995 to collect wide range of clinically relevant data as part of routine practice (16 separate sections)</li> </ul> <p>Purpose – to optimise clinical management, healthcare planning, and research into future progression of hepatitis C in an iatrogenically-induced group; to adopt this as national database</p>	<p>Joint project between CUH and Department of Statistics, University College Cork.</p>	<p>Dr Elizabeth Kenny (locum consultant gastroenterologist) and Professor Fergus Shanahan (professor of medicine, Cork University Hospital)</p>
<p><b>Eastern Health Board (EHB)</b></p> <ul style="list-style-type: none"> <li>■ Postal survey of satisfaction with community services (N=467 covered by scheme; 56% response)</li> </ul> <p>Purpose – internal review to inform board operations</p>	<p>Completed by EHB's Department of Public Health (Dr Emer Feeley – co-ordinator)</p>	<p>Ms Sheila Marshall (liaison officer)</p>
<p><b>Positive Action</b></p> <ul style="list-style-type: none"> <li>■ Postal survey of PA members in 1995 to assess psychological wellbeing. N=600 with 38% response rate</li> </ul> <p>Purpose – baseline psychosocial information for PA</p>	<p>Work facilitated by Positive Action and funded by University College Cork</p>	<p>Drs Ethel Quayle and Elizabeth Dunne (psychologists, Department of Applied Psychology, UCC)</p>
<ul style="list-style-type: none"> <li>■ <b>1999 postal survey</b> of c. 700 members on appointment of Positive Action psychologist. N=170 replies (c. 24% response rate)</li> </ul> <p>Purpose – to ascertain counselling priorities and preferences of group</p>	<p>Funded by Positive Action</p>	<p>Ms Pauline Beegan, (psychologist, Positive Action)</p>
<ul style="list-style-type: none"> <li>■ <b>Quantitative study:</b> 6 focus groups (N=45) of PA members representing urban/rural members</li> </ul> <p>Purpose – evaluation of impact on everyday life</p>	<p>Funded by Positive Action and completed at University College Cork</p>	<p>Drs Ethel Quayle and Elizabeth Dunne (psychologists, Department of Psychology, UCC)</p>
<p><b>St Luke's Hospital, Kilkenny</b></p> <ul style="list-style-type: none"> <li>■ A nursing-focused review of pathological, psychological, and social aspects of anti-D associated hepatitis C</li> </ul> <p>Purpose – to develop evidence-based nursing care strategies</p>	<p>South Eastern Health Board and individual registration for Bachelor of Nursing Studies Courses, TCD</p>	<p>Ms Pauline Carroll (staff nurse) and Dr Gary Courtney (consultant physician)</p>
<p><b>University College Hospital, Galway</b></p> <ul style="list-style-type: none"> <li>■ Two surveys of patient satisfaction with services</li> </ul> <p>Purpose – internal reports to ascertain level of patient concerns re. services (survey 1) and to re-evaluate views following service changes (survey 2)</p>	<p>Completed by Western Health Board</p>	<p>Professor Ciaran McCarthy (professor of medicine, University College Hospital Galway)</p>

