Report to the

Ministry of Health on the

New Zealand National Hepatitis C

Lookback Programme

1994–1996

Prepared for the Ministry of Health by:

Dr Christopher Bullen

Regional Co-ordinator, Hepatitis C Lookback Programme,

Auckland Regional Blood Services

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Abbreviations

ARBS	Auckland Regional Blood Services
BTS	Blood Transfusion Services
CHE	Crown Health Enterprise
CSL	Commonwealth Serum Laboratories
EIA	Enzyme-linked Immunosorbent Assay
ESR	Environmental Science Research
GP	General Practitioner
HCV	Hepatitis C Virus
HIV	Human Immunodeficiency Virus
NHI	National Health Index
PCR	Polymerase Chain Reaction
RHA	Regional Health Authority
RIBA	Recombinant Immunoblot Assay
RNA	Ribonucleic Acid
RR	Repeat Reactive

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The content remains the sole responsibility of the author.

Executive summary

Between October 1994 and December 1996, blood transfusion centres throughout New Zealand worked on a programme of identifying, tracing, testing and counselling the recipients of blood products suspected of being contaminated with hepatitis C virus (HCV), transfused between August 1990 (when the introduction of blood donor screening for hepatitis C was recommended by expert advisory committees) and July 1992 (when screening was available nationwide).

The results of testing and tracing activities held by the regional health authorities, Crown health enterprise blood transfusion centres and the Ministry of Health were collated and reviewed. Confirmatory blood test results from transfusion recipients were obtained from the Institute of Environmental Science Research (ESR). Additional information on local variations in programme methodology, constraints and relevant issues was obtained directly from regional health authorities and blood centres.

This report outlines the lookback programme's rationale and methodology. It provides the findings of the programme, and looks at regional variation. The report discusses the benefits and lessons learnt from the programme, and carries some recommendations for future lookback programmes.

Key findings

- The National Hepatitis C Lookback Programme identified 56 people as having chronic hepatitis C infection contracted from transfusions given between August 1990 and July 1992.

  A further 76 people were found to be HCV antibody positive without evidence of chronic infection.

  This is consistent with estimates made by the Ministry of Health prior to programme implementation.

- Standard lookback methods identified 281 people as having been transfused with blood products possibly contaminated with hepatitis C virus.

- Retrospective testing of 62,811 stored serum specimens found 515 (0.82 percent) specimens to be repeat reactive for hepatitis C.

- As a result of testing, 669 people were identified as being at risk of possible hepatitis C infection, but only 374 people were still alive at the time of the lookback programme. This is consistent with what might be expected based on the findings from studies of post-transfusion mortality elsewhere.

- Of the 374 people still alive at the time of the lookback programme, 339 were contactable either by letter or an interview. Thirty-five people could not be contacted despite vigorous efforts and it is estimated that less than half of these people will have contracted HCV infection.

- Testing and tracing procedures were over- rather than under-inclusive. The risk that people exposed to contaminated blood have been overlooked is very small.

- Although notifying blood donors was not a focus of the programme, 328 donors who had possible chronic hepatitis C infection were also alerted.

- Screening procedures in place nationwide since July 1992 now ensure that any infected donors are detected and their donations withdrawn before being processed.

Introduction

This report describes the New Zealand National Hepatitis C Lookback Programme undertaken at the initiative of the Ministry of Health over the period 1994–1996.

The programme's primary aim was to trace and test recipients of blood products potentially contaminated with hepatitis C virus (HCV) transfused between August 1990 and July 1992.

A number of challenges were presented by the programme, in particular because the programme:

- involved mass testing for a recently-characterised virus with a complex natural history, using evolving and limited diagnostic tools
- aimed to trace and make personal contact with transfusion recipients from three to five years after transfusion
- sought to communicate to these people in as sensitive a way as possible the possibility of their having acquired a potentially serious chronic disease
- had no local precedent on which to base a budget or timeframe
- related to an issue which has been the focus of intense media and public scrutiny.

This report looks at hepatitis C and outlines the lookback programme's rationale and methodology. It provides the findings of the programme, and looks at regional variation. The report discusses the benefits and lessons learnt from the programme, and carries some recommendations for future lookback programmes.

Background

Hepatitis C: epidemiology, natural history, clinical features and treatment

Hepatitis C is the name given to the inflammatory liver disease resulting from infection with HCV, a small, enveloped RNA virus classified as a separate genus in the flavivirus family (van der Poel et al 1994). Although hepatitis C is not a new human pathogen, it has only been recognised since late 1988 when the viral genome was first isolated and cloned (Choo et al 1989). Until then, cases of hepatitis C were either unrecognised or diagnosed as non-A, non-B hepatitis.

The primary route of transmission of HCV is through direct inoculation of infected blood or serum. It is estimated that 1 percent of the world's population is infected with HCV (Strader and Seeff 1996), with prevalences of markers for HCV infection between 0.1 and 5.2 percent of the population across a range of countries (Sherlock 1992; Klein et al 1991; El-Zayadi et al 1992). However, these figures are likely to underestimate the true prevalence, as they are based on surveys of blood donor populations. In New Zealand, a 1990 blood donor study indicated that around 0.5 percent of the donor population had evidence of infection (Gibbons et al 1990).

Hepatitis C has no known predilection for any particular age, sex or ethnic group. Approximately 60 percent of infected people have recognised risk factors, including, in particular, a history of blood transfusion prior to the introduction of donor screening in 1992 and injecting drug use (Strasser et al 1995). Other factors associated with a high prevalence of infection include having multiple sexual partners, the presence of tattoos and body piercing (Farrell 1995). In up to 40 percent of cases, however, no specific source of HCV infection can be identified. The risks of transmission through heterosexual activity, household contact, pregnancy, childbirth and breast milk appear to be low (Farrell 1995). The high infectivity of HCV through blood transfusion makes it of particular concern to consumers of blood products, transfusion authorities and clinicians responsible for prescribing blood products.

Because of its relatively recent characterisation, much of what is known of the natural history of HCV infection is based on studies of patients with non-A, non-B hepatitis, or of patients retrospectively diagnosed with hepatitis C since 1989. More accurate information awaits the completion of a number of prospective studies (Strader and Seeff 1996). Based on current knowledge, it appears that in most cases, acute infection is subclinical, with around 60–80 percent of patients subsequently progressing to chronic hepatitis (Farrell 1995). The majority are asymptomatic with a normal life expectancy (Seeff et al 1992). However, some people experience persistent, incapacitating symptoms such as lethargy, abdominal pain and nausea.

Chronic hepatitis C progresses slowly: it may be 25–40 years before clinically apparent liver disease appears in around one-third of people with persistent hepatitis. A proportion of these will develop cirrhosis, and perhaps 10 percent of these, primary hepatocellular cancer (van der Poel et al 1994). Severity appears to relate to the viral genotype and to viral load. Both factors also appear to be determinants of responsiveness to interferon treatment (Dusheiko et al 1995; Chemello et al 1994; Higiwara et al 1993).

The key to HCV control is primary prevention. In the community, needle exchange programmes, barrier contraceptive use, and sterilisation of tattooing equipment, acupuncture needles and the like are key prevention strategies. In health care settings, prevention of needlestick injuries, sterilisation of surgical and dialysis equipment, and blood donation screening are now known to be important. An effective vaccine against HCV is unlikely for some time (Dusheiko et al 1995), and passive immunisation with immunoglobulin following exposure is of uncertain value (Miller et al 1993).

The only pharmacological treatment for chronic hepatitis C infection currently available in New Zealand, alpha-interferon, is of limited effectiveness: fewer than 25 percent of selected patients show benefit more than six months after two courses of treatment have been completed (a beneficial outcome is defined as disappearance of HCV from serum together with improved liver histology and liver biochemistry) (Ross et al 1995). Early indications from drug trials suggest that ribavarin in combination with interferon may be more effective in clearing HCV than monotherapy alone. However, it is unknown if clearance of viraemia improves long-term survival or prevents cirrhosis. For patients with extensive liver damage in whom liver failure develops, the only prospect of survival lies in liver transplantation, a complex and expensive procedure necessitating lifelong immunosuppressive therapy (Farrell 1995).

In short, hepatitis C is a newly-characterised disease of considerable public health importance. Primary prevention strategies are fundamental to its control, as treatment is of unproven value. The incidence of long-term sequelae from chronic hepatitis C infection is still uncertain, but likely to be substantial. The direct and indirect social and economic costs to individuals and society arising from hepatitis C infection are now known to be significant (Tasman-Jones 1990).

Diagnostic and screening tests

Diagnostic assays were developed soon after the characterisation of the HCV genome. A diagnosis of HCV infection is confirmed by the detection of HCV antibodies (anti-HCV) and/or HCV genome sequences (HCV RNA) in blood.

HCV antibody tests

An enzyme-linked immunosorbent assay (EIA) test for HCV was first developed in 1989 and became available commercially in early 1990 (Kuo et al 1989). First-generation tests available in 1990 gave a high proportion of false negative and false positive reactions, but second and third generation assays have proved to be more sensitive and specific (Lee et al 1995).

Because of the relatively long interval of up to several months before the appearance of antibodies, negative anti-HCV tests in patients with acute liver disease do not preclude a diagnosis of hepatitis C. Positive anti-HCV tests in patients with chronic liver disease do not distinguish between past and current infection. Unlike hepatitis A and B, there is, at present, no reliable IgM antibody test for the detection of recent hepatitis C infection.

EIA tests are generally acceptable for the diagnosis of individuals at high risk, but in the context of screening programmes, the positive predictive value of these tests is low, because of the low prevalence of HCV in the population, and false positive reactions are not uncommon (Moaven 1996). Confirmatory antibody testing using the recombinant immunoblot assay (RIBA) test can help to distinguish true from false positive reactions. RIBA testing provides information about the viral epitopes reacting in the EIA: two or more positive bands confirm HCV infection, and no positive bands indicate the absence of infection. However, if one band is positive, the result is 'indeterminate' and ambiguity remains (Miller et al 1993). RIBA is useful in increasing the specificity of blood donor screening, but its usefulness in diagnostic testing is limited.

HCV RNA

Where doubt exists in the diagnosis of acute or chronic hepatitis C, testing for the presence of circulating HCV RNA using polymerase chain reaction (PCR) amplification techniques can assist. If the test is positive, the patient has hepatitis C. If the test is negative, current infection cannot be excluded because RNA levels can fluctuate. Repeat PCR testing after a period of time may be necessary to establish the diagnosis. The detection of low levels of HCV RNA requires fresh, sterile blood specimens that have not been frozen and thawed repeatedly. The test is expensive, and currently only available in three centres in New Zealand.

Table 1 summarises the various combinations of test results, with their interpretation.

Table 1: Diagnostic tests for HCV

Test	Results			
Anti-HCV EIA	+	+	+	-
RIBA	+	+/indeterminate	-	-
PCR (for HCV RNA)	+	-	-	-
Interpretation	chronic infection	past/current infection	past/current infection	not infected

Blood transfusion services in New Zealand

The introduction of screening for HCV occurred while important changes in the structure of the blood transfusion services (BTS) were taking place. Prior to the 1993 health reforms, the BTS was an association of blood transfusion units funded by the Department of Health through Area Health Boards. Despite this informal structure, there was considerable co-operation among the units, with the Auckland Regional Blood Services (ARBS) acting as the co-ordinating centre and liaising with Commonwealth Serum Laboratories (CSL) in Australia for the supply of specialised products. Responsibility for the supply and quality of blood was not explicitly provided for, but fell within the responsibility of the Department of Health.

Since 1993, the BTS has undergone major administrative change in parallel with the rest of the health service in an attempt to bring more efficiency and innovation, and to improve accountability and quality (Howden-Chapman et al 1996). The Blood Transfusion Trust now monitors supply. Blood processors are responsible for compliance with purchasers' specifications and liable for any breaches, and regional health authorities (RHAs) monitor the performance of the processors. The Therapeutics Section of the Ministry of Health sets and monitors minimum safety standards for the collection, processing and quality assurance of blood. In addition, expert advisory committees keep the Minister of Health informed of relevant issues pertaining to blood safety.

Processing of donated blood

Following its donation at a blood collection centre, blood is screened for a range of infectious diseases prior to being stored as whole blood or fractionated into a range of components. Each donation is assigned a number which remains with the components derived from that donation. The past donations of a particular donor can be identified by manually or electronically linking his or her donor number to these donation numbers.

Some components, such as platelets, are transfused directly, in the same way as whole blood. Other components are sent to CSL, Australia where they are pooled to produce special products such as clotting factor concentrates for administration to people with haemophilia.[1]

Products designated for transfusion are held in storage at a blood centre or Crown health enterprise (CHE) blood bank until they are required. When there is a request for blood, the appropriate blood product is tested for compatibility with a presumptive recipient's blood group. If it is compatible, the blood product is released from the blood bank to the patient, whose National Health Index (NHI) number is recorded by the blood bank along with details of the blood product type, date of release and donation number. Sometimes the blood product may not be needed, and may be returned to the blood bank or disposed of if it has exceeded its expiry date. When a blood product is transfused, a label identifying the donation number is inserted (usually with an adhesive) in the patient's medical records.

Large centres, such as ARBS, collect and store blood from throughout the region, releasing it to CHE blood banks according to demand. In other regions, smaller CHE blood centres collect, process and store blood at a local level or alternatively forward blood to regional centres for processing.

Blood donor screening for HCV in New Zealand

A chronology of the introduction of blood donor screening for HCV in New Zealand has been presented in detail elsewhere (Rodger and Morey 1992). As a result of the introduction of nationwide HCV screening in July 1992, a number of donors infected with HCV were identified for the first time. The recognition of their donations as being potentially contaminated with HCV led to calls for the identification and tracing of recipients of blood products derived from their past donations, a process known as 'lookback'.

[1] Such pooled products were not followed by the lookback programme: as early as 1989, Factor viii from CSL was super-heat treated to eliminate hepatitis C, and Factor ix (Prothrombinex) was the subject of the Rodger Inquiry (Rodger and Morey 1992).

Lookback: aims, rationale and approaches

The aims of lookback are twofold:

1. to enable improved prognosis for those infected from transfusion, through diagnosis, harm minimisation and early treatment; and

2. to limit the spread of infection by alerting asymptomatic infected persons of their potential for transmission of HCV to others.

The term 'lookback' was first coined in the 1970s by blood transfusion centres in the United States in relation to the spread of human immunodeficiency virus (HIV) through the blood supply. It described the process of checking through blood donation records in order to identify the recipients of past blood donations from donors testing positive for HIV. Recipients so identified were offered testing and appropriate management (Busch 1991). Hepatitis C lookback has been more controversial. Some authorities have argued for community and physician education alone, because of the substantial opportunity costs in operating lookback programmes and the likely low returns (Busch 1991). However, lookback programmes are now widely recognised as an appropriate response from health authorities given the clinical, ethical and technical considerations (Kolins 1990).

- Clinical considerations include infectivity, natural history, pathogenicity and availability of treatment. The high infectivity of HCV by transfusion, its ability to cause illness in a substantial proportion of people infected, and the possibility that early diagnosis and treatment may improve prognosis and quality of life all point in favour of hepatitis C lookback.

- Ethical arguments are even more compelling: these revolve around the duty of health authorities to inform patients who may have received infected blood, with the possibility of a net gain to individuals and to society.

- Technical issues include the adequacy of information systems, the availability of high-quality stored serum, appropriate diagnostic tests and the cost-effectiveness of lookback compared with other alternatives.

Lookback programmes differ with respect to how entry into the programme is 'triggered', how far back the tracing of recipients extends, and who is offered screening.

- Standard lookback: donor screening identifies HCV positive donors whose past donations might be infected. Recipients of these past donations are traced and offered testing. Standard lookback does not identify the recipients from donors who have not returned to give blood after the introduction of screening.

- Retrospective lookback: stored donor serum testing identifies HCV positive samples. Recipients of blood products derived from these donations are then traced and offered testing.

- General lookback: publicity encourages blood transfusion recipients to present for testing.

- Case report lookback: blood transfusion recipients diagnosed as HCV positive trigger a search for the donor. Any other recipients of blood products generated by that donor are then traced.

Hepatitis C lookback in New Zealand: history and ethical analysis

By 1993, limited hepatitis C lookback was already occurring in several centres for specific cases of post-transfusion hepatitis. The Otago Blood Transfusion Service commenced case report lookback in late 1992, as well as testing anxious transfusion recipients. Limited case report lookback was also occurring in Auckland and Hawke's Bay. At the same time, the Blood Transfusion Advisory Committee had suggested that a national lookback programme be considered by the Ministry of Health.

A May 1993 report to the Auckland Area Health Board contained comments from Dr David Seedhouse, Senior Lecturer in Medical Ethics at Auckland University, regarding the ethical responsibility of health authorities in regard to hepatitis C lookback (Priest and Hope 1993). Where transfusions were carried out in the absence of the ability to screen, the general responsibility incumbent on health workers to do their best for patients was upheld and there was no absolute ethical duty to undertake lookback for such recipients. However, there was an increased ethical duty to find, inform and offer treatment if appropriate for recipients of transfusions after the capacity to prevent transmission through donor screening was established. Based on the HIV experience, the likelihood was of a relatively poor yield.

Given the uncertain nature of benefits which could be expected for those traced and the expected large resource implications of lookback, Seedhouse was of the opinion that 'on balance, a major lookback programme cannot be recommended'. However, in view of the ethical considerations, a limited retrospective lookback was considered to be appropriate.

In October 1993, the *New Zealand Medical Journal* published a report of a lookback programme in Hawke's Bay triggered by the death of a man with post-transfusion hepatitis C (Jones et al 1993).

Following a series of consultations with transfusion experts, and provider and community groups in late 1993, on 7 June 1994, the Ministry of Health announced the setting up of a National Hepatitis C Lookback Programme. The intention of the programme was to trace all living recipients of blood transfusions given between August 1990 and July 1992 derived from donors who had tested positive for HCV. On making contact, these people were to be offered testing for hepatitis C, counselling provided and treatment arranged where appropriate.

The watershed dates were, to an extent, arbitrary. The capacity to prevent transmission through donor screening was agreed on by the Ministry of Health to be August 1990, the date when the Communicable Diseases Control Advisory Committee recommended that screening of donated blood for HCV should be introduced.

Both standard and retrospective lookback were to be undertaken, as together these approaches fulfilled two requirements:

- the ethical imperative of an increased duty on the part of health authorities to find and inform recipients of infected transfusions after it became technically possible to screen for HCV
- both approaches were practical given existing resources and capabilities, and cost-effective compared with other options.

On the basis of results from HIV lookback, it was estimated that standard lookback for HCV would identify between 217 and 718 living recipients, and retrospective lookback between 10 to 40 living recipients not identified by standard lookback. In addition, a small number of infected donors who had not returned to donate since July 1992 would be identified. It was thought likely that between 190 and 758 people would have contracted HCV infection from blood or blood products. While these estimates were useful for giving an order of magnitude, it was considered that the true figures would be likely to be closer to the lower numbers.

Materials and Methods

Organisational framework

Guidelines

It was recognised early on that there would be local variations in the conduct of the programme due to regional differences in the infrastructure of the blood transfusion services and small-scale lookback already in progress in a few centres. Each region was therefore encouraged to establish its own protocols for implementing the programme, reflecting the local situation, yet within the broad guidelines developed by the Ministry. The Ministry of Health guidelines are shown in Table 2.

Table 2: Ministry of Health guidelines for the National Hepatitis C Lookback Programme: objectives and key elements

Objective	Key elements
• Identify all positive donations made between August 1990 and July 1992	Standard and retrospective lookback testing
• Trace recipients	Compliance with Privacy Code Blood bank record search Medical record review Cross-check with death register prior to making contact
• Advise recipients of exposure	Seek initial face-to-face meeting if possible Provide information and counselling
• Test recipients	Informed consent Testing at no charge to recipient If EIA positive, check HCV PCR
• Post-test counselling of recipients	Face-to-face, if possible, especially where positive Provide written confirmation of results
• Follow-up	Inform general practitioner (where consent for this is given) Arrange further review where anti-HCV RR and/or PCR positive
• Donor notification	Contact donors whose stored sera tested anti-HCV positive

Funding and task allocation

The four RHAs were funded by the Government to purchase and monitor regional lookback programmes from CHE blood transfusion services:

- North Health contracted with ARBS, the region's major blood transfusion laboratory, to undertake all lookback work in the region. In the early 1990s, blood products had been sent from ARBS to Gisborne Hospital and Northland Area Hospital. At the same time, donations were collected by ARBS from Waikato donors. South Auckland Health, Auckland Healthcare Services, Waitemata Health, Tairawhiti Healthcare and Northland Health CHEs, and a private hospital assisted with blood bank and medical record searching and review.
- Midland Health contracted two CHEs, Taranaki Healthcare and Health Waikato, to carry out its region's programme. Lakeland Health, Eastbay Health and Western Bay Health assisted with record searches.
- Central RHA's task was made complex by the number of CHE laboratories involved: Capital Coast Health and MidCentral Health undertook the retrospective testing for the region, while standard lookback testing was carried out by Healthcare Hawkes Bay, Good Health Wanganui, Wairarapa Health, Hutt Valley Health, MidCentral Health and Nelson Marlborough Health Services.
- Southern RHA contracted a number of CHE laboratories to conduct the programme in its region: Canterbury Health and Healthcare Otago carried out retrospective testing. Southern Health, HealthCare Otago, Coast Health Care, Canterbury Health and Health South Canterbury all undertook standard lookback and recipient tracing.

Human resources

ARBS and Waikato BTS employed additional personnel to co-ordinate their programmes and undertake tracing. Other centres utilised staff already working in the BTS.

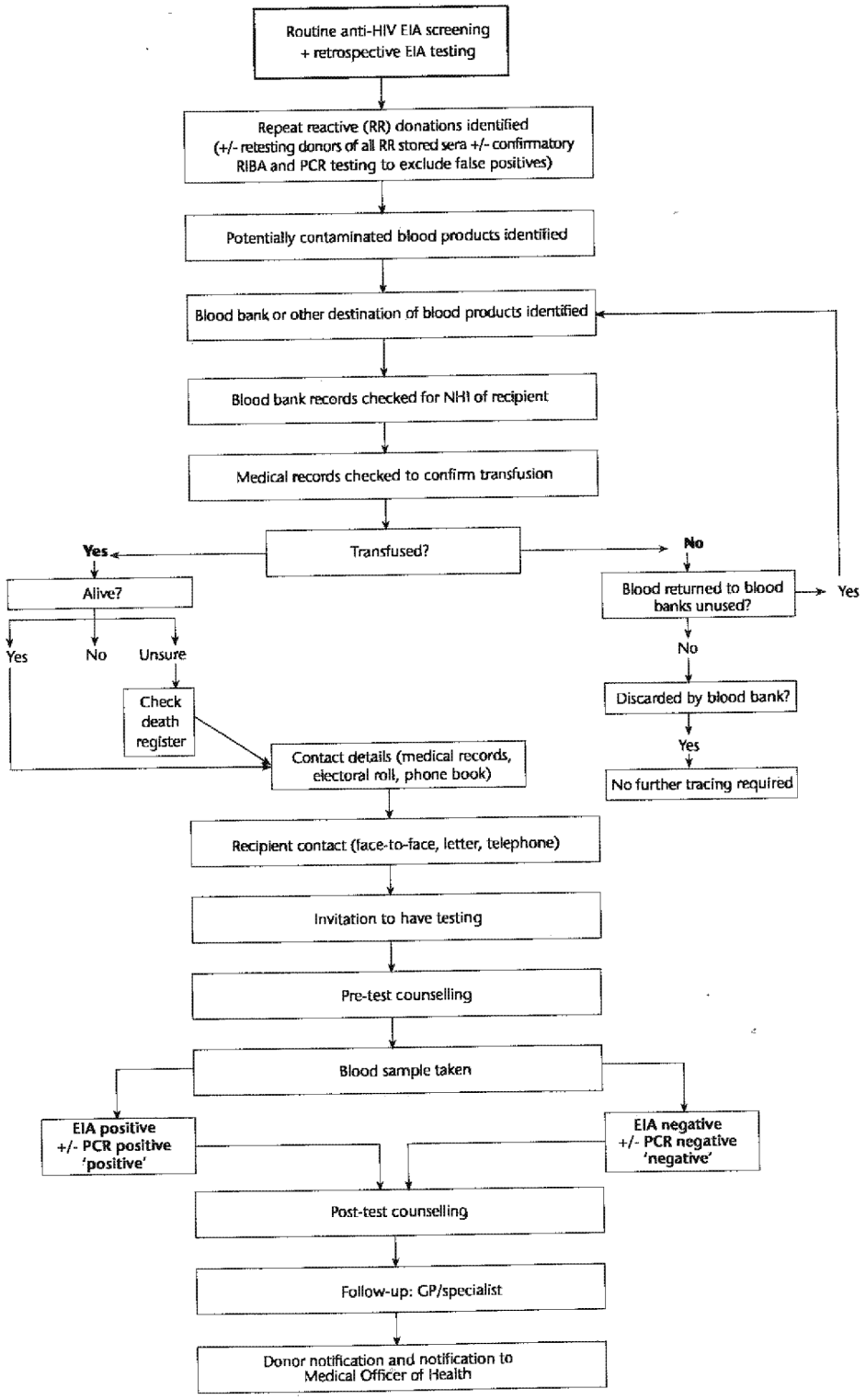
Data management and reporting

Where computer systems were already established, record linkage facilitated the tracing of donations and products. Manual record searching was an arduous and time-consuming task for many centres. Barcoding was used for labelling individual specimen tubes in several centres. Throughout the lookback programme, data were collected by CHEs and ESR, and collated in quarterly reports to RHAs and the Ministry of Health.

Steps in the lookback process

The steps in the lookback process varied among and within regions. A 'generic' lookback framework that takes into account these variations is shown in Figure 1.

Figure 1: Steps in the lookback process



1. Identification of blood products to be traced

Standard and retrospective lookback approaches were used to identify which blood products were to be traced further.

a. The records of donors identified as HCV positive since screening began in July 1992 were reviewed in order to identify all their past donations made from August 1990 onwards. The standard lookback timeframe was accepted by all RHAs except Central RHA, which traced all past donations of any positive donors as far back as records would allow.

b. Specimens of serum from these donations were located in BTS storage freezers and tested using standard EIA methods. An initial EIA test was performed; if positive, this was repeated in duplicate. If two out of the three tests were reactive, this was designated a repeat reactive (RR), or positive, EIA test. If not, the result was classified 'negative' and not followed further.

c. Retrospective serum testing was undertaken as follows. After excluding the stored sera of those donors identified in the standard phase, and those of any other repeat donors post-July 1992 who had tested anti-HCV negative, the remaining sera were systematically tested using standard EIA techniques, as detailed above.

- Canterbury Health and HealthCare Otago obtained fresh specimens from donors whose stored sera tested RR, because of concerns that the poor condition of some stored sera might give false positive results. Where a donor could not be located for retesting, the specimen was treated as if contaminated, and tracing proceeded.

- Other centres took a different approach. Where a sample was in poor condition, insufficient in quantity, missing, or the label illegible or missing, samples from previous donations were tested. If this was not possible, the sample was treated as if contaminated with HCV, and tracing proceeded.

- To avoid unnecessary testing of all samples of repeat donors, the following steps were followed by ARBS and several other centres: the most recent samples were tested first and if negative, any previous donations were excluded from further testing. All RR tests were traced to the first and subsequent donations made in the lookback period. If the earliest sample also tested RR, all subsequent samples from that donor were assumed to be 'positive'. If the earliest sample tested negative, the next most recent sample was located, tested and so on.

There was variation among the centres as to what constituted a 'positive' test and therefore what triggered further tracing of blood products. This variation was in part due to some centres having local lookback programmes under way prior to the inception of the national programme, and also because other centres had in place HCV screening protocols that differed from the one recommended by the Ministry of Health.

- In the Northern region, all RR screening tests were called 'positive'. Tracing of the recipients of products generated from these donations proceeded without further confirmatory testing.

- In the Midland region, Waikato BTS followed the same procedure as ARBS, whereas Taranaki BTS followed up only those RR tests that were confirmed by a positive or indeterminate RIBA.

- Central RHA requested its CHE laboratories to follow their 'current practice' for the standard lookback, whereas for retrospective testing a procedure identical to that of ARBS and Waikato BTS was followed. 'Current practice' was either the method adopted by Taranaki BTS, in which confirmatory testing was undertaken on all RR sera, or the procedure followed by ARBS and Waikato BTS.

- Southern RHA followed up blood products from fresh donor samples giving (a) a RR result supported by a positive or indeterminate RIBA and/or positive PCR test result, or (b) a weak RR where further test information was not available because of insufficient serum or because the donor was unable to be contacted for a fresh test sample.

Thus there were two distinct approaches taken. Both approaches involved steps to ensure that all possible recipients at risk were identified. The fundamental difference related to efforts to reduce the numbers of false positive tests, to avoid contacting recipients of blood products that were in fact not contaminated with HCV.

2. Tracing the fate of blood products derived from the donations

Blood transfusion centre records were reviewed to establish the end use of the products generated from the positive donations. Where these blood products had been forwarded to CHE blood banks, the blood bank registers were reviewed to identify the NHI number of the recipient, which then facilitated the location of hospital records.

3. Tracing recipients of HCV 'positive' blood

Hospital records were examined for a number of reasons:

- to confirm that transfusion had taken place with the suspect blood product
- to confirm that a recipient had not died at the time of the index, or any subsequent, hospital admission
- if the recipient had died, to establish if HCV infection might have contributed to the death
- if the recipient was thought to be alive, to obtain details about his or her current state of health and circumstances, so as to be able to make contact more sensitively
- to obtain sufficient details with which to trace the whereabouts of a recipient.

In a handful of cases, hospital blood bank records and medical records could not be located or labels confirming that the product in question had been transfused were absent from patient's notes. In the latter situation, if nursing, medical or anaesthetic records could not provide convincing evidence to the contrary, the patient was regarded as a recipient and was traced accordingly.

Where there was uncertainty as to whether a recipient was still alive or not, contact was made with the Registry of Births, Deaths and Marriages. In this way, inadvertent disturbance of grieving families could be avoided. Where death was confirmed, the cause of death was noted, and no further action was taken.

Other avenues of access to an individual's current whereabouts included through next-of-kin, the electoral rolls, telephone book listings and the general practitioner (GP) stated at the time of admission. In a few cases, hospital authorities insisted that a recipient's permission be obtained before access to medical records was granted.

4. Contacting recipients

Variation in the means used to contact recipients reflected differences in the regional health system infrastructure and in resources available to the RHAs and CHEs implementing this phase:

- In the Northern region, the majority of recipients resided in the greater Auckland area, and an initial personal contact was sought by visiting the recipient's home, or workplace where a home address was not able to be obtained. If this approach failed after three attempts, a letter was sent with an invitation to make contact. Where a recipient was thought to be alive (a death certificate had not been filed), but not traceable to his or her last known address, contact was made with his or her next-of-kin or GP. Where a recipient had moved to another centre or overseas, a letter was sent directly if a forwarding address was known, or via a medical attendant known to the recipient. Occasionally, the local Medical Officer of Health was involved in arranging contact and notification of exposure.
- Midland Health's initial approach was by telephone, or if that were not possible, by letter, alerting the recipient to his or her exposure, and arranging an appointment for further discussion, testing and counselling, either at the recipient's home or the blood donor centre.
- Central RHA contacted the recipient's usual medical practitioner (GP or specialist) asking him or her to make the initial contact, as it was felt this would best take into account the recipient's particular needs and situation.
- Southern RHA made contact by letter or through the recipient's GP.

If these avenues were exhausted, the recipient was considered 'untraceable'.

5. Pre-test counselling

Recipients were informed that the blood product they had received was from a donor whose stored serum had been found to have antibodies to HCV. It was stressed that this did not necessarily mean that the donor was infective at the time of donation, or that the blood product was contaminated. The need for a blood test to determine whether or not infection had occurred was emphasised. Written material about hepatitis C infection such as the Ministry of Health's *The Facts on Hepatitis* C pamphlet (Ministry of Health 1994), or pamphlets prepared locally, were available for reading and discussion.

6. Recipient testing

With the recipient's consent, the collection of a blood sample was arranged with a CHE or private laboratory. A time and location for discussing the results was agreed upon and the preferred method for notifying the GP and any other relevant medical attendant of the visit and results noted. Contact details were made available to the recipient so he or she could discuss any questions or concerns while awaiting test results.

Where a recipient's anti-HCV test was negative, no further testing was undertaken: the recipient was considered as 'hepatitis C negative'. Where a recipient tested RR, however, a further serum specimen, either from the sample taken at the initial visit, or a fresh one, was sent to ESR for PCR testing. These took upward of two weeks to be processed.

7. Post-test counselling

A co-ordinator/counsellor or a clinician responsible for the ongoing care of the recipient was involved in counselling recipients. The results of a test were always given to the recipient in written form, and in a face-to-face situation where possible.

Where the anti-HCV test was negative, the recipient was informed either directly or by telephone or letter and reassured that there was no evidence of HCV infection past or present.

Regardless of the PCR result, recipients testing RR were counselled regarding the implications of a positive test and the uncertainties of the natural history of hepatitis C infection. The minimisation of liver injury through reducing alcohol intake and immunisation against hepatitis A and B were recommended. Safe sexual practices, the screening of partners, children or others at risk for hepatitis C infection, and treatment options were discussed.

8. Follow-up

Arrangements for further review were made either through the GP or, for those recipients without a GP, directly through hospital outpatient clinics. Recipients testing RR but PCR negative were advised to have a further PCR test in six months' time, through their GP or specialist.

- In the Auckland region, contact details of the Hepatitis C Support Group, a support and advocacy organisation based in Auckland, were made available to all recipients found to be RR.

9. Donor notification

Notifying blood donors was not a focus of the programme and the guidelines for dealing with this were not specific. Accordingly, some centres approached donors in the same way they would contact current donors testing positive on routine screening, whereas others followed the approach used in lookback recipient tracing. Where a donor had moved out of the province or region, or was overseas, a letter was sent to the new address giving information about the lookback programme and advice given to arrange HCV testing through his or her GP, or local blood donor centre.

- ARBS and Waikato Health wrote to those donors whose stored serum had tested RR, explaining the possibility of infection and recommending that contact be made with a GP or directly with the BTS for retesting.
- Central RHA and Taranaki Health made contact with donors by phone to arrange an appointment for face-to-face counselling.
- The Southern CHEs varied: some made contact by phone or letter, encouraging donors to attend for re-testing, while others arranged counselling.

Programme review

A meeting of relevant RHA and blood centre personnel involved in undertaking, co-ordinating and monitoring the programme was held at the Ministry of Health late in 1996, when most centres had completed their lookback programmes. This meeting provided an opportunity to discuss progress and problems and raise issues of concern. This was the only such national meeting held in the course of the programme.

Additional information and comment was derived from discussions with key programme personnel at BTS or RHA level, and from written feedback entered on a report form circulated to all centres by the author in late 1996.

Summary of findings

Overall results by region and CHE

Data presented in this report do not include results from local lookback programmes already in place when the national programme was implemented.

Table 3 presents the results to date by region, with national totals. For the sake of simplicity and clarity, data for key parameters only are presented. More detailed breakdown of the data for each CHE, where appropriate, is found in Tables 4 to 6. (A separate table for the Northern region is not included, because ARBS arranged all testing and tracing.)

Large gaps in data are evident in some tables. These reflect deficits in data collection at the time the programme was undertaken, or an inability to tease out relevant data from aggregated figures at the time of analysis.

Table 3: Overall results to 1 December 1996, National Hepatitis C Lookback Programme, by region

	Northern	Midland	Central	Southern	Total	Ministry of Health estimates
No. screening tests performed (retrospective lookback)	26554*	8600	14656	13001	62811	
No. of these that were RR	164 (0.62%)	96 (1.1%)	90 (0.61%)	165 (1.3%)	515 (0.82%)	
No. recipients of products donated 1990–92 from donors identified as positive since July 1992 (standard lookback)	90	76	82	33	281	217–718
No. recipients identified overall	195	118	213	143	669	227–758
No. recipients traced	80 (41%)	70 (59%)	116 (54%)	73 (51%)***	339 (51%)	
No. recipients tested	77 (96%)	62 (89%)	98 (84%)	40 (55%)	277 (82%)	
No. recipients RR	30 (39% of those tested)	24 (39% of those tested)	58 (59% of those tested)	20 (50% of those tested)	132 (48% of those tested)	190–758
No. recipients PCR positive**	19 (63% of RR recipients)	14 (58% of RR recipients)	unclear?7 (using ESR figures)	16 (80% of RR recipients)	56 (46% of RR recipients, including Central)	
No. donors contacted	90	76	unclear	162	328	
No. donors tested	not available	16 (21%)†	not available	161 (99%)	177 (54%)	
No. donors RR	not available	11 (69%)†	not available	41 (25%)	52 (29%)	

*Further testing on several thousand sera from Waikato donors stored at ARBS is in progress
***Recipient tracing and testing still in progress at Otago BTS
**Repeat PCR testing will detect more HCV EIA RR recipients who are also PCR positive
†Data from Taranaki BTS only

Table 4. Results to 1 December 1996, National Hepatitis C Lookback Programme, Midland region

	Taranaki BTS	Waikato BTS	Total
No. screening tests (retrospective lookback)	2107	6493	8600
No. tests that were RR	15 (0.7%)	81 (1.2%)	96 (1.1%)
No. recipients of products donated 1990–92 from donors identified as positive since July 1992 (standard lookback)	17	59	76
No. recipients identified overall	24	94	118
No. recipients traced	20 (83%)	50 (53%)	70 (59%)
No. recipients tested	14 (70%)	48 (96%)	62 (89%)
No. recipients RR	10 (71% of those tested)	14 (29% of those tested)	24 (39% of those tested)
No. PCR positive	7 (70% of RR recipients)	7 (50% of RR recipients)	14 (58% of RR recipients)
No. donors contacted	16	94	110
No. donors tested	16 (100%)	not available	16+
No. donors RR	11 (69%)	not available	11 +

Table 5. Results to 1 December 1996, National Hepatitis C Lookback Programme, Central region*

CCH Capital Coast Health
MCH MidCentral Health
HCHB Healthcare Hawkes Bay
GHW Good Health Wanganui
HVH Hutt Valley Health
NMH Nelson-Marlborough Health
WH Wairarapa Health

	CCH	MCH	HCHB, GHW	HVH, NMH, WH	TOTAL
No. screening tests (retrospective lookback)	5929	4364	1903	2460	14656
No. tests that were RR	15(0.25%)	36 (0.8%)	21(1.1%)	18(0.7%)	90 (0.6%)
No. recipients of products donated 1990–92 from donors identified as positive since July 1992 (standard lookback)	not available	not available	not available	not available	82
No. recipients identified overall	106	5	1	not available ?101	213
No. recipients traced	65 (61%)	1 (20%)	not available	not available	116 (54%)
No. recipients tested	47 (72% of those traced)	0	not available	not available	98 (84% of those traced)
No. recipients RR	37 (79% of those tested)	0	not available	not available	58 (59% of those tested)
No. PCR positive	not available	not available	not available	not available	not available
No. donors contacted	not available	not available	not available	not available	not available
No. donors tested	not available	not available	not available	not available	not available
No. donors RR	not available	not available	not available	not available	not available

* Note: RHA data does not correlate with individual CHE figures

Table 6. Results to 1 December 1996, National Hepatitis C Lookback Programme, Southern region

CHL Canterbury Health Ltd
HCO HealthCare Otago
HSC Health South Canterbury
CHC Coast Healthcare
SH Southland Health

	CHL	HCO*	HSC**	CHC	SH	Total
No. screening tests (retrospective lookback)	7123	3542	304	592	1440	13001
No. tests that were RR	100 (1.4%)	49 (1.4%)	2 (0.6%)	2 (0.3%)	12 (0.8%)	165 (1.3%)
No. recipients of products donated 1990–92 from donors identified as positive since July 1992 (standard lookback)	14	17	NIL	2	NIL	33
No. recipients identified overall	74	61	NIL	NIL	6	143
No. recipients traced	35 (47%)	35 (57%)	NIL	NIL	3 (50%)	73 (51%)
No. recipients tested	35 (100%)	2 (5%)	NIL	NIL	3 (100%)	40 (55%)
No. recipients RR	16 (46% of those tested)	1 (50% of those tested)	NIL	NIL	3 (100% of those tested)	20 (50% of those tested)
No. PCR positive	13 (81% of RR recipients)	0	NIL	NIL	3 (100% of RR recipients)	16 (80% of RR recipients)
No. donors contacted	114	43	NIL	NIL	5	162
No. donors tested	114 (100%)	43 (100%)	NIL	NIL	4 (80%)	161 (99%)
No. donors RR	33 (29%)	5 (12%)	NIL	NIL	4 (100%)	42 (26%)

* tracing and testing of recipients incomplete
** standard lookback undertaken prior to inception of the national programme

ESR reference laboratory testing

The results of confirmatory testing conducted by ESR are shown in Table 7.

Table 7: Results from ESR confirmatory testing of recipients testing HCV EIA RR as at 14 November 1996

CHE	No. received	RIBA positive	RIBA indeter-minate	RIBA negative	RIBA unknown	PCR positive	PCR negative	PCR not tested
Auckland	23	7	NIL	NIL	16	13	10	NIL
Christchurch	10	7	NIL	3	NIL	5	5	NIL
Greymouth	2	NIL	NIL	2	NIL	NIL	2	NIL
Dunedin	18	NIL	NIL	17	1	NIL	18	NIL
Invercargill	2	2	NIL	NIL	NIL	NIL	2	NIL
Masterton	3	3	NIL	NIL	NIL	1	1	1
Palmerston North	NIL	NIL	NIL	NIL	NIL	NIL	NIL	NIL
Taranaki	6	5	NIL	NIL	1	3	1	2
Tauranga	1	NIL	NIL	NIL	1	NIL	1	NIL
Timaru	1	1	NIL	NIL	NIL	1	NIL	NIL
Waikato	45	9	NIL	22	14	7	37	1
Wanganui	3	NIL	NIL	3	NIL	NIL	1	2
Wellington	7	6	NIL	1	NIL	6	1	NIL
TOTALS	121	40	NIL	48	33	36	79	6

Report findings

- The National Hepatitis C Lookback Programme identified 56 people as having chronic hepatitis C infection contracted from transfusions given between August 1990 and July 1992 and a further 76 people were found to be HCV antibody positive without evidence of chronic infection. This is consistent with estimates made by the Ministry of Health prior to programme implementation.
- Standard lookback methods identified 281 people as having been transfused with blood products possibly contaminated with hepatitis C virus.
- Retrospective testing of 62,811 stored serum specimens found 515 (0.82 percent) specimens to be repeat reactive for hepatitis C.
- As a result of standard lookback and retrospective testing, 669 people were identified as being at risk of possible hepatitis C infection. Only 374 people were still alive at the time of the lookback programme, as almost half of the recipients of these blood products had died as a result of the illness for which they had been transfused. This is consistent with what might be expected based on the findings from studies of post-transfusion mortality elsewhere. For only one recipient was hepatitis C infection considered to be a contributing factor to death.
- Of the 374 people still alive at the time of the lookback programme, 339 were contactable either by letter or an interview. Of these, 277 (82 percent) wished to be tested for HCV. Thirty-five people could not be contacted despite vigorous efforts and it is estimated that less than half of these people will have contracted HCV infection. The tracing methods employed were acceptable to the vast majority of recipients contacted and recipients found sensitive and skilled counselling to be extremely valuable.
- Of the 277 people who wished to be tested for HCV, 132 (48 percent) were found to be HCV antibody positive. Of these 132 people, 56 (42 percent) were identified as having chronic hepatitis C infection, as indicated by a positive PCR test. These people now have an opportunity to be considered for treatment, to take measures to minimise disease progression and to prevent transmission to others.
- As a result of the positive tests noted on retrospective stored serum testing, 328 *donors* who had possible chronic hepatitis C infection were also alerted. Of the 177 who agreed to testing, 52 (29 percent) tested hepatitis C antibody positive. Screening procedures in place nationwide since July 1992 now ensure that any infected donors are detected and their donations withdrawn before being processed.

Demographic details of recipients

Capture of demographic details of recipients was incomplete, as this was not specified in the guidelines issued to RHAs. Complete demographic data on RR recipients was available from ARBS only, on a total of 30 people. Of these, males and females were equally represented, and at the time of contact:

- 3 (10%) were less than 20 years of age
- 10 (33%) were between 20–39 years of age
- 5 (17%) were between 40–59 years of age
- 4 (13%) were in the 60–79 age group
- 8 (27%) were 80 years of age or over.

Feedback from programme personnel

Comments from programme personnel involved in testing, tracing, counselling and co-ordinating programmes at BTS or regional level have been incorporated in the Discussion section of this report. However, a number of salient points were made that bear stating:

- There were difficulties in locating and identifying stored specimens, which highlights a need for improved freezer organisation and specimen labelling. Where barcoding systems were in place, they facilitated speed and accuracy of serum location and identification.
- In a handful of cases, hospital blood bank records and medical records could not be located, but generally, the standard and integrity of medical records was high. Occasionally, labels confirming that the product in question had been transfused were absent from a patient's notes. In this situation, the recipient was included as a possible recipient and traced accordingly. While uncommon, these obstacles made it impossible to trace the fate of a handful blood products and thereby to identify an unknown but small number of recipients.
- It was anticipated that privacy legislation might pose a significant impediment to the identification and location of recipients. In general, this was not the case. Access to CHE medical records was granted following the usual authorisation procedures and most other sources of tracing information were available in the public domain.
- General practice staff were frequently the most valuable source of information with which to locate the whereabouts of recipients.

Feedback from recipients

While no formal evaluation of the acceptability of the programme to recipients was undertaken, comments from recipients, programme co-ordinators and others involved in contacting and counselling recipients were noted. The Hepatitis C Support Group provided feedback regarding aspects of the Northern region's programme. The feedback suggested the following:

- Efforts made to obtain an initial face-to-face meeting were appreciated by the majority of recipients contacted in this way.
- Other means of making contact were generally acceptable where there was the offer of counselling, and personal inconvenience and expense were minimised.
- The value of sensitive, supportive counselling cannot be overstated.
- The Ministry of Health hepatitis C information pamphlets were useful, but a leaflet specifically addressing the lookback programme would have been preferred.

Discussion

Context of the programme

Before discussing the programme findings, it is important to place the lookback programme in context:

- The foresight of transfusion authorities made this programme possible. It has not been widely recognised that the storage of donor sera for at least five years is not practised in many countries.
- No co-ordinated programme of this nature or extent has been attempted before in New Zealand.
- The programme was developed at a time of change in many areas: testing methods were relatively new and evolving; scientific, health professional and public knowledge of HCV was initially superficial but increased rapidly; the health system in New Zealand was restructuring into a regionalised purchaser – provider configuration; and during the course of the programme, staff turnover was high at both BTS and RHA levels.
- Levels of resources, such as access to computerised data management and technical assistance and advice, varied widely among centres. Computers are a fundamental tool for the accurate and timely storage, retrieval and analysis of data. In centres where computerised databases were established, the tracking of test results to blood products and their destinations was rapid and accurate, data entry straightforward and retrieval of data swift.
- The programme was superimposed on staff with heavy workloads. The location, organisation and testing of thousands of samples of frozen sera was a test of perseverance and the technical skills of busy laboratory personnel.
- Geographical and health system infrastructure variations among the regions necessitated the tradeoff between programme feasibility and uniformity of implementation.

Data quality

Differences in definition, testing and tracing processes and data recording presented a challenge to the collation and analysis of the findings from the local CHE and regional programmes.

- Marked differences in findings between CHE blood centres and between regions can be seen, some of which relate to programmes that have not yet completed final testing, others to the small numbers involved and the play of chance.
- In some reports, data from pre-existing local lookback programmes were mixed with those from the national programme and proved difficult to separate. For example, ESR has records of 121 recipient samples, of which 36 (30 percent) tested PCR positive, compared with 49 PCR positives out of 123 samples (40 percent) shown in Table 3. It has not been possible to reconcile these differences.
- Central RHA's decision to proceed back beyond the watershed date of August 1990 reflected a concern for the personal and public health importance of identifying and informing additional infected recipients. However, this made comparability with the other programmes difficult.

- There was evidently confusion between retrospective and standard lookback in some areas. This has made it difficult to compare the yield from these approaches.
- Less emphasis was placed on donor tracing and testing by some centres with the result that the quality of donor follow-up data varied.
- There were discrepancies between some CHE data and data held by the relevant RHA, which made interpretation difficult. Where this was the case, blood centre data were generally found to be the most consistent and plausible.
- The most important variations related to the use of confirmatory testing of RR stored donor specimens by Southern centres, Taranaki BTS and some centres in Central region.

Importantly, these variations did not lead to any potentially infected recipients being overlooked. All centres conducted the programme in ways that tended to be over- rather than under-inclusive.

Currently, several centres are still completing testing and tracing, but it is unlikely that the results of these programmes will substantially alter the overall results of the national programme.

Only a few centres retained demographic data of any sort. While this was not a specific requirement, lack of demographic data has made estimation of the likely future resource implications difficult. Such gaps in the national dataset represent a lost opportunity for the analysis and application of data from this unique programme.

Seroprevalence of stored sera

The overall seroprevalence of 0.82 percent was higher than that anticipated on the basis of a multicentre blood donor survey in New Zealand (Gibbons et al 1990). This almost certainly reflects increased numbers of false positives from centres where long-term cold storage of donor serum was inadequate.

Post-transfusion mortality

The 50 percent loss of recipients between identification and contact largely reflects the impact of post-transfusion mortality, and was not unexpected (Whyte 1988). The *disease for which transfusion was administered* led to the demise of the majority of recipients who died in the intervening years before their identification by the lookback programme. Many recipients had serious illnesses such as cancer, severe trauma or cardiac disease, for which multiple transfusions were required. Hepatitis C infection was considered to be a contributing factor in the death of only one recipient.

Post-transfusion hepatitis

Post-transfusion hepatitis C had been diagnosed in a small number of recipients prior to the inception of the lookback programme, so these people were not included among those contacted or tested in the course of the national programme.

Recipient tracing

Central region had a particularly high number of recipients to trace, relative to the number of screening tests performed. The reason for this is unclear.

Despite vigorous efforts nationwide, 35 recipients thought to be still living were unable to be contacted or did not reply to letters. Many of these were highly mobile people who left no forwarding address and had no regular GP. Some may have presented to their GP or a blood centre overseas for testing, without notifying the programme. Given the moderately high proportion of false positive serum tests, it is expected that perhaps only 50 percent of these people are at risk of having been infected, with a smaller proportion developing chronic disease. An estimate of at the most 20 people unaware of being chronically infected, is probable. The detection of such people is now dependent on their awareness of risk and the acumen and awareness of clinicians.

Recipient testing

The high proportion of individuals who proceeded with testing (85 percent) reflects favourably on the effectiveness and acceptability of pre-test counselling.

Regional variations in the proportion of recipients of RR recipients who were PCR positive reflects the use of confirmatory testing to eliminate false positives in Southern centres. The proportion of RR recipients who were PCR positive is likely to increase with subsequent PCR testing as a single negative PCR test is not a reliable indicator of the absence of chronic infection, due to fluctuations in virus concentration in the peripheral blood (van der Poel et al 1994).

Costs

It is outside the scope of this report to comment on the financial costs of the programme. If the demographic data from ARBS is representative of the overall age composition of these people (around 60 percent are under 60 years of age, and thus more likely to be considered for treatment than the older group), there are major resource implications for health services in New Zealand. A proportion of the people identified with hepatitis C infection will require lifelong medical surveillance and a variety of medical and surgical interventions that are unpleasant and expensive.

Ill-informed and inaccurate media coverage of the programme has added to already negative public perceptions of blood transfusion. It is likely that this has been a contributing factor to recent nationwide declines in blood donation, with some people irrationally ceasing donation, for fear of acquiring HCV infection.

Significant anxiety was experienced by some recipients. For some, who were found to be HCV negative, or the asymptomatic elderly for whom infection is unlikely to present significant adverse health effects in their lifetime, this was 'unnecessary'. This lends support to the approach adopted by centres to eliminate false positives early on in the lookback process. By reducing the number of false positive results resulting from mass serum EIA testing, the number of potentially infected recipients needing to be traced is reduced by almost 50 percent. The costs of confirmatory testing are high, but must be weighed against the costs of tracing recipients of products with false positive EIA results and the engendering of anxiety in such people who were not exposed to HCV in the first place, and further, underlines the importance of skilled communication and appropriate counselling at the time of contact.

Benefits

The benefits for both personal and public health accruing from this programme are considerable:

- People identified as having chronic hepatitis C are now in a position to be considered for treatment and to take measures to minimise the risk of disease progression and transmission. Where there is uncertainty regarding current disease activity, ongoing medical review has been arranged to clarify this.
- The complexities of a national programme are now apparent and the strengths and weaknesses of different approaches identified.
- Deficiencies in data-tracking and record-keeping systems in blood centres and hospital medical records departments have been highlighted.
- An urgent need to review the optimal means of maintaining high-quality, long-term storage of donor serum specimens has been identified.[2]
- There is the likelihood of a measure of public good-will towards the BTS for the efforts made to locate and inform individuals at risk.

[2] Stored serum quality relates to length and temperature of storage and the occurrence of freeze-thaw cycles. Long-term freezing, with or without occasional thawing, may lead to false positive antibody assay and PCR results. The greater the age of the sample, the more likely it is that such problems will occur. Further, the optimal temperature for long-term serum storage, around minus 30 degrees Celsius, is possible only in special freezers. Most of the donor serum in blood centres throughout New Zealand is held in domestic freezers at temperatures above this, and this may contribute additional false positive reactions.

Lessons learnt

The following comments address a number of issues that should be considered in any future lookback programmes.

Programme design

A greater investment in programme design was needed. This would have ensured greater consistency among centres and might have lead to less ambiguity and more precise clarification of definitions (eg, what constitutes a 'positive' HCV result), tighter testing protocols for stored specimens and recipients, and more specific tracing protocols for recipients and donors.

Partnerships with consumers

The forging of partnerships with consumer organisations, such as the Hepatitis C Support Group, would have permitted valuable insights into programme design and implementation, and assisted in communication about the programme with affected individuals and their families.

Programme monitoring

More frequent review throughout the course of the programme and greater support of local co-ordinators would have identified problems early on. This would have avoided some of the difficulties experienced in reporting and interpreting programme results and might have best been achieved by the appointment of a national co-ordinator.

Information

Improved information for health professionals and the public through, for example, a telephone helpline, a purpose-written pamphlet and a handbook for RHA, CHE and blood centre staff covering definitions, testing protocols and data management recommendations would have been helpful.

Data management

More attention to the quality and feasibility of data collection, storage and retrieval at each step would have facilitated the progress of the programme. This programme clearly illustrates that electronic information technology is essential for operating a modern blood service with the capacity to audit and review its activities.

Risk communication

Negative public perceptions of blood transfusion generated by publicity about the programme may have been reduced through greater attention to skilled communication. Public perception of risk is high when an exposure to a 'new' infective agent such as HCV is involved, carrying as it does the threat of serious illness. Improved means of communicating risk are required so that the risks of transfusion-acquired infection, which are now lower than ever before, are balanced against the benefits of transfusion. Health workers involved in transfusion practice must develop skills in this increasingly important area if legitimate public concerns are to be satisfactorily addressed and confidence in the quality of the blood supply maintained.

Conclusions

The National Hepatitis C Lookback Programme sought to alert people who received blood transfusions between August 1990 and July 1992 to the risk of their being infected with HCV, and to offer them testing. This report demonstrates that, despite a number of constraints and variations in approach, this aim has been achieved for over 300 people. Feedback from individual recipients and the Hepatitis C Support Group suggests that, in general, the programme was conducted with sensitivity and skill.

Lookback programmes are difficult to conduct and are demanding of resources. Challenges are posed by the limitations of data-storage systems, doubts about the quality of stored serum, technical issues relating to the interpretation of tests and difficulties tracing the whereabouts of blood products and their recipients up to five years after transfusion.

As this report highlights, the nationwide programme took a variety of alternative routes in order to achieve the desired outcomes. Importantly, the likelihood of infected recipients having been overlooked is minimal.

Additionally, the programme has provided an informal audit of blood transfusion centre serum storage and data tracking systems, identifying areas for further research and improvement.

Finally, a lookback framework has been developed and implemented that will prove to be a valuable resource in the event of any future challenge to the blood services from other bloodborne infections.

Recommendations

Blood transfusion services

- The installation of compatible computer-based data management systems in blood centres throughout New Zealand should be a priority.
- Further research is needed into the optimal conditions for long-term storage of donor serum specimens to ensure secure and easy retrieval.
- The adequacy of current cold storage facilities should be reviewed.

Future lookback programmes

- Attention should be paid to achieving consensus among those conducting the programme regarding definitions, procedures and protocols where appropriate prior to programme implementation.
- Relevant consumer groups should be involved early on in the design phase.
- Close monitoring and co-ordination of programme progress is essential to ensure as much consistency in definition and approach as possible.
- Ready access to high quality information for health workers involved in the programme and for the public is vital to avoid confusion.
- More effective means of risk communication must be developed so that the safety of blood donation and transfusion is emphasised.

References

Busch MP. 1991. Let's look at human immunodeficiency virus look-back before leaping into hepatitis C virus look-back. *Transfusion* 31:655–61.

Chemello L, Alberti A, Rose K et al. 1994. Hepatitis C serotype and response to interferon therapy. *N Engl J Med* 330:143.

Choo Q-L, Kuo G, Weiner AL et al. 1989. Isolation of a cDNA clone derived from a blood-borne non-A, non-B viral hepatitis genome. *Science* 244:359–62.

Dusheiko GM, Soni P, Harrison TJ et al. 1995. Genetic diversity of hepatitis C: implications for pathogenesis, treatment and prevention. *Lancet* 345: 562–6.

El-Zayadi A, Selim O, Rafik M et al. 1992. Prevalence of hepatitis C virus among non-A, non-B related chronic liver disease in Egypt (letter). *J Hepatol* 14:416–7.

Farrell GC. 1995. Hepatitis C: a current perspective. *Aust Fam Physician* 24:321–9.

Gibbons S, Faed J, Fong R et al. 1990. Seroprevalence of hepatitis C antibody in New Zealand blood donors. *NZ Med J* 103:490 (letter).

Higiwara H, Hayashi N, Mita E et al. 1993. Quantitative analysis of hepatitis C virus RNA in serum during interferon-alpha therapy. *Gastroenterology* 104:877–83.

Howden-Chapman P, Park J, Scott K et al. 1996. An intimate reliance: health reform, viral infection and the safety of blood products. In: P Davis (ed). *Intimate Details and Vital Statistics: Aids, sexuality and the social order in New Zealand.* Auckland: Auckland University Press.

Jones AP, Meech RJ, Seldebeek H et al. 1993. Hepatitis C: the tracing dilemma. *NZ Med J* 436–7.

Klein RS, Freeman K, Taylor PE et al. 1991. Occupational risk for hepatitis C virus infection among New York city dentists. *Lancet* 338:1539–42.

Kolins J. 1990. Hepatitis C look-back: our next challenge. *Transfusion* 30:380 (letter).

Kuo G, Choo Q-L, Alter HJ et al. 1989. An assay for circulating antibodies to a major etiologic virus of human non-A, non-B hepatitis. *Science* 244: 362–4.

Lee SR, Wood CL, Lane MJ et al. 1995. Increased detection of hepatitis C virus infection in commercial plasma donors by a third-generation screening assay. *Transfusion* 35:845–9.

Main J. 1995. Hepatitis C: Clinical Aspects. *J Infection* 30:103–6.

Miller J, Baker M, Wilson N. 1993. The epidemiology and control of hepatitis C in New Zealand. *Comm Dis NZ* 93:33–8.

Ministry of Health. 1994. *The Facts on Hepatits C*. Wellington: Ministry of Health.

Moaven L. 1996. Hepatitis C virus. *New Ethicals* April:11–15.

Priest P, Hope V. 1993. *A Review of Options for a Response to Hepatitis C Virus Transmission Through Transfusion; Including Look-Back Programmes for Recipients of Blood Contaminated with Hepatitis C. Report to Auckland Area Health Board*. Auckland: Department of Community Health, Auckland School of Medicine.

Rodger S, Morey S. 1992. *Inquiry into Matters Relating to the Safety of Blood Products in New Zealand*. Wellington: Department of Health.

Ross AG, Burt MJ, Jennings LC et al. 1995. Treatment of chronic hepatitis C with interferon alpha. *NZ Med J* 108:101–3.

Seeff LB, Buskell-Bales Z, Wright EC et al. 1992. Long-term mortality after transfusion-associated non-A, non-B hepatitis. *N England J Med* 327:1906–11.

Sherlock S. 1992. Viral hepatitis. *Lancet* 339:802.

Strader DB, Seeff LB. 1996. The natural history of chronic hepatitis C infection. *Euro J Gastro and Hepatology* 8:324–8.

Strasser S, Watson K, Soon Lee C et al. 1995. Risk factors and predictors of outcome in an Australian cohort with hepatitis C virus infection. *Med J Australia* 162:355–8.

Tasman-Jones C. 1990. Hepatitis C – a viral disease of community importance. *NZ Med J* 103:421.

van der Poel CL, Cuypers,HT, Reesink HW. 1994. Hepatitis C virus six years on. *Lancet* 344:1475–9.

Whyte GS. 1988. The transfused population of Canterbury, New Zealand, and its mortality. *Vox Sang* 54:65–70.