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NHS
National
Services
Scotland

SCOTTISH NATIONAL BLOOD TRANSFUSION SERVICE

PENROSE INQUIRY

LOOKBACK

Procedures to identify, trace and offer counselling and testing to patients who received blood components from donors subsequently found to be positive in tests for HIV and HCV

The question from Mr Tullis on 21 April 2010 was:-

> *A fresh point is that I have been asked by counsel to put a request to you in the undernoted terms which may, in due course and if necessary, form the basis of a formal section 21 order in due course.*
>
> > *"(1) What was the SNBTS policy in relation to HCV look-back (including the counselling and testing of donors and recipients)*
> >
> > *(a) between the introduction of screening for HCV in September 1991 and the commencement of the UK-wide HCV look-back exercise in early 1995,*
> >
> > *(b) during the UK HCV look back exercise,*
> >
> > *(c) after the end of the UK HCV look-back exercise (in 1998?) and*
> >
> > *(d) what is the current SNBTS policy in that regard?*
> >
> > *(2) Please provide the principal documents vouching the SNBTS's policy on these matters during each of these periods.*
> >
> > *(3) Please provide any final report (produced in 1998?) of the look-back undertaken by the SNBTS as part of the UK HCV look-back exercise".*

The following paper has been prepared by the Scottish National Blood Transfusion Service to give as full an explanation to these questions as possible.

GLOSSARY

AIDS:	Acquired Immune Deficiency Syndrome
Component Therapy:	the practice of separating blood into its component parts (red cells, platelets, plasma, etc) so that several patients may benefit from a single donation.
EIA:	enzyme immunoassay. The most widely used test system for detecting antibodies to infectious agents.
Hepatitis B surface antigen (HBsAg) :	the protein coat of hepatitis B virus, which is produced in excess in active infection, and which is easily detected by several types of test.
Hepatitis B virus (HBV):	a highly infectious DNA virus, discovered in 1968, until which time it was known as serum hepatitis (because of predominant route of transmission, which is by contact with infected blood, in contrast to hepatitis A virus ("infectious hepatitis") which is spread by the faecal–oral route). Tests for HBV first became available in 1970. The carrier state is unusual in newly infected adults but common when infection is from mother to child.
Hepatitis C virus (HCV):	the virus primarily responsible for non-A, non-B hepatitis, discovered in 1989. Antibody tests first became available in 1990 and were introduced as routine screening tests by the UK Blood Transfusion Services on 1 September 1991. An RNA virus, mainly transmitted by the parenteral route. Around 80% of infected individuals become chronic carriers.
HIV :	human immunodeficiency virus – the cause of AIDS.
HTLV III :	human T cell leukaemia virus type III. The name first used to designate the virus causing AIDS when it was first isolated in 1983. Later replaced by the designation HIV.
Plasma :	the liquid portion of anticoagulated blood, separated by centrifugation from the cellular components. The medium for circulating proteins and other substances e.g. clotting factors, which are isolated and purified in bulk from a pool of many plasma donations.
Polymerase Chain Reaction (PCR) :	the method by which HCV was discovered, and the technique still used to find and multiply fragments of viral RNA/DNA in blood or tissues. Used by SNBTS as part of the confirmatory tests for HCV when anti-HCV testing began in 1991.
RIBA 2 :	recombinant immunoblot assay, 2nd generation. The supplementary test first used by SNBTS to confirm the presence of antibodies to HCV in the event of a reactive antibody screening test. Now supplanted by RIBA 3.
RNA:	ribonucleic acid. The genetic material of some viruses, including HCV. Other viruses, e.g. HBV, have deoxyribonucleic acid (DNA) as their genetic material.
Seroconversion:	the development of antibodies to an infectious agent following exposure.

Serum :	the liquid portion of non-anticoagulated blood after clotting has occurred. Used mainly for laboratory tests, e.g. detection of virus antibodies.
Window Period :	the interval between exposure to an infectious agent and the appearance of detectable antibody or antigen in laboratory tests on the blood. The exposed individual's blood may be highly infectious during this period, in spite of having negative test results.

Contents

1 Definitions and Background

The term "lookback" was coined in 1986 after the introduction of screening tests for HIV[1]. The procedure to which the term refers was not, however, new. In a paper summarising their early experience in 1970 with the newly developed test for "hepatitis associated antigen" ("HAA", later named hepatitis B surface antigen (HBsAg)), workers in the West of Scotland Regional Transfusion Centre (WRTC) reported that when a positive result was obtained in a donor's blood, "In the case of previous donors (*now commonly referred to as regular donors*) an attempt is made to trace the fate of previous donations, and the recipients of these donations."[2]

This is the procedure that became known as ***targeted lookback***, the starting point being a donor with a laboratory test result indicating possible infection with a transfusion transmissible agent. Note that in addition to the requirement for a positive test result and a history of previous donations, an asymptomatic carrier state (i.e. the donor was not apparently ill) is also implied.

Parenthetically, it is worth noting also that these authors commented that " ... the exercise is proving frustrating". They found that many of the patients had died soon after transfusion, presumably of their primary illness, but they also cited poor hospital records as a major obstacle to tracing these patients, a theme that will be taken up later in this paper.

As well as the rather rigidly defined "targeted lookback" with which this paper will be mainly concerned, the identification of patients contracting a transfusion transmitted infection (TTI) can occur in other circumstances:

1.1 The development of symptomatic illness post-transfusion.

The first report of jaundice in transfused patients was by Beeson in 1943. He commented that the illness resembled "infectious hepatitis"[3], but in fact most of these early cases are likely to have been due to hepatitis B virus (HBV), later designated "serum hepatitis". Even after the introduction of screening tests for HBsAg in 1970, post-transfusion hepatitis was recognised clinically in some patients, and such cases were often referred to transfusion services in the hope that an implicated donor might be identified and further such TTI prevented.

Similarly, evidence that HIV could be transfusion transmissible was obtained from clinical observations before a test for HIV was developed, indeed before the nature of the infectious agent was known[4]. In 1984 Curran et al reported 18 cases of AIDS in adults who were not in a high-risk group but who had been transfused within the previous 5 years[5]. In some cases they identified a donor either from a high-risk group or with an abnormal lymphocyte profile in laboratory tests, the only test then available, but one which was non-specific.

Vigilance for symptoms or signs of illness that may have been caused by transfusion remains important. When the agent responsible is known and a test available, a specific TTI may be diagnosed and the search for an implicated donor may be undertaken either by recalling the donors for testing or by testing stored, frozen samples of serum or plasma. This is sometimes referred to as a ***reverse lookback or traceback***. When such an investigation identifies the donor responsible for transmission, and where that donor has given prior donations, a targeted lookback can then be pursued.

1.2 Screening of patients for non-specific laboratory markers of TTI.

When it was realised in the 1970s that post-transfusion hepatitis (PTH) was still occurring after the introduction of HBsAg testing, researchers in the USA set up a study which became the main source of information during the next 20 years on the clinical outcome of non-A, non-B hepatitis (NANBH)[6,7]. The main project became known as the Transfusion-Transmitted Viruses (TTV) study. Patients undergoing elective surgery were asked to consent to prospective follow-up including frequent blood samples. A donor sample was also obtained for every component transfused. This systematic follow-up identified patients who had biochemical evidence of hepatitis, usually in the absence of symptoms, and in whom hepatitis A and B had been excluded as possible causes. The term NANB hepatitis was thus coined. By looking for hepatitis B antibodies, as well as HBsAg, in the donors, and also measuring alanine aminotransferase (ALT) levels, this study pointed to the possibility of identifying donors who were carriers of NANBH by what became known as ***surrogate tests***, a subject addressed elsewhere in other SNBTS papers.

The TTV study, though not strictly a lookback exercise in view of its prospective nature, was of immense importance. The systematic screening of recipients evolved into the concept of ***haemovigilance***, while the extended follow-up of this cohort of patients provided clinical evidence that NANBH (later shown to be hepatitis C in over 90% of cases), could after many years evolve into a serious and life-threatening illness[8]. This was a major factor in the decision to pursue targeted lookbacks when tests for hepatitis C were introduced (described in detail later).

1.3 General Lookback

This refers to the systematic screening of transfusion recipients for a given, specific marker for a TTI[9]. This may apply to the general transfused patient population, or to specific groups of highly transfused patients such as haemophiliacs, paediatric patients and patients undergoing renal dialysis[10]. Transfusion recipients may be identified by public awareness campaigns asking them to come forward, or from blood bank records, followed by individual letters inviting them to attend. These methods have been found to be disappointing in practice[9,10].

2. Lookback in relation to testing of donors for anti-HIV

It has been shown how studies of transfusion recipients with TTI and their donors had become established by the early 1980s, and how non-specific markers might be used to identify donors capable of transmitting infection. In spite of the previously quoted attempts to trace previous recipients of newly identified carriers of hepatitis B, however, formal procedures for targeted lookback had not been established. The reason for this is probably related to the unusual nature of infection with HBV. Most individuals exposed to the virus in developed countries do not become carriers (only around 5% of exposed adults do so), so once existing blood donor carriers had been excluded by the new screening test, the vast majority of positive tests were in new donors, or regular donors seroconverting due to recent exposure. Neither of these situations would have consequences for recipients, except in the rare case of a window-period transmission from a seroconverting donor. Perhaps for these reasons, as Busch remarked in a review of HIV Lookback[9], "... with regard to infectious risks of transfusion, this principle (of informing patients that they may have been injured as a consequence of prior medical treatment) was relatively ill defined and inconsistently applied prior to the acquired immune deficiency syndrome (AIDS) epidemic."

It has also been shown, however, that elements of lookback had helped in establishing AIDS as a TTI and contributed to the understanding of its epidemiology. This virus, initially known as HTLV III and later redesignated HIV, was isolated in early 1983. By late 1984 prototype tests were being evaluated, and by March 1985 the first commercial tests were introduced. Mindful of the fact that it was a lookback procedure that had established the possibility of AIDS transmission by transfusion[11], and in a heated political and legal environment[9], in 1984 the major blood banking organisations in the USA endorsed the procedure of tracing previous recipients of blood from donors who subsequently developed AIDS[12]. The term "lookback" was subsequently coined to describe recipient tracing triggered by a positive donor screening test[1].

2.1 HIV Lookback in the UK

In the run-up to the introduction of routine testing of donations for anti-HIV in 1985 the UK Regional Transfusion Directors set up a working party to advise on implementation. In their report, dated 11 July 1985, "Screening of blood donations for anti-HTLV III in Regional Blood Transfusion Centres", they made the following recommendation:

> "7.1 Efforts will be made to determine the names of any patients who received blood or components from the donors (found to be positive) taken during the past five years and information given to the consultant in charge of the patient."[13]

This recommendation for lookback was accepted, and also adopted in Scotland. The five year limitation was in line with American recommendations.

From the date of formal commencement of routine testing (October 15 1985), the fate of all blood components donated during the preceding five years by donors now known to be anti-HIV positive was established. Working backwards from the most recent donation, living, traceable patients were offered testing through their clinicians. When the recipients of a donation were found to be negative, the lookback was halted at that point, the recipients of prior donations being assumed not to have been at risk.

Lookbacks were not carried out in the following circumstances:

- When the most recent donation was more than five years previously (this only applied to the first few years of testing, as the introduction of frozen sample archives relating to every blood donation became universally established in Scotland).
- When a frozen sample of the most recent donation was tested and found to be negative.
- When there was a clear history of recent high risk behaviour on the part of the donor and a long intervening period from the previous donation (if archive samples existed they would be tested also).

If any doubt existed, recipients were traced and tested.

Outcome: From a starting point of 39 anti-HIV positive donors with previous donations, targeted lookback initiated by SNBTS resulted in 9 anti-HIV positive patients being identified.

In addition to this "targeted" lookback, SNBTS also received sporadic reports from clinicians of patients with HIV infection where the sole risk factor was blood transfusion. All such cases were investigated to try to establish whether or not an anti-HIV positive donor could be identified. This circumstance relates mainly to donations given prior to the introduction of testing, in which case donors would be recalled for testing if possible, or donors could be ruled out on the basis of having attended and tested negative for anti-HIV subsequent to the transfusion episode being investigated.

Outcome: Number of patients confirmed or accepted on the basis of probability as cases of transfusion-transmitted HIV – 8

HIV was designated a reportable disease for public health purposes, but CD(S) (now known as Health Protection Scotland), established an informal reporting system for clinicians and

microbiology laboratories, to which all of the above patients were notified. For the purposes of the Public Inquiry, SNBTS and HPS have reviewed their records, and apart from the above 17 patients only one further patient is known to HPS as a reported case of transfusion transmitted HIV. This case has never been reported to or investigated by SNBTS, and the information held by HPS is insufficient to allow any conclusion to be drawn.

In 1990 the Department of Health in London (DOH) requested information on all patients identified by lookback for transfusion transmitted HIV, and supplied summary forms to be completed for each investigation. On 8 August 1990 the SNBTS National Medical Director wrote to all SNBTS Directors requesting that these forms be completed[14]. There is no information on the outcome of this exercise, which was never published.

2.2 Factors affecting the effectiveness of a targeted Lookback

The low number of patients identified in the course of the HIV lookback in Scotland may seem surprising, especially since the tracing of patients began immediately. However, this outcome is entirely consistent with experience in the USA. Even in San Francisco, the epicentre of the AIDS epidemic, where the Irwin Memorial Blood Bank went to extraordinary lengths in an "extended lookback" to trace patients at risk, it was apparent that targeted lookback had uncovered only a very small proportion of the estimated numbers potentially exposed[9]. There are many reasons for the relative ineffectiveness of targeted lookback. Most apply equally to other types of lookback:

- **The length of time for which the infectious agent had been present before a test became available.**

In the case of AIDS, this was around 7 years in the USA, but only around 2 years in Scotland. HCV, in contrast, was present for several decades before a test was implemented.

- **The virulence of the infectious agent**

While HCV typically remains silent for many years, HIV may progress rapidly. In at least one case in Scotland, a patient traced through lookback was found to have died of what, in retrospect, was likely to have been an AIDS-related illness.

- **The effectiveness of measures taken to exclude at risk donors in the pre-test phase**

This clearly depends on knowledge of epidemiological factors which allow identification of donors who have been at risk of exposure to the infectious agent. In the case of HIV, the risk factors for AIDS were rapidly established and donor exclusion implemented well before the availability of a test, and in Scotland possibly even before the virus entered the population. The epidemiology of HCV was less well understood, but in fact the HIV related exclusion categories were effective in reducing the numbers of donors with HCV[9].

- **The number of patients traced and found to be alive is inversely proportional to the time that has elapsed between transfusion and discovery through lookback.**

In other words, the greater the delay in tracing the patient, the more likely it is that they will have died of the illness for which they were transfused, or some other cause. The transfused population tends to be elderly, and many published reports of lookback record mortality of the order of 50% or more from the primary disease[10].

- **Transfusion practice**

The increasing use of component therapy in the 1980s, with up to 3 or 4 components made from each whole blood donation, would have had the effect of putting more patients at risk from an infectious donor. In Scotland this tendency was more than offset by the successful drive towards self sufficiency in the supply of plasma for fractionation. In order to meet the ever increasing demand, whole blood donation rates were raised year on year, reaching at one time a level of over 70 donations/1000 population/year. The result was an excess of non-plasma components, chiefly red cells, with a concomitant high level of outdating before use. This factor was very evident in the Scottish lookback experience with both HIV and HCV, i.e. that many units of donated red cells were never actually transfused.

- **Inadequate or non-existent hospital record systems**

This is one of the major difficulties in trying to trace patients transfused some years previously. As Busch noted[9], and the SNBTS experience confirms, blood bank and hospital records are seldom available from the pre-computer era, so that it is virtually impossible to trace the fate of donations from the early 1980s and before. Even in the mid–to late 1980s, many blood banks relied on paper systems which were difficult to search systematically. It is therefore frequently impossible to establish whether, and to whom, a blood component was transfused.

- **Patients move house, emigrate, marry and change names**

In the modern NHS, patient tracking systems are highly efficient, and it is now possible to establish whether a patient is deceased, or if still alive, the GP practice with which they are registered. This is a relatively recent development, but even so, for the reasons given above it may not be possible to trace a patient once identified.

The HIV epidemic prior to the introduction of testing largely predated blood bank and hospital computer systems, and all of the above factors were in play to a greater or lesser extent, thus the relatively low number of affected patients identified through lookback is less surprising than it might have seemed at the time. The main factor, however, is likely to have been the introduction of

donor exclusion for risk groups before the infectious agent became established in Scotland, which, while it would not affect the numbers of affected patients per positive donor, undoubtedly minimised the overall infection rate in the donor population.

3 The HCV lookback debate

The HIV lookback experience was largely uncontroversial in terms of the decision to undertake the exercise. Retrospective analysis in the USA, however, revealed the poor effectiveness of targeted lookback as discussed above. The labour intensiveness of the process had not been seen as a particular contraindication, perhaps because of the highly charged atmosphere surrounding what was seen as a dangerous epidemic, but when the cost of attempted general (see Section 1.3) lookbacks were counted, and the unimpressive returns, transfusion medicine specialists in the USA raised questions about the cost-effectiveness of the process.[9,10].

In 1989, the hepatitis C virus was discovered and a test was in prospect. Initial projections put the population prevalence in the USA and Northern Europe at 1 – 2%[9,10]. By extrapolation, it was thought that around 300,000 transfusion recipients in the USA and 100,000 in France might have been infected by blood transfusion[10,39]. This suggested that several thousand Scottish patients could be similarly affected. When the results of the first few months of testing were analysed, however, it was apparent that the prevalence in Scottish blood donors was less than 0.1%, i.e. greater than 10 fold less than in the general population[15]. This difference can be ascribed mainly to the demographics of blood donors and the effectiveness of donor selection, but even so the numbers remained daunting, and it was by no means certain that transfusion services would be able to cope with a lookback on such a scale.

Leaving the anticipated cost and logistical difficulty to one side, however, two main reasons were cited for the proposal that HCV lookback should not be pursued:

- There was doubt about the clinical significance of hepatitis C. Extended follow-up of patients in the TTV and other similar studies[8,16] had shown that, though a minority of patients would develop cirrhosis of the liver (around 20% after 20 years), and a small number would die of liver failure or hepatic carcinoma, overall mortality in the HCV infected patients was similar to controls. The disease was therefore regarded by many as relatively benign.
- Treatment (with interferon) was still experimental. Unlike in AIDS, where in spite of the lack of specific curative therapy much could be done to prolong life by treating the so-called AIDS related illnesses, no other intervention was available in the treatment of HCV patients.

3.1 HCV Lookback in Scotland

While the debate continued in the USA about lookback, preparations were underway in Scotland for the implementation of testing. In the summer of 1990 the SNBTS Directors set up a working party to advise on policies and procedures, with particular emphasis on counselling and care of donors with positive anti-HCV tests. In their report dated 23 November 1990 the authors advised that lookback should be instituted from the onset of testing[17].

The report was well received north and south of the border, and the materials produced for donor counselling were accepted UK-wide. The proposal for lookback underwent further discussion by both the SNBTS and the NBTS Directors and was finally rejected after referral by the SNBTS National Medical Director (NMD) to the Department of Health, London (DOH)[18,19,20].

3.2 The Edinburgh "Pilot Study" of HCV Lookback

In the Edinburgh and South East Scotland Regional Transfusion Centre (SERTC) HCV lookback was carried out in real time from the commencement of routine donation testing for anti-HCV. The rationale for this was that the principle had been established, when a formal decision was taken to undertake lookback in relation to testing for HIV antibodies throughout the UK suggesting that transfusion medicine specialists had a duty of care in this respect. It was clear that no extra resource would be made available for this, so the stated aim was to assess the workload implications with a view to publishing the results. A visiting blood bank physician (now Medical Director of the Malaysian Blood Transfusion Service) gave invaluable practical assistance under the direction of the Medical Consultant, SERTC who was responsible for the lookback study.

The results of the initial phase of recipient tracing were published in 1994[21]. From a starting point of 15 anti-HCV positive donors who had given blood before testing started, 9 surviving anti-HCV positive patients were identified. Table 1 gives more details of this study, and also results from other countries reporting lookback outcomes[22-31].

Not mentioned in the above list of factors affecting the efficacy of lookback is the importance of the specificity of the screening test and the confirmatory or supplementary tests, if any. The SNBTS screened from the start with a "second generation" antibody test, a second generation supplementary test (RIBA 2) and the polymerase chain reaction test for virus RNA. The result was that a "diagnosis" of hepatitis C in a donor was extremely secure, with very little risk of a lookback being carried out on the basis of what might turn out to be "false positive" results. Cases of apparent anti-HCV positivity but with negative results for virus RNA on the polymerase chain reaction (so-called "indeterminates") were dealt with later, after discussion at the DOH Working Party on HCV Lookback, with largely negative results. The SERTC also had a frozen archive of

donor samples dating from 1984, and this allowed testing of each donor's archived samples, which in turn showed that certain donors had seroconverted recently, obviating the need to trace and test earlier recipients unnecessarily.

The outcome of all of this was that all of the living recipients tested in the initial period were able to be confirmed to be HCV positive, in marked contrast to reports based on first generation tests. The number of donors identified as truly infected with the virus was approximately 10-fold less than had been suggested by preliminary work with first generation tests.

The publication of the early papers listed in Table 1, and the knowledge that the experience in the SERTC would be published in late 1994[21], led to a reconsideration of the HCV lookback policy. The DOH established a Working Party of the Committee for the Microbiological Safety of Blood and Tissues (MSBT) under the chairmanship of the Deputy Chief Medical Officer (DCMO), Dr Metters. On 22 December 1994 the Management Executive of the NHS in Scotland instructed the SNBTS to "…..take forward as expeditiously as possible the look-back exercise for all areas of Scotland" as shown in Appendix 1. Thus the policy on lookback for Scotland was established. Further to that, on 11 January 1995 the Parliamentary Secretary for Health announced that the Government had approved a national HCV lookback, and on 3 April 1995 the CMO issued a letter to all doctors, providing details of the procedures to be followed[32]. These were exactly as used in the Edinburgh pilot study, but the procedures and documentation were standardised for use throughout the UK. The procedures described in the CMO letter are shown in Appendix 2, and the specimen letters and forms in Appendix 3. In this way, from 1995 a generic policy for lookback was adopted by all the UK Transfusion Services based on the CMO letter. This policy can now also be found in the "Red Book" (Guidelines for the Blood Transfusion Services in the United Kingdom, TSO (London) 2005, 7th ed., pp 146-147).

Progress with the tracing, counselling and testing of patients was monitored by MSBT. At a meeting on 12 January 1996 the Committee acknowledged that progress had been slower than had been hoped, and proposed alternative ways of moving forward:

1. Continue Look-Back (sic) using the present strategy, but with central exhortation to speed up the process.
2. Abandon the Look-Back entirely and offer hepatitis C tests to anyone who has been transfused.
3. Continue with the Look-Back but offer assistance to overcome the bottlenecks due to problems in tracing hospital records and a shortage of suitably trained counsellors."[33]

The Committee unanimously agreed to continue with lookback as initially proposed, but suggested ways in which extra resource might be provided, "…. should Ministers feel action needs to be taken to overcome bottlenecks".

Progress, however, remained slow, and the Scottish Home and Health Department (SHHD) did indeed feel that extra resource was required, particularly in the West of Scotland, and additional medical and nursing staff were provided (mainly from within the Scottish Centre for Infection and Environmental Health (SCIEH), now known as Health Protection Scotland).

On 10 June 1998 Dr Keel, Senior Medical Officer at SHHD, wrote to Professor Franklin, National Medical and Scientific Director of SNBTS stating that the MSBT, at its meeting on 4 June 1998, had decided that "… all reasonable measures have been taken to trace components and recipients in Scotland, and that the tracing exercise could therefore stop."[34]. Efforts were also to be made to ensure that the documentation was accurate before the lookback exercise could be closed, but no formal report was requested from SNBTS at that time.

In fact, the lookback can never be considered to be closed, as donors with evidence of hepatitis C continue to be found on routine testing of donations. It is rare, however, for a donor presenting now to have donated prior to September 1991, and not to have donated in the 18 years that have elapsed. It is even rarer for living recipients of those earlier donations to be identified, but all efforts continue to be made to do so.

The final outcome of the Scottish Hepatitis C Lookback was detailed in a letter from Andy Kerr MSP, Minister for Health and Community Care, to Roseanna Cunningham MSP, Convener or the Health Committee of the Scottish Parliament, on 20 February 2006[35]. The results are given in full in Table 2.

3.3 International perspective

In the Netherlands it was national policy to carry out lookback from the initiation of anti-HCV testing[23], but other countries such as Denmark, France, Canada and New Zealand only instituted national programmes at around the same time as the UK[10]. The US Food and Drug Administration finally followed suit in March 1998[36]. Published results from many of these programmes are given in Table 1, together with the outcome of the UK lookbacks.

4 Cost-effectiveness of targeted lookbacks

The limited effectiveness of targeted lookback has been referred to above. In the San Francisco area it was estimated that less than 3% of the projected total number of patients infected with HIV

through transfusion were identified by lookback[9]. In the Canadian experience with HCV lookback, in contrast, the return was considerably greater, but still they estimated that less than 20% of surviving patients had been identified[10]. The costs of the lookback process, however, were relatively modest, at around US $6,000 per newly diagnosed HCV-positive patient.

An accurate assessment of cost-effectiveness requires more than an estimate of the cost of the lookback process. Most importantly, an assessment of the potential health benefit to the patient, and associated costs and potential savings, is required. Decision analysis modelling predicted that fewer than 1% of transfusion recipients identified through lookback would derive an overall health benefit through being identified by lookback[37], but a later review suggested that HCV lookback might increase patients' life expectancy, though by a modest amount, and could reduce health care costs[38]. A crucial issue is the effectiveness of treatment for HCV, which has been increasing as knowledge accumulates and anti-viral therapy improves. Set against this is the fact that most transfusion recipients are elderly and many will not be considered for aggressive treatment.

While acknowledging that, as an exercise in public health, the HCV lookback in the USA was "helping very few people" – only 1 to 2 percent of affected patients were newly diagnosed as a result of the American HCV lookback – AuBuchon concluded that there were benefits to the transfusion services, and thereby to the community, resulting from the respect and recovered trust that these efforts engendered[39,40]. To quote Busch, "The principle of informing patients that they may have been injured as a consequence of prior medical treatment is well established and rests on a solid medical, ethical, and legal foundation."[9]. In the UK, this principle has been invoked most recently in carrying out systematic lookback on the introduction of testing for human T cell leukaemia viruses (HTLV) in 1998, and also in dealing with the consequences of the finding that vCJD has been transmitted by blood transfusion to 4 recipients.

In the case of vCJD transmission, the recipients of other donations from the implicated donations have been traced and informed, though no benefit can accrue to these individuals in the foreseeable future, both in satisfaction of the stated principle and also as a preventive public health measure to avoid secondary spread. If and when a test for vCJD in blood donations is introduced it is highly likely that targeted lookback will be required again, regardless of cost.

TABLE 1 **SUMMARY OF HCV LOOKBACK LITERATURE**

Details of Lookback	Index Donors (n)	Donations	Components	Components not traced	Recipients	Deceased	Recipients not traced	Alive and Tested	Anti-HCV Positive
Ayob et al (Scotland) (Sept 1991 – March 1992)[21]	15 (RIBA-2/PCR)	63	83	9	39	27	3	9	9
Koerner et al (Germany 1990 – 93)[22]	27 (RIBA –2 only)		62	4	47	29		16	9
Vrielink (Netherlands) May 1990 – January 1992[23]	22 (RIBA-2/PCR)	172	270	143 ("pending")	127	57	31	32	26
Foberg et al (Sweden) (1988-1991)[24]	9 (RIBA-2/PCR)	--	--	--	--	--	--	27	16
Kolho et al (Finland) (1989-1990)[25]	85 (RIBA-1)		193	?14	148	57	14	73	14
Long et al (Canada) (Lookback commenced March 1995)[26]	561 (RIBA-1/2		3196		1381	1028	590	353	215
Cristensen et al (Denmark) (commenced 1996, "at least 10 years back"). Earliest 1975[27]	150	--	--	--	1018	685	45	157	128

Details of Lookback	Index Donors (n)	Donations	Components	Components not traced	Recipients	Deceased	Recipients not traced	Alive and Tested	Anti-HCV Positive
Williams et al (Alaska) (1980 – 1992)[28]	RECIPIENT BASED				3169	1813		764	41
Heddle et al (Canada) Paediatric Patients 1978 – 1985[29]	PATIENT BASED 1546 patients (by letter)				493 (33.8% returned undelivered; 531 did not respond			455 agreed to HCV tests : no results given	---
Culver et al (USA) (Commenced 1998)[30]	72,193 (RIBA-2)		97,743	28,848	58,816	32,430		4921	1115
Soldan et al (England) (Commenced 1995)[31]	1286 (RIBA-2)		9222	2119	4424	2711	154	1209	677
SNBTS "final" outcome (June 1998) (unpublished)	360 (RIBA-2/3 + PCR)	1658	2026	670	880	536	78	203 (63 not tested)	133
Edinburgh "final" (March 1998) Includes indeterminates n = 10 donors	66	357	439	112	180	111	16	48	23

TABLE 2

RESULTS OF SCOTTISH HEPATITIS C LOOKBACK

Hepatitis C positive donors who had given before 1991	360
Donations by those donors	1658
Components prepared from those donations	2026
of which traced	1356
not traceable	670
Number of recipients identified by hospitals	880
Potentially eligible for counselling and testing	266
of which counselled and tested positive	133
counselled and tested negative	70
other – declined; not appropriate for testing; results not reported back to SNBTS	63
Deceased	536
Not traceable	78

References

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National Health Service in Scotland
Management Executive

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CONFIDENTIAL

D B McIntosh Esq
General Manager
Scottish National Blood Transfusion Service
National Headquarters
21 Ellen's Glen Road
EDINBURGH
EH17 7QT

APPENDIX 1

21 December 1994

Dear David

HEPATITIS C - LOOK-BACK

I enclose for your information a copy of a letter which Lord Fraser has today sent to Mr Tom Sackville, MP, Parliamentary Under Secretary of State for Health.

I should be grateful if you would now take forward as expeditiously as possible the look-back exercise for all areas in Scotland. You will no doubt keep the Department informed of progress.

Yours sincerely

GRO-C

G W TUCKER

SSM00421.124

PEN.017.2243

THE SCOTTISH OFFICE

0047

From the Minister for Home Affairs and Health
The Rt Hon the Lord Fraser of Carmyllie QC

St. Andrew's House
Edinburgh EH1 3DG

Telephone 031GR@4017

Tom Sackville Esq MP
Parliamentary Under Secretary of State
Department of Health
Richmond House
LONDON

12 December 1994

Dear Tom,

HEPATITIS C VIRUS - LOOK-BACK EXERCISE

As you will be aware a number of patients may have contracted the Hepatitis C virus (HCV) from blood transfusions or blood products using blood from infected donors prior to the introduction of screening for HCV in 1991. Until now there have been no arrangements made to carry out any look-back exercise to identify these recipients of the infected blood and to arrange counselling with a view to treatment. Part of the reason for this lack of any follow up action was a concern that it would be impossible to identify all recipients of infected blood and even if it were possible there was a lack of accepted treatment which would be beneficial. It was accepted that if no effective treatment was available, informing those patients who were unaware of their situation could not be justified, since this would cause further distress and anxiety without any benefit.

Following a pilot research study carried out last year by the Edinburgh and South East Scotland Blood Transfusion Service it has been established that a look-back exercise for Scottish patients would be feasible and practicable. The results of this study have already appeared in a professional journal and are therefore in the public domain. The advice which I have received from medical and legal staff is that as such a look-back exercise is practicable then the Secretary of State and I have a duty to undertake the exercise as soon as possible. Failure to do so may result in a liability for loss or injury occasioned to the individuals through any failure or delay in identifying the recipients, and, where clinically advised, offering treatment.

I am conscious that the matter of a look-back policy for HCV was considered by the Microbiological Safety of Blood and Tissue for Transplantation Committee (MSBT) at their recent meeting and that they have advised that procedures should be put in place to identify those at risk but "whatever is done should be done equally and uniformly

SSM00220.124

Recycled

throughout the UK". The Committee has also recommended that guidance should be drawn up but this leaves unresolved the question of timing of the introduction and the implementation of the look-back exercise. The advice which I have received from my medical and legal staff is such that I consider that it is no longer a matter of policy but of legal liability, and that the look-back should take place as soon as possible in Scotland. I am informed that the Scottish National Blood Transfusion Service is ready to carry out such an exercise and I have no alternative but to instruct them to proceed.

I appreciate that there are sensitivities in proceeding in advance of the rest of the UK, but given that it may be some time before all parts are ready, I consider that I have little choice but to take this forward in view of the position in Scotland. I shall ensure that you will be kept informed of the progress of this exercise since I recognise that this may have value as a pilot for any similar exercise elsewhere in the UK (although I would not, of course, wish our action to be presented or seen as a pilot exercise).

I accept that any exercise may encourage further pressure for compensation for those infected but we shall continue to resist this robustly in line with our general policy. We shall not of course be publicising the look-back exercise and shall do all we can to avoid media interest. If, however, direct questions are asked, it would be difficult to avoid answering them.

I do hope that you will understand that the Scottish circumstances make it imperative that action is taken now.

I am copying this letter to Rod Richards, Welsh Office and Malcolm Moss, Northern Ireland.

Yours ever,

PRO-C

FRASER OF CARMYLLIE

SSM00220.124

APPENDIX 2

3 April 1995

DEPARTMENT OF HEALTH

From the Chief Medical Officer

Dr Kenneth C Calman
MD PhD FRCS (Glas,Ed) FRCP (Lond,Ed) FRCGP FRCR FFPHM FRSE

Richmond House
79 Whitehall
London SW1A 2NS

Hepatitis C and Blood Transfusion Look Back

For action
• All Doctors

For information
• Regional Directors/Managers
• District General Managers
• Chief Executives, NHS Trusts
• General Managers FHSAs
• General Managers DMUs

For further information please contact the professional secretariat

Dr A T M Rajan, Room 420
Ellen House
80-94 Newington Causeway
London SE1 6BF
Tel: GRO-C

and for administrative enquiries

David Burrage, Room 313
Ellen House
80-94 Newington Causeway
London SE1 6BF
Tel: GRO-C

Dear Doctor

HEPATITIS C AND BLOOD TRANSFUSION LOOK BACK

I am sending this letter to inform you of the guidance and procedures for the look back exercise announced by Tom Sackville, Parliamentary Secretary for Health, on 11 January 1995, to trace, counsel and, if necessary, treat those people who may have been inadvertently infected with hepatitis C through blood transfusions.

Many of you will have received information in January 1995 about the Government's announcement of the look back exercise.

I am asking for your help in identifying those patients who may have been infected with hepatitis C through blood transfusion. This will concern primarily hospital consultants in a number of specialities, those working in blood transfusion centres, and general practitioners. I am sure that your patients will appreciate your efforts on their behalf.

An ad hoc Working Party of experts has now drawn up guidance on the procedures for undertaking the look back exercise and for counselling those identified as being at risk, as well as guidance on the treatment options available.

The guidance and procedures are set out in the Annexes:

* Guidance on the look back procedures - Annex A

* Guidance on counselling and treatment options - Annex B

It is important that all testing to determine a patient's hepatitis C status is undertaken by diagnostic microbiology laboratories with the capability of performing polymerase chain reaction (PCR) for hepatitis C on site. A list of recommended laboratories will be provided by the National Blood Authority. Arrangements have been made for the National Blood Authority to bear the cost of such testing.

Dr Kenneth C Calman
Chief Medical Officer

Requests for further copies should be addressed to
Department of Health Store
Health Publications Unit
No 2 Site, Manchester Road
Heywood
Lancashire OL10 2PZ
quoting code and serial number appearing above.

For correction of any discrepancies in changes of address, practice or name, please contact
The Medical Mailing Company
PO Box 60, Loughborough
Leicestershire LE11 0WP
Telephone Freephone 0800 626387

ANNEX A

PROGRAMME TO IDENTIFY RECIPIENTS OF BLOOD INFECTED WITH HEPATITIS C VIRUS (HCV)

April 1995

1. Action by Regional Transfusion Centre

All reference laboratory confirmed HCV antibody positive donors to be identified and their donor record examined. Where the final HCV test result is deemed to be indeterminate this should be recorded, but no further action is required at the present time.

All donations given prior to the index HCV antibody positive donations to be identified by donation number together with all the unfractionated blood components prepared from these previous donations.

The fate of all these previously donated units and their associated unfractionated components must be established, ie,

red cells
platelets
clinical fresh frozen plasma
cryoprecipitate

A list of all components issued to each hospital must be prepared. This list must provide the donation number, the type of component and the date of issue to the hospital.

Regardless of how far back individual hospital records are kept, the BTS must endeavour to provide a complete list of components issued and the date of issue for each previous donation from reference laboratory identified anti-HCV positive donors. This is crucial information as even if the hospitals no longer have records going back as far, the BTS will still be able to provide an estimate of how many potentially at risk recipients cannot be traced and when and at which hospital they were transfused.

Based on available data, it is sensible to work on the assumption that all previous donations were potentially infectious. It is not therefore considered necessary to test archived samples for the presence of anti-HCV but where available they should be kept. An exception could be made where individual patient circumstances make it desirable to know whether or not they were put at risk, ie, in individual patients where it would be preferable not to inform them that they had been put at risk unless the presence of an HCV infection would alter their management.

hospitals concerned where blood or blood components from these donors has been sent stating that the donor has subsequently been shown to be hep C positive.

2. Action by Hospital Departments of Haematology and by Consultants

(i) The blood bank record should be searched to identify the fate of each individual component. Record name of the putative recipient and the date of issue from the blood bank.

(ii) If the unit appears to have been transfused the patient's hospital records should be obtained and the transfusion confirmed. Record whether the patient is:

(a) alive and still under hospital consultant follow up
(b) alive and discharged from hospital care
(c) dead (note cause of death if known)

(If the hospital records indicate blood was given, but do not give details of the donation number, it should be assumed that the implicated donation was used in this individual and the patient should be counselled and offered a test. If the case notes state that blood was not given, then every effort should be made to try to identify where the blood went).

(iii) From the hospital records it should be possible to identify the consultant who was responsible for the patient at the time of the relevant transfusion. This consultant or his successor should be contacted using a standard letter which will be provided. The consultant will be asked to indicate within 14 days whether or not he wishes to counsel the patient personally.

(iv) If the original consultant either does not respond within 14 days or indicates that he/she does not wish to counsel the patient personally, the RTC consultant will arrange to send a standard letter, which will be provided, to the consultant responsible for the continuing care of the patient or to the recipient's GP. The consultant or the GP will be required to complete a questionnaire asking for details such as whether:

it is appropriate to contact the patient? and

if not, the reasons why, and whether the consultant or GP

wishes to follow up the patient himself.

(v) If the consultant looking after the patient decides that it is inappropriate for the patient to be contacted, the reason should be documented and the GP and the RTC informed.

(vi) If the patient has been discharged or the hospital consultant does not wish to be involved, the RTC should be informed and they will contact the GP.

3. General Principles of the Look Back

The presumption will be that each identified recipient would be counselled and tested. However, in exceptional situations such as severe psychiatric illness or terminal physical illness the consultant or GP may feel it inappropriate to add to the patient's distress. It is also essential that the patient's current GP should check to ensure the patient is alive, if letters addressed to deceased recipients are to be avoided.

The RTC will prepare a confidential file card/data base for each donation cross referenced with a file card/data base for each hospital. A monthly update system modified according to circumstances would be appropriate. It is essential that all relevant data is notified to the RTC.

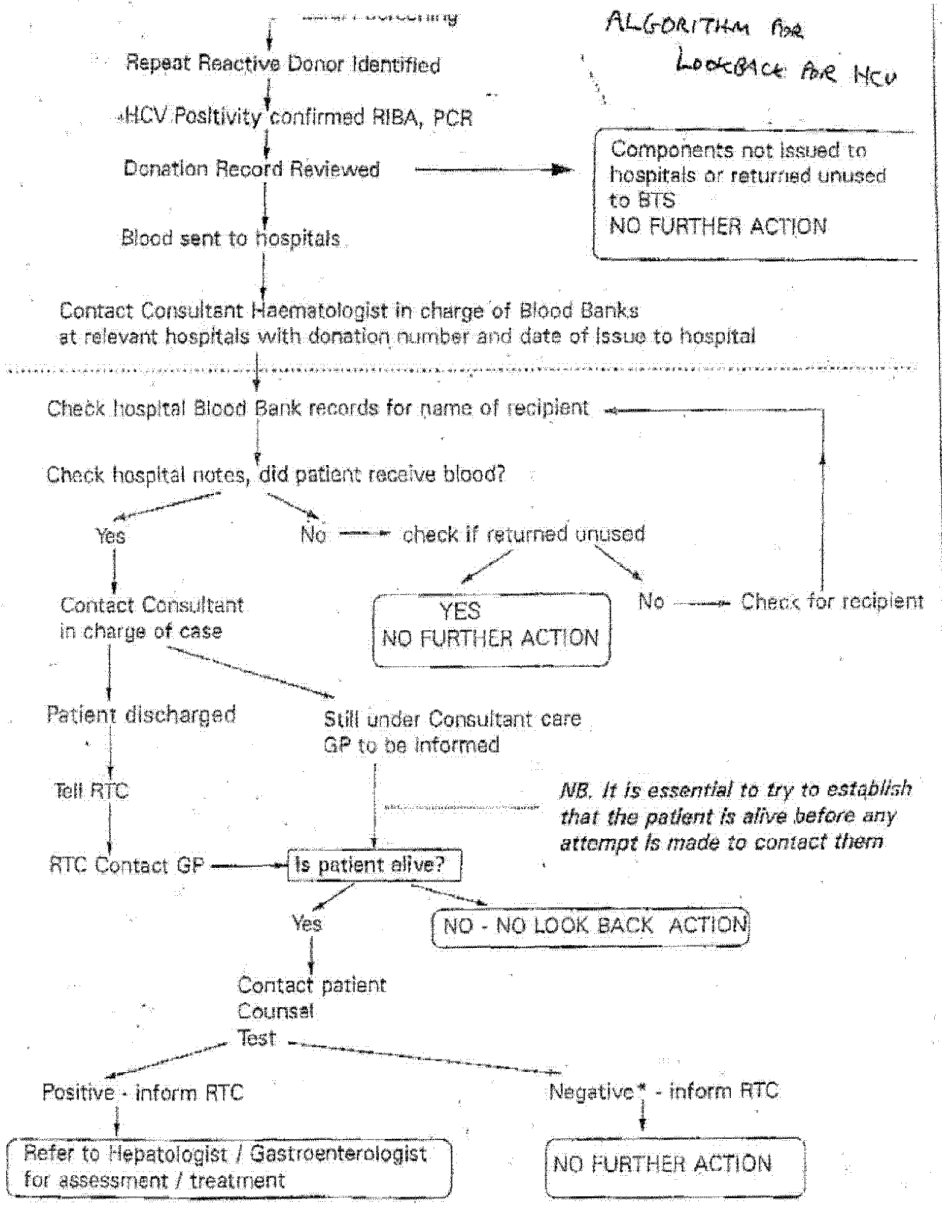
Plasma that went for fractionation does not need to be traced back but its destination needs to be noted for completeness. In addition transmission of hepatitis C may have occurred in recipients of IVIG and coagulation factor concentrates before viral inactivation procedures were introduced. RTCs will be able to advise on the need for testing which depends on the product and the date of treatment. Recipients of albumin and IMIG are not at risk.

Immuno compromised patients may need special testing including polymerase chain reaction (PCR).

4. Further Information

Any questions about this procedure should be addressed to the Director of your Regional Transfusion Service.

PEN.017.2250


ALGORITHM FOR LOOKBACK FOR HCV
Repeat Reactive Donor Identified
HCV Positivity confirmed RIBA, PCR
Donation Record Reviewed
Components not issued to hospitals or returned unused to BTS
NO FURTHER ACTION
Blood sent to hospitals
Contact Consultant Haematologist in charge of Blood Banks at relevant hospitals with donation number and date of issue to hospital
Check hospital Blood Bank records for name of recipient
Check hospital notes, did patient receive blood?
Yes
No
check if returned unused
YES
NO FURTHER ACTION
No
Check for recipient
Contact Consultant in charge of case
Patient discharged
Still under Consultant care
GP to be informed
Tell RTC
NB. It is essential to try to establish that the patient is alive before any attempt is made to contact them
RTC Contact GP
Is patient alive?
Yes
NO - NO LOOK BACK ACTION
Contact patient
Counsel
Test
Positive - inform RTC
Negative* - inform RTC
Refer to Hepatologist / Gastroenterologist for assessment / treatment
NO FURTHER ACTION
*If patient is immunocompromised, ELISA may give a false negative result and PCR may be required

...-TRANSMITTED HEPATITIS C : ANNEX B

GUIDELINES FOR COUNSELLING PATIENTS April 1995

Introduction

1. Recipients of blood or blood components from donors now known to be carriers of Hepatitis C virus (HCV) are being traced with a view to providing counselling, testing and specialist referral as appropriate.

2. These guidelines are intended for use in counselling patients identified through the look back exercise as hepatitis C positive. They give some background to this exercise, explain the implications of being found to be anti-HCV positive, provide information on ways of avoiding infecting others, provide advice as to the appropriate steps to be taken and briefly provide notes about the likely management at specialist centres about which patients are likely to ask.

3. Patients found to be infected with hepatitis C are likely to have concerns both about their own current and future health and also about possible spread to others including their family. Patients may only gradually come to terms with their situation and may require several consultations. An independent support network may be a helpful adjunct and the British Liver Trust can be a source of appropriate information and patient support.

Background

4. The prevalence of Hepatitis C in the UK is estimated to be between 0.1% and 1% of the general population, and the most frequent mode of transmission is as a result of intravenous drug misuse and needle sharing.

5. It was recognised for many years that there was a viral infection which following blood transfusion, despite negative tests for hepatitis A and B, could cause acute and chronic hepatitis. This was termed parenterally-transmitted or post transfusion non-A, non-B hepatitis. In 1989 HCV was discovered and antibody tests were developed. The initial tests had high rates of false positivity but the current tests are much more specific and it is now possible using molecular biological techniques to detect the virus genome (HCV RNA) in patients' blood.

6. Transfusion services in the UK began screening for antibodies to HCV on 1 September 1991. Patients transfused subsequent to that date have a negligible risk of having been infected by transfusion. Not all of those transfused with potentially infectious blood prior to the commencement of testing will, however, be identified by the "look back" procedure; as this relates to donors who have given blood since HCV testing was introduced in September 1991. For patients transfused prior to September 1991, it may only be possible to provide full reassurance by offering to test them for antibodies to HCV.

It is estimated that in the UK up to 3000 recipients will be traced as part of the "look back" exercise. Chronic hepatitis is often asymptomatic and the diagnosis of chronic hepatitis C in recipients of blood is likely to be an unwelcome surprise for most patients although public awareness has been heightened in recent weeks with media coverage.

8. Patients confirmed to be anti-HCV positive (see below) should be counselled on the implications of the test result and referred for a specialist opinion. It should be borne in mind that the infection may have been contracted as a result of risk behaviours rather than blood transfusion, and since this, and the duration of infection, may have some bearing on the prognosis and on the outcome of treatment, the patient should be questioned in a sensitive manner about such risk behaviours.

Implications of a positive test - prognosis

9. Following infection with Hepatitis C virus the natural history varies widely. Some patients may recover spontaneously and completely. Some go on to develop liver damage often without symptoms. Cirrhosis may develop in 10% to 20% of those infected but this may take 20-30 years to develop and may be unrecognised clinically. A much smaller number may then go on to develop hepatocellular carcinoma.

10. Patients are described as anti-HCV positive when a screening test is positive and the result has been confirmed by recombinant immunoblot assay (RIBA). Most such patients will also be positive for HCV RNA using the polymerase chain reaction (PCR). PCR positive patients usually have raised transaminases (especially ALT), though this may be intermittent and unimpressive.

Epidemiology - modes of transmission

11. The commonest route of transmission is by sharing needles or equipment during intravenous drug misuse. Transfusion of blood or fresh components (platelets, fresh frozen plasma or cryoprecipitate) prior to the introduction of routine screening on 1 September 1991, or of clotting factor concentrate prior to the use of virus inactivation procedures in 1984, also carried a risk of infection. (Other blood products which were not virally inactivated have transmitted Hepatitis C more recently.) Other parenteral routes capable of hepatitis C transmission include tattooing, and, theoretically, electrolysis, ear-piercing and acupuncture. Sexual transmission occurs, but the frequency is controversial - most studies indicate infection rates of less than 5% in sexual partners. However use of barrier contraception should be discussed with each couple. Vertical transmission (mother to baby) appears to be of a similar order. These figures are based on figures from N America and Europe. There is thought to be increased risk of transmission if the patient has concomitant HIV infection.

will be available for several years. The risk of spread by ordinary household spread appears very small. Offering to screen regular sexual contacts and children born since their mother's transfusion may help to alleviate some of the anxiety associated with a new diagnosis of chronic hepatitis C and may influence advice on whether barrier contraception is necessary.

Avoiding infecting others

13. In counselling HCV positive recipients, they should be asked whether they have ever donated blood or a tissue. Anti-HCV positive individuals should not donate blood, tissue or semen, and should not carry an organ donor card and, notwithstanding the estimated low risk of sexual transmission, the same advice should be given to their regular sexual partners regardless of their HCV status.

14. Toothbrushes and razors must not be shared, and cuts or skin lesions should be covered with waterproof dressings.

15. When seeking medical or dental care, patients should be advised to inform those responsible for their care of their anti-HCV status.

16. At present there is insufficient evidence to recommend changes to current sexual practices, although regular sexual partners should be counselled and offered testing. Hepatitis C positive patients should be advised to forewarn and practise safe sex with new partners.

17. Children born to HCV positive mothers should be tested for HCV, preferably 2 years or more after birth to avoid false positives due to passive antibody. Transmission from mother to infant has been reported but the risk is believed to be low.

Further assessment and follow up

18. All anti-HCV positive patients should be referred to a specialist with an interest in the condition for further assessment. This will usually involve a period of observation and, in most cases, a liver biopsy. Patients considered to be at risk of progressive liver disease may be offered treatment with interferon.

transaminase value suggests on going hepatitis but is not useful in determining the severity of disease. A normal transaminase value does not exclude active liver disease; it has been shown that patients with normal liver biochemistry can have serious underlying liver disease including cirrhosis. All patients who are HCV antibody positive (confirmed by RIBA) should therefore be referred on to an appropriate specialist centre with expertise in antiviral therapy where more detailed testing can be arranged such as detection of HCV RNA.

Notes about management at specialist centres

20. Further counselling will be given at specialist centres and treatment options can be discussed in more detail. Liver biopsies are likely to be offered to patients with raised transaminases (ALT) values or those with normal transaminase values and positive HCV RNA tests.

21. In specialist centres the liver biopsies can generally be performed as day cases but admission is organised for those patients where there is a high chance of underlying cirrhosis. The liver biopsy helps determine the level of inflammation and the stage of the disease. Other coexistent liver diseases may also be diagnosed. This helps the physician and the patient decide on the best treatment option.

22. The aims of antiviral therapy, of which Interferon is an example, are to eradicate the infection thereby preventing further progression of hepatitis and to render the patient no longer an infection risk to others. Effective viral therapy given early in the disease process will reduce the chance of the more serious long-term sequelae of chronic hepatitis C such as cirrhosis and the development of hepatocellular carcinoma. Interferon alpha is the only licensed therapy for chronic hepatitis C. A typical regime is 3-6 MU administered subcutaneously or intramuscularly thrice weekly for 6 to 18 months. Most patients can be taught to self administer the drug and need to be warned about possible side effects (myalgia, fever etc). Regular blood counts are required to detect leucopenia and thrombocytopenia and to alter the interferon dose accordingly.

23. Although 40-80% of patients respond initially to interferon with normalisation of transaminase values, only 50% of the responders (ie 20-40% of those treated) have a sustained response after cessation of treatment. Response rates depend upon the particular genotype of hepatitis C; patients infected with type 1 (and particularly type 1b) respond less well than do patients with types 2 or 3. In the UK around 60% of infections are due to genotype 1. Patients with a higher viral load are in general more resistant to treatment as are patients with cirrhosis. In some of these more resistant patients, better results may be obtained with higher doses and longer duration of interferon treatment.

24. Patients with minimal disease will be kept under review. Interferon treatment is likely to be offered to patients with significant hepatic inflammation.

Other treatment approaches are under development including the combination of interferon with other antiviral agents such as ribavirin. It is important to diagnose cirrhosis in patients with chronic hepatitis C as these patients require careful monitoring of their liver function and regular imaging to detect hepatocellular carcinomas. Transplantation may be a life saving option for patients with end stage disease; although HCV is likely to recur in the patient despite a successful operation.

STRICTLY PRIVATE AND CONFIDENTIAL

Please quote reference number on all communications

APPENDIX 3

<ref>

<gp/clinician>

<date>

<address>

Dear <gp/clinician>

RE: HEPATITIS C LOOK-BACK
<PATIENT NAME, ADDRESS, DOB>

We have been reviewing the records of previous donations from donors now known to be infected with Hepatitis C. The Health Departments have decided that the recipients of blood transfusions originating from such donors should be traced so that they may be offered appropriate counselling, testing and follow-up including consideration of treatment.

According to the available records, the above patient was transfused with a presumed hepatitis C positive blood component on <date> while under the care of <consultant physician/surgeon> at <hospital>. <Dr/Mr (or his successor)> is aware that I am approaching you with this request.

In accordance with the Health Department's guidance, the patient will need to be approached with a view to counselling and testing to determine his/her HCV status. If you are willing to undertake this role, we will provide details of the blood samples needed, and where these should be sent, and we will offer any further support or advice which you may need. If, on the other hand, you would like us to notify and counsel the patient we are happy to do so.

I would be grateful if you would complete the enclosed questionnaire, so that we may complete our records for this blood component. The questionnaire also asks for your intentions in relation to counselling. A copy is enclosed for you to retain. Please be sure to inform me of the results of any investigations for hepatitis C performed on your patient.

In rare cases, you may feel that informing the recipient is inadvisable. In this situation, I would be grateful for details on the enclosed form. For those who are known to have gone abroad, please return what details you have about their current whereabouts and/or attending physician.

Please do not hesitate to contact me if you have any questions or concerns arising out of this letter. I shall be pleased to advise you regarding referral of hepatitis C recipients who may require further assessment.

With many thanks.

Yours sincerely

CONSULTANT
REGIONAL TRANSFUSION CENTRE

Enc
1.Form LBF 3

STRICTLY PRIVATE AND CONFIDENTIAL

Please quote reference number on all communications

<ref>

<clinician>

<date>

<address>

Dear <clinician>

RE: HEPATITIS C LOOK-BACK
<PATIENT, DOB, HOSPITAL UNIT NUMBER, CASE NO>

The transfusion service has been reviewing the records of previous donations from donors now known to be infected with hepatitis C. The Health Departments have decided that the recipients of blood originating from these donors should be traced, so that they may be offered appropriate counselling, testing and follow-up, including consideration of treatment. According to the hospital records, the above patient was transfused with a presumed hepatitis C positive blood component <donation no> on <date> while under your care (or your predecessor's) and is likely to have been infected as a result of the transfusion.

This letter is to inform you that the patient will need to be approached with a view to counselling and testing to determine his/her hepatitis C status. Unless you know that the patient is alive it is strongly recommended that no approach to the patient be made without checking first with the GP. If you intend to counsel the patient yourself please indicate your willingness by completing the questionnaire below and returning this letter to the transfusion centre in the reply paid envelope provided. You will then be provided with further notes on hepatitis C that should assist you. Unless you indicate within the next 14 days that you yourself wish to contact this patient, I propose to pass details of this patient to the clinician or GP currently responsible for their care so that contact can be made with them prior to notification of the recipient. If you know that the patient has died, please provide details of the date and cause of death.

Please do not hesitate to contact me if you have any questions or concerns arising from this letter.

With many thanks.

Yours sincerely

CONSULTANT HAEMATOLOGIST

.....

I do/do not wish to counsel this patient

....

DATE SIGNATURE PRINTED NAME

DLHCV 2

STRICTLY PRIVATE AND CONFIDENTIAL

Please quote reference number on all communications

<ref>

<titlename>

<date>

<address>

Dear <titlename>

I am writing to you with the agreement of your General Practitioner Dr <doctor>. This is in relation to the blood transfusion you had in <hospital> in 19<years>.

We have now discovered that the blood may have been carrying an infection known as hepatitis C virus. This could have been passed on to you and I would like to check your blood now. The test result will show whether or not there is evidence of Hepatitis C infection.

It is important that I have the opportunity to discuss this with you. Please contact <doctor/receptionist> to make an early appointment for you to see me.

I should emphasise that there is no relationship between hepatitis C and HIV or AIDS.

I am sending a copy of this letter to Dr <doctor>.

Yours sincerely

CONSULTANT
REGIONAL TRANSFUSION CENTRE

DLHCV 5

STRICTLY PRIVATE AND CONFIDENTIAL

Please quote reference number on all communications
<ref>

<gp/clinician>

<date>

<address>

Dear <gp/clinician>

RE: HEPATITIS C LOOKBACK
<PATIENT NAME, ADDRESS, DOB>

Thank you for agreeing to counsel and test this patient. For your assistance and information I am enclosing the following documents:

1. Draft letter (DLHCV 5) that can be used to contact the recipient.

2. Nationally agreed counselling guidelines.

3. A form (LBF 4) to document the outcome of the counselling process.

4. Advice on sampling and testing for HCV together with a request form.

It is important that the sample for anti-HCV testing is sent to a diagnostic microbiology laboratory that has the capability for HCV-PCR testing on site and that a copy of the results of of the test are forwarded to the Transfusion Centre. For this reason I would like to recommend that this patient's sample is sent to <laboratory> as the arrangements have been made for the National Blood Service to cover the costs of anti-HCV testing undertaken during this look back exercise.

If you have any further queries as a result of this letter please do not hesitate to contact me.

Yours sincerely

CONSULTANT HAEMATOLOGIST
REGIONAL TRANSFUSION CENTRE

NATIONAL HCV LOOK BACK PROGRAMME

IDENTIFICATION OF FATE OF IMPLICATED COMPONENT

Component details:

DONATION NUMBER	
COMPONENT TYPE	
ISSUED TO	
DATE OF ISSUE	
ABO & RH GROUP	

Please complete section A and Section B overleaf.

When completed this form should be returned to the Consultant at the Blood Centre. A copy should be retained for your own records and another copy inserted in the notes.

SECTION A: To be completed from blood bank records

DONATION NUMBER.....	COMPONENT TYPE.....

1.

Are records available to identify receipt of component	YES/NO

2.

Are records available to identify fate of component	YES/NO

3. If NO to above please indicate reason:

4. If YES to above questions please indicate fate (tick ONE BOX)

TRANSFUSED TO PATIENT		Go to 5
RETURNED TO TRANSFUSION CENTRE		Go to 6
DISPOSED OF WITHIN HOSPITAL		Go to 6
TRANSFERRED TO OTHER HOSPITAL		Go to 6

5. If unit transfused to Patient please indicate

PATIENT SURNAME	
PATIENT FORENAME	
DATE OF BIRTH	
HOSPITAL NUMBER	
DATE OF TRANSFUSION	

6. If unit NOT Transfused please indicate (as appropriate)

DATE UNIT RETURNED TO TRANSFUSION CENTRE	
DATE & DESTINATION IF UNIT TRANSFERRED	
REASON FOR DISPOSAL	

7. DETAILS OF INDIVIDUAL COMPLETING SECTION A (complete in all cases)

NAME	
DESIGNATION	
SIGNATURE	
DATE	

FURTHER ACTION

If unit was not transfused return form to Transfusion Centre, keeping a copy for your records.

If unit was transfused obtain patient records & proceed to Section B

SECTION B: To be completed from Patient records

1. Are hospital records available for this patient YES/NO

If NO indicate reason _____

If YES go to question 2

2.

Do notes confirm that the patient was transfused on the appropriate date	YES/NO
Do notes confirm that the patient received this unit	YES/NO

If YES to either or both questions proceed to question 3

If NO to both questions please review blood bank records.

3. Current status of patients (tick one box only)

Alive and remains under hospital care[1]	
Discharged from hospital care	
Dead (indicate cause)	

4. Details of Consultant responsible for patient at time of transfusion

NAME	
SPECIALTY	
CONTACT ADDRESS	

5. If patient remains under hospital care details of Consultant currently undertaking care (if different from above).

NAME	
SPECIALTY	
CONTACT ADDRESS	

6. Details of General Practitioner

GP NAME	
ADDRESS	

and additional patient details

PATIENT ADDRESS	

6. DETAILS OF INDIVIDUAL COMPLETING SECTION B (complete in all cases)

NAME	
DESIGNATION	
SIGNATURE	

7. To be completed by Consultant Haematologist responsible for Blood Transfusion Department

I confirm that the above details are accurate

NAME	
SIGNATURE	
DATE	

When completed return to Transfusion Centre, keeping a copy for your own records.

SECTION C: To be completed at Blood Centre on return of completed form

1.

DATE COMPLETED FORM RETURNED	

2. FATE OF UNIT (TICK ONE BOX)

FATE	TICK IF APPROPRIATE	FURTHER ACTION
Hospital unable to trace		No further action
DLHCV2 returned. Consultant responsible for transfusion wishes to undertake counselling		CONTACT Consultant. Send DLHCV4 with counselling package, including DLHCV5 and form LBF3.
DLHCV2 returned. Transfused to patient, patient alive and under active follow-up. Responsible consultant does not wish to undertake counselling.		CONTACT named Consultant - letter DLHCV3 and form LBF2.
DLHCV2 not returned. Transfused to patient, patient alive but discharged from hospital		CONTACT GP letter DLHCV 3/form LBF2
Transfused to patient, patient Died		No further action
Unit not transfused		No further action
Unit transferred to other hospital		Send form LBF 1 with letter to appropriate hospital

3. INDICATE FURTHER ACTION TAKEN

_____

_____

_____

4. Details medical officer completing section C

NAME	
SIGNATURE	
DATE	

NATIONAL HCV LOOKBACK PROGRAMME

Assessment of Suitability of recipient for counselling

Recipient details:

Surname	
Other name	
D.o.B.	
Unit Number	

Transfusion details:

Date of transfusion	
Hospital	
Donation number	
Component type	

notes

Please complete the details overleaf and return it to the Blood Transfusion Centre in the enclosed envelope.

If you wish to undertake counselling of the patient yourself the necessary forms and information will be returned to you.

If you do not wish to arrange counselling of the patient yourself the Transfusion Centre will undertake to contact the patient direct, you will of course be kept informed of the outcome.

National HCV Lookback form LBF2

To be completed by Medical Practitioner responsible for patient

1. Please indicate the current status of the patient (tick box).

Alive and remains under my care		Go to 4
Died		Go to 3
Transferred to other GP		Go to 2

2. If transferred to the care of another General Practitioner please complete this section and proceed to section 7

Name of GP	
Year of transfer	
Address of GP	

3. If the patient has died please complete this section and proceed to section 7

Main cause of death	
Date of death	
Did patient suffer from any form of liver disease (give details)	

4. (i) If the patient is alive and remains under your care please indicate

Do you feel it is appropriate for the patient to be contacted for counselling	YES NO	Proceed to 5 complete 4 ii

(ii)

If you feel the patient should not be counselled please indicate the reason below (see note i)

5.

Do you wish to undertake the counselling yourself (please delete)	YES NO	Go to 6

If YES please return form, please do not contact patient until you receive further information from the Transfusion Centre

6. This section will identify the means by which the patient will be counselled. Please complete the appropriate section.

(i) If a Consultant has been identified in your hospital please indicate

Name of Consultant	
Specialty of Consultant	
Contact Address	

(ii) If you wish a Consultant from the Transfusion Centre to contact the patient please indicate (such counselling will be undertaken by experienced medical counsellors who will keep you informed).

Address of patient	

7. Please complete this section in all cases before returning the form to the Transfusion Centre.
Details of Medical Practitioner completing form

Name	
Status	
Signature	
Date	

Please return the completed form to the Blood Centre

Note 1: It is advised that unless there are exceptional reasons, such as severe psychiatric illness or terminal physical illness, the patient should be counselled and offered appropriate medical follow-up.

PEN.017.2266

This form to be retained at Transfusion Centre

SUMMARY LBF2

Donation Number		Component type	
Patient Name			

1.

Date completed form returned	

2. Further action (please complete relevant section)

Patient died		No further action
Patient alive but clinician indicates patient not to be counselled		No further action
Clinician wishes to undertake counselling		Letter HCV4 with counselling pack to clinician
Clinician nominated Consultant to undertake counselling		Letter HCV4 with counselling pack to Consultant
RTC to undertake counselling		letter HCV5 to patient

3. If counselling to be undertaken by Clinician or nominated Consultant indicate

Consultant Name	
Consultant specialty	
Contact address	
Date counselling pack sent	

4. If RTC to undertaken counselling indicate

Date letter HCV5 sent	
Date patient contacts Centre	
Interview date	

5. Details of person completing form

Name	
Status	
Date	
Signature	

When completed please attach to FORM LBF2

NATIONAL HCV LOOKBACK PROGRAMME

Documentation of Recipient Counselling

To be completed at RTC

Recipient details

Surname	
Other name	
D.o.B.	
Unit Number	

Transfusion details

Date of Transfusion	
Hospital	
Donation Number	
Component Type	

notes:

This form should be used to document information gained during the counselling session, it will also act as the request form for referred for patient testing.

To be completed by Counsellor

1. Details of counsellor

Name of Counsellor	
Designation	
Date of counselling visit	
Address	
Signature	

2. Address to which laboratory report should be sent if different to above

3. Patient Details

Patient name	
Date of birth	
Marital status	
Number of children	
Ethnic origin	
Country of birth	

4. Please indicate the current status of the patient (tick as appropriate)

Well, with no symptoms		Go to 6
Symptomatic liver disease		Go to 5
Other medical problems		Go to 5

5. If patient is currently unwell, or has symptoms suggestive of liver disease please indicate below.

6. (i) Does the patient have any other potential risk factors for HCV (tick if appropriate).

Other transfusion episodes		Occupational exposure to blood	
History of injecting drug use		History of skin piercing	

If answered YES to any of the above please give details below

THIS PAGE WILL ACT AS THE REQUEST FORM FOR VIROLOGY STUDIES. PLEASE COPY AND SEND TO THE LABORATORY DESIGNATED IN THE LETTER ACCOMPANYING THIS FORM ALONG WITH THE APPROPRIATE SAMPLES.

7. Please indicate average alcohol intake in units per week _____

8. Has the patient donated blood since receiving the transfusion? YES/NO

If yes give details (place and year)

_____

_____

9. Please indicate below any significant issues that arise during the counselling visit

10. Please complete this section when the results of liver function tests are available.

Test	Result	Reference Range
Bilirubin		
ALT		
AST		
Albumin		

11. If the patient is confirmed to be HCV antibody positive further specialist assessment by a Liver Specialist will be required. Please indicate below the Consultant to whom you plan to refer this patient.

Consultant Name	
Title	
Address	

WHEN COMPLETED RETURN THE FORM TO THE TRANSFUSION CENTRE, PLEASE RETAIN A COPY FOR YOUR OWN USE AND ENSURE THAT A COPY IS AVAILABLE IN THE PATIENT NOTES.

This section to be completed by Transfusion Centre when results of virology tests are known.

HCV antibody status	
HCV PCR result (if known)	
Hepatitis B Core antibody result	