D R A F T

Mrs Weatherseed PS/PS(H)

From:

Date:

Copy: See attached list

INTERIM REPORT ON THE HEPATITIS C LOOKBACK EXERCISE

Introduction

1. This submission is for information to update Ministers nine months after the scheme went live. No action is required.

Background

2. In December 1994, the Advisory Committee on the Microbiological safety of Blood and Tissues for Transplantation (MSBT) recommended to Ministers the introduction of a Look Back of those blood transfusion recipients infected with Hepatitis C prior to the introduction of Hepatitis C screening in September 1991. More details are given in Annex A. The MSBT felt there was a duty of care to those infected as a result of NHS treatment.

3. Two factors determined the recomendation at that time:

(i) the feasability of a Look Back had been demonstrated by a study in Scotland

(ii) Interferon, a drug which is useful for some patients infected with hepatitis C, became licensed in the UK.

4. Ministers agreed to the submission from MSBT dated 15 December 1994 and on 11 January an inspired PQ announced this. To coincide with this announcement a press release was distributed and a press conference was held. An EPINET message was sent to GPs and all hospital consultants and a freephone helpline was set up.

5. Ministers also agreed that a Working Party should be set up under the chairmanship of Dr Metters to draw up guidance on procedures for undertaking Look Back, protocols for counselling and options for treatment, together with any other action which should be taken to satisfy the NHS's duty of care. This might include, for example, recommending additional research.

Response to the Announcement

6. There were over 12,000 calls to the helpline. BBC Panorama broadcast a programme on 16 January "Bad Blood" which was critical. Some anxiety was generated by this and by some parts of the media, but overall the response was not particularly negative. There were individual problems re whose duty it was to provide testing and counselling etc.

Meetings of the Working Party prior to Launch of Look Back

7. The membership of the Working Party is at Annex B.

8. Meetings were held on 20 January, 24 February and 14 March. These prepared a CMO letter, appended at Annex C, which gave details of how the Look back would work, and general guidance to non-specialist medical practitioners on handling. The CMO letter was issued on 3 April 1995 and was accompanied by an HSG (Annex D), PQ and press notices. The Look Back phase officially went live although in some parts of the UK, notably Scotland, a lot of the work had already been started.

Results so far

9. Further meetings of the Working Party were held on 25 May and 13 October. The most up-to-date figures available are given in Annex E which show 1727 donors positive for hepatitis C who had given blood prior to 1991. 9048 donations have been identified and 2808 recipients have been identified by hospitals of whom 1631 have already died, of unrelated causes. These figures suggest that the original estimate of identifying approximately 3000 recipients who are alive was reasonably accurate.

Other Related Matters

Research

10. The Working Party considered aspects of the Look Back which could be used for research into the medical history of Hepatitis C as well as transmission routes and disease management and treatment. The Working Party had some draft proposals and suggested the setting up of a database. Other research projects are to be prioritised following on from this.

Testing/Counselling

11. There were difficulties with some GPs, who were unhappy about being involved in additional work, and there were some criticisms of the Blood Transfusion Services.

Referral to Specialists and position of treatment

12. A number of letters were received by DH asking for ring fencing for treatment of hepatitis C. Officials replied "despite the very substantial real increases in funding, which

the Government has allocated to the NHS, the resources of the NHS are finite. It is for doctors and managers to make local decisions as to what forms of treatment and what drugs are to be made available to patients based on the needs of the local population. There are inevitably and rightly rising expectations of what the NHS should provide as developments in medical science continue to make new treatments available. We are keen to respond and funding is sufficient to allow new treatments to be introduced. However, decisions on whether individual patients are likely to benefit from particular drugs are for the clinical judgement of the doctors concerned''. In most instances it would appear recipients are being referred to appropriate specialists.

Summary

The Look Back so far has been slower in achieving its objectives than had been predicted. The Blood Transfusion Services are being encouraged to work better and faster on this project. Ministers are asked to note the results so far in paragraph 9.

ANNEX A

1 INTRODUCTION OF HEPATITIS C LOOK BACK

Reason for No Action before December 1994

1.1 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. Previously there had 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.

Definition

1.2 Look Back is a process of identifying patients who were previously given blood from donors who have since been shown to be Hepatitis C positive. Such patients would be counselled, tested and if found to be infected advised of the appropriate treatment.

Pilot Study

1.3 Early in 1994, the East of Scotland Blood Transfusion Service conducted a pilot study to identify recipients of blood from donors subsequently found to be positive for HCV. Following this pilot it was established that a look-back exercise in the UK would be feasible and practicable.

Position in December 1994

1.4 The position had changed on both counts. There was now some confidence that many, but not all, recipients of blood infected with Hepatitis C could be identified by a process known as Look Back and some treatment regimes using Interferon Alpha had been licensed.

Recommendation

1.5 The Advisory Committee on the Microbiological safety of Blood and Tissues for Transplantation (MSBT) at their meeting on 15 December 1994 decided to make recommendations to the Secretaries of State of the four Health Departments concerning the identification and follow up of people who may have been put at risk of hepatitis C infection through NHS treatment. Any such action was to be on a UK wide basis and to require the drawing up of clear guidance on identification procedures and action to be taken.

Terms of Recommendation

1.6 MSBT's advice to Ministers was based on the following considerations:

i In MSBT's view there is a duty of care towards those infected with Hepatitis C as a result of NHS treatment. It follows that procedures should be put in place to identify those patients at risk.

ii Whatever is done should be done equally and uniformly throughout the UK.

iii Guidance should be drawn up as soon as possible:

a) on procedures for identifying those at risk, and

b) while it was for the medical practioner responsible for each patient identified as at risk to decide what should be made known to the patient about his/her risk status, and to decide whether and what treatment should be advised, guidance on the counselling and treatment options would be desirable.

1.7 The committee also suggested that, if Ministers wished, an ad hoc Working Party could be established drawn from the membership of the MSBT and the Advisory Group on Hepatitis.

1.8 The Government accepted recommendations of the MSBT and Ministers instructed Dr Metters to establish an ad hoc working party to draw up guidance on procedures for undertaking Look Back, protocols for counselling and options for treatment, together with any other action which should be taken to satisfy the NHS's duty of care. This might include, for example, recommending additional research.

Announcement

1.9 On 11 January 1995 the Government announced a UK wide look-back exercise. The aim was to trace, counsel and, where appropriate, treat those identified as being at risk. The announcement was made in the form of PQ answer at 3.30pm. A press conference was held and a press release issued to coincide with this announcement.

Freephone Helpline

1.10 A helpline was established to provide a central freephone information service for members of the public who were concerned following announcement of the look-back exercise. The aim was to provide authoritative details to those who have heard about it second hand; to reassure those who are not affected and to advise those who might be at risk to consult their GP for further information.

Guidance to Hospital Consultants and GPs

1.11 Many people were expected to consult their hospital consultant or GP to find out whether they had any cause for concern. Accordingly all hospital consultants and GPs were sent a short briefing statement together with a copy of the Q and A brief used by the helpline. This was distributed via the EPINET system. GPs were informed when the system first contacted DPHs who in turn passed the message on to all FHSAs in their area. The FHSAs had responsibility for getting the message via facsimile to GPs.

2 BACKGROUND - HEPATITIS C IN BLOOD TRANSFUSION RECIPIENTS AND HAEMOPHILIACS

Testing

2.1 It has been known for several decades that hepatitis could be transmitted by blood. A test for hepatitis C was developed in 1989. The original tests were very poor, with only 16 per cent positives being correct. The test has been improved considerably since then, and also confirmatory tests became available. The testing was considered by the Advisory Committee for Virological Safety of Blood (ACVSB - predecessor of the MSBT) and following their advice testing was introduced in the UK on 1 September 1991. After that date all donations of blood were tested for Hepatitis C.

Position in other Countries

2.2 Access to information from elsewhere in the world also influenced the decision on when to introduce hepatitis C testing. Even today the information relating to the position in other countries is not completely clear. The best information we have at present is that the first country to introduce universal screening was Japan in November 1989. It should be noted, however, that HCV is believed to be a major cause of liver disease and cancer there, and it is thought likely that between two and four million people are infected. France introduced screening in March 1990. We understand that Luxembourg and Italy introduced screening in April 1990, although in Italy it was on a voluntary basis. Holland introduced it in May 1990. The test was licensed in the USA in May 1990 but it is not known when it was introduced. Testing was introduced in Belgium in July 1990.

2.3 We have no further information on when other countries introduced screening although it was much later in central and eastern Europe.

Haemophiliacs

2.4 The occurrence of hepatitis C (then called non A non B) in haemophiliacs was recognised from the late 60's onwards. It is probable that all haemophiliacs who were treated before 1985 would have been infected with hepatitis C. Since 1985, all factor VIII and factor IX has been treated to destroy HIV and hepatitis C. A very small number of haemophiliacs who had been treated with cryoprecipitate after 1985 and before September 1991 may have become infected with hepatitis C.

Blood Transfusion Recipients

2.5 Blood transfusion recipients receive individual donations and, because of the relatively low incidence of hepatitis C in blood donors generally, only a small proportion will have become hepatitis C infected. (No blood is imported into the UK and so no paid donors or donors from countries with a higher prevalence of hepatitis C are involved.) The first significant reduction in the risk of hepatitis C transmission via blood occurred in 1983 when exclusion criteria were set up to reduce the risk of HIV transmission, prior to the availability of HIV screening tests. Among the exclusion categories were intravenous drug misusers and homosexuals.

Numbers

2.6 There are many uncertainties about hepatitis C but in terms of the numbers infected we can only guess that about 3,000 haemophiliacs who are not also HIV positive are alive who are hepatitis C positive. It is thought likely that 3,000 blood transfusion recipients who are alive will be identified by the look-back exercise. There are others who will not be so identified. The Department has no better figures than this.

Prognosis

2.7 50% of suffers from Hepatitis may progress to chronic Hepatitis with varying degrees of ill health. It can cause liver damage and mortality. Prehaps 20% of infected patients will develop cirrhosis, a progressive destruction of the liver, that may take 20 to 30 years. In addition a small proportion will develop primary liver cancer after time. Certain patient groups may have a worse prognosis and a more rapid disease progression, eg immunosuppressed patients, those coinfected with HIV, and/or Hepatitis B, and possibly haemophiliacs.

New Treatment

2.8 Until recently there has been no widely accepted treatment for hepatitis C. In November 1994, a licence was granted for Interferon Alpha to be used in the treatment of chronic Hepatitis C. Interferon Alpha is the only extensively studied agent shown to be effective but results are disappointing. In approximately 50% of patients with chronic Hepatitis C who were treated with Interferon Alpha there is evidence of the virus being cleared from the body. While relapse rates are high some 20 to 25% of patients currently being treated have a sustained response. Advances in the treatment of viral disorders are expected in the next few years that may improve response rates.

2.9 Consideration will also need to be given to ensure that those infected through NHS treatment will get access to treatment.

Pressure for Action

2.10 We have expected at any time a campaign to be mounted along the lines of that for HIV. On 16 January 1995, BBC Panorama screen a programme on Hepatitis C critisising the failure of the Health Service to trace and provide treatment for patients who may have contracted the hepatitis C virus before testing was introduced in September 1991. In Spring 1995 there was increased media interest and a series of EDMs, a House of Lords debate, an Adjournment debate, PQs and a large number of letters. There have been several writs received by regional transfusion centres, which have primarily referred to the time between 1989 when HCV tests first became available and September 1991 when screening was introduced in the UK. The Haemophilia Society launched a campain seeking compensation for those patients with haemophilia who may have been infected with Hepatitis C on 14 March 1995. A writ in respect of a haemophiliac has recently

been served on DH. More recently there has been a further EDM, an oral PQ and an adjournment debate in December. SofS met a group of infected haemophiliacs together with Roy Hattersley on 19 December.

Claims for Negligence

2.11 The Health Departments do not accept that there has been any negligence. Screening was introduced on 1 September 1991. The first anti-hepatitis C tests were reported in the literature in March 1989 but did not become available until later that year. These first tests had a significant number of false positive and false negative results and expert advice was that these tests should not be introduced because of these deficienties. The Department of health funded several trials of the first and second generation anti-Hepatitis C test kits before satisfactory kits together with confirmatory tests became available in late summer 1991. Those at highest risk of acquiring Hepatitis C virus now are drug misusers who share blood contaminated needles. The Government has taken action to reduce the number of intravenous drug misusers who share equipment. With the screening of blood and tissue donations and the heat treatment of blood products, transmission by these routes has been largely eliminated. The risk of sexual transmission is thought to be low.

3 WORKING PARTY

Membership of Working Party

3.1 Invitations were sent on 6 January 1995 to prospective members including representatives from Scotland, Wales and Northern Ireland to make up a Working Party. A list of members is appended at Annex B.

Action plan

3.2 It was agreed that the look-back exercise should be concentrated in the first instance upon donors who had given blood prior to September 1991 and been found to be Hepatitis C antibody positive after the introduction of testing in September 1991. The services would not try to trace donors who had not come back to a Transfusion Centre since then. The work involved in doing so would be disproportionate to the benefit. The Working Party considered the testing of serum samples stored from before September 1991 and agreed that Ministers should be advised that the testing of such samples would also be disproportionate, although a legal view on this should be obtained and the subject would be considered again following the results of the current Look Back. However, where an individual who had been given blood requested a test this should be made available, particularly where there had been multiple transfusions. The Working Party also advised that the lookback should not be extended to other blood products.

Funding of Testing and Treatment

3.3 The NHS Executive would not expect to make additional funds available to either purchasers or providers to meet the additional cost of tracing (including testing), counselling and, where appropriate, treatment under the look-back exercise. In many cases the cost will be absorbed as a displacement of other work and elsewhere it will be seen as another mid year pressure. Where significant costs are incurred it will be up to the unit in question to make a case to its parent organisation for an addition to its budget as a result of this extra financial pressure.

Procedural Guidance

3.4 The ad hoc Working Party considered their first priority would be to draw up guidance for the blood transfusion services in the four Health Departments on the procedures to be followed for undertaking Look Back. Comprehensive guidance was issued to all doctors on 3 April 1995 in the form of a CMO letter supported by an HSG (Annex C). The advantage of a CMO letter is that the Department could be assured that no group of doctors which needed to be included would be left out of this important exercise. The Working Party also prepared draft documentation for the Blood Transfusion Services, consultants and GPs to use for recording all information which needs to be collected.

3.5 Blood transfusion centres were asked to implement the first stages immediately.

Feedback

3.6 Progress is taking longer than initially envisaged. Some difficulties in tracing records and the problem of funding Interferon and the increase in workload at some haematology departments and at large liver units was noted.

Research

3.7 This exercise provides a unique opportunity to investigate epidemiological questions, routes of transmission, and disease management and treatment. There is a strong case for bringing together a series of research activies on Hepatitis C. It also provides an opportunity to see if counselling works.

3.8 It was accepted that a national register be created with archive samples of serum and clot (to alow DNA storage).

3.9 A formal proposal for research funding is being prepared and will be passed to RDD for consideration.

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Mr Lapsley PS/PS(C)
Mr Dyson PS/Per Sec
Miss Probert PSCE
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ANNEX B

MEMBERS OF THE AD HOC WORKING PARTY ON HEPATITIS C LOOK BACK

Chairman

Dr Jeremy Metters	Deputy Chief Medical Officer	Department of Health

Nominated by the Advisory Committee on the Microbiological Safety of Blood and Tissues for Transplantation

Dr D W Gorst	Consultant Haematologist	Royal Lancaster Infirmary
Dr R Mitchell	Director	Glasgow and West of Scotland Blood Transfusion Service
Dr E Angela Robinson	Medical Director	National Blood Authority
Professor Howard Thomas	Professor of Medicine	St Mary's Hospital London
Dr R E Warren	Director	PHLS Laboratory Royal Shrewsbury Hospital
Professor J D Williams	Professor of Medical Microbiology	London Hospital Medical School
Professor Arie Zuckerman	Dean and	The Royal Free Hospital School of Medicine
	Professor of Microbiology	London University

Nominated by the Chief Medical Officers of the Territorial Health Departments

Dr J Gillon	Consultant Physician	Edinburgh & S E Scotland Blood Transfusion Service
Dr A Keel	Senior Medical Officer	Scottish Office
Dr Liz Mitchell	Senior Medical Officer	Department of Health and Social Services Northern Ireland
Dr Diana Westmoreland	Consultant Virologist	Cardiff Public Health Laboratory

Departmental Officials

Mrs Jenny Griffin	RD2
Dr H Nicholas	HP3B
Mr Kevin Guinness	CA-OPU
Dr A Rejman	CA-OPU

Secretariat

Mr Paul Pudlo	CA-OPU2
Miss A Towner	CA-OPU2
John Nash	CA-OPU2

ANNEX C

3 April 1995

From the Chief Medical Officer

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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 for professional enquiries:

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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 specialties, 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.

GRO-C

Dr Kenneth C Calman
Chief Medical Officer

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PROCEDURAL GUIDANCE 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.

Write **in confidence**, to haematologists responsible for the blood banks at the 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.

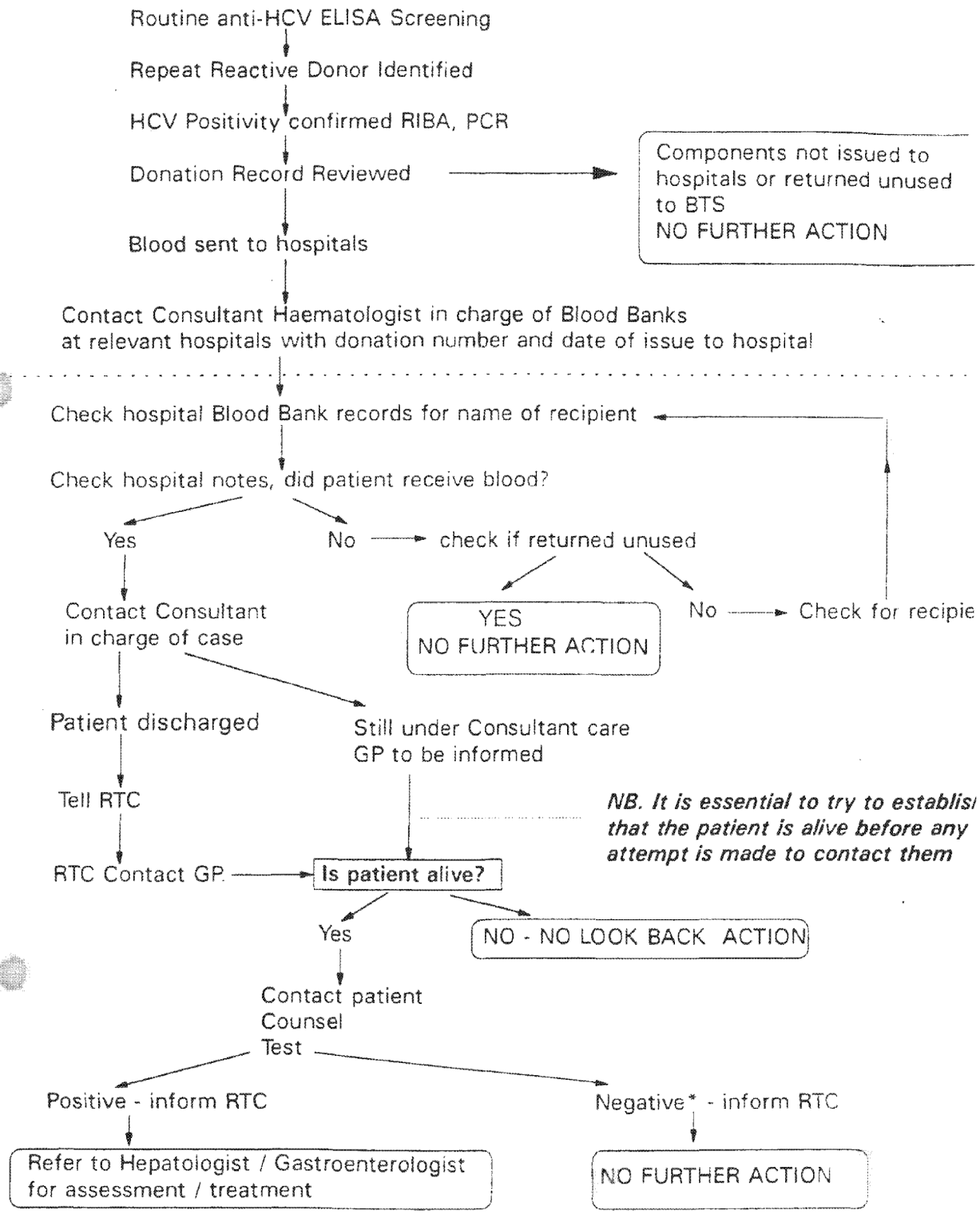
Plasma that went for fractionation does not need to be traced back but its destination needs to be noted for completeness. In addition transmission of hepatitis C may have occurred in recipients of IVIG and coagulation factor concentrates before viral inactivation procedures were introduced. RTCs will 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.

ALGORITHM FOR LOOK BACK FOR HCV



*If patient is immunocompromised, ELISA may give a false negative result and PCR may be required

TRANSFUSION-TRANSMITTED HEPATITIS C : GUIDELINES FOR COUNSELLING PATIENTS

ANNEX B

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.

7. 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.

12. No vaccine is available to protect against hepatitis C, and it is unlikely one 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.

19. An elevated serum 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.

25. 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.

ANNEX D

Health Service
Guidelines

NHS
Executive
HSG(95)23

Hepatitis and blood transfusion look back

3 April 1995

Addressees

For action:
NHS Trusts
Directly Managed Units
District Health Authorities
Family Health Services Authorities

For information:
Regional Health Authorities
Community Health Councils

From

NHS Executive
Corporate Affairs - Operational Policy Unit 2
Room 313 Eileen House
80-94 Newington Causeway
London SE1 6EF
Tel: 0171-972 2912

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Hepatitis and blood transfusion look back

Executive summary

On 3 April 1995 a Chief Medical Officer letter (PL CMO(95)1) was issued to all Medical Practitioners in England containing guidance and procedures for the look back exercise announced by Tom Sackville, Parliamentary Secretary for Health, on 11 January 1995.

The exercise is to trace, counsel and, if necessary, treat those people who may have been inadvertently infected with hepatitis C through blood transfusions. A similar letter has also been sent by the Chief Medical Officers of the Territorial Health Departments. The letter has been copied to Regional Directors/Managers, District General Managers, Chief Executives of NHS Trusts and Directly Managed Units.

Action

General Managers and Chief Executives are asked to:

- make the necessary arrangements to ensure that the maximum co-operation is given in the conduct of this exercise, particularly in the tracing of the appropriate records;

- bring this matter to the attention of all appropriate staff.

ANNEX E

UDATE OF CURRENT STATUS OF LOOK BACK

	England	Scotland	Wales	N Ireland
Number of donors identified who had given blood pre 1991	1,328	340	42	17
Number of relevant donations identified (and transfused); if e unknown, assume transfused		1,504 (T-1574 ?)	328 (302 transfused)	196
Number of donations notified to hospitals	7,113	1,516	302	117
Number of recipients identified by hospitals	2,122	378	245 + 44 irretrievably lost	63
Number of recipients followed up	440	40	77 + 107 records not yet found	18
Number of recipients counselled and tested	217[1]	35	1	7
Number of recipients tested positive	129[2]	30	1	RIBA Pos PCR Neg 3 RIBA Pos PCR Pos 1
Number of recipients tested negative	47[3]	5	0	RIBA Neg 3
Number of recipients who died	1,315	225	69	22

1. LBF3 forms so far only received from:
   Leeds
   Manchester
   Newcastle
   Bristol

2. 2 by PCR only
   19 HCV antibody positive but PCR negative

3. 8 HCV antibody negatives not yet confirmed by PCR

15/12/95