

3 April 1995

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.

From the Chief Medical Officer

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PL CMO (95)1

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

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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.

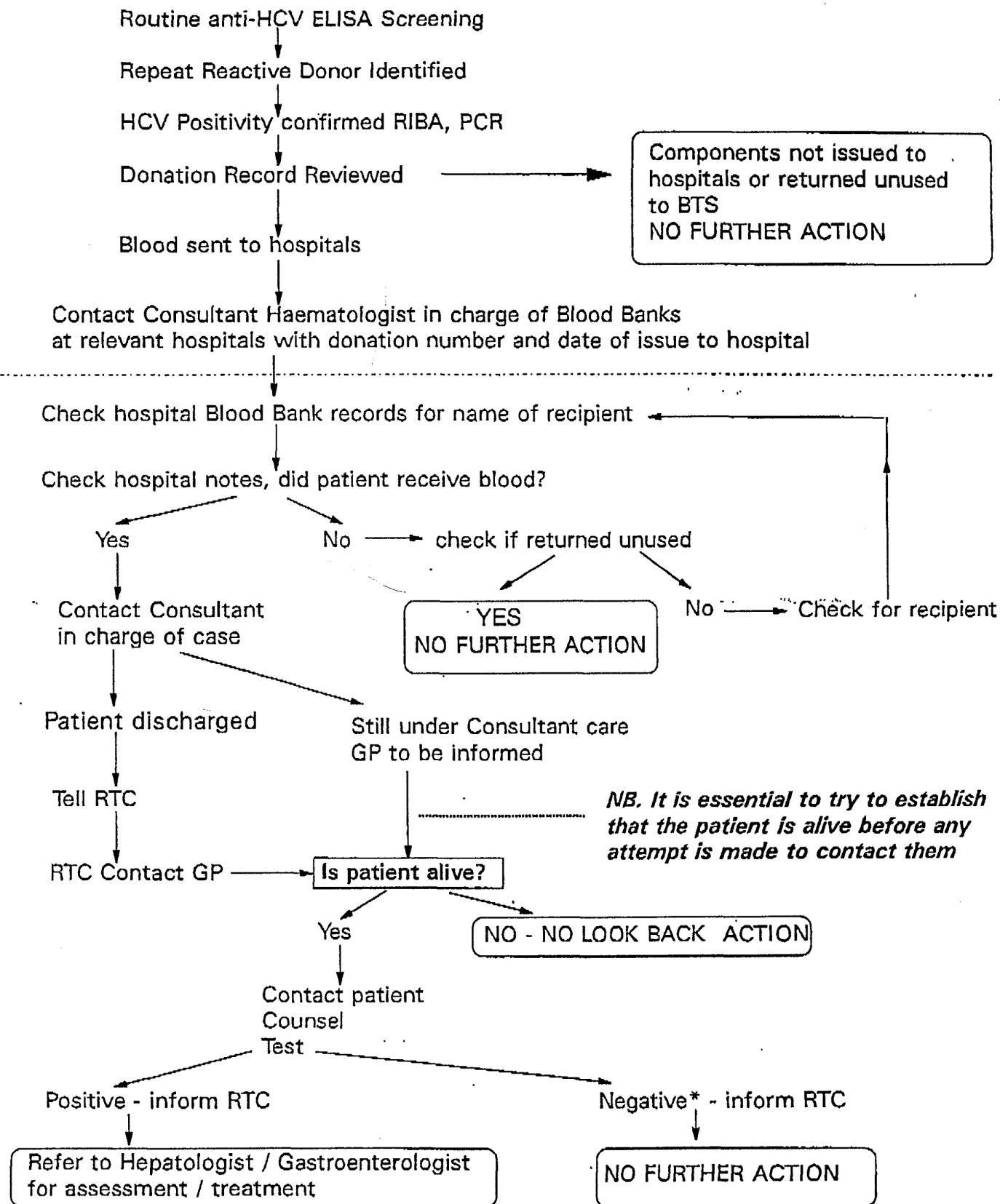
Plasma that went for fractionation does not need to be traced back but its destination needs to be noted for completeness. In addition transmission of hepatitis C may have occurred in recipients of IVIG and coagulation factor concentrates before viral inactivation procedures were introduced. RTCs will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

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.

file HCV Look Back
HSG letter issued same
day as CMO letter 3/4/95

DR MOCK

for Hepatitis C
12/4/95 94/4

Health Service Guidelines



Executive HSG(95)23

Hepatitis and blood transfusion look
back

3 April 1995

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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.