Dr Rejman

From: Dr J S Metters DCMO
22 December 1995

Copies to: Mr Guinness
Dr Nicholas
Dr Doyle
Mr Pudlo
Mr Nash

INTERIM REPORT ON THE HEPATITIS C LOOK-BACK EXERCISE

1. Your minute of 20 December refers. I have a number of suggestions for your draft submission. As Chairman of the Look-Back Working Party, I think I should put this forward.

Amendments

Paragraph 1, 1st line: Replace "nine months" by "one year".

Paragraph 8, 1st line: Change to: "To plan the Look-Back meetings of the Working Party were held on ..... 14 March. As these documents were drafted for use during the Look-Back including a CMO letter, appended at Annex C, which spelt out how the process would work and guidance for non-specialist medical practitioners."

Paragraph 9, last line: Replace "reasonably accurate" by "realistic".

Paragraph 10, 1st line: Replace "could" by "should".

Paragraph 11, 1st line: Replace "unhappy about being" by "did not wish to be".

Paragraph 12, 2nd sentence: Amend to "After consulting Mr Sackville, then PS(H), officials used the following response "despite the very substantial real increases in funding ..."

2. Lastly, between the end of the current paragraph 12 and the Summary paragraph you may wish to include a short note about further follow up action on the Look-Back and a proposed timetable for the next report to Ministers. Also as PS(H) has not previously been involved, it might be worth offering a meeting to fill in some of the details.

J S METTERS
Room 509
Richmond House

202/YdeS

CONTENTS

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 fate 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

AN INTERIM REPORT ON THE HEPATITIS C LOOK-BACK EXERCISE

John Nash

9 October 1995

Introduction

1. This submission is for information to update Ministers six 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 councilling 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, 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.

Initial Results

9. A meeting of the Working Party was on 25 May. Reports received from the NBA and the territorials indicated 1,405 donors had given blood previously and 179 recipients identified. On 13 October these figures were updated and currently are as follows:

? donors

? recipients

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 accept 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 HCV 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.

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.

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.

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