DRAFT

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From: Dr J Metters DCMO

Date:

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INTERIM REPORT ON THE HEPATITIS C LOOKBACK EXERCISE

Introduction

1. This submission is for information to update Ministers one year after the scheme went live. No action is required, although Minister may wish to meet with officials to discuss this report.

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 recommendation at that time:

(i) the feasibility 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. To plan the Look Back, meetings of the Working Party were held on 20 January, 24 February and 14 March. At these meetings documents were drafted for use during the lookback including a CMO Letter, appended at Annex C, which spelt out how the process would work and guidance for non-specialist medical practitioners. 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 realistic.

Reasons for slow progress

10. Members of the MSBT considered why the exercise was taking longer than originally envisaged. They identified two particular bottlenecks, one was tracing medical records for recipients identified in the hospital blood banks and secondly a shortage of counsellors available to see patients prior to and post testing.

11. The MSBT accepted that if both of these areas of difficulty were overcome, it was likely that the hepatology services for specialist assessment and where appropriate commencement of treatment would probably not be able to cope.

Alternate Ways Forward

12. The MSBT felt that there were several opinions available. These are outlined in Annex F. Overall their view was that central exhortation to speed up the process was unlikely to achieve much. They were against abandoning the planned Look Back. It was felt that communications between the BTS and hospitals where there were particular problems was the best way forward, supplemented by the offer of assistance to overcome the bottlenecks in tracing hospital records and a shortage of suitably trained counsellors.

13. The Committee felt that a delay in identification that might be extended for the rest of 1996 would not disadvantage patients as the evidence was of a 20-30 year time frame for significant liver damage to occur.

Other Related Matters

Research

14. The Working Party considered aspects of the Look Back which should 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

15. There were difficulties with some GPs, who did not wish to be involved in additional work, and there were some criticisms of the Blood Transfusion Services.

Referral to Specialists and position of treatment

16. A number of letters were received by DH asking for ring fencing for treatment of hepatitis C. After consulting Mr Sackville, then PS(H), officials used the following response "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.

Further follow-up reports

17. Further follow-up on the lookback exercise will be carried out by the MSBT. The few members of the Working Party who are not members of MSBT have been invited to attend for this item at the next meeting of the MSBT on 8 January 1996.

18. A further report will be made to Ministers in approximately 6-9 months, depending upon the rate of further progress with the Look Back exercise.

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. The MSBT considered possible ways to overcome bottlenecks in respect of hospital patient records and counselling. Possible ways forward were identified. Ministers are asked to note the results so far in paragraph 9, and PS(H) may wish for a meeting with officials.

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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	341	42	17
Number of relevant donations identified (and transfused); if fate unknown, assume transfused		1,693 (No of components)	328 (302 transfused)	196
Number of donations notified to hospitals	7,113	1,516	302	117
Number of recipients identified by hospitals	2,122	412	245 + 44 irretrievably lost	63
Number of recipients followed up	440	59	77 + 107 records not yet found	18
Number of recipients counselled and tested	217[1]	44	1	7
Number of recipients tested positive	129[2]	35	1	RIBA Pos PCR Neg 3 RIBA Pos PCR Pos 1
Number of recipients tested negative	47[3]	9	0	RIBA Neg 3
Number of recipients who died	1,315	247	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

ANNEX F

HEPATITIS C LOOK BACK: PROPOSED ALTERNATIVE WAYS FORWARD

At the recent MSBT meeting it was noted that the Look-Back had been slower in achieving its objectives than had been predicted. A number of options on the way forward were considered.

1. Continue Look-Back 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.

4. The Committee considered these options, but unanimously concluded it was important to continue with the present strategy. This had been carefully designed to identify and offer counselling and treatment to recipients of blood transfusion units implicated in the Look-Back in a structured way that would maximise benefits to them. At the same time the Look-Back would obtain important information about the rate of transmission and natural history of Hepatitis C when acquired from transfusion that was not currently available.

5. The Committee also agreed that a delay in the identification process that might be extended for the rest of 1996 would not disadvantage patients as the evidence was of a 20-30 year time frame for significant liver damage to occur.

6. Should Ministers feel action needs to be taken to overcome bottle-necks in the present Look-Back strategy the following were among the possible actions that might be appropriate:

    a. establish a task force

    b. use nurses with epidemiological research experience or infection control nurses to look at hospital records.

    c. approach Medical Directors of Trusts to try to identify medical records more quickly.

    d. use professional counsellors, suitably briefed, as in the case of CJD/HGH recipients.

e. direct referral of patients to liver units for testing and counselling.

f. representatives of the BTS to visit/telephone hospitals where there are particular problems.

The Committee also felt that hospitals that had not largely completed their programme of identifying patients, should be approached by NBA (or the equivalent in other countries) to inquire what their anticipated timescales were for completion of the patient identification stage of the programme.