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ITEM 4 ADHOC WORKING PARTY ON HEPATITIS C LOOKBACK 25/5/95

**PROGRESS REPORT FROM THE NBA ON THE HCV -
LOOKBACK PROGRAMME**

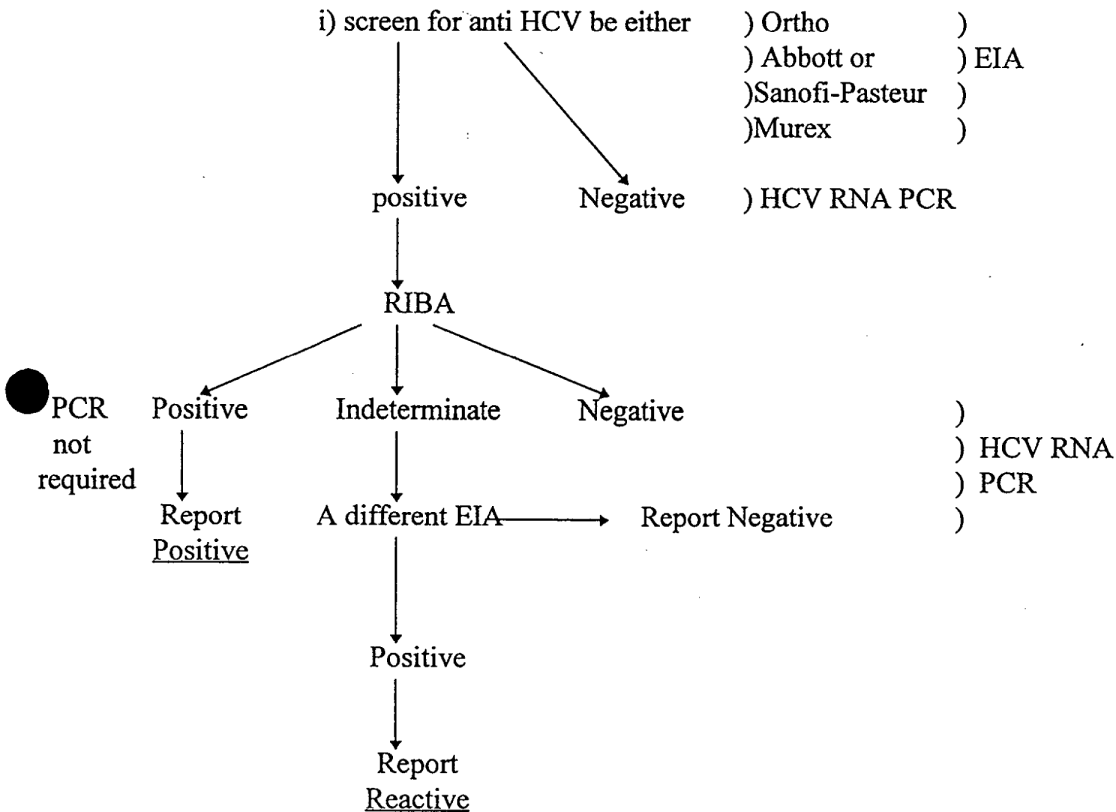
Progress Report from the NBA on the HCV - Lookback programme

All Transfusion Centres in England and Wales were sent instructions and the complete package of forms and draft letters to be used for the 2nd stage of this programme on 31st March 1995. By the end of May all hospitals concerned should have received lists of potentially infected components. Every effort was made by the Transfusion centre medical staff to communicate with the key haematologists concerned. An LBF I form has been distributed for each component on the hospital lists.

Distribution in the London Zone was delayed until secure methods of overprinting the LBF I forms had been established to avoid transcription errors and local computerised database had been created to keep track of the process and outcome. All Transfusion centres have now reached the stage where they are beginning to receive LBF I returns. An agreed testing algorithm has now been distributed to designated testing laboratories and to all transfusion centres. Each Transfusion centre has a designated consultant in charge of their local Look-Back programme, and the situation is being monitored regularly by the Zonal Clinical Director with regular feed back reports to the NBA Medical Director.

**HCV LOOK BACK LABORATORY TESTING
FOR HEPATITIS INFECTION**

1. Recipients of blood components from donors subsequently found to be anti HCV positive will be counselled and asked to give blood for HCV and other tests. Eight to ten ml of clotted blood sample should be drawn and sent by courier without delay, to arrive by 4pm that day, at the local specialist virology laboratory. This will be chosen from Birmingham, Bristol, Cambridge, Cardiff, Leeds, Manchester, Newcastle, Nottingham, Oxford PHLS; Virus Reference Division (VRD) Colindale; and Division of Virology, University College London Hospitals (UCLH).
2. Serum must be separated immediately and two 1 ml aliquots of serum put in store at -70°C. These two bottles will be labelled for easy retrieval and re-identification, and retained long term in a readily identified box/rack in the freezer. The blood clot will be kept until after the second sample has been received and tested by the laboratory (see below, para 6)
3. The remaining serum will be used for antibody tests as follows:



AW L
Robinson
Rps

- ii) Screen for anti HBc by EIA/RIA: report reactive
non reactive
- iii) Repeat anti HCV EIA

4. The recipients are likely to be anxious following the counselling and blood sampling, and it is essential that the antibody test results are available within the 3 working days after the receipt of the specimen in the laboratory.
5. When the recipients are seen again they will be asked to give a second sample the purpose of this is to check the identity of the original specimen tested.
6. Rarely, recipients who are found to be anti HCV negative may be HCV PCR positive. By special arrangement stored aliquots of serum from these individuals will be tested for HCV RNA.
7. **Reporting**
Specimens will be sent accompanied by a distinctive form. This form must be used to report laboratory findings to the counsellor who should then return the completed LBF3 form to their local Transfusion Centre. Each Transfusion Centre is required to forward copies of the laboratory findings on form LBF3 to Dr Robinson, Medical Director, National Blood Authority, Oak House, Reeds Crescent, Watford, Herts WD1 1QH, in an envelope marked confidential.
8. **Reimbursement**
The following charges for antibody tests, etc. have been agreed with NBA

Initial anti EIA and	
RIBA	£45
Anti HBc EIA	£5
Storage and admin	£5
Repeat anti HCV	£10

Total:	£65

PHLS will be reimbursed on receipt by Dr Robinson, NBA, of a copy of their report.

Update on current situation

London and South East Zone

	Known Donors	Clinical Components
Brentwood	75	517
Cambridge	88	335
NLBTC	150	953
STBTS	<u>230</u>	<u>1500*</u>
	543	3305

* Moved donors and some imported components still being searched

Northern Zone

			RTC unable to trace fate of component*	
Newcastle	53	224	268	
Leeds	65	237	31	
Sheffield	84	435	196	
Manchester	83	426	0	
Lancaster	47	181	12	
Liverpool	<u>72</u>	<u>456</u>	137	<u>recipients</u>
	404	1979	644	<u>identified</u>
Wales	92	328		138

* This failure to trace the fate of implicated components at the RTC's is being followed up.

Midlands and South West Zone

Bristol	164	263	some
Birmingham	56	762	
Oxford	115	410	
Southampton	<u>100</u>	<u>394</u>	125*
	435	1829	

* 1984-1988 Destination records stored by RHA - Irrevocable damaged

England & Wales total	<u>1382</u>	7434
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expected 11,000

Costs

Quarterly monitoring of Transfusion Centre costs relating to the HCV LookBack Programme will be undertaken. It is hoped that estimates for the total costs of the exercise will be available in the next week, although it is early days yet to establish the increased clinical/administrative/medical sessional time that will need to be devoted to this programme. This will become clearer once the majority of LBF I forms have been returned to the transfusion centres.

This quarterly monitoring will also include the central monitoring of the returned LBF 3 forms which will be used as a mechanism for central invoicing and quarterly payment system for the HCV testing Laboratories.

Estimated Maximum number of samples

= 3000 @ £65 / test
= £195,000

Estimated number of samples requiring HCV PCR testing (5%) = 150

@ £55 / test
= £8250

(estimated costs agreed between PHLS, UCL and NBA based on the HCV testing algorithm)

A number of people have raised questions with regard to the funding of the work being undertaken by the hospitals both in the context of the LookBacks Search Process and subsequent patient investigation and management. A clear statement of intent would be helpful to clarify my confusion with regard to this situation.

Problems Identified to date

1 Transfusion Centres

Some Transfusion Centres have been unable to trace the fate of some implicated components. This problem is now being addressed but there may be some gaps left.

2 Hospitals

There has been good liason so far between Transfusion Centres and hospital haematologists. However concerns are being expressed about how some hospitals are going to find the necessary funds to provide for adequate numbers of trained staff to undertake the manual searches of the hospitals' blood bank and medical records. Concerns are also being expressed about how interferon treatment if necessary is going to be funded. [Royal Free and Hammersmith].

There is a specific concern in some hospitals about the need to record the cause of death on the LBF 1 since most of the other information can in some hospitals be extracted from the Laboratory records. Comment from Queen Charlotte's Hospital:- if red cell have been given as an intra-uterine transfusion then it would be prudent to consider both mother and baby as recipients.

Mixed reaction to the reporting forms, some complimentary, some complaints re the complexity, but attempts by hospitals to create their own systems are being actively discouraged.

3 Haematologists and GP's

Counselling guidelines :- A straw poll of GP's in the South West Zone suggests that these have not been 'digested', none could recall the CMO's letter on Look-Back.

Most haematologists (SW) expect the Transfusion Centre medical staff to do the counselling. This could impact on the extra medical sessional time that will be for counselling required by Transfusion Centres for the HCV LookBack programme