1st March 1996

«name»
«rtc»
«address» «info»

Dear «dear»

HCV LOOK BACK

From the LBF3 forms I have so far had returned; it is clear that the instruction to identify "all reference laboratory confirmed HCV antibody positive donors" has been subject to different interpretations, such that some "indeterminate" cases have already been included in the Look Back.

An analysis was then carried out on how each centre undertook confirmatory testing during the period in question to determine if there was a means of defining, as tightly as possible, patterns of HCV serology which might be predictive of true HCV infections such that these cases could be included in the HCV Look Back programme. If this proved to be possible, without increasing the workload too much, the MSBT felt that this would then provide a much more consistent approach throughout the country and assist in identifying the majority of transfusion recipients who might have been put at risk of acquiring HCV infection pre 1991.

I am enclosing a SACTTI recommendation for the definition of selected HCV indeterminates for inclusion in the Look Back Programme. This has been endorsed by the MSBT with the recommendation that all UK Transfusion Centres should extend the HCV Look Back Programme to include HCV indeterminates as defined by the enclosed document by 1st April 1996. Please could you now therefore take the necessary steps to include these carefully defined HCV indeterminate cases into your Look Back Programme by 1st April 1996.

For your information, I am also enclosing the latest update on the current status of the Look Back with many thanks for all your efforts in getting the progress we have to date. However, you will see that to date I have only so far received 400 LBF3 forms so there is some concern about where the "bottlenecks" are occurring which appear to be slowing down the process. I am aware that the Zonal Clinical Directors have been trying to establish throughout the country what the specific problems are, such that I can report back to the MSBT and advise on whether any central assistance could help expedite the process, as the Minister is concerned that the programme is taking such a long time to complete. So thank you again for your assistance with this problem.

Cont'd.../

It also became apparent from this Look Back exercise that individual transfusion centres utilise different procedures for counselling donors with confirmed positive microbiological markers, and also within centres different approaches are taken for different markers. Information obtained from counselling such donors is one of the ways we can monitor the effectiveness and appropriateness of current donor exclusions in this field of "at risk behaviour". Hence, it is important to try and ensure that a consistent quality of information will be available for analysis.

To try and establish the degree of variability that now exists we are about to undertake an audit of the practice within individual centres. Dr Alison Townley (Yorkshire Blood Centre) has kindly agreed to manage this process on my behalf, and you will shortly be receiving a series of questionnaire forms which have been approved by SACTTI for this purpose. These have been constructed as simply as possible for ease of response, and I would be most grateful if you could deal with them as quickly as possible upon their receipt so this exercise can be completed as soon as possible.

It is obviously an area where standards of best practice need to be defined in the best interests of donor care. Equally, national analysis of quality information obtained from donor counselling will be of immense value in assessing our effectiveness in excluding "donors with at risk behaviour".

Again, many thanks for undertaking the extra work that the HCV Look Back Programme has created for you. This may have been a burdensome task, but many long term benefits are now beginning to result from this exercise and all your efforts will hence prove well worthwhile in the long term.

Best wishes.

GRO-C

Dr E A E Robinson
Medical Director

Distribution: Consultants with responsibility for HCV Look Back in NBS Centres.

Copied to: Alan Slopecki
Kate Soldan
Professor Richard Tedder
Dr Atrah

Enclosures

Definition of HCV indeterminate for inclusion in lookback

Donors with those patterns of indeterminate HCV serology which might be predictive of true HCV infection should be included within the lookback programme. It is recognised that the confirmatory algorithms used by reference laboratories may differ, and most importantly that they will have changed during the four years that routine HCV antibody screening of donations has been undertaken. It will be necessary to review the serological results of all donors reported to be indeterminate in order to identify those donors who will be required to be included within the programme.

Donors with indeterminate serology that was reported at the time to show a very clear band of at least 3+ to either c22 or NS3(c33c) are those most likely to be predictive of true HCV infection. The results of EIAs on these donors should be assessed and included in the programme in accordance with the following.

(a) **If results of at least 2 EIAs from different manufacturers are available**

(i) Donors whose sera is reactive, in accordance with the manufacturers instructions, in 2 generically distinct EIAs should be included in the lookback programme (see note 1).

(ii) Donors whose serum is negative in at least one EIA should not be included in the lookback programme

(b) **If results from only a single EIA are available** donors should be included in the lookback programme if the result is reactive, in accordance with the manufacturers instructions.

It is recognised that PCR testing methods currently available have a low but significant false negative rate and also that in some donors PCR for HCV RNA may be intermittently positive. In view of this indeterminate donors who are identified by the above criteria. should be included in the HCV lookback programme irrespective of the results of PCR testing for HCV RNA.

Donors with indeterminate serology that does not meet the above criteria should not be included in the lookback programme.

Note

1. The term "generically distinct" refers to the source type and formulation of the antigen used within the EIA. The main groups of antigens that should be considered divergent are Chiron derived antigens (Ortho/ Abbott), Murex, UBI and SanofiPasteur.

Examples of results in different EIAs and the requirement for inclusion in the lookback are shown below

EIA type			Include in lookback
Ortho	**Abbott**	**Murex**	
Reactive	Reactive	Negative	NO
Negative	Reactive	Reactive	NO
Reactive	Reactive	Reactive	YES
Reactive	Not performed	Reactive	YES

2. When donors have been tested by EIAs of more than one generation, the results with the most recent assay format should be applied in determining whether to include the donor in the lookback.

Peter Flanagan 17/10/95.

UPDATE OF CURRENT STATUS OF LOOK BACK

	England
Number of donors identified who had given blood pre 1991	1328
Number of components identifed and notified to hospitals	6743
Number of recipients identified by hospitals	4280
Loss of transfusion records/untraced	922
Number recipients followed up	1128
Number of recipients alive and untraced	313
Number of recipients counselled	422
Number of recipients tested positive	223
Number of recipients tested negative	106
Number of recipients tested indeterminate	11
Results awaited	19
Number of recipients counselled who refused testing	4
Number of recipients awaiting counselling interview	7
Number of recipients who have died	1863

Only ~~268~~ 460 LBF3 forms returned to date.

Angela Robinson - 29/02/96

name	rtc	address	dear	info.
Dr E Love	Manchester Blood Centre	Plymouth Grove Manchester M13 9LL	Liz	
Dr N Anderson	National Blood Service - South West Centre	Southmead Road Bristol BS10 5ND	Nicky	
Dr V James	Trent Regional Transfusion Centre	Longley Lane SHEFFIELD S5 7JN	Virge	
Dr K H Shwe	Lancaster Blood Centre	Lancaster Centre Quernmore Road Lancaster LA1 3JP	Kim	
Dr V Martlew	National Blood Service, Mersey & North Wales Centre	Regional Transfusion Centre West Derby Street LIVERPOOL L7 8TW	Vanessa	
Dr A Townley	National Blood Service Yorkshire	Regional Transfusion Centre Bridle Path LEEDS LS15 7TW	Alison	
Dr C E Chapman	National Blood Service, Newcastle	The Transfusion Centre Holland Drive Barrack Road Newcastle Upon	Catherine	

name	rtc	address	dear	info.
		Tyne NE2 4NQ		
Dr F Ala	National Blood Service - West Midlands Centre	Vincent Drive Edgbaston Birmingham B15 2DG	Fereydoun	
Dr M Fisher	Oxford Blood Transfusion Service	The John Radcliffe Headington Oxford OX3 9DU	Marlene	
Dr P Flanagan	National Blood Service Yorkshire	Regional Transfusion Centre Bridle Path LEEDS LS15 7TW	Peter	
Dr P Hewitt	North London Blood Transfusion Service	Colindale Avenue London NW9 5BG	Pat	
Dr S Knowles	North London Blood Transfusion Service	Colindale Avenue London NW9 5BG	Sue	
Dr L Williamson	East Anglian Blood Transfusion Centre	University of Cambridge Long Road Cambridge CB2 2PT	Lorna	
Dr F Boulton	Wessex Blood Transfusion Service	Coxford Road Southampton SO9 5UP	Frank	

name	rtc	address	dear	info.
Dr T Wallington	National Blood Service - South West Centre	Southmead Road Bristol BS10 5ND	Tim	
Dr S Rawlinson	Army Blood Supply Depot	Ordnance Road Aldershot Hants GU11 2AF	Sam	
Dr J A F Napier	National Blood Transfusion Service (Wales)	Blood Transfusion Centre Rhydlafar St Fagans Cardiff CF5 6XF	Tony	**For information**
Dr P Mortimer	Public Health Laboratory Service	Central Virus Laboratory 61 Colindale Avenue LONDON NW9 5EQ	Philip	
Dr D B L McClelland	Edinburgh & South-East Scotland Regional Blood Transfusion Service	Department of Transfusion Medicine Royal Infirmary 41 Lauriston Place Edinburgh EH3 9HB	Brian	**For information**
Dr W M McClelland	Northern Ireland Blood Transfusion Service	Belfast City Hospital Complex Lisburn Road Belfast BT9 7TS	Maurice	**For information**

Copied to: Alan Slopecki, Prof. Richard Tedder and Kate Soldan and Dr Alra