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Fax No GRO-C

Dear Angela

HCV Look Back - Draft 13/01/95

Joint comments from Dr P E Hewitt and Dr J A J Barbara.

1. Action by RTC

This should specify that **blot indeterminate** positive are not to be included in this group **unless PCR positive.**

The questionnaire to haematologists should include a further category - name of clinician currently caring for patient, if currently under hospital care.

We would suggest that the contact with the recipient is made by the GP or by the clinician caring for the patient if currently under hospital care. The hospital haematologists cannot be expected to communicate with GPs and clinicians since they will have no additional resources to do this. Therefore, an additional step is required after the questionnaire is received from the hospital haematologist. The RTC should notify the clinician or GP and suggest/advise counselling and testing for hepatitis C. By this means, the RTC will be able to maintain a track of progress in tracing of recipients.

2. Action by Haematologists at the hospital

In our experience, haematologists are usually able to return information very quickly if there are computer records available in the blood transfusion laboratory. The further back the donation was transfused, the more likely there is to be a delay since computer records were not generally introduced until the late 1980s. The major reason for delay is likely to be difficulty in locating the medical records. The haematologists have no control over the storage of medical records and this may well be a major stumbling block. This may require input from sources other than the Transfusion Service.

In the majority of cases, a simple reminder letter, sent after a specified interval, elicits a response if only to say that investigations are still continuing.

3. Action by Clinician in charge of the patient at the time of transfusion

We suggest that it is unnecessarily complex to involve a clinician in charge of the patient at a remote date, who no longer retains clinical responsibility for that patient. In our experience of HIV Look Back, involvement will lead to universal non-compliance! On the other hand, if the patient is currently under the care of a clinician at a hospital, then compliance is likely to be much better. This may not necessarily be the clinician who was caring for the patient at the time of the transfusion, but that is not the point. Trying to involve clinicians who were in charge of the patient at the time of the transfusion can lead to problems as they do not wish to become involved in what might potentially be accusations of medical negligence for inappropriate transfusions! We should keep well clear of this complicating factor.

There may be delays in involving clinicians currently in charge of patients, dependent upon the time interval between hospital visits of the patient. There may be occasions when decisions are needed about whether to recall a patient earlier or to go through the GP, even though the patient is currently under hospital care.

4. Action by GP

The major issue here is who should perform the counselling. Many GPs will not feel themselves equipped to carry out this task as they have no in-depth knowledge of the issues relating to hepatitis C testing. The most obvious solution would be for the Transfusion Service to train appropriate staff (possibly nurses) to carry out this work but there will be resource implications. There is, however, no obvious alternative. Certainly, in our area, we would see the majority of GPs unable/unwilling to take on this task themselves. Some recipients will decide to accept testing immediately after counselling and it would be ideal to have a facility to take samples there and then. Others would wish to have time to consider the implications and would need to have a sample taken at later date.

5. Responsibility for testing

We need to ensure consistency in test results and in data gathering. Confirmation will also be very important. We are probably not alone in having had to unravel discrepancies between RTC testing and hospital testing in donors. For these recipients it is very important that the testing is of the highest quality, precise and defined. For these reasons we would recommend that the transfusion service carries out the recipient testing. It has been suggested that the most efficient means of doing this would be to carry out an ELISA, followed by a PCR on ELISA reactive samples. We support this concept.

6. Stored donor samples prior to September 1991, where donor has not given blood since

The work involved in defining which samples relate to donors who have not been tested for anti-HCV is enormous. Furthermore, RTCs have different extents of archived samples, and the approach must be consistent across the country. There would be enormous operational problems, on top of the ethical and legal considerations. Very often, it will be impossible to adequately confirm an ELISA reaction on a stored serum sample, which is likely to be of small quantity.

For these reasons, we would not advise any plans (at present) to test stored donor samples for donors who have not given blood since September 1991.

7. NBS procedures to be followed

In our case, dealing with large numbers of donations, it will be impossible to produce a list for each hospital as a one-stage procedure. Furthermore, the hospital will be unable to deal with all that information at one time. It will therefore need to be a staged procedure.

As far as issue records are concerned, it is very easy for us to obtain data back to December 1985, when all components were on computer records. It becomes more time consuming and difficult to trace the fate of components issued before December 1985, but it has usually been possible to get back to 1982. These, however, should be a small number compared with the total. We would propose initially restricting our Look-Back to donations held on the computerised issue records i.e. December 1985.

8. Resources

We are currently discussing the resources required for this exercise. To some extent, this will depend on some of the comments we have made e.g. with regard to who contacts the GP or hospital clinician and who carries out the testing. Once we have the answers to these questions we can more accurately determine the resources we will need.

Yours sincerely

GRO-C

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Acting Medical Director

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