INVESTIGATION OF DONATIONS TRANSMITTING HIV AND HBsAg

Plasma donations for the preparation of fractionated products must be non-reactive for anti-HIV and HBsAg. There are occasional reports of patients, particularly those who are immunocompromised, developing an infection from the transfusion of cellular components from a donation the plasma from which has been sent to BPL. This usually involves hepatitis but could equally well be HIV seroconversion.

In order to ensure that each RTC has an operating procedure to handle these investigations I have recently received from RTCs the procedures employed in investigating such instances. Below I have analysed the response from two aspects:

(1) The initial stages of the investigation so that BPL can be informed of any plasma donations that may be at risk.

(2) Follow-up of the implicated donor so that he/she can be removed from the panel of active donors.

The procedures at each RTC will be considered.

1. **Newcastle**

   1.1 Within 72 hours of a confirmed report of post-transfusion infection the donations involved can be identified. The test results are held on a computer file and can be rapidly checked and BPL notified accordingly.

1.2 The record system allows for identification of the donors involved and follow-up would proceed by recall of the donors and further testing of their blood.

2. **Leeds**

2.1 If the initial report is by telephone, details of the patient's name, date of the diagnosis of the infection with appropriate laboratory details, date of the transfusion(s) and donation number of the implicated donations are recorded and a request is made for confirmation of these details in writing to the Consultant in charge of Microbiology.

2.2 Checks are made that the donation numbers correspond to the units despatched to the relevant hospital, the components produced from the relevant donation and details of their issue, checks on any subsequent donations and the donation numbers of these. Any components still held at the RTC are found, marked reject and sent for disposal.

2.3 A "J-file" is opened and the implicated donors record is flagged. Test records are obtained and results checked to ensure that donations were non-reactive and controls satisfactory. A stored frozen sample of the original serum is retested (if this is available).

2.4 BPL is notified in writing of any units of plasma from the implicated donations (including donations following the index donation), together with confirmation of microbiology results. This can usually be achieved within 3 working days.

2.5 Samples from the implicated donors are obtained from the G.P. The donors are informed of the results accordingly and may be retained on the panel or withdrawn as appropriate.

3. **Sheffield**

3.1 All notifications must be received in writing and a proforma is completed. This includes details of the donors involved and a check list to ensure appropriate action is taken, e.g. inform BPL as on the proforma.

3.2 The laboratory work sheets for the implicated donations are checked and if available stored sera are retested.

3.3 The donors are identified and the records flagged. Donors who have not donated since the suspect donation receive a letter requesting a further sample. If a sample is not received within one month a further letter is sent. Samples are tested for HBsAg, anti-HBc and anti-HBs.

3.4 The following action is taken:

3.4.1 If the donor is found HBsAg positive he/she is informed, BPL is notified and clinicians who have received other products are also notified.

3.4.2 If the donor is anti-HBc positive, anti-HBs negative, the donor is considered to be implicated. BPL is notified.

3.4.3 Donors who test as non-reactive are informed accordingly.

NOTE: Although the initial test records are checked, and a repeat test is performed on the initial sample, if possible, reporting the incident to BPL does not occur until after repeat samples from the donors. This could involved delays of several weeks if the donor does not respond quickly.

4. **Cambridge**

4.1 A consultant is responsible for the enquiry. Within 48 hours the following procedures are undertaken:

- obtained donor records of implicated donor
- check medical history of donors
- make arrangement for further samples from donors

- identify products involved
- withdraw products if possible
- obtain test result print-out and check results
- retrieve stored sample and retest in house and send aliquot to reference laboratory

4.2 If all enquiries negative await results from reference laboratory (within 72 hours).

4.3 If these results identify positive donor, hospitals and BPL are informed accordingly

4.4 If negative result from reference laboratory BPL notified of jaundice enquiry.

4.5 Further samples obtained from donors as soon as possible. These are tested at RTC and reference laboratory.

If a positive is found, hospitals and BPL informed. If all negative BPL notified.

5. **North London**

5.1 All enquiries are performed by authorised persons. Upon notification a file is opened and a letter is sent to the person in the referring hospital who notified the case.

5.2 When details are returned the file is reviewed and a decision is made whether to initiate an enquiry.

5.3 Donation numbers on the notification form are forwarded to Consultant in charge of Q.A. for onward transmission to BPL.

5.4 Donors are identified from the donation numbers and each donor contacted by letter with a request for a further sample. If the donor does not respond within one month a further letter is sent. If there is still no response a decision is made whether to withdraw the donor.

5.5 After all tests have been completed, appropriate action is taken with respect to the donor, the hospital and a summary is sent to the Consultant in charge of QA so that BPL can be informed of the donations which have been cleared and any which may be implicated.

NOTE: The final notification to BPL takes place at the conclusion of the enquiry. This could result in BPL holding in quarantine a large number of plasma donations. This is in accordance with current specifications and presents a problem which needs resolving.

6. **Brentwood**

6.1 An SOP has not yet been finalised but a working procedure is in existence.

6.2 Donations implicated in a jaundice enquiry are communicated to BPL. The samples are retested using the original test method and BPL informed of the results. Details of subsequent donations are also given to BPL.

6.3 It is considered that the implicated donors should be followed up in order that a donor or donors who had hepatitis not determined by laboratory tests at the time of donation could be identified.

7. **South London**

7.1 There are no written protocols.

7.2 All donors are written to and request is made for their doctor to take a blood sample for repeat tests.

7.3 If and when all donors have responded, and when the results have been received from the PHLS, the case is resolved accordingly.

8. **Lewisham**

8.1 A report sheet is completed with the following information:

- hospital and consultant involved

- patient's name, age and nationality
- clinical details including laboratory findings
- date(s) of transfusion
- all donation numbers of product types

A written confirmation is requested.

8.2 A check is made that the donation numbers and the products reported were sent to the hospital concerned.

8.3 The donors are identified.

8.4 Plasma donations sent to BPL are identified and the QA Manager is telephoned immediately informing him of implicated donations, the pool of plasma and the box numbers as appropriate. This information is confirmed by FAX.

8.5 Each implicated donor is contacted and a further sample obtained. The stored frozen sample (if within one year) is retrieved and, together with the freshly collected sample, is sent to PHLS (Colindale).

8.6 When the results are negative, the donor is recalled after 6 months and a further sample sent to PHLS. If this is still negative the donor is reinstated to the active panel.

8.7 When a positive result is received the donor is contacted for counselling and all products from the donation are traced and the hospitals concerned are informed.

9. **Southampton**

9.1 A written SOP is not available.

9.2 A procedure for follow-up of the donors concerned is in existence, but does not include notification of BPL. I was assured by Dr. Herborn that the RTC would ensure that BPL would be given full details.

10. **Oxford**

10.1 After the diagnosis is substantiated all blood products given to the patient within the incubation period are investigated.

10.2 If plasma from any of these donations has been sent for fractionation, BPL will be informed without delay.

10.3 Implicated donors are temporarily withdrawn until they can be traced, repeat samples obtained and tested. If a donor is identified as a possible source of infection he/she is withdrawn.

10.4 Recipients of blood products from the same donations are followed up if possible.

11. **Bristol**

11.1 Information requested from the notifying hospital

- clinical summary with dates
- list of products, donation numbers and dates transfused
- results of virological investigations

11.2 File is initiated and BPL informed of details of plasma donations sent to them.

11.3 Repeat testing is performed on stored frozen samples from each implicated donation and an aliquot is sent to PHLS for confirmatory testing. If all results are negative BPL is informed.

11.4 The donor records are flagged and the donor is allowed to donate again. When the donor attends the donation is marked for "Laboratory use". The donation will be routinely tested at the RTC and a sample sent to PHLS.

11.5 If all the results are negative the donor is restored to the active panel.

11.6 Any donor involved in more than one incident is seen by a medical officer and repeat virology tests and liver function tests performed.

11.7 If the number of donors implicated is no more than five they will be contacted for further blood samples in case they do not attend for their next appointment.

12. **Birmingham**

12.1 Upon notification the Director opens a file and the following information is recorded:

- date(s) of infusion
- identity of blood units and products implicated
- initiates computer trace of donor(s)

12.2 Archived frozen sample is retested and microbiological test results of any subsequent donations (if any) are checked. The donor record is flagged.

12.3 Director/QA Manager notifies BPL by mail and telephone of suspect plasma donations.

12.4 Director contacts donor(s) by telephone and/or mail to obtain further sample.

12.5 Hospitals to which products have been issued are notified and identification of recipients is requested. Blood samples are requested from recipients still in hospital. GPs of discharged recipients are notified.

12.6 Any positive results are sent to Reference Laboratory for confirmation.

12.7 BPL is notified of final results by telephone and mail.

12.8 The case is concluded by informing negative results to donors and the initiation of counselling of positives and withdrawal of these donors.

13. **Liverpool**

13.1 Details of the incident are requested in writing and a list of donation numbers obtained.

13.2 The donor records are flagged and if an implicated donor gives blood again the donation is quarantined.

13.3 Repeat tests are carried out on the stored frozen sera. If a positive donor is found then the donor is withdrawn. If all repeat tests are negative then all donors should be retained on a medical file and subsequent donations quarantined until a full serological screen can be performed.

13.4 Any remaining blood products held from a positive donor will be destroyed and BPL will be notified by telephone and confirmation in writing.

NOTE: As far as I can see, only those donations which are found to have a positive results on retest are notified to BPL.

14. **Manchester**

14.1 An SOP is not yet available but a working procedure is in existence.

14.2 After substantive information of a case of post-transfusion infection is received all donation numbers of products transfused are detailed and the donors involved are entered into a special file. The products prepared from the donations are identified.

14.3 Where samples are available from the original donor samples these are retested and sent to PHLS for further tests.

14.4 Additional samples taken at the next donation from implicated donors are requested and after re-testing if one or more positive donors are found they are withdrawn. Others with non-reactive results are reinstated and their records flagged.

14.5 Any donor implicated in more than one post-transfusion infection is withdrawn.

NOTE: The procedures do not include notification of

plasma donations to BPL but I am aware from personal experience that this was a priority and BPL were informed of any "suspect" donations with the minimum of delay.

15. **Lancaster**

15.1 An essentially similar procedure to that in Manchester is operated at Lancaster.

15.2 The comment applicable to Manchester also is pertinent for Lancaster.

16. **Cardiff**

16.1 Information required following notification:

- clinical background
- implicated donation numbers
- written confirmation

16.2 Open file for donor details.

16.3 QA Manager to action:

- local recall of blood/products
- notification of BPL
- product return from BPL

16.4 Implicated donors are contacted for additional samples.

These are tested at RTC. If all donors are negative

the referring clinician is informed. If any positive donor(s) are found then all concerned, (hospitals, other BTS regions to whom products of the donation(s) have been sent, BPL) are informed.

17. **Army Blood Supply Depot**

17.1 When a case of post-transfusion infection is reported a file is opened and all details of implicated donations are recorded.

17.2 A product recall procedure is put into effect for the implicated donations. This includes both hospitals and BPL.

COMMENTS AND CONCLUSIONS

The majority of RTCs have procedures for investigating donors implicated in transfusion-associated infections. These involved contacting the donor and retesting of an additional sample using reference laboratories for confirmatory testing.

I am generally confident that procedures are satisfactory to ensure the withdrawal of suspect donors from the panel if appropriate.

However, procedures do vary, particularly with the reporting of

suspect donations to BPL and in some RTCs this could take a significant time. With BPL stocks reducing it is imperative that notification of such donations to BPL are carried out with the minimum of delay.

Draft specifications for the notification of non-conforming plasma donations are being considered at present and when agreed will be circulated to RTCs.

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