Introduction of HCV NAT Testing: Donor and Recipient Notification Issues

Notes of a meeting held on
Monday 11 January 1999 at NBA HQ, Watford

Present:	**Dr Andrew Herborn (AH)** **Dr Patricia Hewitt (PEH)** **Dr David DeLeacy (DL)** **Barbara Cant (BC)** **Denis Gough (DG)** **Paul Harrison (PH**
In attendance:	**Dr David Hutton (Wales)** **Dr J Paley (Wales)**
Apologies:	**Steve Ramskill (SR)** **Phil Mellor (PM)**

ACTION

Introduction

PEH welcomed those present. DG was attending in place of PM representing Midlands and South West Pooling Laboratory. There was no representative from the Northern Zone Pooling Laboratory, although PEH had had discussions with both Terry Male and Chris Hodson before the meeting.

The purpose of the meeting was to consider the action which should be taken once a positive NAT result is reported from the NAT Testing Laboratory (at BPL). Action with respect to the donation, donor, and any recipient, would be needed, as set out in the guidelines on donor and recipient notification issues (GDE/NBS/CM/002/01) which was distributed in June 1998.

The guidelines were prepared early last year, when it was anticipated that NAT testing would "go live" by the summer of 1998. Since the time scales have changed and the project has developed, some of the details contained in the guidelines are no longer strictly accurate. As the NAT project is still developing at a great pace, it is difficult to be definitive in a guideline document. Zonal SOPs will be needed to reflect local procedures and this will be a priority of those present. Although L and SE Zone documentation has been appended to the guidelines as an example, even these were now requiring revision.

It was anticipated, on best possible estimates, that there will be approximately 10 NAT positive, serology negative, cases per year in England and Wales. PH confirmed that the testing laboratory had so far tested approximately 200,000 donations and no case has yet been detected. It therefore appears that 10

ACTION

cases per year is not a serious under estimate.

1. Review of the Document

The major features of the guidelines have not altered. In essence, no contact of a donor should take place until all available results have been reviewed by a central expert group. A second review will be required when the donor has been seen and resampled, before any contact of recipients takes place. These two steps have been incorporated in order to ensure that no centre/zone takes action which is premature or inappropriate.

2. The Constitution of the Central Expert Group, not defined in the document, is as follows:

Paul Harrison (or a member of his staff) NAT Laboratory
Member of staff from the Reference Laboratory (Professor Richard Tedder's Department at University College London Medical School (UCLMS))
Dr John Barbara
Dr Patricia Hewitt (PEH)
Zonal Designated Consultant (i.e. PEH,AH,DL) or deputy.

Review of test results would not necessarily require all to be present a meeting since results can be faxed and a telephone conference arranged. It is important, however, to have a zonal clinical representative who can take forward recommendations from the group and direct action at local centre level.

PEH suggests that, in the event of the zonal consultant not being available, then the clinician from the centre which supplied the donation should be involved. For L & SE Zone there are 4 nominated senior medical staff with responsibility for transfusion microbiology. If PEH is not available then one of the other three will take her place.

AH, DL to designate "deputies"

3. PEH emphasised that the guidelines were designed to deal with NAT positive results resolved to the level of a single donation. Unresolved results (i.e. not resolved to a single donation by testing of cross pools) are a matter for a higher level decision and have been referred back to the steering group.

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4. The time of release of results from the NAT Testing Laboratory to the Zonal Pooling Laboratory was discussed. It is clear that the proposed working times for the NAT Laboratory are longer than those for the Zonal Pooling Laboratories. In particular, it is planned that the NAT Laboratory will work on Saturday. At present, pooling laboratories are not expecting to work all day Saturday. The general principle of the NAT Laboratory not releasing results at times that the Pooling Laboratory is not staffed was considered, but declared to be untenable since ethically it would not be acceptable for an issued donation to be transfused at hospital level, when an NAT positive result is know at the testing laboratory. An "out of hours" procedure will therefore be necessary. This will require further consideration. **PH** undertook to review the planning of work for the NAT Laboratory, so that test runs and release of results would coincide with working hours for zonal pooling laboratories. Even if results are received at a time when they can be dealt with in Zonal pooling/donation testing laboratories (i.e. in the evening), mechanisms will need to be in place to ensure that appropriate action can be taken to recall any issued components. This will, in effect, be an extension of local recall procedures. Each Zonal pooling laboratory will need a communication chain, including out of hours procedures.

PH

BC, PM, SR

5. Further testing of the suspect donation.

It was clarified that the "PCR archive" is now named the "resolution plate". It has been agreed that the resolution plate will be supplied by the pooling laboratory to the NAT Reference Laboratory (UCLMS) and not to the NAT Laboratory at BPL. Confirmatory NAT testing will therefore have taken place. It was agreed that the pooling laboratory would supply the resolution plate as a routine, and would not require clinical authorisation. This should be considered a routine procedure, similar to the donation testing laboratory referring a sample to a reference laboratory once repeat reactive screening results have been obtained.

The donation testing laboratory would re-screen the original sample for anti HCV, to confirm the negative result. If any FFP is available, this will also be tested by the Donation Testing Laboratory and NAT Reference Laboratory.

At this point, the National Expert Group will review all results and advise on further action

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6. Retesting and Counselling the Donor

This section is straightforward. It was confirmed that the follow-up blood sample obtained from the donor would be referred for reference testing through the usual channels for serology testing, and to the NAT Reference Laboratory (UCLMS).

7. Action when results on follow-up sample are obtained

These actions are straightforward and do not require any clarification/amendment at present. The importance of reporting through the NBA/CDSC reporting system was stressed. New documentation for any look-back procedure has been designed by Kate Soldan.

8. Action for NAT positive/serology positive donations

It was stressed that no special action is required for NAT positive/serology positive donations. The donation would have already been set to discard by virtue by the serology positive result. The donor would in any case be seen and counselled. Therefore , no special or additional procedures were required in these cases.

Actions

PEH to summarise meeting and report back to NAT Steering Group. — **PEH**

DL to meet with SR and ensure that he is briefed on the salient points. — **DL**

Zonal/local procedures required for action when NAT positive results are received in the pooling laboratory, for donations which are serology negative. — **ALL**

Extension of Zonal/local recall procedures to accommodate the possibility of NAT positive results being received out of normal working hours. — **ALL**

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