MANAGEMENT PROCESS DESCRIPTION MPD577/6

Management of Donors with confirmed Positive Microbiological Markers

This Management Process Description replaces MPD577/5	**Copy Number (obsolete)**
	Effective **29/01/16**

Summary of Significant Changes

Inclusion of information on hepatitis E virus (HEV).

Policy

It is the policy of NHSBT to inform donors confirmed positive for a microbiological marker of their test results and the implications to their health.

Purpose

To ensure that appropriate arrangements are in place to enable donors with confirmed microbiological markers to be managed in a consistently efficient and professional way.

Responsibilities

NHSBT Consultant in Transfusion Medicine/ Clinical Transfusion Microbiology – The Consultant in Transfusion Medicine/Clinical Transfusion Microbiology has overall responsibility for this process

In special circumstances the Consultant in Transfusion Medicine / Clinical Transfusion Microbiology and/or the Consultant in Epidemiology and Health Protection has responsibility for divulging information without consent

All staff involved in the process – All staff involved in the process are responsible for preserving donor confidentiality

Member of clinical staff designated for this function – The designated member of the clinical staff at each Centre

relays test result information to the donor

- advises on the implications to the donor's health
- agrees further action with the donor including referral for further medical care

Definitions

Applicable Documents

MPD591 – To Identify Recipients of Possibly Infected Blood

MPD584 – Guidelines for post-test discussion with donors confirmed to be positive for treponemal antibodies

MPD580 – Guidelines for post-test discussion with donors confirmed to be HBV positive

MPD652 – Guidelines for post-test discussion with donors confirmed to be HCV positive

MPD653 – Guidelines for post-test discussion with donors confirmed to be HIV positive

MPD574 – Guidelines for post-test discussion with donors confirmed to be HTLV positive

MPD914 – Guidelines for management of donors confirmed to be positive for West Nile Virus (WNV) or who report a clinical diagnosis of WNV infection

MPD1214 – Guidelines for management of donors confirmed to be positive for hepatitis E (HEV) or who report a clinical diagnosis of HEV infection

FRM1515 – File Progress Sheet

FRM1516 – Consent to Exchange Information about Test Results

FRM1518 – Post-test discussion checklist (HBeAb)

FRM1519 – Post-test discussion checklist (HBeAg)

FRM1520 – Post-test discussion checklist (HCV)

FRM1521 – Post-test discussion checklist (HIV)

FRM1522 – Post-test discussion checklist (HTLV)

FRM1523 – Post-test discussion checklist (syphilis)

FRM1540 – Specialist Referral of Donors with Confirmed Positive Microbiological Test Results

INTRODUCTION

- All staff involved with the handling of information relating to donors should be reminded of their obligation to preserve donor confidentiality, and the provisions of the Data Protection Act.
- NHSBT has a responsibility to inform donors who are confirmed positive for any microbiological marker of significance to the donor's health. This responsibility extends to cord blood, living tissue donors and relevant families/contacts of deceased donors. The Service must ensure that appropriate arrangements are in place to enable notification to happen efficiently and professionally.
- Guidelines for post-test discussion with donors are available as follows: confirmed to be positive for treponemal antibodies (MPD584), HBV positive (MPD580), HCV positive (MPD652), HIV positive (MPD653), HTLV positive (MPD574), WNV positive (MPD914) and HEV positive (**MPD1214**).
- The management of donors with confirmed positive microbiological markers is the responsibility of the designated member of the clinical staff who, for this function, is responsible to the Consultant in Transfusion Medicine/Clinical Transfusion Microbiology. This designated staff member ensures that all the necessary facilities are in place and that staff are available, when required. In order to maintain staff experience and expertise, the number of staff must be kept at the minimum level necessary to provide the service.
- If any special or unusual circumstance requires actions other than those specified in this MPD, staff must report to the Consultant in Transfusion Medicine/Clinical Transfusion Microbiology and/or Consultant in Epidemiology and/or Consultant Virologist and must document decisions and actions in the donor file.
- Results are considered to be confirmed when a written report from the National Transfusion Microbiology Reference Laboratory (NTMRL) indicates that results are confirmed positive. Alternatively, for HIV and HCV infection a result is considered to be confirmed when a repeat reactive serology screening test result and a reactive NAT screening result have both been entered into Pulse by the Testing Laboratory. In this latter situation, the donor may be contacted in respect of the repeat reactive serology result (confirmed by a NAT reactive screening result) in advance of a final written report from NTMRL. It should be borne in mind that additional unexpected findings may very rarely be present and not apparent from the screening test results. The importance of notifying the donor about the confirmed result with minimal delay is considered to outweigh the very rare chance of an unexpected second infection revealed only on reference testing.
- In the rare case where there is a repeat reactive result for more than one microbiological marker, clarification of the donor status through rapid/urgent tests in NTMRL will be necessary before notification is started.
- Donors should, primarily, be contacted by letter and the letters used for contacting donors should be signed by the member of the clinical staff who is taking responsibility for the notification. Recommendations about the content of the letters are attached in Addendum 2.
- The decision to notify families/contacts of deceased donors with significant test results will depend on the implications for the health of the family member or contact. Each case must be assessed on an individual basis and the most appropriate notification route explored. Contact may be through the general practitioner or a transplant co-ordinator working together with NHSBT staff.
- In exceptional circumstances, for example elderly surgical donors with test results indicative of long past treponemal infection, a decision may be made not to notify the donor. These cases should be discussed with the Consultant in Transfusion Medicine/Clinical Transfusion Microbiology or the Consultant in Epidemiology and Health Protection or another senior member of the Transfusion Microbiology Clinical Group.
- Individual confidential files should be kept on each donor where a confirmed positive result would lead to withdrawal from the donor panel and referral for medical care. Copies of all the relevant documentation must be included in the file. *See 'Planning for contact'.* Where confirmed infection leads only to temporary suspension from donation (e.g., WNV, HEV) communications with the donor may be managed on Pulse.
- The post-test discussion will normally be held over the telephone, with the use of interpreters if necessary (Language Line or similar). NHSBT staff must ensure that the correct individual is on the telephone, and that circumstances are convenient to the donor, particularly in regard to confidentiality. In the interest of

timely notification, and taking account of geographical consideration, HIV test results will be discussed over the telephone, with arrangements made for the donor to be referred immediately to a local specialist service for further advice and care.

- Exceptionally, donors may be seen in person. This should be either on NHSBT premises or elsewhere e.g. at their local hospital. The choice of location will be determined by local circumstances and the donor's convenience. Donors should not be seen in their own homes. In the rare situation where a donor or patient is seen face-to-face, this must be at a donor clinic site, in order to ensure that NHSBT's registration with the Care Quality Commission is not infringed.
- It should not usually be necessary for a second (follow-up) sample to be tested in cases of straightforward confirmed positive test results. Identification errors are exceedingly rare with current procedures for sample identification. As the donor will be referred to the GP or to a specialist unit for further management, the testing of a follow-up sample should be carried out at that stage. Obtaining a second sample for testing within NHSBT may add to delays in the donor receiving specialist assessment and advice, and in other necessary actions (e.g. protection of family members). In a minority of cases testing of a second sample within NHSBT may be helpful, for example when there is evidence of seroconversion/ early acute infection, or to assist in further advice to the donor. The sample may be arranged locally and posted to NHSBT for testing. In this situation, the donor should be notified of the test results on the second sample. The method chosen will depend on the individual circumstances and should be agreed with the donor during the discussion, and recorded in the file.
- All samples from donors must have donation numbers and be recorded on the donor's record and in the file.
- Informed consent should normally be obtained before information about donors' test results, medical or risk history is disclosed to any third party. Consent may be in writing or taken verbally at the time of a telephone conversation. When consent is obtained, whether written or verbal, this must be documented in the donor file. It is recommended that the NHSBT donor consent form, designed specifically for donors with positive results, is used. Where donor consent is not obtained, the donor should be warned that results will be passed on to other services for instance local Health Protection teams in the case of notifiable infections, so that all necessary actions are taken. Results may be passed on without consent in cases where there are potential public health issues, others at risk, or where the donor has failed to make contact and results are passed on for the purpose of future medical care. In cases where the donor positively refuses consent to pass on test results/information, every effort should be made to ensure that the donor will be seen by an appropriate specialist service for further care.
- In circumstances where it may be necessary to divulge information without consent, such as for the protection of others, the case must be discussed with the Consultant in Transfusion Medicine/Clinical Transfusion Microbiology and/or the Consultant in Epidemiology and Health Protection before any action is taken.
- With the exception of known recently treated cases of treponemal infection, WNV infection, HEV infection and cases of apparent cleared HCV infection, specialist follow-up is recommended for all donors. Notification of general practitioners should be agreed if possible.
- Links with clinicians should be fostered to facilitate referral and two-way information flow.
- When specialist referral is not arranged by NHSBT, e.g. by the GP, the referring clinician should be asked to confirm whether or not the donor has been referred.
- Donor information leaflets for each marker are available and should be provided to donors.
- Staff training, monitoring and assessment are essential to ensure that NHSBT offers a high quality service to donors. Recommendations with regard to training include regular local and national meetings and assessment and review of individual skills at local level.

PLANNING FOR NOTIFICATION:

Donors who will be withdrawn from the donor panel and referred for medical care

- A file must be made into which are placed the following:
  - copies of the donor's microbiological test results; screen results for all markers and the reference report for the positive marker
  - a printout of the donor's Pulse record, showing demographic details and donation history, and medical history, as a minimum
  - a copy of the donor's completed Donor Health Check form relating to the positive (index) donation or sample
  - a donor profile prompt
  - a consent form (FRM1516)
  - the relevant information leaflet
  - the donor's NHS number should be recorded and included on all clinical letters
- If the donor's address as recorded on Pulse does not agree with the address recorded on NHS Spine, all available information should be evaluated and, if the Clinician considers it appropriate, measures should be taken to establish the correct address – such as contacting the donor, via telephone or e-mail, or checking with the GP practice.
- A file progress sheet (FRM1515), attached inside the file cover and completed at each stage of the management process, may be used.
- In addition the relevant discussion checklist may be used.
- The Infection Surveillance Form must be completed electronically promptly after the discussion.
- A Pulse check should be made to confirm whether there are other individuals living at the same address who donated on the same day, and whose donation might be considered unsuitable (for instance, a possible sexual partner). In this situation, the donation should be removed from the supply chain until the situation is clarified.
- The test results and donor details should be reviewed and contingency plans made for any particular issues which may be relevant, e.g. health care workers who may need specific occupational advice.
- A check should be made through the NHS Spine records to determine whether the donor is registered with a GP. The information should be included in the donor file.
- For HIV positive donors, options for direct specialist referral should be assessed, without giving the donor's name.
- If the donor is to be seen in person, a check should be made that suitable accommodation for the discussion of the test results will be available. This should provide the following
  - confidentiality
  - pleasant surroundings
  - a waiting area for those who may accompany the donor
  - suitable facilities for taking blood samples (this maybe a donor clinic in the vicinity)
  - reasonable access to a telephone

- Ideally, it should be possible to provide refreshments for the donor and the staff member should be able to alert other staff or have access to a 'panic' button, in case of need e.g. an anxious donor may faint.

Donors who will be suspended temporarily from the donor panel

- A medical file is not necessary in these cases, and interactions may be recorded on Pulse.

PROCEDURE FOR CONTACTING DONORS

- Letters are the primary means of contact for all donors. Only in exceptional cases of clinical urgency (e.g. acute hepatitis B infection, where there has been no response to an initial letter), should the telephone be used. Text message and e-mail may be used for subsequent contact.
- Except in the cases of HIV and syphilis, the letter should name the microbiological marker which is positive and a copy of the relevant information leaflet should be enclosed.
- In the case of HIV and syphilis, the donor should be informed of the need for a discussion with a member of the clinical staff.
- The letters should normally be signed by the member of the clinical staff who is taking responsibility for the notification. If this is not possible, it should be authorised by another member of the clinical team.
- Letters must be posted to arrive at a time when there is someone at the centre available to speak to the donor, should he/she choose to telephone on receipt of the letter.
- The decision whether to put the NHSBT logo/address on the envelope, or whether to send letters by recorded delivery, is made by clinical staff, based on local experience.
- Copies of all correspondence, and a record of all contact with the donor, must be kept in the donor's file and/or on Pulse.
- Secretarial/clerical staff must be ready to receive a reply from the donor and be able to make the necessary arrangements for an appointment for the donor to speak to one of the clinical team.

An out-of-hours message service must be provided for donors who ring outside normal office hours.

ACTION IF NO RESPONSE RECEIVED TO INITIAL LETTER

- The outcome of contact must be regularly reviewed and further attempts made to contact non-responding donors.
- In the first instance the donor's address must be re-checked to ensure the letter was correctly addressed. Checks should be made against both the Donor Health Check, and on Pulse (if the donor has moved he/she may have informed the NCC). The address should also be checked again against the NHS Spine.
- The following are suggested intervals for sending further letters, but timing will also depend on the availability of staff to hold the discussion
  - one week for HIV, acute HBV, HBV e-antigen positive individuals and HCV sero-conversion
  - two to four weeks for HBV e-antibody positive individuals, HCV, HTLV and syphilis
  - Recorded-delivery may be used for the second letter. However, if there is no one at home at the time of delivery of the letter, it will be taken back to the post delivery office and a card left asking the addressee to collect it. This may be a significant disincentive for a donor, who may choose not to go and collect the letter. In these circumstances further correspondence is best sent by ordinary mail.

- Further contact by other methods should be attempted: if the donor has a telephone number (often a mobile phone) it may be expedient to telephone the donor or a text message can be sent asking the donor to ring. Alternatively, a message may be sent by e mail if an address has been provided.

ACTION IF NO RESPONSE RECEIVED TO SUBSEQUENT ATTEMPTS AT CONTACT

- If no contact is made, it will generally be in the donor's best interest to pass the test results to the GP, indicating that it has not been possible to discuss the results with the donor. The donor should be informed that this action will be taken, and given an opportunity to respond.
- If there is still no contact the case must be discussed with colleagues. The responsibility that all reasonable action has been taken to contact the donor rests with the Consultant in Transfusion Medicine/Clinical Transfusion Microbiology. In most cases, contact with the GP or with the local Health Protection Unit, without consent, will be considered necessary. In such cases, the case should be discussed with the Consultant in Transfusion Medicine/Clinical Transfusion Microbiology and/or the Consultant in Epidemiology and Health Protection.

DOCUMENTATION

- Copies of all letters to the donor and specialist or GP must be kept in the file and/or on Pulse.
- All contacts with the donor and a summary of the content must be recorded.
- All documentation associated with the discussion session must be completed and retained.
- The file progress sheet may be used to document the process as an aid to clerical staff, and to summarise the final outcome.
- All donor files must be held securely and placed in locked filing cabinets when not under direct supervision. The security of the cabinets must be the responsibility of nominated individuals.
- If using Pulse to record information, these details must be confidentially-coded and cross-referenced with the files held in the locked filing cabinets.

STAFF

- Only NHSBT clinical staff who have been trained and assessed may carry out post-test discussions with donors.
- If, after being made aware of the result, a donor will be seen by non-NHSBT staff, such as his/her general practitioner or a hospital clinician, the NHSBT must provide in writing details of donor test results as well as NHSBT testing procedures, and information on the meaning of the test results.

THE OBJECTIVES OF THE POST-TEST DISCUSSION

- To confirm donor identity.
- To explain the meaning of the test results and implications for donation.
- To explore the consequences for the donor's future health and circumstances.
- To arrange appropriate medical referral.
- To reduce the risk of onward transmission.
- To obtain information about source of infection.
- To maintain confidentiality.

THE POST-TEST DISCUSSION (PTD)

- The PTD will normally be held over the telephone. A check should be made that the donor is in a position to carry out a conversation, or a suitable alternative time should be arranged.

- Donors must be given the opportunity to be interviewed alone and, initially at least, the presence of others should be discouraged. This is essential when the infectious agent has not been notified in the letter. When donors are aware of what is for discussion, however, they may choose to include others and should be able to do so. Individuals from outside agencies should not be included at this stage, since this would be a breach of confidentiality.
- Immediately after the introductions have been made, a check should be made to ensure that the correct person has been contacted and the donation date is confirmed. The test results and their implications should be fully explained to the donor in clear and easy-to-understand terms.
- The donor's response should be monitored and he/she must be given time to absorb the information and to ask questions. It may be necessary to repeat the information several times and staff should be satisfied that the donor has understood.
- The discussion should help the donor to identify and express his/her particular concerns. These may include some or all of the following:
  - implications for future health
  - medical referral/investigations/treatment
  - transmission to others
  - lifestyle changes
  - sexual practices
  - pregnancy
  - implications for employment, finances and insurance
  - confidentiality
  - whom to tell/concerns about telling partners
  - concerns about early death/care for dependants
  - what the donor will do immediately after leaving the session
  - a plan for future action
- The donor's reaction to the information must be assessed. This may include, on occasion, an assessment of suicide risk.
- If it is felt necessary, the purpose of a further blood sample must be explained and permission sought to take it. The donor must, however, be told that the test on the original sample has been confirmed and that a different result is not expected. It must be explained why a second sample is required. The means by which the donor will be given the second test result must be agreed, and this must be recorded in the file.
- Specialist referral must be recommended to all donors, except for cases of WNV, HEV and cleared HCV infection. In the latter case, two separate negative individual HCV PCR results, preferably 6 months apart, will be sufficient. In cases of very recently treated trepomenal infection referral may not be strictly necessary, but in general all cases of treponemal infection should be referred for specialist opinion, even when there is a history of treatment in the past, as interpretation of history and test results can be difficult and should be performed by experts.
- Informed consent to contact the donor's general practitioner and/or for a direct referral must be obtained. Verbal consent is acceptable, provided it is recorded in the file at the time of the discussion, and referral should not be delayed while awaiting a written consent if verbal consent has been given.
- The donor must be given clear information about when test results are likely to be available, and therefore when the general practitioner/specialist is likely to be informed.
- It is usual practice to send the donor a copy of the letter sent to the GP or referral centre, but in some cases, in particular in HIV, the donor may not want to read a letter detailing information about him/herself. Donors must be asked if they want a copy of the letter, and the donor's response must be recorded in the file.

- Testing of contacts/sexual partners must not be undertaken by the NHSBT, unless that individual is also a blood donor. Testing of sexual partners and other family members is recommended via the general practitioner or hospital specialist.
- If the donor's sexual partner is also a donor, details must be requested so that appropriate action can be taken e.g. withdrawing partner on Pulse, flagging a recent donation for discard. The donor must also be informed of the relevant regulations relating to donor eligibility and be asked to pass on the information to his/her partner. Only in exceptional circumstances will the blood centre pass on such information directly to the partner, since this is a breach of confidentiality.
- At the end of the session
  - the donor's main concerns must have been addressed
  - a course of action, whether it be another appointment, direct referral to a specialist or advice about seeing the donor's general practitioner, must have been agreed.
  - the donor should be offered an NHSBT information leaflet, if he/she has not already received one.

DOCUMENTING THE POST-TEST DISCUSSION

- There is a checklist (FRM1518, FRM1519, FRM1520, FRM1521, FRM1522 and FRM1523) available for each marker which can be used as a record that all standard information has been given to the donor. In addition, any specific concerns, and the means of communicating test results must be recorded in the file.
- For medico-legal reasons, advice given to the donor, e.g. about the importance of medical referral should be noted, as should the donor's agreement to take part in research, if applicable. Similarly, it is important to record when a donor, whose sexual partner is also a donor, has been advised to inform his/her partner of the donor eligibility regulations.
- An infected donor surveillance form should be completed and returned to the Epidemiology team as soon as possible.
- In cases of seroconverting donors, (mostly HIV) a decision about lookback must be made and recorded. Decisions will need to be made about transfused units which may have been donated in the 'window period' for that infection, and therefore might be capable of transmitting infection to a recipient. The procedure is described in MPD591: "To identify recipients of possibly infected blood".
- When the case is closed, the file progress sheet should be checked, to ensure that all actions are complete.

TELEPHONE DISCUSSIONS

- It is acceptable to hold any discussion over the telephone.

REPORTS AND REFERRAL

- Unless already involved by the donor, the general practitioner will usually be informed once the reference laboratory reports are available.
- Reports must be sent by letter to donors' general practitioners, whether or not there has been any telephone contact. The letter to the general practitioner
  - must include details of the donor's results and their interpretation (the NTMRL report form alone is not appropriate),
  - should recommend referral where appropriate
  - may include a list of geographically appropriate specialists (unless the referral is to be made by the NHSBT)
  - should include a request for confirmation of referral using the form FRM1540 'Specialist Referral of Donors with Confirmed Positive Microbiological Test Results' and providing a return envelope.

- may be copied to the donor, depending on the donor's wishes.

- Specialist referral should be according to local arrangements i.e. via the general practitioner or direct to the specialist.
- Direct specialist referral must be by letter, whether or not there has been any telephone contact, and the letter must include the donor's results. This letter may be copied to the donor according to the donor's wishes.
- A request for follow-up information from the specialist may be required in some cases, in particular those where 'lookback' may be indicated and timing and source of infection is unclear.

STAFF TRAINING AND ASSESSMENT

Training of newly-appointed NHSBT medical staff

- Training should include
  - A theoretical and ethical overview
  - Observing experienced medical staff
  - Discussion session with donors in the presence of experienced medical staff
  - A system of review

On-going supervision/consultation groups

- All staff involved in notification and post-test discussion should have the opportunity to attend regular review sessions with experienced members of staff.
- These meetings should aim to identify what has been going well, any difficulties, new issues and interesting cases for discussion.
- Transfusion Microbiology Clinical Meetings (both local and national) should regularly include discussion of cases of donors with positive test results.

ADDENDUM 1

INFECTED HEALTH CARE WORKERS

- The Department of Health has issued documents providing guidance on the management of infected health care workers, with particular reference to individuals who are infected with HIV, hepatitis B or hepatitis C, and who undertake exposure-prone procedures.
- It is the responsibility of the NHSBT clinician to ensure that the advice given to health care workers at post-test discussions is in accordance with current Department of Health guidance

ADDENDUM 2

RECOMMENDED CONTENT FOR DONOR CONTACT LETTERS

First letters

- The objectives in writing to the donor are:-
  - to ensure that he/she makes contact for a post-test discussion
  - to arrange appropriate onward referral
- The wording of the letters used to make first contact with donors needs careful consideration to ensure that these objectives are met. This means that the letters need to convey enough information for the purpose and are clear about who to contact and how.

Hepatitis B Virus, hepatitis C virus, HTLV, HEV and WNV

- specify that a positive result has been obtained relating to hepatitis B/hepatitis C/HTLV/HEV/WNV
- recommend a discussion with an NHSBT clinician before any contact with GP
- invite the donor to telephone to make an appointment
- give the contact telephone number
- include the information leaflet with the letter
- a consent form (and return envelope) should be included

Human Immunodeficiency Virus

- state the results of testing of the donation have revealed a significant result which needs discussion with an NHSBT clinician
- invite the donor to telephone to make an appointment
- give the contact telephone number

Syphilis

- testing of the donation reveals a test result possibly related to a past infection.
- (for acute infection the letter will need to mention a recent infection)
- ask the donor to telephone
- to discuss the result with an NHSBT clinician
- give the contact telephone number

Further letters

- These may:
  - explain that the matter is of significance to the donor's health.
  - ask for permission to contact the donor's general practitioner
  - explain that we will inform the GP unless the donor objects (these must be recorded delivery)

Telephone contact

- Donors who fail to respond to letters may be contacted by telephone. This contact may be made by clerical staff who
  - ask if the donor received our letter(s)
  - arrange an appointment
  - pass the call to the clinical staff or agree a time for a discussion.

Text message / e-mail

- These may be used for subsequent contact, without including any personal information.