MANAGEMENT PROCESS DESCRIPTION MPD591/2

To Identify Recipients of Possibly Infected Blood

This Management Process Description replaces MPD591/1 - MPD/MED/CM/034/04

Copy Number (obsolete)

Effective **16/11/09**

Summary of Significant Changes

Clarify reporting to SHOT/ Clinical Adverse Events

Policy

It is the policy of the NBS to trace the fate of possibly infected blood components in order to offer advice/testing to recipients.

Purpose

To define the actions to be taken with regard to tracing the recipients of components from donors later found to be infected with a transmissible agent.

Responsibilities

NBS Consultant Specialist in Transfusion Microbiology

- has over all responsibility for this process.

Haematology departments at the hospital where the component was issued

- identify recipients and confirm the fate of the components

Clinician in charge of the patient that received the component

- decides whether to inform the patient.

Staff nominated by Consultant Specialist in Transfusion Microbiology

- records and traces the components
- contacts the haematologist at the hospital where the component was issued
- liaises with hospital clinicians and GPs
- notifies recipients and offers testing as required
- records all actions taken
- informs the recipients and clinicians of results as appropriate.

Definitions

N/A

Applicable Documents

FRM1525 - Lookback LBF1

FRM1526 - Lookback LBF2

FRM1527 - Lookback LBF3

MPD1 - Management of Adverse Events

FRM499 - Clinical Adverse Event Report

Introduction

Before any attempt is made to trace recipients of blood from donors confirmed positive for a microbiological marker a decision will need to made about whether a lookback is indicated, and if so which donations should be investigated.

Seroconverting donors

Most commonly seroconversion is for HIV infection, but in all cases the donor will have a record of at least one previous blood donation with a negative test result. A decision will need to be made whether lookback on this last negative donation is required. This donation may have been donated in the 'window period', i.e. tested negative in routine screening but be infectious. It is not necessary to perform lookback on any donations given before this latest negative donation, as with a minimum donation interval of 12 weeks for blood donations any earlier donation must be outside the 'window period'. Apheresis donations require consideration on a case by case basis.

The history taken at the time of the post-test discussion is important in providing information about the likely route and timing of infection. Information from the GUM referral site may also be helpful. Before approaching hospitals, genomic testing for the relevant agent should be performed on the archive sample from the last negative donation, if an archive sample is available. These cases should also be discussed with the Consultant Specialist for Transfusion Microbiology, or deputy, who will give advice about the need for lookback and about what information should be given to the clinicians currently caring for potential recipients. For example, cumulative results on lookbacks (especially for HIV infection) are available and can be provided to help in decision making.

Lookback associated with a new screening test

When a new screening test is introduced it is usual to carry out a lookback exercise on ALL donations given before the introduction of the test since these donations will not have been tested for that agent and are potentially infectious. It is known that donors who are persistently infected with a transmissible agent have usually been infected life-long or for many years and testing archive samples (which are kept for only 3 years) only rarely shows that any previous donations are negative for the agent. Time and resources spent on archive testing is usually better employed on the lookback exercise itself.

However, since the purpose of the exercise is to trace recipients who may benefit from testing, and it is known that both hospital and NBS records become harder to trace the further back we search, and that the likelihood of recipients having died or being untraceable increases with time, it is probably justified to conduct the lookback in phases, tracing the more recent, and therefore more 'productive' donations first. A decision may also be made to set a date before which it is considered not justified to search, given the time and resources required. It is the responsibility of the Consultant Specialist for Transfusion Microbiology to make these decisions.

Procedural guidance to identify recipients of possibly infected blood components

1. Action by NHSBT

All records relating to donors confirmed positive for a microbiological agent must be examined.

Where there are earlier donations on record, further action must be taken to identify whether any such donations may have been donated in the window period, and therefore might be capable of transmitting infection to a recipient.

The last seronegative donation must therefore be investigated, unless there is clear evidence that the donor's infection post-dated this donation. While all such situations cannot be listed, examples would be: where the current (confirmed positive) donation is clearly a window period donation and the last seronegative donation was given many years ago; or where the donor has a clear history of contact in the period between donations with a partner who has been documented to be infected. In any case where a decision is made not to carry out any further investigation into the previous donation, the decision must be approved by the Consultant Specialist in Transfusion Microbiology. In all other cases investigation of the last seronegative donation must be carried out.

The donation testing results of the last seronegative donation must be reviewed, to confirm that the donation was tested and was negative in the standard testing at the time.

The archive sample of the last seronegative donation (if available) must be retrieved and referred for genomic testing (as a single sample) for the agent in question.

Following the introduction of a new test:

Where lookback is carried out following the introduction of a new screening test, NHSBT must write in confidence to the haematologists responsible for the transfusion laboratories at the hospitals which have received components from the infected donors. The form LBF1 (FRM1526) is issued for each component, and return envelopes provided for the return of completed forms. A list of components must be provided to facilitate the search, and copies of the correspondence should be sent to the hospital transfusion laboratory manager to expedite the search. For each component, hospitals must be provided with the donation number (in alternative formats where appropriate), type of component and date of issue to the hospital. NHSBT must endeavour to provide details of all components issued and date of issue even if it is known that the hospital no longer has records. The identity of the donors should NOT be revealed.

NHSBT is responsible for producing and maintaining records linking each component to the relevant hospital. These files must be reviewed every few weeks so that hospitals can be reminded about unreturned forms. In cases where there is no immediate trace of receipt of the component at the hospital, it will be necessary to check NHSBT records again and to emphasise to the hospital haematologist the importance of a further search. The check at the blood centre may necessitate the retrieval of issue records from archive storage.

2. Action by hospital departments of haematology and consultants

The hospital transfusion laboratory records must be searched to identify the fate of each component. The name of recipient and putative date of issue of the component must be identified.

If the unit appears to have been transfused, the patient's record should be obtained and transfusion confirmed. If the record is unavailable or if transfusion is not confirmed, it should be assumed that the unit was transfused, unless instructions for specific infectious agents dictate that only those recipients for whom transfusion is confirmed by their medical record are to be notified. If the notes show that the unit was **not** transfused, every effort must be made to trace the final fate of the unit. If the unit cannot be traced this must be recorded.

Large scale lookbacks

Details of each patient's current status, indicating whether the patient is thought to be alive and if so, under hospital or other care, must be recorded on the LBF1 (FRM1525). These forms must be returned to the NBS, and copies kept by the hospital.

The consultant caring for the patient at the time of transfusion must be informed and asked whether he/she wishes to notify and offer testing to the patient. A reply to the NBS within 14 days should be requested.

If the consultant does not reply within 14 days, or indicates that he/she does not wish to inform the patient, the NBS must approach the consultant currently caring for the patient, or the GP. Before approaching the patient it is essential that steps are taken to ensure the patient is still alive. Letters to deceased recipients must be avoided.

The consultant or GP must be asked to complete a questionnaire LBF2 (FRM1526) indicating whether or not it is appropriate to contact the patient, and if so, whether the consultant or GP wishes to undertake this task, or whether the NBS should do so.

The presumption is that each recipient identified at risk will be notified and offered testing. However, the consultant or GP caring for the patient may feel that in view of age or general medical condition, informing the patient is not in the patient's best interest. In these cases the reasons must be stated on the LBF2

(FRM1526). An NHSBT consultant must be available to discuss this issue, as any decision will be influenced by the availability of treatment and/or the introduction of a payments scheme for individuals infected through blood or tissues.

Lookback for individual recipients (usually for HIV testing)

In these cases it is probably more appropriate to liaise directly with the hospital haematologist in charge of the transfusion laboratory and, if the patient is thought to be still alive, the haematologist will usually approach the current clinician (consultant or GP) to discuss the notification arrangements. A member of the NHSBT clinical team must be available to give advice as required.

3. Notification and testing

In some cases testing will be arranged, or done by, NHSBT. Clinicians must be provided with details of the samples required. Advice about the infectious agent must be available, and documents and information leaflets can be made available to hospital clinicians and GPs if required. A record of the notification discussion should be kept wherever possible, and a form LBF3 (FRM1527) is available for this purpose. Details of recipients' other possible exposures to the agent may also be recorded.

NHSBT clinicians must ensure that all interested parties, including any clinicians currently caring for the patient, are provided with the test results, in writing.

Where testing is performed outside NHSBT every effort should be made to obtain the results, as this information is important for surveillance purposes.

4. Reporting transmissions

In the case of demonstration of transmission of infection to a patient, where a donation underwent screening for the agent in question, a Clinical Adverse Event Report Form (FRM499) must be completed in accordance with the MPD for adverse events MPD1. The case should be reported to Infection Surveillance, and thence to SHOT. It is the hospital's responsibility to report to SABRE, but in the case of a patient who has been dischargedthere may be difficulties in the reporting chain. The patient must also be given the opportunity to have a discussion with an NHSBT Consultant and advised about the legal position. Where a lookback has been performed following the introduction of a new screening test, there is no requirement to report a Clinical Adverse Event, nor to report the case to SHOT/ SABRE.