MANAGEMENT PROCESS DESCRIPTION MPD/DDR/TM/004/01

The Investigation of Suspected (Non-Bacterial) Transfusion Transmitted Infection

This Management Process Description replaces
GDE/NBS/CM/001/03

Copy Number

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Summary of Significant Changes

N/A

Clinical Policy

Purpose

To document and investigate suspected cases of (non-bacterial) transfusion transmitted investigations.

Responsibilities

Consultant on the site responsible for the hospital where the possible TTI has occurred is responsible for

- assessing whether an investigation is warranted
- the investigation of the possible case of TTI
- co-ordination of the investigation
- liaison with the hospital transfusion laboratory and reporting cinician
- documenting possible cases of TTI
- obtaining relevant information from and feeding back information to all relevant departments
- keeping the LCTM informed

Lead Consultant Transfusion Microbiology or designated member of the medical staff is responsible for

- making sure that the investigation is carried out
- giving advice on the conduct of the case
- feedback to all departments involved
- closing the investigation

NBS Clinical Virologist is jointly responsible for

- giving advice on the conduct of the case

Definitions

N/A

Applicable Documents

FRM/DDR/TM/005 PTI progress sheet

FRM/DDR/TM/003 Post transfusion inquiry record

FRM/DDR/TM/004 Post transfusion report

LET/DDR/TM/0011 PTH notify letter

Report prepared for the Clinical Directors Group

National Blood Authority

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The Investigation of Suspected (Non-Bacterial)Transfusion-Transmitted Infection

Introduction

Investigation of Transfusion-Transmitted Infection (TTI) is a vital task for any blood centre. Any suspected case of transfusion-transmitted infection should be documented and fully assessed to determine whether investigation of donors is required or warranted. The guidance contained within this document covers the action to be taken at the blood centre in such cases.

Because TTI may be asymptomatic, cases may not be recognised or detected until months or years after the transfusion, and only come to light through incidental screening or specific testing on development of late clinical features of the infection in question. In these cases, notification may arise from sources other than the hospital transfusion laboratory, for example, other clinical departments or General Practitioners. In all cases, close liaison will be required with the hospital transfusion laboratory and the reporting clinician.

Staff Involved

One Consultant, accountable to the Lead Consultant in Transfusion Microbiology (LCTM), should be identified as responsible for investigation of possible cases of TTI. He/she would usually be at the blood centre which covers the hospital where the possible TTI has occurred. Advice about the conduct of cases should be sought as necessary from the LCTM and/or NBS Clinical Virologist. Although the Consultant with responsibility at the blood centre may delegate day to day conduct of cases to a designated member of the medical staff, he/she should co-ordinate the investigation and ensure that relevant information is obtained from, and fed back to, all involved departments, and that the LCTM is kept informed. It is the responsibility of the designated Consultant to ensure that a final report of the investigation is prepared and provided to relevant parties.

The staff and departments likely to be involved within the blood centre include clinical staff, Hospital Services staff, Transfusion Microbiology staff, Quality Department, Components/Processing Laboratory and Donor Care Department.

Action

1.0 Reporting of suspected TTI

1.1 Reports of suspected TTI may come from a variety of sources.

Possible sources:
- Hospital Clinician/GP
- Hospital Haematologist in charge of Blood Transfusion Laboratory
- MLSO in Blood Transfusion
- Control of Infection Officer (Hospital or Community Based)
- Testing Laboratories (Hospital Microbiology or PHLS)
- PHLS reporting system

1.2 **The blood centre must record and retain the original notification of the suspected TTI; this should be documented and cross-referenced to the CDSC reporting system.** The initial report may be by telephone or letter. A note of the telephone conversation must be kept. The notification must be relayed to, and acknowledged by, the Consultant in charge (see above).

1.3 The blood centre will require confirmation of the clinical and laboratory details. This may require contact with other individuals/ organisations in addition to the source of the original report. All sources of information must be documented and all details retained in the investigation file.

1.4 A standard notification form should be used to obtain the relevant clinical information (Post Transfusion Report). Laboratory results on the recipient, especially those confirming the infection in question, should wherever possible be provided in the form of copies of original reports. Transcriptions of such results should not be accepted as the sole evidence of infection. If necessary, direct contact should be made with the testing laboratory to obtain these results.

1.5 A list of all blood and blood components transfused must be obtained as soon as possible either from the source of the report or from the hospital blood transfusion laboratory. **This information must be in writing,** preferably in the form of a computer printout. It is important to ensure that the full transfusion history is obtained and that additional transfusion episodes, either at the same hospital or elsewhere, are included before the case is assessed and a decision about investigation reached. A proforma letter is provided.

2.0 Assessment of validity of the possible diagnosis of TTI

2.1 Both clinical and laboratory details must be reviewed by the Consultant in charge to assess the validity of a diagnosis of possible TTI.

2.2 Further information or test results may be required and requested at this stage. It may be necessary to discuss the case with the LCTM, who should, in any case, be informed.

2.3 When a decision has been made to start an investigation a National Incident Number should be obtained by reference to the national list of inquiries for the year. Log numbers should be coded according to the number of inquiry for the year, the infectious agent, using the Pulse code for that marker , and the year. (eg PTX/5/01 is the 5th inquiry for 2001 & relates to HIV). The log number must appear on all subsequent correspondence (internal and external) and on request forms relating to further investigations on donors.

2.4. A list of donations given to the PTI recipient must be made, and confirmation that each designated component was issued to the hospital where the patient was transfused should be sought and recorded in the inquiry file, in order to complete the audit trail.

2.5 In cases where the recipient has been multiply transfused, the clinical and laboratory details must be examined by the Consultant in overall charge to determine whether all, or only some, of the listed donations require investigation. It may be necessary to obtain further advice from the LCTM. If it appears likely that a decision cannot be taken immediately, systems must be in place to ensure that no further donations from any involved donors can be issued for use, until a definitive decision is taken over which donations and donors require further investigation. If it is decided that some donations are not implicated in the possible transfusion transmitted infection, the reasons for this decision must be clearly documented in the investigation file. If the available facts point to a diagnosis other than TTI, a decision may be taken not to investigate the donors. Such a decision should be agreed between the Consultant responsible and the LCTM.

3.0 Withdrawal of components in stock

3.1 A system must be in place to ensure that all components from the same donations and from subsequent donations from all donors involved in the inquiry are checked. Those components still within their shelf life must be notified to the responsible person for further action. Components still in stock at the blood centre should be held, components issued to hospitals should be recalled. If already transfused, the hospital should be advised to take no further action, pending further investigation.

3.2 The record of each donor involved in the inquiry should be flagged so that no further donations can be issued for clinical use until a considered decision is made to reinstate the donor.

4.0 Checking of blood centre results

4.1 A clerical check of the original test results on the involved donations must be done and all donations should be documented as tested and found negative in the relevant original test.

4.2 Archive samples, stored from the donations which went to the patient (index donations), should be retrieved and sent to the National Transfusion Microbiology Reference Laboratory for further testing. The tests to be requested and carried out must be discussed with the Clinical Microbiologist/Virologist and the LCTM should be kept informed. The use of archive samples provides a mechanism for extended testing on the original samples, in particular tests for viral DNA/RNA, and is valuable because a proportion of donors will have lapsed since the donation date and may never respond to requests for further samples.

5.0 Contact with donors

5.1 A follow up serum sample should be obtained from each donor. This may be available without the need to contact the donor if the donor has given blood since the index donation. Otherwise the donor should be contacted and a sample requested.

5.2 Donors who are contacted for samples should be suspended from further call to donate until test results are known and a considered decision has been made that they may continue.

5.3 Communications with donors must be carefully considered. Many donors will respond to a request for samples by telephoning for further information because of anxiety or confusion. Systems must be in place to ensure that such enquiries are directed to identified staff, who are able to answer donors' concerns or pass them on, as appropriate.

5.4 A variety of arrangements may be made to obtain further blood samples from involved donors, either via the GP, through static or mobile collection clinics, or through hospital pathology laboratories. It is always helpful to provide the donors with a letter which can be shown as a means of explanation wherever the samples are obtained. However obtained, such samples from recalled donors should be clearly identified with the log number and a destination at the blood centre. If taken at collection clinics, there should be a system to ensure that they are separated from routine samples, to avoid inappropriate handling of the samples.

6.0 Testing of donor samples

6.1 The appropriate test/s on donor samples should be decided, taking expert advice (see 4.2 above). The two areas to be considered are:

- What tests are required to decide whether any donor could have transmitted infection through transfusion?
- What tests are required to determine whether a donor can be returned to the panel?

7.0 Return of donors to the active panel

7.1 In general, donors should not be reinstated to the donor panel and their donations issued for clinical use until they have been excluded as the source of the suspected TTI. Once excluded, such donors may generally be reinstated without awaiting the results on all other donors. In rare situations, donor reinstatement may not be advisable until the source of infection has been identified. Conversely, an external source may be found before the donors have been tested, in which case the need for tests on the donors should be reviewed.

8.0 Notification of test results to donors

8.1 Donors must always be notified of their results if they have been recalled to provide further samples. Donors who have reattended and donated before being recalled for special samples may not have been informed of their involvement in the investigation. They do not need to be notified of their test results, unless the results affect their eligibility for future donations.

8.2 Notification of test results to donors must be prompt, courteous, and appropriate. Contact with the donor will generally be by letter, and those donors who have been recalled by letter should always receive written confirmation of their test results and their eligibility for future donation. An exception to this general rule may be made in the case of apheresis donors who are well known to clinic staff and who have been spoken to personally by appropriate clinic staff.

9.0 Identification of possible infectious donations

9.1 When investigations result in the identification of a possible or likely infectious donation/donor, that donor should be removed from the donor panel. The donor should be informed, preferably through a personal interview, and counselled appropriately.

9.2 All components from the same donation, believed to have transmitted infection, and from any subsequent donations which could have been capable of transmitting infection must be followed up and their fate should be recorded. If such components have been transfused, the relevant hospital haematologists must be notified of the situation and advised of the possibility of transmission of infection through the component in question. Action with respect to the recipients of such components should take account of the particular circumstances and the risk of transmission. The decision on what action should be taken will usually involve discussion between the relevant haematologist and the clinician caring for the recipient. A record should be kept of the action taken, including any discussions, conversations and advice involving blood centre staff.

9.3 Tracing of previous donations (lookback) should be performed if there is a risk of transmission of infection from previous donations. This will generally be restricted to untested donations and to the last seronegative donation before seroconversion. Lookback for other, potentially infectious, donations or in any situations other than those specified should be undertaken only after discussion with the LCTM.

10.0 Closing TTI enquiries

10.1 Each TTI inquiry should be formally closed by the responsible Consultant, with a conclusion.

10.2 In order for an inquiry to be closed, there should be an identified source of infection, or thorough investigation of all donors without any source of infection being proven.

10.3 In cases where it has been impossible to investigate all donors, this should be noted in the closing report.

10.4 There should be a system for identifying the fact that reinstated donors have been involved in a TTI enquiry, in case of further reports involving a common donor.

10.5 A closing letter should be written, usually to the individual who originally notified the case, the Consultant in Charge of the blood transfusion laboratory which supplied the blood, and to any other relevant clinician (e.g. GP, clinician currently caring for the patient). As the original notification is often made by a junior member of the hospital clinical staff, who may well have moved to another post during the time of the investigation, the closing letter should be addressed to the relevant Consultant.

10.6 At all stages, the anonymity of donors is paramount. No communications with hospitals, clinicians, fractionators etc. should ever contain identifying features of the donors. Any donor notified as causing or likely to have caused a TTI must also be given this assurance.

11.0 Recording and documentation of cases of TTI

11.1 Each reported case of suspected TTI, whether investigated or not, should be allocated a reference number (see 2.3) and a file. The file should contain all documentation related to the investigation and a record of all actions taken. Every file entry must be signed and dated, and all new entries should be reviewed by the responsible Consultant or delegated member of the medical staff. Systems must be in place to ensure that all files are reviewed on a regular basis, even if no new entries have been made, to ensure that lack of progress in an investigation is detected and appropriate action is initiated.

11.2 It is recommended that each file should contain an investigation progress sheet, which summarises the stage of the investigation for each donor and includes the final decision of the fate of the donor, signed and dated by the responsible Consultant. This document should be readily accessible, for example inside the front cover of the file, so that it can be easily referred to during and after the investigation.

11.3 Each file should contain a summary sheet, listing the log number of the case, the donation number of all involved donations, the relevant donor ID number for each donation, and the donation number of any subsequent donations made by that donor. A copy of the summary sheet should be forwarded to the Reference Laboratory. (PTI Progress Sheet)

11.4 All samples referred to the Reference Laboratory must be accompanied by a referral form bearing the log number of the case, the donor ID number, and the donation number (if one has been allocated). The laboratory can then clearly identify follow up samples and reconcile them with other results on the same donor. Referral forms should specify the tests required, in the order of priority.

11.5 An NBA/PHLS-CDSC infection surveillance report for each case should be submitted on the standard forms as soon as the investigation is complete. An interim report may be appropriate for those cases in which completion of the investigation is anticipated to be delayed.