

Guidelines for the Blood Transfusion Services

Chapter 10: Investigation of suspected transfusion-transmitted infection

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Chapter 10:

Investigation of suspected transfusion-transmitted infection

10.1: General considerations

The guidelines in this section apply to reports of possible transfusion-transmitted infection (TTI) arising from blood or blood components supplied by the UK Blood Transfusion Services. Any suspected cases of TTI should be documented and fully assessed to determine whether further investigation of donors and/or donation samples is required or warranted. The guidance contained within this section covers the action to be taken by blood services in such cases.

Suspected cases of bacterial contamination of blood components may be notified by reports from the hospital of a significant transfusion reaction or, following a reaction, the identification of bacteria either within the pack or in a patient's blood culture. Reports will normally be received close to the time of transfusion of the blood component, when other components from the same blood donation may be in stock at either a Blood Centre or a hospital.

Because non-bacterial TTI may be asymptomatic, cases may not be recognised or detected until months or years after the transfusion. Many cases come to light through incidental screening of a patient who has received a blood component transfusion in the past or specific testing on development of late clinical features of the infection in question. Cases may therefore be notified by sources other than the hospital blood transfusion laboratory, but close liaison will be required with the reporting clinician and with the hospital blood transfusion laboratory that supplied the blood component(s) for transfusion.

10.1.1: Documentation

Reports of possible TTI must be recorded and retained. Details of the notification should be confirmed in writing by the reporter. For each report, confirmation of clinical and laboratory details will be required. Ideally, these should take the form of copies of the relevant recipient blood tests and computer printouts of transfusion records. Other forms of reporting of donation numbers (by letter, typed lists etc.) should be avoided in view of the risk of transcription errors.

10.2: Assessment of validity of the possible diagnosis of TTI

Clinical and laboratory details of the case should be reviewed to assess the validity of a diagnosis of possible TTI. Further information or test results may be required and requested at this stage.

Investigation of reported cases of TTI can be extremely time-consuming and impact on several different areas. In general, no investigation of archived samples or contact with involved donors should take place until all necessary information has been made available. However, in cases where complete details are not immediately available and a full assessment cannot be made, there should be consideration of the need to prevent issue of any further components from involved blood donors. Similarly, there should be consideration of the need to recall any in-date components from the same/recent donations to prevent their transfusion pending a decision about whether full investigation is necessary.

10.3: Non-bacterial TTI: identification of possible infectious donations

When a decision has been made to conduct an investigation into a reported non-bacterial TTI case, it may be possible to obtain sufficient information by reviewing results of testing of subsequent donations from the involved donor(s). If this is not the case, consideration should be given as to which donors require further investigation, and whether this can be satisfactorily carried out with samples already available from the index or any subsequent donation. This decision is dependent on the premise that subsequent samples may conclusively demonstrate the development of infectious markers (e.g. antibodies) in one of the implicated donors. It is expected that Blood Establishments will retain samples from each donation for a minimum period of 3 years in a suitable frozen archive. The retrieval of samples from this archive must be fully documented and be restricted mainly to such investigations.

If further investigation is required, and suitable blood samples are not available from the donor, then the decision may be made to contact the donor(s) and request further samples.

Decisions for each case and each donor will be on an individual basis depending upon the circumstances, timing, assessed likelihood of TTI and resources required. In cases of doubt, there should be a mechanism to ensure that there is a system for review and agreement on the way forward, taking expert advice as necessary.

In instances where there is doubt whether a donor has been the source of a TTI, specialised molecular genotyping of both implicated donor and infected recipient may be necessary to prove conclusively whether TTI did indeed occur.

10.4: Investigation of possible bacterial TTI

Refer to Chapter 9, section 9.8 for details of laboratory investigations.

10.5: Closing TTI investigations

Each investigation must be formally closed, with a conclusion and written notification to the reporter and any other interested party. In those cases where the recipient has been discharged from hospital, agreement should be reached as to who will notify the recipient: normally the GP or another clinician. It must be remembered that confidentiality of donor details is paramount and no information should be released which could lead, either directly or indirectly, to identification of any donor.

In cases of proven transmission, the recipient (or family, in the case of fatal cases) should be provided with an explanation of the cause of the transmission, and should be given the opportunity of a meeting with relevant staff, in keeping with Health Service guidelines following a serious adverse event. Details of legal implications and the availability of any ex-gratia payment schemes should be provided, as appropriate.

Each case investigated must be reported to the appropriate surveillance system: NHSBT/UKHSA transfusion-transmitted infection surveillance scheme for England and Wales, SNBTS National Microbiology Reference Unit for Scotland, Northern Irish Blood Transfusion Centre for Northern Ireland. These reports are collated and published in the annual report of the Serious Hazards of Transfusion (SHOT) scheme.

10.6: Look-back investigations

Look-back investigations are initiated on recognition that there may have been a risk of transmitting infection from a donor to a recipient. Such a situation may arise in the following circumstances:

- donors identified as infected through the introduction of a new screening test applied to all donations
- donors identified to be infected through seroconversion during their blood donation career
- donors identified to be infected and reported to the Blood Service from an outside source
- donors identified to be responsible for transmission of infection to a recipient.

10.6.1: General principles for look-back investigations

National look-back investigations, following introduction of a new screening test, should be managed through a generic system which incorporates the following steps:

- identification of potentially infectious donations
- identification of all blood components prepared from those donations
- documentation of the fate of the blood components
- notification of hospital transfusion laboratories in receipt of involved blood components
- identification of the fate of the component at the hospital, including details of any identified recipient
- for recipients not known to be dead, a procedure for notification, generally following notification of the GP/hospital clinician
- a protocol for management of recipient notification and testing (if required)
- notification of recipient test results to recipient and other interested parties.

Look-back investigations following identification of a donor who has seroconverted and/or been responsible for transmission of infection and/or is identified through post-donation information should be carried out using the same principles.

Wherever possible, retrospective testing of stored samples should be carried out in order to identify those donations which must be included in the look-back. If samples can be tested, look-back should be performed to include the last seronegative donation, unless there is evidence about the timing of infection which would make such action unnecessary, e.g. a documented negative test result after the last negative blood donation, a clear history of risk exposure post-dating the last seronegative donation etc.

If retained samples are not available for testing, then case-by-case decisions on the number of donations to be included in the look-back will be influenced by the dates of donations and the availability of the particular hospital transfusion records.

10.6.2: Documentation and reporting

All cases of look-back should be documented in the same fashion as investigation of TTI. There should be a full audit trail of decisions made and actions taken.

Where look-back results in the identification of infected recipients, a report should be made to the surveillance system as appropriate, and cases included in the annual SHOT report.