HEALTH HOLDING

HAFER ALBATIN HEALTH CLUSTER
MATERNITY AND CHILDREN HOSPITAL

Department:	Laboratory and Blood Bank		
Document:	Multidisciplinary Policy and Procedure		
Title:	Investigation of Suspected Cases of Post-Transfusion Infection and Look back		
Applies To:	All Staff Involved in the Administration of Blood or Blood Components in all Clinical Departments		
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1. PURPOSE:

1.1 To ensure that suspected cases of post transfusion infection are properly investigated and documented.

2. DEFINITONS:

2.1 Look Back is the process of identifying, notifying, investigating and documenting cases of recipients of blood or blood components from donors who are subsequently found to have infection with blood transmitted diseases.

2.2 Transfusion Transmitted Diseases Surveillance (TTDS) is the process of investigating and documenting cases of post transfusion infection with HIV, HTLV, and HCV. HBV or syphilis.

3. POLICY:

3.1 Several steps are taken by the blood bank to ensure safety of the transfused blood units.

3.2 Prompt investigation of suspected cases of post-transfusion infection must be done. This process should ensure the following:

- 3.2.1 Prompt identification of the implicated donors.
- 3.2.2 Prompt notification of the collecting facility (if applicable).
- 3.2.3 Prompt quarantine of available components from the implicated donors.
- 3.2.4 Investigating the implicated donors.
- 3.2.5 Assigning appropriate deferrals to the implicated donors.
- 3.2.6 Reporting the investigation results (internally and externally), as applicable.

3.3 The appropriate measures for the investigation of donors subsequently found to have transfusion transmissible disease (Look Back) must be taken. This process should ensure the following:

- 3.3.1 Prompt quarantine of available components from the same donor.
- 3.3.2 Prompt identification of the recipients.
- 3.3.3 Prompt notification of the facility where the transfusion was conducted (if applicable).
- 3.3.4 Prompt notification of the patient's physician and/or infection control.
- 3.3.5 Investigation and follow-up of recipients.
- 3.3.6 Reporting the investigation results (internally and externally), as applicable.

3.4 Reporting the event and the investigation results to the medical director must occur and he must take the applicable measures.

4. PROCEDURE:

4.1 **Bacterial transmission by transfusion:** Refer to **"limiting and detecting bacterial contamination in platelet concentrate"** chapter (LB-IPP-233).

- 4.1.1 Bacterial transmission by transfusion remains a significant problem in transfusion medicine .
- 4.1.2 Platelet components present the greatest risk due to their storage at 20 - 24°C, which enhances the proliferation of most bacterial species .

4.1.3 The blood bank has a process to limit and detect bacterial contamination in platelet components.

4.1.4 Signs and Symptoms of Transfusion-Associated Sepsis:

4.1.4.1 The transfusion of a contaminated cellular blood product unit may be associated with variable signs and symptoms. Not all contaminated blood products cause symptoms in the recipient; in fact, it appears that many do not .

4.1.4.2 The initial signs and symptoms, when they occur, include fever and chills, which usually begin shortly after (within 2 hours) the start of the transfusion .

4.1.4.3 It is important to note that a majority of septic transfusion reactions associated with contaminated platelets usually occur with units that have been stored for 3 days or more.

4.1.4.4 The clinical severity of a transfusion-associated septic reaction can vary considerably, depending on many factors.

4.1.5 When platelet component recipient has signs or symptoms consistent with post-transfusion bacteremia:

4.1.5.1 Because no test is 100% sensitive, false-negative results of platelet screening for bacterial contamination will occur.

4.1.5.2 Transfusing physicians should continue to evaluate all transfused patients with onset of signs or symptoms consistent with bacteraemia or sepsis for a transfusion reaction.

4.1.5.3 The minimal evaluation of a patient with suspected sepsis following platelet transfusion should include:

4.1.5.3.1 Culture of any residual component, it available, and

4.1.5.3.2 Blood cultures of the patient.

4.1.5.3.3 Any isolates should be retained until the case investigation is completed.

4.1.5.4 Results of the patient workup should be communicated to the blood bank physician, these data will help determine the significance of the initially negative test result.

4.2 Transfusion transmitted diseases (TTD):

4.2.1 Prevention of transfusion transmitted diseases (TTD):

4.2.1.1 For ensuring safety of the transfused blood units, the following measures are done by the blood bank:

4.2.1.1.1 Blood donor screening.

4.2.1.1.2 Screening of the donated blood.

4.2.1.1.3 Donor deferral list.

4.2.1.1.4 Quarantine.

4.2.1.1.5 Inactivation of Pathogens (e.g. by using Solvent-detergent method),not available in MCH, and leucoreduction.

4.2.1.1.6 Lookback.

4.2.1.1.7 Confidential unit exclusion (CUE): Refer to "Confidential Self Unit and 3rd party Exclusion And Handling Post Donation Information" chapter (LB-IPP-229).

4.2.2 Management of suspected TTD:

4.2.2.1 The treating doctor must promptly investigate each event:

4.2.2.1.1 Ask the nurse to withdraw the appropriate samples and send them to the serology and NAT (PCR) units for testing (Non-available tests are sent to central labs).

4.2.2.1.2 Review the patient's file for any previous TTD result and history of blood (component) transfusion.

4.2.2.1.3 Compare the current result with the previous result (if available).

4.2.2.1.4 If the seroconversion is confirmed or not ruled out, inform the infection control department and the medical director by an official E-Mail to do RCA and take the appropriate measures.

4.2.2.1.5 If the patient is previously transfused and seroconversion is confirmed or not ruled out, the identity of the implicated donor units must be reported promptly to the blood bank by an official E-Mail.

4.2.2.2 The supervisor of blood bank technicians or his deputy:

4.2.2.2.1 Investigate reports of transfusion-transmitted diseases.

4.2.2.2.2 Recall other potentially infectious blood components (if available) from the same donation to be retested for the same TTD and discarded or quarantined.

4.2.2.2.3 Record in the deferred donor list so that blood donors who are thought to be infectious can be excluded from the list of eligible donor (if the component from an outside facility, officially notify the facility.

4.2.2.2.4 Call the donor (s) and get other samples and retest them for TTD; contact the donor either directly or through the 'preventive medicine department' in Hafr Al Batin health affairs (through the hospital director).

4.2.2.2.5 If the result(s) is negative:

4.2.2.2.5.1 Inform infection control department and the treating physician to look for another source of infection (RCA= Root Cause Analysis).

4.2.2.2.5.2 Follow up the donor by testing another samples later on.

4.2.2.2.6 If the result(s) is positive:

4.2.2.2.6.1 Inform the infection control department.

4.2.2.2.6.2 Report the donor information to the 'preventive medicine department' in Hafr Al Batin health affairs (through the hospital director).

4.2.2.2.6.3 Add the donor ID(s) to the deferred donor list.

4.2.2.2.6.4 Send one sample from the donor and another one from the recipient for genotyping (as applicable).

4.2.2.2.7 If there is matched virus (infectious agent) genotype between the donor and the recipient, TTD is confirmed.

4.2.2.2.8 If there is no match of virus (infectious agent) genotype between the donor and the recipient, inform infection control department to do RCA and follow the patient.

4.2.2.2.9 Search for other recipients from the infected blood donor regardless of the genotyping results.

4.2.2.2.10 Report the recipient's information (name, ID, department) to infection control department and the treating doctor to take the preventive and treating measures.

4.2.2.3 The treating physician:

4.2.2.3.1 Call the recipient through patients' affairs.

4.2.2.3.2 In OPD, samples are withdrawn from the recipient and are sent for serology and NAT testing.

4.2.2.3.3 If the result is negative, repeat the tests after 6 months. If the result is negative after 6 months, no need for other appointment.

4.2.2.3.4 If the result is positive, inform infection control department to take the appropriate measures and follow the recipients.

4.2.2.4 The event and the investigation results must be reported to the medical director who must take the applicable measures.

4.3 **Lookback**:

4.3.1 Lookback programs are designed to identify and notify recipients who may have received blood components from a previously negative, screened donor who has now become positive for an infectious agent. Lookback programs represent an attempt to reduce further blood-borne transmission of the infectious agent and to provide a chance for the infected recipients to seek medical attention.

4.3.2 Once a blood bank identifies a positive donor, the supervisor of blood bank technicians or his deputy must do the following:

4.3.2.1 Send samples for confirmatory test after getting the positive screen to confirm the diagnosis (Following the regulations of Hafar Al Batin Central Laboratory And Blood Bank).

4.3.2.2 Quarantine/discard the blood products, if any, from the newly diagnosed positive donor.

4.3.2.3 Search in the donor register (or computer, as applicable) for components of previous donation. If the component (s) is available, retest for the same TTD and discard (as applicable).

4.3.2.4 Review the records and identify the consignees (departments or other hospitals) who received blood products from that particular donor. Promptly notify the receiving hospital.

4.3.2.5 Identify recipients of blood or components promptly.

4.3.2.6 Promptly, inform the current attending physician or the physician who initially ordered the blood product and infection control department by an official E-Mail. The informed physician and infection control department have the responsibility to investigate and follow up the recipients and notify them.

4.3.2.7 The event and the investigation results must be reported to the medical director who must take the applicable measures.

5. MATERIALS AND EQUIPMENT:

5.1 Hematos system of blood bank to check the donation history and laboratory results of donor and to check the patient who received the blood products

6. RESPONSIBILITIES:

6.1 It is the responsibility of blood bank supervisor to complete information of look back request under supervision of blood bank physician.

6.2 The information should be approved by the blood bank physician and laboratory and blood bank director before returning the request to facility sending the request letter.

7. APPENDICES:

7.1 N/A

8. REFERENCES:

8.1 The Unified Practical Procedure Manual For Blood Banks In The Arab Countries, 1434-2013.

8.2 The Standard Policy For Blood Banks In The Kingdom Of Saudi Arabia, 1st edition, 1435-2014

8.3 National Standards For Clinical laboratories and Blood Banks, 1st edition, 2015.

8.4 AABB Technical manual, 18th edition, 2014.

8.5 AABB Standards for Blood Banks and Transfusion Services, 30th edition, 2016.

8.6 Mollison's Blood Transfusion in Clinical Medicine; 12th edition, 2014.

8.7 Modern Blood Banking & Transfusion Practices, 6th edition, 2012.

8.8 Transfusion medicine checklist, College of American Pathologists, 2014.

8.9 Good Manufacturing Practice for Blood Establishments, Version 2.0, May 2019, Saudi FDA

9. APPROVALS:

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