Institution Name: Directorate General of Specialized Medical Care, MOH

Document Title: Policy and Procedure of National Look Back and Trace Back Procedure

Approval Process

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Acronyms:

LBTB	look back/trace back
HBV	Hepatitis B virus
HCV	Hepatitis C virus
HIV	Human Immune Deficiency virus
HTLV	Human T lymphotrophic virus
TTIs	Transfusion Transmitted Infections
CBB	Central Blood Bank
SQUH	Sultan Qaboos University Hospital
AFH	Armed Force Hospital
NAT	Nucleic Acid test

Policy and Procedure of National Look Back and Trace Back Procedure

1. Introduction

Blood and blood components received from the blood bank undergo stringent laboratory testing for infectious markers before they can be issued for patients' transfusion. However when positive serology or NAT results are obtained on a donor or when a transfusion recipient is suspected to have developed an infection through a blood transfusion, a LB or TB process is initiated.

During a LB/TB investigations, identifying individuals with positive tests for TTI is important so that the donor or recipient can receive appropriate testing, counselling and follow up. Donors may be indefinitely deferred following a LB/TB investigation, depending on the nature of the infectious agent.

Any information that may affect the safety of a transfusion recipient must be reported. Such information can be received from many sources, including the blood bank itself (donor testing), donors, hospitals, physicians and health authorities. All reports are fully investigated by the blood bank, depending on the nature of the information.

2. Scope

2.1 This procedure applies to all Blood Bank and transfusion services in MOH.

3. Purpose

3.1 To detail the procedures that needs to be followed in the case of a reported LB/TB case.

4. Definitions

4.1 **Look back**: is the process of identifying and contacting recipients of blood components from a donor who, on a subsequent donation or testing, is confirmed to have tested positive for the presence of a transmissible infectious agent (e.g. HIV-1, HIV-2, HBV, HCV, HTLV-1, HTLV-2).

4.2 **Trace back:** is the process of investigating a report of a potentially transfusion-transmitted infection (e.g. HIV 1 & 2, HBV, HCV, HTLV 1 & 2) in a blood recipient in order to identify any associated, potentially implicated or implicated donors.

4.3 **Clearing donation:** a donation which has a negative test result for the marker in question, 6 months or more AFTER the claimant's transfusion date

4.4 **Claimant:** a recipient who claims acquisition of a TTI through blood transfusion

5. Policy

5.1 TTI markers which are involved in the LB/TB process: HIV 1&2 serology, HBC antibody, HBsAg, Anti-HBV core, HBV/HCV/HIV NAT, and HTLV I/II serology

5.2 LB procedure applies to all donations that result in permanent deferral of an infected blood donor

5.3 When a LB is performed, and if previous donations were identified, a recall procedure of components of previous donations should be initiated. The supplier of blood components shall inform the receiving hospital transfusion service (if different) within 30 days of positive donor test results. Once the hospital transfusion service is notified, and if the components were transfused, the recipient physician must be notified and recipient notification for testing shall be made within 30 days. All notifications should be documented. Documents outlining the recipient's notification in the recipient's medical records shall be kept confidential.

5.4 TB is initiated upon detection of a positive infectious marker in a recipient of blood and blood components. If the TB procedure identified confirmed positive donors, a look back on previous donation(s) need to be initiated

5.5 All identified positive donors in a LB/TB procedure must be permanently deferred and referred to appropriate clinics as per local procedures

5.6 All notifications and investigations must be documented in writing including the physician's request, communications between the blood bank and transfusion services, and communication with the microbiology/virology department

5.7 A finalized LB/TB report need to be generated to close the case. A LB/TB report shall include information on all donated units, all donations (excluded, implicated and associated), implicated recipients (if any), all donor serology and NAT investigations and final conclusions.

6. Procedure

6.1 Look back procedure:

6.1.1 A LB is triggered at any of the following:

6.1.1.1 Positive serology or NAT results for HIV-1, HIV-2, HCV or HBV detected on a blood donor

6.1.1.2 Confirmatory positive HIV-1, HIV-2, HCV, HBsAg or HTLV test result following a repeat reactive serology test on the donor

6.1.2 The purpose of the LB investigation is to

6.1.2.1 Identify previous donations (and related blood components) from the donor to ensure that no past infected donations were inadvertently transfused

6.1.2.2 Retrieve/recall available in-date components from the donor

6.1.2.3 Identify recipients who received blood components from the donor from previous donations

6.1.3 When a donor is identified to have a positive serology or NAT test at time of donation, the blood bank will identify all past donation records from the same donor.

6.1.3.1 If no previous donations, the LB file is closed the donor will have a permanent deferral and is referred to the appropriate clinic

6.1.3.2 If past donations records exist, the blood bank need to review all previous donations from the donor.

6.1.4 The blood bank need to identify all donation numbers and date of past donations

6.1.4.1 If LB is related to HIV, HCV, HBV positive markers: up to 6 months prior to the last serology & NAT-negative donation

6.1.4.2 if LB is related to HTLV positive marker: up to 1 year prior to the last serology negative donation

6.1.5 List of donation numbers of previous donations need to be submitted to the donor virology testing laboratory to recall any retained donor samples from these donations

6.1.6 The donor testing laboratories need to repeat serology and NAT tests on the retained donor samples

6.1.6.1 If the results of the repeat serology &/or NAT are negative, the donation is considered clear and is **excluded**

6.1.6.2 If the results of the repeat serology &/or NAT are positive, the donation is **implicated**.

6.1.6.3 If the retained donor samples from the donations under invitation are not available, the donations are considered **potentially implicated.**

6.1.7 The blood bank need to obtain a list of components made from each implicated or potentially implicated donation, and identify the

recipients of all blood components (in collaboration with issuing transfusion services if different)

6.1.8 The blood bank pathologist (or designate) need to inform the treating physicians' of the implicated recipients with the donor results to call the recipient(s) for testing

6.1.9 If the blood component was issued to another hospital, the issuing blood bank need to notify the hospital's transfusion services with the test results in writing to retrieve/recall components if possible and test recipient.

6.1.10 The blood bank must generate a final LB report of the case that include information on all units donated, all donor serology and NAT investigations, implicated recipients (if any), and the final conclusion that is made.

6.1.11 The report need to be approved by the pathologist covering the blood bank or head of department (as applicable).

6.2 **Trace back procedure**

6.2.1 The purpose of the TB investigation is to:

6.2.1.1 Investigate any associated/implicated donation to determine whether any donor who contributed to the transfusion is infected with or positive for the serologic markers of the implicated infectious agent

6.2.1.2 Retrieve available in-date components from these donors

6.2.1.3 Notify & test other recipients of other components collected from donors confirmed with the case (if any present)

6.2.2 A TB procedure can be initiated when the blood bank is notified about a sero-converting transfusion recipient by the caring clinical team or by public health authorities.

6.2.3 Cases reported for the TB need to be examined for transfusion history before initiating a TB process.

6.2.4 Details on the time of transfusion, date of last negative recipient's TTI test results and positive patient's TTI test result MUST be provided to the investigating blood bank at time of requesting an initiation of a TB process.

6.2.5 The blood bank need to identify and track back all units issued for the recipient during the hospital admission

6.2.5.1 If no units issued previously, The TB request is closed. The status is to be documented in the final report

6.2.6 If records of past transfused units exist, the blood bank need to determine the donors who donated the transfused units up to 6 months PRIOR to the negative TTI test results on the recipient.

6.2.7 The blood bank need to identify all donation numbers and date of donations

6.2.8 The blood bank need to investigate the serological results of all the donors by assessing the donor's records and determine if there is a **'clearing donation'** on file on each of the donors **AFTER** the potentially implicated date of transmission

6.2.8.1 If a "clearing donation" exist, donor is considered **associated** with the case, but **not implicated**

6.2.8.2 If a "clearing donation" doesn't exist, follow the next step, the blood bank need to investigate all non-cleared donors who donated components transfused to the claimant up to:

6.2.8.2.1 HIV, HCV, HBV (serology and NAT): 6 months prior to the last negative donation

6.2.8.2.2 HTLV: 1 year prior to the last negative donation

6.2.9 Identify all past donation numbers and date of donations of non-cleared donors and submit to the donor testing laboratory to recall retained donor samples from these donations and test them by serology and NAT.

6.2.9.1 If the results of the repeat serology &/or NAT are negative, the donation is considered **excluded**

6.2.9.2 If the results of the repeat serology &/or NAT are positive, the donation is **implicated**.

6.2.9.3 If residual samples from the donation are not available in the testing laboratories, Donation is considered **potentially implicated.** Donors a need to be contacted to come to the blood bank for testing

6.2.10 The blood bank need to call those donors without retained samples and those associated but not implicated for repeat serology and NAT testing

6.2.11 The blood bank need to assess the repeat serology and/or NAT results on each donor

6.2.11.1 If these are negative, the donor is considered **associated with the case but not implicated**

6.2.11.2 If these are positive, the donor is considered **implicated** with the case, will need a permanent deferral and referral to the appropriate clinic

6.2.11.3 If the donor cannot be brought back, donor is **potentially implicated**, the TB case is closed as **Inconclusive**.

6.2.12 The blood bank need to generate a final TB report including information on transfusion recipient details and test results, all units donated, all donors (excluded, associated, potentially implicated, implicated), all donor serology and NAT investigations, implicated recipients (if any), and final conclusion.

6.2.13 The report need to be approved by the blood bank pathologist or head of department (as applicable).

7. Responsibilities

7.1 Blood banks and transfusion services is responsible for:

7.1.1 Initiate and investigate LB cases as appropriate

7.1.2 Investigate TB cases as per the procedure

7.1.3 Trace all implicated donors of reported LB/TB investigations

7.1.4 Trace all previous donations, donation numbers and test results of donors under investigations.

7.1.5 Preform all repeat tests as part of the investigations

7.1.6 Generate a final LB/TB report

7.2 Physician is responsible for:

7.2.1 Report seropositive recipient of blood components to the blood bank to initiate a TB procedure

7.2.2 Contact recipients of components from a donor under investigation in a LB/TB procedure

7.3 Hospital transfusion committee is responsible for:

7.3.1 Monitor reported cases for LB/TB investigations

8 Document History and Version Control

Document History and Version Control			
Version	**Description of Amendment**	**Author**	**Review Date**
01	Initial Release	Dr Arwa Al Riyami	November 2024
02			
03			
04			
05			

Written by	**Reviewed by**	**Approved by**
Dr Arwa Al Riyami	National Blood Transfusion committee	Dr.Kadhim Jaffar Sulaiman

9 Related Documents:

There is no related document for this policy and procedure

10 References:

Title of book/ journal/ articles/ Website	Author	Year of publication	Page
Clinical Guide to Transfusion	Canadian Blood Services	2019	4-5
Guidance Document: Blood Regulations	Canadian Blood Services	2014	92-93 103-104 160-162

11 Appendix 1: Flowchart of look back

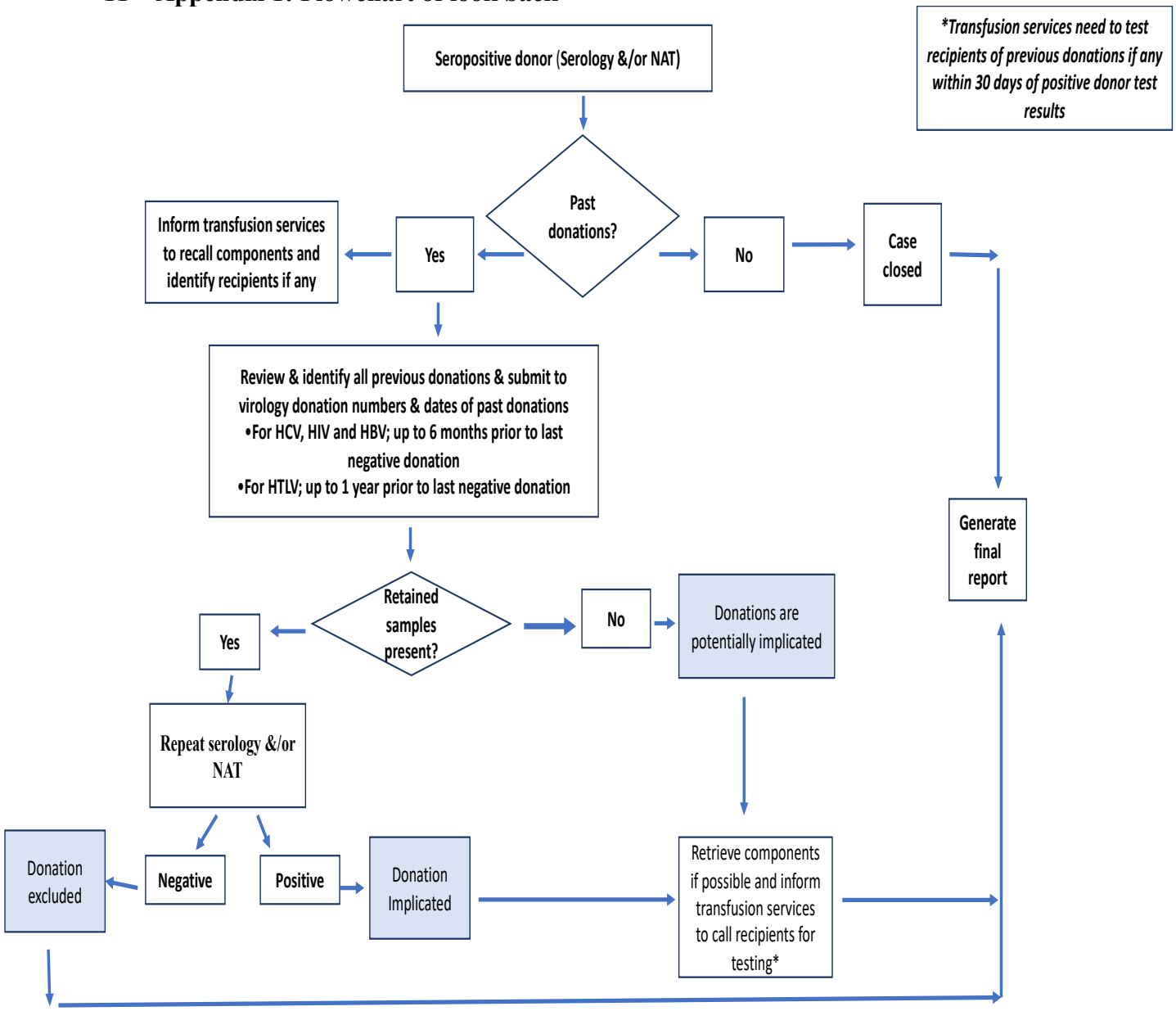

Figure 2: Flowchart of Trace back