

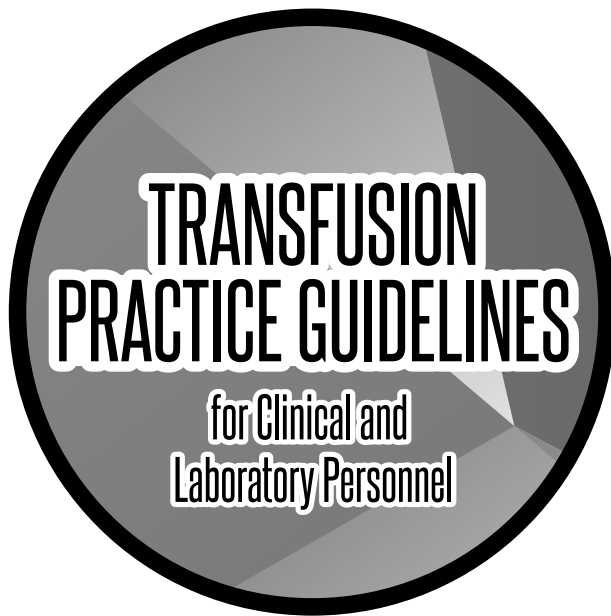
TRANSFUSION PRACTICE GUIDELINES

for Clinical and
Laboratory Personnel



National Blood Centre
Ministry of Health Malaysia

4th Edition 2016



NATIONAL BLOOD CENTRE

Ministry of Health Malaysia

4TH EDITION 2016

*National Blood Centre
Ministry of Health, Malaysia*

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*Transfusion Practice Guidelines
for Clinical and Laboratory Personnel*

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Foreword by the Director General of Health, Malaysia

The Blood Transfusion Service (BTS) has contributed significantly to the progress of health care in Malaysia by providing adequate, safe and high quality blood and blood products. The demand for a reliable transfusion service is ever increasing. Despite technological and medical advances blood transfusion risks still exist and blood safety remains a major concern to medical personnel, patients and communities. One of the efforts to address this concern was the publication of *Transfusion Practice Guidelines for Clinical and Laboratory Personnel*. It has been utilised as a practice guideline both in the government and private hospitals in Malaysia.

With rapid development in transfusion medicine, there is a need to provide an updated guidance document to facilitate standardisation and consistency of current technical and clinical transfusion practices throughout the country. Thus I am pleased to see that the 4th edition has materialised with improvements in presentation as well as technical and clinical contents.

This edition has been extensively revised by a group of technical and clinical experts. All personnel involved in BTS must be well versed with its content and adhere to the requirements in this guideline. I urge all hospital directors and head of BTS to ensure that appropriate and adequate training is provided to their personnel. Elimination of errors and achieving safer and more effective blood transfusion shall be a priority for all healthcare facilities.

For safe and appropriate transfusion practices, each hospital must have a functionally active Hospital Transfusion Committee (HTC). One of its many roles shall be the surveillance of adverse transfusion events through an effective haemovigilance programme within the hospital, where these events are collected, analysed and its findings used in formulating corrective and preventive measures.

I wish to congratulate members of the working committee for their perseverance in spending many laborious hours revising this guideline. I also wish to thank all external reviewers and editors for contributing to the completion of this guideline.

Datuk Dr. Noor Hisham Abdullah

Director General

Ministry of Health Malaysia

Preface

Transfusion Medicine field is a rapidly evolving medical specialty. This *4th edition of Transfusion Practice Guidelines for Clinical and Laboratory Personnel* is produced after thorough revision and update of all the chapters in the previous edition. The guideline is aimed to ensure safe practice in every step of the blood transfusion chain.

As far as possible, the recommendations made in this edition are evidence based, information are obtained from published journals and established international standards and guidelines. Where local practical adaptations are necessary, findings from local scientific studies and expert opinion from consultants are considered.

Providing safe and adequate blood is a vital component of healthcare delivery system. In addition to that, all processes involved in the blood transfusion chain must be of quality which will result in the best patient care. Understanding and implementing the requirements of this guideline will result in adherence to quality management system that includes *Good Manufacturing and Good Transfusion Practices* which are the basis of safe and quality BTS.

Special acknowledgement is conveyed to all contributors for their efforts in revising this edition, to the external reviewers for their valuable comments and suggestions and to the co-editors for their excellent cooperation and input.

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Code of Ethics for Blood Donation and Transfusion

I. THE DONOR

1. Blood donation shall, in all circumstances, be voluntary; no pressure of any kind shall be brought upon the donor.
2. The donor shall be advised of the risks connected with the procedure; the health and safety of the donor shall be a constant concern.
3. Financial profit shall never be a motive either for the donor or for those responsible for collecting the donation. Voluntary non-remunerated donor should always be encouraged.
4. Anonymity between donor and recipient shall be respected except in special cases.
5. Blood donation shall not entail discrimination of any kind, either of race, nationality or religion.
6. Blood shall be collected under the responsibility of a registered medical practitioner.
7. The frequency of donations and total volume of blood collected according to the sex and weight of the individual, as well as the minimum and maximum age limits for blood donation, shall be as specified by the Director General.
8. Suitable testing of each donor and blood donation shall be performed in an attempt to detect any abnormalities –
 - a) that would make the donation dangerous for the donor; and
 - b) that would likely be harmful to the recipient.
9. Donation by plasmapheresis should be the subject of special regulations that would specify –
 - a) the nature of additional tests to be carried out on the donor;
 - b) the maximum volume of plasma to be taken during one session;
 - c) the maximum time interval between two consecutive sessions; and
 - d) the maximum volume of plasma to be taken in one year.
10. Donations of leukocytes or platelets by cytapheeresis should be the subject of special regulations that would specify –
 - a) the information to be given to the donor about any drugs injected and about the risks connected with the procedure;
 - b) the nature of any additional tests to be carried out on the donor; and
 - c) the number of sessions within a given time frame.

11. Deliberate immunization of donors by any foreign antigen with the aim of obtaining products with specific diagnostic or therapeutic activity should be the subject of special regulations that would specify –
 - a) the information to be given to the donor about the substance injected and the risks involved; and
 - b) the nature of any additional tests which have to be carried out on the donor.
12. Pursuant to paragraphs 9, 10 and 11 of this Code, after being told about the nature of the operation and the risks involved, a statement of consent must be signed by the donor.
13. For donor immunized against red cell antigens, a special card should indicate the antibodies and specific details as to the appropriate blood to be used in case donors need to be transfused.

II. THE RECIPIENT

1. The object of transfusion is to ensure for the recipient the most efficient therapy compatible with maximum safety.
2. Before any transfusion of blood or blood products, a written request signed by a registered medical practitioner or issued under his responsibility shall be made, which specifies the identity of the recipient and the nature and quantity of the substances to be administered.
3. Except for the emergency use of type “O” blood or red blood cells, every red blood cell transfusion necessitates preliminary blood grouping tests on the recipient and compatibility tests between the donor and the recipient.
4. Before the administration, one shall verify the blood and blood products are correctly identified and that the expiry date has not been passed. The identity of the recipient shall be verified.
5. The actual transfusion shall be given under the responsibility of a registered medical practitioner.
6. In the case of a reaction during or after the injection of blood or blood products, appropriate investigations may be required to ascertain the origin of the reaction and to prevent its recurrence. A reaction may require the interruption of the transfusion.
7. Blood and blood products shall not be given unless there is genuine therapeutic need. There shall be no financial motivation on the part of either the prescriber or the establishment where the patient is treated.
8. Whatever their financial resources, all patients must be able to benefit from the administration of blood or blood products, subject only to their availability.
9. As far as possible the patient should receive only the particular component (cells, plasma or plasma derivatives) that is needed. To transfuse whole blood into a patient who requires

only part of it may deprive other patients of necessary components, and may carry some additional risks to the recipients.

10. Owing to the human origin of blood and to the limited quantities available, it is important to safeguard the interest of both recipient and donor by avoiding abuse or waste.
11. The optimal use of blood and blood products requires regular contact between the physician who prescribe and those who work in blood transfusion centres.

RELATED PROCEDURES/DOCUMENTS

Eleventh Schedule; Code of ethic for blood donation and transfusion, Law of Malaysia, Jil.50, No.7, version 2006, (Regulation 299); Page;1312 – 1314.

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1.0 Introduction

This 4th edition of Transfusion Practice Guidelines For Clinical and Laboratory Personnel has been revised extensively to include the development that has occurred in transfusion medicine and the body of knowledge that has accumulated in the last few years. Relevant requirements of established standards, guidelines and principles such as MS ISO 15189, current good manufacturing practice (GMP) and good clinical practice (GCP) in the BTS have been incorporated.

This document shall be used as a guide for all healthcare personnel in Malaysia. It provides the minimum requirements expected to ensure that the products and services are safe, reliable and of good quality. Both clinicians and laboratory personnel in transfusion practice, are therefore expected to comply with the requirements. Where practices differ, they shall be based on sound scientific and medical evidence.

The role of healthcare personnel is crucial in meeting the needs of patients. Adherence to standard operating procedures, regular training and constant supervision are important. Healthcare personnel involved in the transfusion chain need to comply with National Blood Service Policies and relevant codes of ethics that has been adopted by MOH.

It is the responsibility of BTS to provide “Adequate and Safe” blood at any time. In order to achieve that, every activity in the BTS from blood procurement from voluntary donors, processing, screening till supply of blood to patients will emphasize on quality, safety, accountability, responsibility and traceability of every personnel involved. This can only be achieved by implementing effective Quality Management System (QMS) for the whole transfusion chain.

Each hospital shall establish a Hospital Transfusion Committee (HTC) which serves as an effective forum for all stakeholders. The HTC shall monitor transfusion practices, identify challenges and implement corrective and preventive measures. Its activities shall also include Patient Blood Management and Haemovigilance Programme.

Complementary to this guideline, “Handbook of rational use of blood and blood products” shall be used as reference. These two documents will provide a more comprehensive guidance for blood transfusion in Malaysia.

Right blood are given to the right patient, in the right place at the right time

2.0 Procurement of Blood

Blood shall be procured only from voluntary non-remunerated blood donors. The blood collection centre shall ensure that there is a blood procurement team to manage the blood collection activities.

2.1 Blood Procurement Team

2.1.1 Composition

The blood procurement team should comprise of the following personnel:

- Medical Officer(s).
- Health Education Officer or Public Relation Officer(s) (*Penolong Pegawai Penerangan*).
- Nurse(s).
- Medical Laboratory Technologist(s).
- Clerical Staff.
- Health Attendant(s) (*Pembantu Perawatan Kesihatan*).
- Driver(s).

2.1.2 Responsibilities

The blood procurement team is responsible for:

- Promotion of blood donation.
- Recruitment and retentions of healthy, voluntary non-remunerated donors.
- Assessment of suitable and safe donors.
- Collection of quality blood from donors.
- Providing effective counselling services to donors screened reactive to markers of transfusion transmitted infections (TTIs).
- Maintenance of records, data and information pertaining to its activities for traceability, reference and quality improvement.

2.2 Promotion and Recruitment

2.2.1 Promotion

- Creating public awareness on blood donation.

- Giving talks to targeted group such as students and communities.
- Organizing and promote blood donation campaign for new organiser.
- Promoting health education through exhibitions, social media, mass media and others and disseminating health education materials such as pamphlets and posters.
- Managing, monitoring and coordinating all complaints/feedback from customers/the public received via suggestion boxes, emails, integrated system for monitoring of complains from the public to the government agencies (ISPAAA) and others.
- Handling visits at blood collection centre.
- Managing and coordinating World Blood Donor Day.

2.2.2 Recruitment

- Recruitment of donor organisers.
- Recruitment of blood donor through donation campaigns.
- Target collection setting by weekly, monthly and yearly.
- Overcome the seasonal blood shortage by having blood stock forecasting system.

2.3 Identification of Blood Donor

2.3.1 Acceptable identification documents

The following documents are acceptable for blood donor registration:

- MyKad ID.
- Army ID card.
- Police ID card.
- Driving license with photo.
- Worker pass with photo and MyKad or passport number.
- Student pass with photo and MyKad or passport number.
- Passport (Photostated copy must be verified by relevant authority e.g. employer).

2.3.2 Documents not acceptable for identification

The following documents MUST NOT be accepted for registration of blood donors:

- PATI form (Pendatang Asing Tanpa Izin).
- United Nation High Commissioner for Refugees (UNHCR) card.

2.4 Criteria for Acceptance of Blood Donors (Donor Eligibility Criteria)

2.4.1 To be eligible to donate, each prospective donor must meet the following criteria:

a. Age

- Between 17 to 70 years old.
- Prospective donor aged 17 years old must provide written consent from his or her parent or guardian. This consent must be duly signed, and must contain the name and identity card number of the parent or guardian.
- First time donor can be accepted up to the age of 60 years old.
- Regular donors can be allowed to donate up to the age of 70 years. However, donors aged more than 60 years old, are required to undergo and pass yearly medical examinations which, among others, should include chest X-Ray, ECG, liver function tests, renal profile tests, fasting serum lipid test, fasting blood sugar test and full blood count, or produce an official letter from a qualified physician stating his or her fitness to donate.

b. Weight and Haemoglobin Level

- The minimum weight for a whole blood donor shall be 45kg.
- The minimum weight for an apheresis donor shall be 55kg.
- The haemoglobin level of a male donor shall be between 13.5g/dl and 18.0g/dl while for female donor between 12.5g/dl and 18.0g/dl.

c. Blood Pressure

The acceptable limits of blood pressure of the donor are:

- 100 to 150mm Hg for systolic pressure, and
- 70 to 100mm Hg for diastolic pressure.

d. Medical History

The blood collection centre must not accept as a donor any person who is found to have any medical history that could cause harm to the donor during donation, or to the recipient of the donated blood. Please

refer to the Guidelines for the Acceptance and Deferral of Donors (Appendix 1).

- Each prospective donor must be screened against the data base in the central registry (e.g. SUKUSA- Sistem Pengumpulan Maklumat untuk Pusat Kutipan & Pusat Saringan) or records of any previous deferrals. Any person found to have been permanently deferred should not be accepted as a donor. A person who has been temporarily deferred must be assessed by the doctor in-charge to ascertain if the person is eligible to donate again.
- e. High Risk Behaviour
 - Persons involved in any activities that put oneself at high risk of being infected with TTIs shall not be allowed to donate and shall be permanently deferred from future donation.
 - Sexual partners of the above mentioned person shall also not be accepted as blood donors.
 - The last sexual partner must be maintained more than twelve (12) months before donation is allowable.
- f. Replacement or Directed Blood Donation
 - The blood collection centre must not allow blood donation for the purpose of replacement or directed to specified recipient.
 - Exceptions however are applicable subject to the approval by the medical officer or specialist in-charge.
- g. Specific Criterion for Foreigners (Non-Malaysian Citizen)
A prospective donor who is a foreigner (non-Malaysian citizen) can be considered for donation only if he or she:
 - Has resided in Malaysia for at least 12 months.
 - Able to provide a residential or postal where the donor is contactable.
 - Must be able to read and understand Bahasa Malaysia or English.

2.5 Frequency of Donation

2.5.1 Whole blood donation

- A donor is allowed a maximum of 4 whole blood donations in a period of 12 months subject to a minimum interval of 8 weeks between successive donations.

- If a donor donates whole blood regularly every 8 weeks, (subject to 2.4.1 a.), iron store of the donor should be estimated at least once per annum.
- Whole blood donor must be deferred from donating for at least 8 weeks if more than 100m of red blood cells was lost during blood donation.
- The maximum quantity of whole blood allowed to be collected from a donor per donation is 15% of the estimated body blood volume, or 10.5ml/kg of body weight, whichever is lower.

2.5.2 Apheresis donation

- A donor donating platelet and/or plasma via apheresis is allowed a maximum donation of a total volume of 15 liters, or 24 times in a period of 12 months, whichever comes first, subject to a minimum interval of 2 weeks between successive donations.
- An apheresis donor must revert to whole blood donation if there is a lapse of more than 6 months from the last apheresis donation.
- An apheresis donor may choose to donate whole blood at anytime subject to a minimum interval of 2 weeks from the last apheresis donation.
- An apheresis donor must be deferred from donating for at least 8 weeks if more than 100ml of red blood cells was lost or unreturnable during the last apheresis donation.
- The minimum pre-donation platelet count for a prospective platelet apheresis donor must be $150 \times 10^9/L$.

2.6 Record of Donors

- 2.6.1 Record of each donation must be maintained and updated. The eligibility status of a prospective donor to donate shall also be clearly stated in the records.
- 2.6.2 A prospective donor must complete the Blood Donor Registration Form (Appendix 2) before donation.
- 2.6.3 All donor registration forms and records shall be kept secure and confidential.

2.7 Pre-Donation Questionnaire

- 2.7.1 A prospective donor is required to read, understood, and answer all the questions in the pre-donation questionnaire in the Blood Donor Registration Form before being allowed for donation.
- 2.7.2 Appropriate assistance may be provided to those who are unable to read or understand the questionnaire (applicable only to Malaysian citizen).
- 2.7.3 Consent for the donation must be clearly indicated on the Blood Donor Registration Form.

2.8 Pre-Donation Interview

- 2.8.1 Pre-donation interview must be conducted in privacy by a doctor or nurse who has been trained and qualified in blood donation process.
- 2.8.2 The interviewer must explain to the prospective donor about the blood donation process.
- 2.8.3 There must be adequate assessment made of the health status of the prospective donor.
- 2.8.4 If the prospective donor is on any medication, it must be ascertained that it does not have any potential negative impact on the safety of the donor during the blood donation process, and safety of the recipient of blood and blood product.
- 2.8.5 The interviewer should enquire from the prospective donor for presence of relevant symptoms such as skin rashes, swollen glands, needle marks, pallor or jaundice that may indicate that the prospective donor may not be fit to donate. Where feasible or necessary a physical examination should be carried out.
- 2.8.6 The interviewer must explain to the prospective donor about high risk behaviours that expose oneself to TTIs, and assess if the prospective donor has or is suspected to have any of these high risk behaviours.

- 2.8.7 The prospective donor must be made aware of the possible legal action that can be made on donors who make false declaration about their high risk behaviour:

“Any blood donor who is found to make false declaration pertaining to his or her high risk lifestyle behaviour will be prosecuted in Court under the existing laws” (ref: KKM87/A6/1/23(16) Jld.2 dated 9/4/2012 – Bahagian Amalan Perubatan, Ministry of Health Malaysia).

- 2.7.8 If a prospective donor is deferred, the reasons for deferral must be clearly recorded in the donor’s Blood Donor Registration Form and in the donor’s record.

2.9 Collection of Blood

2.9.1 Identification of donor

- The identity of the donor must be asked and checked against the record in the Blood Donor Registration Form.
- Check (expiry date and any physical defect) and identify the type of blood bag and the volume to be collected.
- Label the blood bag with blood group sticker and barcode at the bedside before performing the venepuncture.

2.9.2 Venepuncture

- Venepuncture must be done by aseptic technique.
- The sterilised area must not be touched by unsterilised finger.
- The standard operating procedure must be strictly adhered to during the venepuncture process.
- In the event of an unsuccessful venepuncture at the first attempt, use a new set at a different venepuncture site/arm subject to consent of the donor.

2.9.3 Mixing of donated whole blood

- Validated automated blood mixer is recommended for the purpose of mixing the donated whole blood. The personnel attending to a donation must ensure that blood flows uninterrupted into the bag at an acceptable rate.

- In the absence of an automated blood mixer, the contents of the collection bag should be manually mixed immediately at the start of the collection, and then at regular intervals every 30 to 45 seconds throughout the whole collection period.

2.9.4 Duration of bleeding for whole blood donation

- Ideal bleeding time should not take more than 10 minutes.
- Where the duration of bleeding exceeds 12 minutes, the blood must not be used to prepare platelets.
- Where the duration of bleeding exceeds 15 minutes, the plasma must not be used for direct transfusion or the preparation of coagulation factors.

2.9.5 Handling of blood containers and collection of blood samples

- Tubes or containers should be checked before and after donation for any defect.
- Samples of blood for laboratory testing must be collected from the pouch of the blood collection set or directly from the donor venepuncture tubing at the end of the donation.
- The blood samples must not be obtained by squeezing the blood out from the blood bag.
- The collection of the blood samples and the labelling of the samples must be carried out at the bedside.
- The blood bag and the corresponding blood samples must not be removed from the donor bedside until all of the sample tubes or containers have been correctly labelled and duly checked and verified against the donor's identification.

2.9.6 Blood donation identification

- Each blood donation shall be uniquely identified. The identification shall contain a code identifying the blood collection centre and a serial number identifying each individual donation.
- The above identification for each donation must be secured onto:
 - the Blood Donor Registration Form,
 - the primary blood bag,
 - the satellite blood bag(s), and,
 - sample tubes for laboratory tests.
- Records of donors and donations shall be traceable to the blood donation identification.

2.10 Blood Donor Confidentiality

All information relating to the blood donor shall be kept confidential, and this includes:

- During donor screening and blood collection.
- Donor record.
- Donor consent.
- Published information.

2.11 Training

All personnel involved in blood procurement must be adequately and properly trained and made to understand the principles of the following:

- Blood donor eligibility criteria.
- Donor health assessment.
- Blood collection, sampling and handling of blood and blood containers.
- Storage and transport of blood.

2.12 Competency of Personnel for Bleeding of Blood Donors.

- 2.12.1 All personnel involved in collection of blood from blood donor must undergo appropriate training and pass a practical competency tests before they are allowed to perform unsupervised venepuncture.
- 2.12.2 A competency certificate should be issued to the competent personnel.
- 2.12.3 Only competent personnel should be allowed to perform venepuncture on blood donors.
- 2.12.4 Competency of the personnel should be re-evaluated every 2 years.

2.13 Confidential Unit Exclusion

- 2.13.1 The prospective donor must be made to understand fully about confidential unit exclusion.

- 2.13.2 Confidential unit exclusion is the act of the donor notifying the blood centre/blood collection centre as soon as the donor has any doubts that the donated blood is safe for use. This may be due to risk factors or any medical reasons.
- 2.13.3 Upon such notification, the blood and any blood component(s) prepared from this donor shall be immediately removed and disposed of. Records of this event shall be maintained.

2.14 Adverse Reactions in Donors

- 2.14.1 Donors should be managed with high standards of care to assure them safe during blood donation process.
- 2.14.2 Despite this, adverse donor reactions (ADR) do occur.

Table 2A: Some Common Adverse Donor Reactions

A. Local Symptoms	
A1. Blood outside the vessel	- Haematomas - Arterial puncture - Delayed bleeding
A2. Arm pain	- Nerve injury/ irritation - Other arm pain
A3. Localised infection/ inflammation of vein or soft tissue	- Superficial thrombophlebitis - Cellulitis
A4. Other major blood vessel injury	- Deep Venous Thrombosis (DVT) - Arteriovenous Fistula - Compartment Syndrome - Brachial Artery Pseudoaneurysm
B. General Reactions	
Vasovagal reaction	- With injury/ without injury - Immediate/ delayed type
C. Related to Apheresis	
• Citrate toxicity • Haemolysis • Air embolism	

D. Allergic Reactions

- Local allergic reaction
- Generalized (anaphylactic) reaction

E. Other Serious Complications Related to Blood Donation

- Acute Cardiac symptoms (other than Myocardial Infarct or cardiac arrest)
- Myocardial Infarct
- Cardiac Arrest
- Transient Ischemic Attack (TIA)
- Cerebrovascular Accident

F. Others

2.15 Management of Adverse Reaction in Donors

- 2.15.1 Special attention shall be given to donors in whom an adverse reaction associated with blood donation is identified.
- 2.15.2 Any ADR should be attended immediately. The donor shall be referred as soon as possible to the doctor in-charge for further management.
- 2.15.3 The necessary treatment measures shall be instituted as soon as possible and investigations shall be carried out to identify the cause of the reaction.
- 2.15.4 Donors shall be explained about the adverse reaction and reassurance shall be given.
- 2.15.5 Appropriate preventive and corrective measures shall be implemented.
- 2.15.6 All staff shall be trained to recognize early signs and symptoms of an adverse reaction and to be able to respond immediately and appropriately manage such events in donor.
- 2.15.7 A guide to the management of specific adverse donor reactions is provided in Appendix 3.

2.16 Documentation of Adverse Reactions in Donors

- 2.16.1 The doctor in charge and/ or health personnel shall fully document the incident, treatment and outcome of all adverse donor reactions.
- 2.16.2 All adverse reactions shall be documented in a dedicated incident reporting form for donor reaction. An example of such a form – see Appendix 4 (BTS/DV/2/2016) and the reports shall be kept at the respective collection centres. A copy of the completed form shall be sent to the National Haemovigilance Coordinating Centre every month. Appendices 5 and 6 provide description and grading of severity of adverse reactions.

2.17 Registry

- 2.17.1 The blood collection centre shall maintain registries of the following:
- Whole blood and apheresis donors.
 - Donors with positive markers to Transfusion Transmitted Infection (TTI).
 - RhD negative donors and donors with rare blood groups.
- 2.17.2 The blood collection centre should establish registries for
- Permanently deferred donors (due to reasons other than positivity to TTI).
 - Temporarily deferred donors.

2.18 Record Keeping

- 2.18.1 Retention
- 2.18.1.1 Manual keeping
- All the donor records shall be kept for at least 20 years. (*Surat Pekeliling Ketua Pengarah Kesihatan Malaysia Bil 13/2001 - Garis Panduan Penyimpanan Rekod Penderma dan Penerima Darah*).

2.18.1.2 Database/systems

- | | | |
|------------------------|---|--------------------------------------|
| i. Donor Database | - | Online for 3 years for active record |
| | - | Archive database for 12 years |
| | - | Microfiche storage permanently |
| ii. Recipient Database | - | Online for 3 years for active record |
| | - | Archive database for 10 years |
| | - | Microfiche storage permanently |

2.18.2 Policy

- “Public officials are prohibited from destroying records without written permission of the *Ketua Pengarah Arkib Negara Malaysia* (Section 25-ANM Act 2003)”.

2.18.3 Penalties

- Section 25(5) of the National Archive Act: “a fine of not more than RM5,000 or 1 year imprisonment or both”.

2.18.4 Destruction of records

- Records should always be disposed of with the same level of security that was maintained during the life of the records.
- Wherever possible, destruction of records should be supervised by an officer.
- Before records destruction can occur, the following must take place:
 - i. National Archives should be consulted first before any destruction of any records including electronic data.
 - ii. There is no active or pending litigation and audit for the records.
 - iii. The records are no longer required under any other legislation, and all statutory and regulatory requirements are fulfilled.
 - iv. All records have been authorized for destruction in accordance with the requirements of an approved Records Retention Schedule and also permission from *Ketua Pengarah Arkib Negara Malaysia*.
 - v. The destruction of all records must be documented, so that it is able to determine whether a record has been destroyed.

3.0 Production of Blood Components

Blood components shall be prepared in adherence to the principles of Good Manufacturing Practice (GMP), and any other applicable regulatory requirements. The blood processing centre shall establish documented procedures and instructions for the preparation and storage of blood and blood components.

3.1 Procedures for Preparation of Blood Components

- 3.1.1 Procedures for the preparation of blood components shall clearly state the acceptable specifications of the starting materials, anticoagulant and/or additive solutions, packaging materials (e.g. blood bags), equipment as well as intermediate and final components. The specifications shall include all factors that influence the quality of the component(s) prepared.
- 3.1.2 Blood cold chain shall be monitored and maintained from the time of collection to processing, including during transportation.
- 3.1.3 Components should be prepared according to the time frames specified below (para 3.2) where applicable.
- 3.1.4 Preparation of components beyond the time limits mentioned in para 3.2 below shall be fully validated before implementation. The validation shall be documented and records made easily available.
- 3.1.5 Underweight whole blood units shall not be used for the preparation of components.

3.2 Types of Blood and Blood Components

Below are the definition, criteria, preparation method, storage and shelf life of blood and blood components.

3.2.1	Component	: Whole Blood
	Definition	: Blood taken from a suitable donor and collected into a pyrogen-free anticoagulant bag without further processing.

Criteria for preparation	: No further preparation required.
Preparation	: Not applicable.
Storage temperature	: $4^{\circ} \pm 2^{\circ}\text{C}$.
Shelf life	: 28 to 35 days depending on the anticoagulant/preservative used.
3.2.2 Component	: Whole Blood, Leukocyte-depleted
Definition	: Derived from whole blood by removing the leukocytes to a residual leukocyte content of less than 1×10^6 per unit.
Criteria for preparation	: Volume of whole blood within 10% of the range as specified for the type of bag used.
Preparation	: Filtration technique is used to produce whole blood, leukocyte-depleted. Leukocyte depletion should be done within 48 hours after donation.
Storage temperature	: $4^{\circ} \pm 2^{\circ}\text{C}$.
Shelf life	: 28 to 35 days depending on the anticoagulant/preservative used.
3.2.3 Component	: Red Cell Concentrate
Definition	: A component obtained by removing most of the plasma from whole blood.
Criteria for preparation	: Whole blood volume within 10% of the range as specified for the type of bag used.
Preparation	: Plasma is removed from whole blood after centrifugation.
Storage temperature	: $4^{\circ} \pm 2^{\circ}\text{C}$.
Shelf life	: 28 to 35 days depending on the anticoagulant/preservative used.
3.2.4 Component	: Red Cells in Additive Solution
Definition	: A component derived from whole blood by removing plasma with subsequent addition of an additive solution.
Criteria for preparation	: Whole blood volume within 10% of the range as specified for the type of bag used.

Preparation	:	Plasma is removed from whole blood after centrifugation with immediate addition of additive solution.
Storage temperature	:	$4^{\circ} \pm 2^{\circ}\text{C}$.
Shelf life	:	35 to 42 days depending on the anticoagulant/additive used.
3.2.5 Component	:	Red Cells, Leukocyte-depleted
Definition	:	A component obtained from red cells by removing the leukocytes to a residual leukocyte content of less than 1×10^6 per unit.
Criteria for preparation	:	Red cell concentrate and red cell in additive solution within the volume range as specified for the type of bag used.
Preparation	:	Filtration technique is used to produce whole blood, leukocyte-depleted. Leukocyte depletion should be done within 48 hours after donation.
Storage temperature	:	$4^{\circ} \pm 2^{\circ}\text{C}$.
Shelf life	:	35 to 42 days depending on the anticoagulant/additive solution used.
3.2.6 Component	:	Red Cells, Buffy Coat Removed, in Additive Solution
Definition	:	A component prepared by the removal of most of the plasma and the buffy coat layer from whole blood with subsequent addition of an additive solution.
Criteria for preparation	:	Whole blood volume shall be within 10% of the range as specified for the type of bag used.
Preparation	:	Prepared from whole blood by centrifugation, with 20-60ml of the buffy coat layer removed followed by suspension of the red cells in additive solution. Leukocyte count in red cell, buffy coat removed, should be less than 1.2×10^9 cells per unit.
Storage temperature	:	$4^{\circ} \pm 2^{\circ}\text{C}$.
Shelf life	:	28 to 42 days depending on the anticoagulant/additive solution used.

3.2.7	Component	: Red Cells, Leukocyte-depleted for Paediatric Transfusion (Paedipack)
	Definition	: A unit of leukocyte-depleted red cells aliquotted into smaller volumes of 25-100ml per pack.
	Criteria for preparation	: Prepared from blood of regular donors.
	Preparation	: Refer to 3.2.3 and 3.2.4 for the preparation of red cell concentrate and red cells in additive solution. The prepared component is then transferred into several small volume packs which contain a residual content of leukocyte count of less than 1×10^6 per unit. A closed system preferably an aliquot blood bag system shall be used to ensure sterility during transfer of the red cells.
	Storage temperature	: $4^\circ \pm 2^\circ\text{C}$.
	Shelf life	: 35 to 42 days depending on the anticoagulant/additive solution used.
3.2.8	Component	: Red Cells, Washed
	Definition	: A component derived from red cells or whole blood through sequential washing in an isotonic solution, followed by re-suspension of the red cells in an additive or saline solution.
	Criteria for preparation	: Whole blood, red cell concentrate and red cells in additive solution within the volume range as specified for the type of bag used.
	Preparation	: According to in-house validated protocol (manual or automated). Redcells or whole blood is suspended in the isotonic solution and the supernatant containing protein is removed. The total protein of the final supernatant shall be less than 0.5g per unit.
	Storage temperature	: $4^\circ \pm 2^\circ\text{C}$.
	Shelf life	: Shelf life is 24 hours using open system. The shelf life for closed system is subject to local validation.

3.2.9	Component	:	Red Cells, Cryo-preserved/deglycerolized
	Definition	:	A component derived from thawing frozen red cells, where most of the cryoprotectant (glycerol) is removed.
	Criteria for preparation	:	3.2.1, 3.2.3, 3.2.4 can be used as starting material. Freezing (glycerolization) of red cells is preferably carried out within 7 days of donation.
	Preparation	:	Red cells are frozen in cyroprotectant using either low or high glycerol technique. Regardless of the techniques, washing/deglycerolization procedure is required.
	Storage temperature	:	Red cells, cryopreserved: a. Below minus 65°C ($\leq -65^{\circ}\text{C}$). b. Deglycerolized red cells : $4^{\circ} \pm 2^{\circ}\text{C}$.
	Shelf life	:	Red cells, cryopreserved:10 years. Deglycerolized red cells: Maximum of 14 days.
3.2.10	Component	:	Red cells, Irradiated
	Definition	:	Red cells that have been irradiated to inactivate lymphocytes to prevent TA-GVHD.
	Criteria for preparation	:	Can be irradiated anytime up to 14 days after collection. All irradiated units shall be labelled as such using appropriate barcode labels.
	Preparation	:	Unit shall be labelled with irradiation indicator tag to indicate successful irradiation process.
	Storage temperature	:	Red Cells: $4^{\circ} \pm 2^{\circ}\text{C}$.
	Shelf life	:	Maximum of 14 days after irradiation or up to the expiry date of the blood, whichever is earlier.
3.2.11	Component	:	Platelet Concentrate, Random
	Definition	:	Derived from whole blood containing majority of the original platelet content, suspended in plasma.

Criteria for preparation	: The whole blood (Refer to 3.2.1) used for preparation of platelet concentrates shall meet the following criteria: - Duration of bleeding is less than 12 minutes. - Storage temperature prior to preparation: 20° to 24°C .
Preparation	: Preparation within 24 hours of collection.
Storage temperature	: 22° ± 2°C under constant agitation throughout storage and shall be placed and arranged such as to allow maximum respiration.
Shelf life	: 5 days.
3.2.12 Component	: Plateletpheresis
Definition	: A component which contains platelet in a therapeutically effective dose suspended in plasma obtained from a single donor by apheresis technique using automated cell separation equipment.
Criteria for preparation	: None.
Preparation	: Whole blood is removed from the donor by the apheresis machine and platelets are harvested from it.
Storage temperature	: 22° ± 2°C under constant agitation throughout storage and shall be placed and arranged such as to allow maximum respiration.
Shelf life	: 5 days.
3.2.13 Component	: Fresh Frozen Plasma (FFP)
Definition	: A component which contains labile clotting factors and other constituents, for transfusion or fractionation.
Criteria for preparation	: Duration of whole blood donation shall not exceed 15 minutes. Plasma should be prepared within 24 hours of whole blood collection, preferably within 12 hours.
Preparation	: Plasma is obtained from whole blood after centrifugation, or by plasmapheresis and immediately frozen to achieve complete freezing within 1 hour to a core temperature of below minus 30°C (-30°C).

Storage temperature and shelf life	a. 36 months at or below -25°C ($\leq$ -25°C). b. 3 months at -18°C to -25°C.
3.2.14 Component	: Cryoprecipitate
Definition	: A component containing the cryoglobulin fraction obtained by thawing and further processing of FFP.
Acceptance criteria	: Refer to 3.2.13.
Preparation	: Prepared by slow thawing of plasma at 2°C to 6°C overnight. After thawing, the component is re-centrifuged using a hard spin at the same temperature. The supernatant, cryo-poor plasma is then partially removed while the remaining cryo-poor plasma is used for resuspension. The resulting cryoprecipitate is then rapidly frozen.
Storage temperature and shelf life	a. 36 months at or below -25°C ($\leq$ -25°C). b. 3 months at -18°C to -25°C.
3.2.15 Component	: Cryosupernatant
Definition	: A by-product from the preparation of cryoprecipitate.
Acceptance criteria	: Refer to 3.2.13 and 3.2.14.
Preparation	: Refer to 3.2.14.
Storage temperature and shelf life	a. 36 months at or below -25°C ($\leq$ -25°C). b. 3 months at -18°C to -25°C.
3.2.16 Component	: Pathogen inactivated plasma
Definition	: Plasma subjected to pathogen inactivating procedure to reduce the risk of pathogen transmission.
Acceptance criteria	: Plasma obtained from a single donor by apheresis technique.
Preparation	: Prepared by pathogen inactivation procedures using one of the following methods: methylene blue, amotosalen and riboflavin methods.
Storage temperature and shelf life	a. 36 months at or below -25°C ($\leq$ -25°C). b. 3 months at -18°C to -25°C.

3.3 Labelling

- 3.3.1 Each blood component shall be uniquely identified by a unique barcode number to allow for full traceability to the donor and the collection, testing, processing, storage, release, distribution and the final fate of the component (e.g. transfusion or discard of the blood component).
- 3.3.2 The labelling of blood components must be able to distinguish non-released from released blood and blood components.
- 3.3.3 Each unit of component shall be labelled, at the minimum, with the following information:
 - a. Unique barcode number as described in 3.3.1.
 - b. Date of collection.
 - c. Date of expiry.
 - d. ABO and RhD group.
 - e. Name of the blood component.
 - f. Volume of the blood component.
 - g. The name of the blood processing centre.
 - h. The word **SCREENED**.
 - i. Additional component information e.g. Irradiated, Phenotype.

3.4 Quarantine

- 3.4.1 The blood centre shall establish and implement a system of administrative and physical quarantine for blood and blood components to ensure that only blood and blood components that meet all mandatory requirements are allowed to be released.
- 3.4.2 All unscreened blood and blood components shall be quarantined in storage compartments distinctly separate from storage compartments used for screened blood.

3.5 Storage

- 3.5.1 Complete segregation of screened and unscreened blood shall be maintained at all times. The system of storage shall not give rise to unintended release of unscreened blood.
- 3.5.2 Storage temperatures shall be controlled and appropriate for the blood or blood components stored and temperature monitoring shall be carried out and documented.
- 3.5.3 Storage equipment and facilities shall be equipped with appropriate alarm systems which have both audible and visual signals. Alarm systems shall be regularly checked and tested to ensure they are in working condition. Records of tests and checks shall be maintained.
- 3.5.4 Documented procedures on actions to be taken in response to alarms shall be established. Records of actions taken in response to occasions in which alarms are activated shall be maintained.

3.6 Release of Screened Blood Components from Quarantine

- 3.6.1 Each unit of blood component shall be individually checked before it is released into inventory/ for use by an authorized person.
- 3.6.2 Computer systems (if available) used to release blood or blood components must be validated to prevent the inadvertent release of blood components that do not meet all mandatory requirements. In the absence of a computer system for release or in the event of computer system failure, the labelling of blood component must be able to distinguish between a quarantined and a released component.

3.7 Discard of Unsuitable Units of Blood

- 3.7.1 Units of blood that are found unsuitable to be released owing to reactivity to markers of TTI shall follow the requirements in Section 5.11.
- 3.7.2 Units of blood that are found unsuitable due to reasons other than reactivity to markers of TTI shall be systematically separated and discarded.
- 3.7.3 The discard of blood shall be fully recorded to ensure full traceability and the chain of custody.

3.8 Quality Control

- 3.8.1 Acceptance parameters for blood shall be defined. Appropriate tests and assessments shall be performed to monitor these parameters at regular intervals. Table 3A below lists the recommended parameters to be monitored and the frequencies of monitoring.

Table 3A: Quality Parameters and The Frequencies of Monitoring for Blood

Type	Parameter	Quality Requirement (Specification)	Frequency of Control
Whole Blood	a. Volume in:		1% of all units with a minimum of 4 units per month
	i. 450ml bag	450ml $\pm$ 10%	
	ii. 350ml bag	350ml $\pm$ 10%	
	iii. 250ml bag	250ml $\pm$ 10%	
	b. Haemoglobin for:		
	i. 450ml bag	>45g/unit	
	ii. 350ml bag	>35g/unit	
	iii. 250ml bag	>25g/unit	
	c. Haemolysis at the end of storage	< 0.8% of red cell mass	
	d. Sterility at the end of the shelf-life	No Growth	
Red Cell	a. Volume in:	To be defined for the system used	1% of all units with a minimum of 4 units per month
	i. 450ml bag		
	ii. 350ml bag		
	b. Haematocrit	0.65–0.75	
	c. Haemoglobin	>45g/unit	
	d. Haemolysis at the end of storage	<0.8% of red cell mass	
	e. Sterility at the end of the shelf-life	No Growth	

Type	Parameter	Quality Requirement (Specification)	Frequency of Control
Red Cells, in Additive Solution	a. Volume	To be defined for the particular system used	1% of all units with a minimum of 4 units per month
	b. Haematocrit	0.50 - 0.70	
	c. Haemoglobin	>45g/unit	
	d. Haemolysis at the end of storage	<0.8% of red cell mass	
	e. Sterility at the end of the shelf-life	No Growth	
Red Cells, Leukocyte-Depleted	a. Volume	To be defined for the system used	1% of all units with a minimum of 4 units per month
	b. Haematocrit	0.50 – 0.70	
	c. Haemoglobin	>40g/unit	
	d. Haemolysis at the end of storage	<0.8% of red cell mass	
	e. Residual Leukocytes content ¹	$<1.0 \times 10^6$ cell per unit	1% of all units with a minimum of 10 units per month
Whole Blood, Leukocyte-Depleted	a. Volume	450ml $\pm$ 10%	1% of all units with a minimum of 4 units per month
	b. Haemoglobin	>43g per unit	
	c. Haemolysis at the end of storage	<0.8% of red cell mass	
	d. Residual Leukocyte content ¹	$<1.0 \times 10^6$ cell per unit	1% of all units with a minimum of 10 units per month

Type	Parameter	Quality Requirement (Specification)	Frequency of Control
Red Cells, Buffy Coat Removed, in Additive Solution	a. Volume	To be defined for the system used	1% of all units with a minimum of 4 units per month
	b. Haematocrit	0.50-0.7	
	c. Haemoglobin	>43g/unit	
	d. Residual Leukocytes content ¹	$<1.2 \times 10^9$ cell per unit	
	e. Haemolysis at the end of storage	<0.8% of red cell mass	
Red Cell, Leukocyte-Depleted for Paediatric	a. Volume	25ml – 100ml	1% of all units with a minimum of 4 units per month
	b. Other related parameters	Refer to specifications for primary component from which the red cells were derived	
Red Cell, Washed	a. Volume	To be defined	All units
	b. Haematocrit	0.65 – 0.75	
	c. Haemoglobin	>40g/unit	
	d. Haemolysis at the end of storage	<0.8% of red cell mass	
	e. Protein content of final supernatant	<0.5g/unit	
Platelet Concentrates, Random	a. Volume	50 - 70ml	1% of all units with a minimum of 10 units per month
	b. Platelet content per final unit	$>60 \times 10^9$ cell per unit	
	c. Residual Leukocytes content ¹		
	– prepared from PRP	$<0.2 \times 10^9$ cell per unit	
	– prepared from Buffy-coat	$<0.05 \times 10^9$ cell per unit	
	d. pH measured (22°C) at the end of the recommended shelf life	>6.4	
	e. Sterility at the end of the shelflife	No Growth	

Type	Parameter	Quality Requirement (Specification)	Frequency of Control
Plateletpheresis	a. Volume	>40ml per 60×10^9 platelets	1% of all units with a minimum of 10 units per month
	b. Platelet content	>200 $\times 10^9$ /unit	
	c. Residual Leukocytes content ¹	<0.3 $\times 10^9$ /unit	
	d. pH measured (22°C) upon issue	>6.4	
Fresh Frozen Plasma	a. Volume	Stated volume $\pm 10\%$ (based on the blood bag used)	Every 3 months 10 units in the first month of storage.
	b. Factor VIII level	>0.7IU/ml	
	c. Leakage	No leakage at any part of container e.g. visual inspection after pressure in a plasma extractor, before freezing and after thawing	
	d. Visual changes	No abnormal colour or visible clots	
Cryoprecipitate	a. Volume	35ml $\pm$ 5ml	Pool of 6 units of same blood group
	b. Factor VIII level - Group A,B,AB - Group O	>70IU/unit To be define by user	
	c. Fibrinogen Concentration	>140mg/unit	

Standards of Compliance:

At least 75% of the units sampled should have the relevant parameters fall within the specifications indicated in the table. However for parameters marked with superscript 1, 90% of the units sampled should have the relevant parameters fall within the values indicated.

4.0 Blood Supply Management

There shall be procedure in place to ensure that only blood SCREENED NEGATIVE for TTI are kept in the inventory.

4.1 Stock Forecasting

- 4.1.1 Data on blood collected, blood supplied, and usable blood stock-in-hand shall be systematically recorded and analysed. Information derived from the data can be used, among others, to forecast blood stock, predict impending shortages and plan blood procurement.

4.2 Optimal Inventory

- 4.2.1 The blood centre/hospital blood bank shall estimate the optimal, the minimum and the maximum stock levels of blood component of each ABO and RhD group.
- 4.2.2 The minimum and maximum stock levels shall also be established, from the average baseline usage and one of the methods to establish this is as follows.
- Record the weekly usage over a 6 month period.
 - Arrange them according to the ABO and RhD groups.
 - Total the weekly usage for each group. Divide this total by 26. This will give the average of weekly usage for that group.
 - The final inventory levels may be based on number of beds and are also influenced by the logistics and distances from the collection centres.

4.3 Minimum and Maximum Stock of Red Blood Cells

- 4.3.1 Each blood centre/hospital blood bank should hold 7 days of stock of red blood cells. The minimum level of red blood cells should be between 2 to 3 days of stock.

4.4 Stock Counts

- 4.4.1 Daily stock count shall be performed to manage the stock to optimal levels. Appropriate records shall be maintained.

4.5 Storage

- 4.5.1 Blood shall be systematically arranged according to groups, component types and expiry dates, so as to facilitate the issuance on a 'First In First Out' (FIFO) basis.
- 4.5.2 However, in cases which require fresh blood, the blood centre/hospital blood bank may choose not to follow FIFO.

4.6 Blood Supply Systems

- 4.6.1 Reliable blood supply systems for emergency and routine shall be established and implemented.

4.7 Safe O

- 4.7.1 If and when necessary, the hospital blood bank shall make available Safe O (that is Group O RhD positive packed cells) at suitable sites for managing emergencies.
- 4.7.2 Procedures for managing Safe O shall be established and implemented.
- 4.7.3 Appropriate records of the use and movement of Safe O shall be maintained.

4.8 RhD Negative Blood Stock

- 4.8.1 Blood collection centre shall maintained ABO and RhD negative blood stock.

4.9 Maximum Surgical Blood Ordering Schedules (MSBOS)

- 4.9.1 Hospitals shall develop own MSBOS to meet local requirements. Refer Guidelines for the Rational Use of Blood and Blood Products, Ministry of Health 3rd edition for details.

4.10 Storage of Blood

- 4.10.1 Blood shall be stored at appropriate temperatures at all times. Storage temperatures shall be monitored. Records of temperature monitoring shall be maintained and made readily available. Refer Table 4A.

4.11 Cold Chain

- 4.11.1 The blood centre/hospital blood bank shall ensure blood cold chains are maintained during storage and transportation as shown in the table below:

Table 4A: Storage and Transportation Temperatures for Blood

Component	Temperature		Transport Boxes
	Storage	Transportation	
Red Cell (all types of red cell)	2°C to 6°C	2°C to 10°C	– Insulated box with coolant pack – Direct contact with coolant shall be AVOIDED
Platelet	20°C to 24°C	20°C to 24°C	Insulated box with NO ICE
Frozen products (Fresh Frozen Plasma/ Cryoprecipitate/ Cryosupernatant)	More than minus -25°C	More than minus -25°C	Insulated box. If temperature rises less than -25°C, the shelf life will be shortened to 3 months
Thawed FFP, Cryoprecipitate/ Cryosupernatant	To be issued out immediately	2°C to 10°C	– Insulated box with coolant pack – Direct contact with coolant shall be AVOIDED

4.12 Containers for Transporting Blood

- 4.12.1 Containers (re-useable or disposable) for transporting blood shall be adequately insulated, robust, tamper proof and clearly labelled for easy identification.
- 4.12.2 The containers and the ratios of coolant to blood and component shall be validated.
- 4.12.3 Records of validation shall be maintained.

4.13 Crossmatch to Transfusion (CT) Ratio and Expiry Rate

- 4.13.1 The hospital blood bank shall closely monitor
 - a. CT ratio.
 - b. Expiry rates of blood and platelet.

5.0 Transfusion Microbiology

The primary function of the Transfusion Microbiology Laboratory (TML) is to screen blood for Transfusion Transmitted Infections (TTIs). The TML shall be placed directly under the purview of the blood centre. This is to ensure that donated blood, donors and screening algorithms are effectively managed.

5.1 Setting up TML

- 5.1.1 The setting up of any TML shall comply strictly to the criteria shown in Appendix 7.

5.2 Scope of Screening

- 5.2.1 All donated blood shall be screened for the following TTIs:
- Human Immunodeficiency Virus (HIV).
 - Hepatitis C virus.
 - Hepatitis B virus.
 - Syphilis.
- 5.2.2 Blood collected in areas with high risk of malaria infection should be screened for malaria parasites.
- 5.2.3 Screening for other infectious diseases may be carried out if deemed necessary.

5.3 Assays and Methods

- 5.3.1 TML within the Ministry of Health shall use only assays and standard methods approved by the Ministry of Health. Test methods shall be strictly adhered to at all times. Modifications to the standards methods are not allowed.
- 5.3.2 Rapid test **SHALL NOT BE USED** for screening of donated blood.

5.4 Samples

- 5.4.1 All donations, any subsequent components and their laboratory samples shall be correctly identified by barcoded and eye-readable numbers which can be linked to their donor.

5.5 Screening Procedure

- 5.5.1 All unscreened donations and their blood components should be placed in a secured physical segregation/ quarantine until all the required tests have been completed.
- 5.5.2 Use single assay and test each blood donation singly.
- 5.5.3 All initially reactive pilot tubes shall be retested in duplicates.
- 5.5.4 Component preparation unit shall retrieve the corresponding blood bag of all initially reactive donations.
- 5.5.5 Samples, for serology testing, from the corresponding blood bags should also be tested to verify the source of the reactive pilot tubes.
- 5.5.6 A collection batch shall be quarantined if there is any discrepancy between the results of the pilot tubes and those of the corresponding blood bags in that batch. The quarantine shall be lifted only after thorough investigations, and resolution of the discrepancies. Appropriate corrective and preventive actions shall be taken. Records of the events, the findings of the investigations, and the corrective and preventive actions taken shall be maintained.

5.6 Release Algorithm

- 5.6.1 A complete result must be obtained from each batch before the final results can be released. Only blood and blood components that are non-reactive for all markers can be released for use. TMLs within the Ministry of Health shall follow the algorithm in Appendix 8A for screening and release of screening results.

The alternative protocol (Appendix 8B) is for the blood bank which has an established and effective quality system for all its processes. Risk assessment shall be made and approval from the Head of Department is required before implementing such protocol.

5.7 Verification and Release of Results

- 5.7.1 All screening results shall be verified and released by a trained and competent Scientific Officer (Microbiologist).

5.8 Quality

- 5.8.1 To ensure quality in screening of donated blood, the TML shall, at the minimum:
- a. Perform daily internal quality control monitoring for both reagents and techniques.
 - b. Participate in external quality assessment/proficiency programs.
- 5.8.2 Additional quality assurance efforts should be established and implemented for continual improvement.

5.9 New Methods and Assays

- 5.9.1 The National Blood Centre (NBC) TML is the national reference laboratory for Transfusion Microbiology and shall be responsible for evaluation of new assays and methods for use in blood screening.
- 5.9.2 Each TML shall perform verification or validation (whichever is applicable) before implementing any new methods or assays.

5.10 Handling of Reactive Samples

- 5.10.1 Each TML shall establish and implement procedures to handle all reactive donation and reactive results. These shall encompass, at the minimum procedures to:

- a. Ensure repeat testing on segments of the blood bag for all initial reactive pilot tube samples as per 5.6.
- b. Ensure donation reactive to HBsAg are confirmed.
- c. Ensure all donations that are repeatedly reactive to anti-HIV and anti-HCV are sent to NBC TML for further testing.

5.11 Disposal of Reactive Blood

- 5.11.1 The component preparation unit or its equivalent shall be responsible to immediately retrieve all blood and its component that have been found reactive. These shall be immediately removed from its storage and sent to the TML for discard.
- 5.11.2 All reactive blood and blood components shall be autoclaved before it is sent for final disposal.
- 5.11.3 The disposal of the reactive blood shall be fully documented to ensure audit trail.

5.12 Documentation

- 5.12.1 Proper documentation of test procedures and records of results such as worksheets and printed results shall be made available and properly maintained. Worksheets shall contain, among others, the following:
 - a. Personnel performing the test.
 - b. Date and time of testing.
 - c. Reagent name, lot number and expiry date.
 - d. Personnel verifying the test results.
- 5.12.3 Record of the tests on donation samples shall be reviewed and compiled on monthly basis.
- 5.12.3 All the screening results and monthly statistics shall be updated in *Sistem Pengumpulan Maklumat untuk Pusat Kutipan & Pusat Saringan (SUKUSA)*.
- 5.12.4 All screening records shall be kept for at least 20 years.

5.13 Chain of Custody

- 5.13.1 The whole process starting from the time specimens are delivered to TML for testing till blood is released and tainted blood is identified and disposed of, involves various personnel and several departments/unit. Documented procedure(s) shall be established and implement to ensure appropriate chains of custody are maintained.
- 5.13.2 In establishing such procedures, proper checks shall be put in place especially during critical steps to prevent errors. It is strongly recommended that checklists are used for all critical steps.

5.14 Confidentiality

- 5.14.1 All test results and donor particulars shall be kept confidential. The TML shall establish and implement a system for delineating access to controlled data and information to appropriately authorized personnel.

6.0 Blood Grouping

6.1 Blood Grouping of Donors at the Donation Site

Blood grouping of donors at the donation site should be done using anti-A and anti-B antisera on blood samples obtained by finger prick. The blood grouping result obtained should only be considered a preliminary result of the blood group and should not be used for any other purpose whatsoever.

6.2 Blood Grouping of Donors in the Laboratory

Blood grouping of donors in the laboratory shall employ full ABO and RhD blood grouping procedure, as follows:

- 6.2.1 Forward grouping shall be performed using anti-A, anti-B, anti-AB and anti-D antisera. Tests for RhD shall be carried out with two different IgM/IgG blends of monoclonal anti-D. One of the two monoclonal anti-D used shall not detect DVI for RhD negative blood.
- 6.2.2 Reverse grouping shall be performed using A1-cells, B-cells and O-cells. The O-cell test is incorporated to detect Bombay blood group and other unexpected IgM antibodies.
- 6.2.3 The results of the forward grouping have to match the results of the reverse grouping. In the event these results do not match, an investigation of this discrepancy shall be carried out.
- 6.2.4 Any blood donor found to be RhD negative shall be confirmed as described in 6.3 below. The blood grouping result obtained from this full blood grouping procedure is the final result.

6.3 Further Confirmation of Donation Typed as RhD Negative

- 6.3.1 All donated blood that is typed as RhD negative shall be subjected to a weak-D test (also known as Du test).
- 6.3.2 If the weak-D test is negative, the donated blood is confirmed as RhD negative.

- 6.3.3 If the weak-D test is positive, a direct antihuman globulin (DAT) test shall be carried out and the results shall be interpreted as below:
- If the weak-D positive blood is DAT negative, the blood is a D variant.
 - If the weak-D positive blood is DAT positive, the blood is probably a false positive D.
 - The true RhD status of the above can only be determined through further tests.
- 6.3.4 Donations confirmed to be RhD negative by the above tests shall be phenotyped for C, c, E and e antigen. In the event the blood transfusion centre is unable to perform this, the tests concerned shall be outsourced.
- Blood that is phenotyped as cde/cde (rr) shall be labelled as “RhD negative” blood.
 - RhD phenotype other than cde/cde (rr) shall be labelled with its actual Rh phenotype, e.g. Cde/Cde (r'r') or cdE/cdE (r''r''). This type of blood can be given to patient with same phenotype or RhD positive patients.
 - All cases of cde/cde (rr) phenotype shall be informed to the respective collection centres. This is to enable the centres to develop, maintain and regularly update their 'Registry of rare blood donors'.

6.4 Blood Grouping for Patients Scheduled for Transfusion - Refer 8.2

6.5 Blood Grouping for Medical or Antenatal Check Up

- 6.5.1 The blood grouping shall be performed using a full grouping procedure.
- 6.5.2 All RhD negative cases shall be subjected to further tests for confirmation (see 6.3 above).

6.6 Methods for Blood Grouping

- 6.6.1 The methods recommended to be used in blood grouping are as follows:
- Tile method:
This is considered a rapid grouping test. It shall be allowed **ONLY** for

blood grouping on donors at blood donation sites. Results obtained from the tile method shall be considered as preliminary results only and **SHALL NOT BE TREATED** as the final grouping result.

- b. Microtitre plate method:
This is recommended for testing large numbers of samples such as grouping of donor samples in the laboratory, or testing patient samples. The results obtained are acceptable as final results.
- c. Tube method:
This is considered the 'gold standard method' for blood grouping. This is recommended for samples from patients or donors. The results obtained are acceptable as final results.
- d. Column agglutination method:
This is recommended for patient blood grouping. The results obtained are acceptable as final results.

7.0 Ordering Blood for Transfusion

The decision to transfuse shall be made based on clinical judgment. The benefits and risks shall be assessed, and alternative therapy considered. Among the risks of blood transfusion are the transmission of infectious disease agents and transfusion reactions.

The clinician managing the patient shall be responsible for prescribing blood for that patient. When necessary the clinician should discuss with the doctor in-charge of the hospital blood bank.

7.1 Processes, Procedures, Methods and Records

- 7.1.1 Each hospital shall establish adequate documented processes, procedures and methods pertaining to the ordering of blood for transfusion. Records shall be kept.

7.2 Consent for Transfusion

- 7.2.1 The patient must give written informed consent prior to transfusion.
- 7.2.2 The clinician in charge of the patient shall explain to the patient the indication, benefits, risks and alternatives to transfusion therapy, and ensure that the patient understands the issues discussed. The patient should be given an opportunity to ask questions. The decision of the patient regarding which therapy to take shall be clearly documented.
- 7.2.3 If for any reason, the patient is unable to personally give consent, a responsible family member of the patient shall be asked to do so. If no such family member is available, or in emergencies when the need for transfusion leaves no time for consent, the decision shall be made by two fully registered medical practitioners. This decision shall be clearly documented. Refer to Appendix 9 for a sample of consent form.
- 7.2.4 Each hospital shall develop its own policy for obtaining consent for patients receiving long term transfusion support, example annual consent for Thalassaemia cases.

7.3 Positive Patient Identification

- 7.3.1 Positive patient identification is a process to correctly identify patients thus avoiding medical error.
- 7.3.2 The phlebotomist shall ensure that the patient is correctly identified by:
 - a. Asking the patient to state their full name and IC number (use of at least 2 identifier) in open ended questions such as “Can you tell me your full name and IC number?”.
 - b. Check the answers given against the information stated on the patient’s identification wristband and/or case notes.
- 7.3.3 If it is not possible to identify the patient in the above manner (e.g. in the case of an unconscious patient, paediatric patients or in cases of emergencies), the phlebotomist shall identify the patient by asking the relative or carer to name the patient and then check the answer given against the information stated on the patient’s identification wristband, and case notes.

7.4 Taking and Labelling Patient’s Blood Sample

- 7.4.1 The process of taking and labelling of blood samples is critical to ensure that the right blood sample is collected from the right patient.
- 7.4.2 The above procedure shall be carried out as one process by one person at the bedside.
- 7.4.3 Only one patient shall be attended to at any one time till completion.
- 7.4.4 The phlebotomist shall clearly and accurately label the blood sample at the patient’s bedside immediately after blood taking.
- 7.4.5 Use of pre-printed label is not encouraged. If this cannot be avoided the hospital shall be responsible to establish and implement a procedure to ensure that patients are correctly identified using the printed labels.
- 7.4.6 Information on the label shall include, at the minimum, the patient’s full name, hospital registration number (or Identity Card (IC) number), the date and time of collection and the initial of the phlebotomist.

7.5 Blood Samples for Red Cells Transfusion

7.5.1 Collect the required amount of blood into the appropriate sample tube as follows:

a. Infant up to 4 months old

i. The sample to be taken from the infant shall be 1.5 to 2.0ml blood sample in EDTA tube.

ii. 3-5ml blood sample in EDTA tube shall be also taken from the mother.

The sample from the infant and the sample from the mother shall be sent to the hospital blood bank together under a single request.

b. Older than 4 months old

The sample to be taken shall be 3-5ml of blood sample in EDTA tube.

7.5.2 Repeated red cell transfusion

7.5.2.1 For infant up to 4 months old

No further sample is required for repeat transfusion of the same set of the paedipack. However infant's sample is required for subsequent transfusion if another set of paedipack is going to be issued. For this, crossmatching will be performed using the infant's sample.

7.5.2.2 For patient older than 4 months

If a patient requires repeated red cell transfusion, each request for red cells shall be accompanied by a new request form and blood sample of 3-5ml of blood in EDTA tube.

7.5.2.3 Elective cases

For elective cases, samples should be sent to the hospital blood bank during office hours at least 24 hours before the blood is required except for rare blood groups and/or RhD negative where the hospital blood bank should be informed at least 5 working days in advance.

7.6 Blood Samples for Blood Components (other than Red Cells) Transfusion

- 7.6.1 A new request for blood component other than red cells shall be accompanied by a blood sample taken in EDTA tube.
- 7.6.2 For a patient who has at least two previous blood grouping records at the hospital blood bank, a new blood sample need NOT accompany the request for blood component. However, a copy of the previous request form clearly stating the blood grouping results shall be attached to the new request form.
- 7.6.3 If previous request form is not available, a fresh blood sample shall be sent to the hospital blood bank to determine the patient's blood group.
- 7.6.4 For ABO mismatched haemopoietic stem cell transplantation, this is not applicable. A new sample must accompany all requests in the immediate post transplant period until the patient's blood group has change to that of the donor.

7.7 Request Forms

- 7.7.1 The clinician shall ensure that each request form is completed. Refer Appendix 10 for the request form.
- 7.7.2 For elective surgery, the clinician shall ensure that the quantity of red cells requested for patients follow the local Maximum Surgical Blood Ordering Schedules (MSBOS).
- 7.7.3 The clinician shall sign, and clearly state his name in block letters on the request form.

7.8 Type of Request

- 7.8.1 Group and Crossmatching (GXM)
 - a. GXM consists of checking ABO & RhD grouping and antibody screening for the patient's sample and crossmatching patient and donor unit for compatibility.
 - b. GXM shall be requested for cases with high certainty for transfusion at that time.

- c. The full procedure takes about 2 hours to be completed. However in emergency situation blood can be issued out as described in section 12.1.

7.8.2 Group, Screen and Hold (GSH)

- a. GSH is a procedure that consists of ABO and RhD grouping, and antibody screening for the patient's sample. The patient's serum or plasma is subsequently retained for a minimum of 48 hours.
- b. It is recommended only for cases where there is a higher chance of requiring blood transfusion during admission.
- c. For elective clinical procedures, GSH shall be requested in accordance to the locally established Maximum Surgical Blood Ordering Schedule (MSBOS).
- d. Should the patient require transfusion following GSH, blood should be made available on time.

7.9 Receiving Requests

- 7.9.1 All requests for transfusion shall be registered.
- 7.9.2 The hospital blood bank personnel receiving a request shall ensure that the request form is complete and the corresponding samples are correctly labelled. Information on the request form and the label of the sample shall tally.

7.10 Rejection of Requests

- 7.10.1 Rejection of requests shall comply with local policies and procedures. Refer Appendix 11 for an example of rejection criteria.
- 7.10.2 However in **LIFE THREATENING SITUATIONS**, the hospital blood bank shall immediately facilitate the resolution of any discrepancies that cause the rejection of the request, by discussing with the clinician. Any resolution including that made through telephone conversation shall be fully documented.

8.0 Pre-transfusion Testing

Pre-transfusion testing in the laboratory should include ABO and RhD grouping, antibody screening and crossmatching. Other relevant tests such as antibody identification or sub group identification are carried out when necessary. The rationale is to ensure that the appropriate blood type is given to the patient.

8.1 Registration of Request for Transfusion

8.1.1 All requests for transfusion shall be registered.

8.2 Determination of ABO and RhD Group

8.2.1 Blood grouping shall be carried out twice, as follows:

- a. The first and second blood grouping tests shall be performed using samples from the **SAME SOURCE** of pre-transfusion specimen (EDTA specimen) but from **DIFFERENT CELL SUSPENSION** preparations. The first and second grouping tests shall be performed by two persons, independently.
- b. In situations where it is absolutely not feasible to have two persons available, the grouping may be carried out by one person. However, the first and the second grouping shall be carried out at different times and using different cell suspensions. The two grouping tests shall NOT be carried out simultaneously.
- c. Blood can be released only if the results of both the two groupings are identical.

8.2.2 Refer 6.3 for procedure of ABO and RhD grouping.

8.2.3 All unanticipated findings noted when determining the ABO and RhD shall be fully investigated and documented.

8.3 Antibody Screening

Antibody screening is mandatory for all requests for transfusion.

- 8.3.1 In laboratories that carry out antibody screening by tube method, the following phases shall be performed at,
 - a. Room temperature,
 - b. 37°C and
 - c. Anti Human Globulin (AHG).
- 8.3.2 In laboratories that use other standard methods (e.g. column agglutination technology) manufacturer's recommendations shall be followed.
- 8.3.3 The red cell reagents used shall consist of at least two group O red cells, (not pooled), and shall express all of the following antigens: C, c, D, E, e, M, N, S, s, K, k, Fya, Fyb, Jka, Jkb. Where possible, one of the red cell reagents should be of the R1R1 phenotype (CDe phenotype) and another of R2R2 phenotype (cDE phenotype). Additional red cell antigens may be considered to reflect the antigenic profile of the local population.

8.4 Records of Previous Transfusions

- 8.4.1 Records of previous transfusions shall be traced.
- 8.4.2 Any discrepancy between current and previous blood group shall be fully investigated and documented.

8.5 Antibody Identification

- 8.5.1 Antibody identification shall be carried out whenever the antibody screening test is positive, and/ or incompatible crossmatch is detected.
- 8.5.2 If the antibody identification result is inconclusive, or difficult case, reference laboratory shall be consulted.
- 8.5.3 If the discussion cannot provide the solution, the case should be referred to the reference laboratory for further investigation with the followings: 10ml of blood in EDTA tube and 10ml blood in plain tube accompanied by a duly completed request form.

- a. Provide the reference laboratory with initial laboratory findings.
- b. Notify the reference laboratory before sending the sample.

8.6 Crossmatching

- 8.6.1 Red cell unit selected for crossmatching shall be of the same ABO and RhD type as that of the patient. In special circumstances, refer chapter 11 and chapter 12.
- 8.6.2 In laboratory that carry out crossmatching using tube method, the following phases shall be performed at:
 - a. Room temperature,
 - b. 37° C, and
 - c. AHG .
- 8.6.3 In laboratory that use other standard methods (e.g. column agglutination technology), manufacturer's recommendations shall be followed.
- 8.6.4 When a clinically significant red cell antibody is identified, every effort shall be made to provide blood that is antigen negative (with respect to the identified antibody). Refer 12.5 for selection of blood in antibody cases.
- 8.6.5 Where fully compatible blood is not available, and the patient needs urgent transfusion, the hospital blood bank shall discuss with the clinician in charge of the patient for the issue of the most compatible blood. The decision to use the most compatible blood shall be arrived at after taking into consideration.
 - a. The potential risks of adverse reactions, and
 - b. the potential risks of harm to the patient owing to delay in transfusion arising from searching for fully compatible blood.
- 8.6.6 Crossmatched samples shall be retained securely under appropriate storage conditions for a minimum of 7 days.
- 8.6.7 Crossmatched blood that has not been issued shall be released into general stock after 48 hours.

8.7 Selection of Non Red Cell Components

- 8.7.1 Plasma and platelet concentrates selected for transfusion shall be compatible and preferably of the same ABO group.
- 8.7.2 Recommendations for selection of plasma and platelets.

Table 8B: Guide for The Selection of Plasma and Platelets

ABO blood group of patient	ABO group of plasma to be issued in order of preference	ABO group of platelet to be issued *
Unknown (request sample for baseline grouping)	Issue AB if urgent	Issue O if urgent
O	O, A, B, AB	O
A	A , AB	A, O
B	B, AB	B, O
AB	AB	AB , O

8.8 Transfusion Records

- 8.8.1 All transfusion records, in the form of hard or soft copies or both, shall be archived for not less than 20 years.
- 8.8.2 The following requirements shall be fulfilled when an IT system is used,
 - a. Active records shall be maintained online for not less than three years.
 - b. The database shall be archived for the legally designated period of retention.
 - c. A mechanism for maintaining and protecting records from loss or unintentional removal or destruction shall be put in place.

9.0 Issue and Transport of Blood to the Ward

Blood shall be kept at appropriate temperature and condition at all times before transfusion. There shall be an appropriate procedure to ensure that the correct blood is issued out to the correct patient.

9.1 Issue and Collection of Blood

- 9.1.1 Only authorized hospital blood bank personnel shall be allowed to issue blood.
- 9.1.2 The ward personnel collecting the blood shall bring documentary proof of the patient's identity.
- 9.1.3 The blood compatibility label shall be duly completed by the hospital blood bank and shall carry at least the following information:
 - a. Full name of patient.
 - b. Identity card or passport number of patient.
 - c. Hospital registration number of patient.
 - d. ABO and RhD blood group of patient.
 - e. Unique pack number (donation barcode number) of the blood product.
 - f. Date of issue.
 - g. Type of component.
- 9.1.4 The authorized hospital blood bank and ward personnel shall verify that the particulars of patient match those of the blood to be issued.
- 9.1.5 The authorized hospital blood bank personnel shall record the dates and times of issue and collection, the name of person issuing and the name of the person collecting the blood.

9.2 Storage and Transport

- 9.2.1 The ward personnel shall transport the issued blood to the ward or returned blood to the hospital blood bank without delay. Transportation shall be carried out in an appropriate temperature.

- 9.2.2 Issued blood shall be transfused without undue delay. However, in the event where delay is inevitable, the ward shall maintain the blood at the appropriate temperatures and condition until they are used or returned to the blood bank immediately. (Please see Appendix 12.)

10.0 Transfusion Process

Patient identification before commencing administration of blood or blood components is critical to ensure that the right blood is transfused to the right patient.

10.1 Identification Check Prior to Transfusion - FINAL BEDSIDE CHECK

- 10.1.1 Each hospital shall establish procedure for carrying out identification checks, to prevent any error occurring at this final stage before transfusion commenced. The check shall include the blood bag label, blood compatibility label, request form, and the patient's identification.
- 10.1.2 Each unit of blood supplied by the hospital blood bank shall be appropriately labelled (Figure 10A) and accompanied by a blood compatibility label (Figure 10B).



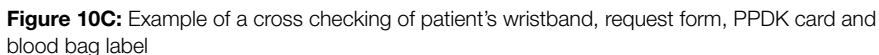
Figure 10A: Example of a blood bag label



Figure 10B: Example of a blood compatibility label (PPDK 1)

- 10.1. Prior to transfusion, personnel in charge shall perform a positive patient identification as elaborated in 7.3.

- Blood bag label.
- Patient's wristband.
- Patient's blood request form.
- Case notes.



- No change in colour.
- Absence of clots.
- No foamy appearance.
- No leakage.

These shall be carried out BEFORE the transfusion. The checking and the counterchecking shall be documented in a transfusion checklist form. Refer for example of transfusion checklist.

- 10.1.7 In the event of any discrepancy in the identification check of intended recipient, blood compatibility label, request form and blood component, the blood bank shall be immediately informed. The implicated blood shall be immediately returned to the blood bank for appropriate measures to be taken. The chain of custody shall be documented.
- 10.1.8 **DO NOT** transfuse if there is any non-compliance to any of the requirements stated in 10.1.2 to 10.1.6 above.

All the steps performed above are intended to minimize the risk of a patient receiving wrong blood. Failure to adhere to these steps may lead to wrong blood transfusion resulting in harm or even death of the patient.

10.2 Monitoring of Patient

- 10.2.1 The patient shall be closely observed and monitored during blood transfusion.
- 10.2.2 Parameters to be monitored shall include:
- Blood pressure.
 - Pulse rate.
 - Temperature.
 - Clinical features of acute transfusion reactions.
- 10.2.3 The vital signs shall be monitored and recorded:
- Before starting transfusion.
 - During the transfusion (close observation and monitoring for the first 5 to 10 minutes, and subsequently half hourly and then hourly. Perform vital sign monitoring every 15 minutes for unconscious patients receiving transfusion).
 - After completion of transfusion.

The first 50ml of red cells should be transfused slowly as it serves as an in vitro compatibility testing.

10.3 Record Keeping

- 10.3.1 The following information for each transfusion shall be recorded into the patient's case note:
- Type of product transfused.
 - Identification of product transfused (donation barcode number).
 - Times transfusion starts and ends.
 - Date of transfusion.
 - Adverse transfusion reaction, if any.
- 10.3.2 A copy of the blood request form (with clear compatibility test results from the blood bank) shall be kept with the patient's case notes.

10.4 Duration for Transfusion of Blood

10.4.1 Red cells:

Packed red cells and whole blood should be transfused within 30 minutes of removal from the blood refrigerator. The transfusion of each unit shall not exceed 4 hours.

Note: There is significant risk of bacterial contamination if a unit of red cells is kept at room temperature for too long.

10.4.2 Platelets:

Platelets should be transfused as soon as it is received from the hospital blood bank. The transfusion of each pack should not exceed 30 minutes.

Do not refrigerate platelets. Keep platelets at room temperature (20-24°C).

10.4.3 Plasma

Plasma should be transfused as soon as the thawed unit is received from the hospital blood bank. The transfusion should be carried out at a rate that the patient can tolerate.

10.5 Blood Administration Sets

- 10.5.1 ALL blood and blood components shall be transfused through a blood administration set containing special IV tubing with an integrated filter (170 - 260 micron) to remove blood clots and particles.
- 10.5.2 A mechanism should exist in the IV setup to allow the administration of 0.9% NaCl in the event of transfusion reaction e.g. a “Y” port.
- 10.5.3 The tubing of the administration set shall be primed with 0.9% NaCl or with the component itself.
- 10.5.4 If an administration set has previously been used for the transfusion of red cells, it shall NOT be used for transfusing platelets. A fresh transfusion set shall be used.

10.6 Microaggregate Filters

- 10.6.1 Microaggregate filters retain degenerating platelets, fibrin strands and clumps of red cells of 20-40 micron. These are formed in all blood stored beyond 5-10 days.
- 10.6.2 Microaggregate filters are not used for routine blood administration.
- 10.6.3 These filters are recommended to be used in:
 - a. Cardio-pulmonary bypass.
 - b. Patients with pre-existing lung disease receiving large volume transfusion.

Microaggregate filters shall not be used for granulocyte and platelet transfusions.

10.7 Leukocyte Filters

The reduction of the numbers of leukocytes in red cells can be achieved by using leukocyte filters designated for this purpose.

10.7.1 Leukocyte filters may be used for the following purposes:-

- a. To decrease the incidence of febrile non-haemolytic transfusion reactions.
- b. To reduce the rate of HLA alloimmunization.
- c. To reduce the rate of platelet alloimmunization.
- d. To decrease the incidence of CMV transmission.

Leukocyte filters shall not be used for granulocyte transfusions.

10.8 Blood Warmers

Blood warmers are rarely needed during routine transfusion situations as there is no evidence that warming blood is beneficial to patients when the transfusion is slow (1 unit over 2 hours). Warmed blood minimizes the incidence of hypothermia, cardiac arrest and arrhythmia associated with massive transfusion of cold blood components.

10.8.1 The ward shall ensure that only validated blood warmers are used.

10.8.2 Indications for use:

- a. Massive or rapid transfusion
 - i. >15ml/kg/hr in children
 - ii. >5 ml/kg/hr in adult
- b. Transfusion in neonates e.g. exchange transfusion.
- c. Cold agglutinin syndrome.

When using blood warmers ensure that:

- a. Blood warmers shall be validated before use and maintained regularly.
- b. Each blood warmer shall have a visible thermometer and an audible warning device to detect malfunctions and to prevent haemolysis.
- c. **NEVER** warm blood by placing it in hot water, in microwave, on radiator, under running water or near any uncontrolled heat source.

- d. **NEVER** refrigerate blood, which has been warmed.
- e. Recheck the blood unit against the intended recipient before commencing the transfusion if blood is placed in a common blood warmer.

10.9 Sodium Chloride (0.9%NaCl)/ Normal Saline

- 10.9.1 0.9% NaCl is iso-osmotic with red blood cells. Red cell concentrates may be diluted with 0.9% NaCl to improve the flow rate.
- 10.9.2 Medications or solutions, other than 0.9% NaCl, **SHALL NOT** be administered through the same tubing used for blood transfusion.

The reasons for this are:

- a. *Other solutions may affect the properties of the blood components e.g. Ringer's lactate solution which contains calcium additive can cause citrated blood to clot, and 5% Dextrose solution can cause haemolysis.*
- b. *It may be difficult to determine the cause of an adverse transfusion reaction. (Whether it is due to the blood or blood component, or the medication, or to an interaction of these.)*

- 10.9.3 If administration of medication is required and there is no other venous access available to allow separate administration of medication:
 - a. Stop the transfusion and flush the IV tubing with 0.9% NaCl before administering medication.
 - b. Flush the medication with 0.9% NaCl before resuming transfusion.

10.10 Discontinued Transfusion

- 10.10.1 Any blood remaining from a discontinued transfusion **SHALL NOT** be used.
- 10.10.2 Remnants of blood shall be clearly labelled as **USED BLOOD** and returned to the hospital blood bank immediately.
- 10.10.3 Details and reasons for discontinuing the transfusion shall be clearly documented in the patient's case notes.

10.11 Return of Used Blood Bags

- 10.11.1 The ward shall be responsible to return used blood bags and compatibility card/ label which has been completely filled up to the hospital blood bank within 24 hours.
- 10.11.2 The ward shall correctly and completely fill up a compatibility card/ label.
- 10.11.3 The compatibility card/ label shall contain at least the following information:
 - a. Name of hospital.
 - b. Ward.
 - c. Full name of recipient.
 - d. Identity card/passport number of recipient/hospital registration number of recipient.
 - e. Recipient's blood group (ABO and RhD), age and gender.
 - f. Date of transfusion.
 - g. Time transfusion starts and ends.
 - h. Volume transfused.
 - i. Adverse transfusion reaction, if any.
 - j. Name and signature of staff.
- 10.11.4 The hospital blood bank shall keep the used blood bags in a refrigerator duly marked and designated for this purpose, for 7 days after transfusion.

10.12 Return of Untransfused Blood

- 10.12.1 The ward shall return all untransfused blood immediately to the hospital blood bank. (Refer Appendix 12 for instructions on proper handling of blood and blood component in the ward.)
- 10.12.2 Untransfused blood that is returned to the blood bank shall be discarded unless it is kept in an appropriate condition and temperature.
- 10.12.2 The ward shall inform the hospital blood bank if any of the untransfused blood returned to the blood bank has not complied with the storage or transportation temperature.

11.0 Paediatric Transfusion

The requirement for paediatric transfusion takes into account the ability of the patient to form alloantibodies which is generally from 4 months old and above. Patients less than 4 months may have passive transfer of antibodies from the mother.

11.1 Intrauterine Transfusion

Intrauterine transfusion of red cells is indicated to prevent fetal death due to severe anaemia or haemorrhage. This is generally limited to hospitals which have established facilities for this procedure.

For intrauterine transfusion, the blood shall be:

- Fresh (preferably not more than 5 days old),
- group O RhD positive or negative red cells, depending on maternal ABO and Rh blood group,
- leukodepleted blood by filtration,
- irradiated to prevent Transfusion-Associated Graft-Vs-Host Disease (TA- GVHD), and
- Cytomegalovirus (CMV) negative if indicated.

11.2 Neonatal Transfusion

Volume of blood to be transfused is calculated based on the neonate's body weight.

$$\text{Volume required (mls)} = \text{body weight (kg)} \times \text{Hb rise required (g/dL)} \times \text{transfusion factor (0.4)}$$

- 11.2.1 Blood used for neonatal transfusions shall be compatible with the mother's blood.

The choice of red cells:

- Group O packed cells are generally suitable for top-up transfusion.
- Use infant's own ABO group if crossmatching is done using infant's blood.
- Blood for exchange transfusions in neonatal jaundice cases are as provided in Table 11A below.

11.2.2 Pre-transfusion testing

- a. Samples from mother and neonate should be obtained for the following tests:
 - i. Sample from the mother:
 - Determine the ABO group using both forward and reverse methods.
 - Determine the Rh group.
 - Screen for the presence of unexpected red cell antibodies.
 - ii. Sample from the neonate:
 - Determine the ABO group using forward method only.
 - Determine the Rh group.
 - Perform direct antiglobulin test (DAT).
- b. If the maternal blood is not available, the neonatal serum/plasma shall be screened to exclude unexpected red cell antibodies.
- c. If unexpected red cell antibodies are detected during screening, and/or DAT is positive, investigations shall be performed to further identify the unexpected antibodies.
- d. Crossmatching with the maternal serum/plasma shall be performed. Where maternal serum is not available, infant serum/plasma can be used. However, this is not encouraged.

11.2.3 For neonatal transfusion, the blood shall be:

- a. Fresh (preferably not more than 5 days old).
- b. Leukodepleted by filtration.
- c. Irradiated.

11.2.4 Blood for neonatal transfusion

- a. Red cells
 - i. Red cells in exchange transfusion (ET)

Indications for ET include the management of severe anaemia at birth, particularly in the presence of heart failure and the treatment of severe hyperbilirubinaemia, usually caused by haemolytic disease of newborn (HDN).

In the treatment of HDN, the primary aim is to remove both the antibody-coated red cells and excess bilirubin.

Recommended groups of blood to be used for ETs in cases of neonatal jaundice are as provided below:

Table 11A: Recommended Blood To Be Used Based on Blood Groups of Recipient Neonate and Corresponding Mother

Blood Group of Neonate	Blood Group Of Mother			
	O	A	B	AB
	O	O	O	O
	A	EO	A	EO
	B	EO	EO	B
	AB	EO	A	B

Note: In Malaysia, emergency O blood (EO) is group O RhD positive whole blood with low titres of Anti-A and Anti-B, and negative for haemolysin.

In hospital blood banks which do not have facilities to identify EO by performing haemolysin test, blood group O RhD positive fresh packed cells suspended in fresh AB plasma can be used.

- ii Red cell transfusion for correction of anaemia (“top-up” transfusion)

Anaemia in neonatal period may require blood transfusion. The common causes of anaemia include congenital or acquired disease, and or blood loss from trauma or surgery. Red cells for top up transfusion may not be less than 5 days old.

- b. Platelets and plasma:

Requirements are as per transfusion in adults. It is preferable that all FFP used are pathogen inactivated.

12.0 Transfusion in Special Circumstances

In emergency situation whereby patient is bleeding and in dire need of blood, the choice of blood to be transfused to the patient might be different with regards to its compatibility testing. Whereas for multiply transfuse and transplant patient, the requirement of the blood might be different in view of its preparation such as phenotype blood, filtration and irradiation.

12.1 Transfusion in Cases of Life Threatening Bleeding

Life-threatening bleeding is defined as bleeding that could result in severe morbidity and mortality unless there is prompt intervention. Every hospital shall establish its own protocol and procedures on managing life threatening bleeding cases. Health care personnel who are likely to be involved in such cases must be well versed with the local protocols.

12.1.1 Choice of blood

The choice of blood for transfusion in cases of life threatening bleeding is dependent on the urgency for transfusion and the time available. The options available are:

a. Uncrossmatched Group O RhD positive packed red cells (Safe O)

In Malaysia where RhD negative phenotype is not common, Group O RhD positive packed cells is used as Safe O. Safe O can be used for resuscitation in dire emergency while waiting for group specific or crossmatched blood to be available.

Any decision to use Safe O shall only be made after the clinician has carefully assessed the urgency of the patient's need for blood. The requesting doctor shall clearly state the reasons for the transfusion in the patient's records and in the request form. A sample of the patient's blood shall be taken before the transfusion of Safe O for the purpose of determining the patient's actual blood group, and for subsequent management.

It is recommended that Safe O be made available in the A&E, Labour Room and where necessary

- b. Uncrossmatched group specific packed cells
If the blood group of the patient is known, uncrossmatched group specific blood may be given.
- c. Emergency crossmatch
If the blood is required within 30 minutes, units of blood that are found to be compatible at immediate spin after 5 minute incubation at room temperature may be issued. The hospital blood bank shall proceed to completion of the compatibility testing and antibody screening of the units of blood issued, at 37°C and in the AHG phase. Any incompatibility detected shall be immediately informed to the clinician concerned for appropriate action.

12.1.2 The indication and personnel responsible for deciding the usage of Safe O, uncrossmatched group specific and emergency crossmatch shall be documented in the patient's records and in the request form.

12.1.3 All requests for emergency crossmatch should be accompanied by a phone call to the hospital blood bank to facilitate the process. Details of the communication shall be documented, including the names of the caller and the receiver.

12.2 Transfusion in Thalassaemia and Other Multiply Transfused Patients

Multiply transfused patients are potentially at risks of acquiring alloimmunization and TTI through transfusion.

12.2.1 Baseline data for each potential multiply transfused patient shall be established before starting the transfusion program. This involves:

- a. Phenotyping of red cells, which should include Rh, Kell, Kidd, Duffy and MNSs.
- b. Screening for TTIs.
- c. Screening for red cell antibodies.

12.2.2 Subsequently, screening for TTIs shall also be carried out every 6 months and screening for red cell antibody shall be carried out each time transfusion is required by the patient.

12.2.3 Blood units that are issued shall be ABO and Rh compatible. Phenotype compatible and filtered blood should be considered.

12.2.4 Patients who are immunosuppressed or immunocompromised including bone marrow transplant patients should be given irradiated cellular blood products.

12.3 Transfusion in Stem Cell and Organ Transplant Patients

12.3.1 Transfusion in stem cell transplant patients

Haemolysis due to ABO incompatibility may occur immediately on stem cell infusion (usually with bone marrow transplants that are heavily contaminated with red cells) or be delayed for 7 to 14 days due to production of antibodies by residual host or transplanted lymphocytes (more common with peripheral blood-derived haematopoietic stem cell). It is occasionally life threatening.

Table 12A: Categories of ABO-Incompatible HSC transplant

Categories of ABO-incompatible HSC transplant	
Major ABO incompatibility	The recipient's plasma contains anti-A, anti-B or anti-A,B antibodies that are incompatible with donor red cells (e.g. group A donor and group O recipient)
Minor ABO incompatibility	The donor's plasma contains anti-A, anti-B or anti-A,B antibodies that can react with the recipient's red cells (e.g. donor group O and recipient group A)
Bidirectional ABO incompatibility	Both the donor and recipient's plasma contain anti-A, anti-B or anti-A,B antibodies reactive with recipient and donor red cells respectively (e.g. donor group A and recipient group B)

- a. Selection of blood for transfusion
- Below are table to guide the selection of blood to be crossmatched for transfusion in patients after ABO incompatibility stem cell transplantation.

Table 12B: Recommended ABO Blood Group of Components Transfused in The Early Post Transplant Period

Categories of ABO incompatibility	Donor	Recipient	Red cells	Platelets	FFP
Major ABO incompatibility	A	O	O	A	A
	B	O	O	B	B
	AB	O	O	A	AB
	AB	A	A	A	AB
	AB	B	B	B	AB
Minor ABO incompatibility	O	A	O	A	A
	O	B	O	B	B
	O	AB	O	A	AB
	A	AB	A	A	AB
	B	AB	B	B	AB
Bidirectional ABO incompatibility	A	B	O	B	AB
	B	A	O	A	AB

12.3.2 Transfusion in organ transplant patients

ABO compatible transplant is generally carried out because ABO antigens are present on the vascular endothelium of tissues and organs throughout the body. However, ABO incompatible transplant have been successful using living donors when the recipient's incompatible antibodies are temporarily removed or brought to a low titre by plasma exchange, before surgery.

Transfusion to these patients shall use blood that is ABO compatible. Any additional requirements, such as irradiation, are subject to discussions between the treating clinician and the specialist in hospital blood bank.

12.4 Transfusion in RhD Negative Patients

Blood bank normally stock minimum RhD negative blood for emergency use.

- 12.4.1 Each hospital shall establish its own procedure on managing RhD negative cases.
- 12.4.2 In elective cases involving RhD negative patient, the treating clinician shall inform the hospital blood bank of the case at least five working days prior to the procedure that may require transfusion. This notification is essential to allow the hospital blood bank enough time to source for the required blood.

12.4.3 In emergency situation, where ABO group specific RhD negative blood is not available in time, the hospital blood bank may issue, in order of preference:

- a. Group O RhD negative blood, or
- b. ABO group specific RhD positive blood, only if the patient does not have pre-formed anti-D.

This shall be done only after discussing with and agreed by the treating clinician.

12.4.4 Appendix 14 summarises the steps to follow in transfusion of RhD negative patients.

12.5 Transfusion in Antibody Cases

For cases where antibody is present, refer to the table below for the guide of selection of red cells for transfusion.

**Table 8A: Guide For The Selection of Suitable Red Cell Units
For Transfusion In The Presence of Antibodies**

Specificity	Clinical significance	Selection of units
Rh antibodies	Yes	Antigen negative
Kidd antibodies	Yes	Antigen negative
Duffy antibodies	Yes	Antigen negative
Kell antibodies	Yes	Antigen negative
Anti-S, -s	Yes	Antigen negative
Anti- A1, -P1, -N	Rarely	Red cells compatible by AHG at 370°C
Anti-M	Rarely	Red cells compatible by AHG at 370°C
Anti-M reactive at 370C	Yes	Antigen negative
Anti-Le a , - Le a+b, Anti-Le b	Rarely	Red cells compatible by AHG at 370°C
Anti-Le a , - Le a+b, Anti-Le b reactive at 370C	Yes	Antigen negative

High titre low-avidity antibodies	Unlikely	Seek advice from Reference Laboratory
Antibodies against low/ high frequency antigens	Depends on specificity	Seek advice from Reference Laboratory

12.6 Rare Red Cell Phenotype

Rare red cell phenotypes are those that are not commonly found with incidence of less than 1 in 1000. Examples are:

- i. The absence of a high prevalence antigen or the absence of several antigens within a single blood group system.
- ii. Absence of common antigens.
- iii. Inheritance of an "Inhibitor" gene e.g. Lu(a-b-).
- iv. Null phenotype e.g. Jk(a-b-), Fy(a-b-), Rhnull.

The potential source of rare phenotype blood would be:

- i. Family members
 - Siblings are often the best source of serologically compatible blood.
- ii. Rare donor registry.
- iii. Rare donor registry from other blood centres.
- iv. Frozen red cells.

12.6.1 All blood centres shall have their own rare donor registry and shall report to the National Rare Donor Registry .

12.6.2 In elective cases involving rare red cell phenotype patients, the treating clinician shall inform the hospital blood bank of the case at least five working days prior to the procedure that may require transfusion. This notification is essential to allow the hospital blood bank enough time to source for the required blood.

12.6.3 If the clinical situation allows, autologous RBC transfusions should be considered for patient with rare phenotypes who are expected to need rare blood in the future.

12.6.4 Effort should be made to phenotype the siblings.

12.6.5 Appendix 15 summarises the steps to follow in transfusion of patients with rare phenotype.

Note: For details on the clinical aspects on transfusion in special circumstances, please refer to the Guidelines for the Use of Blood and Blood Products, Ministry of Health. 3rd Edition

13.0 Adverse Transfusion Reaction

Adverse transfusion reaction is an undesirable response or effect in a patient temporarily associated with the administration of blood or blood component.

13.1 General Management

All transfusion reactions shall be investigated and reported as described in Section 18.0.

13.2 Training and Competency

All personnel involved in ordering and administering transfusions shall be trained and assessed in their competency:

- a. Recognizing the signs and symptoms of transfusion reactions, and
- b. Management of transfusion reactions.

13.3 Investigation and Immediate Management

All adverse transfusion reactions shall be managed accordingly.

13.3.1 If an adverse transfusion reaction is detected or suspected, the transfusion shall be stopped immediately. A doctor shall immediately assess and stabilize the patient. Further management depends on the type and severity of the reaction.

13.3.2 To facilitate investigation of an adverse transfusion reaction, the following shall be carried out:

- a. Blood samples (at least 8-10mls) in EDTA shall be taken for :-
 - i. Repeat ABO/Rh grouping.
 - ii. Repeat crossmatching.
 - iii. Direct and indirect antihuman globulin test (Coombs).
 - iv. Urine examination for haemoglobin and red cell.

These specimens shall be accompanied by a request form for investigation of transfusion reaction. Example as in Appendix 18.

- b. In addition, for cases suspected of haemolytic transfusion reactions, further investigation should include full blood picture (FBP), liver function test (LFT) and lactate dehydrogenase (LDH).

13.3.3 The ward shall keep the transfused blood bag and its transfusion set under appropriate conditions to ensure integrity and to avoid microbial contamination. These shall be sent to the hospital blood bank as soon as possible, together with any unused blood bags and the corresponding blood compatibility labels.

14.0 Management of Donors with Reactive TTI Markers

All donors whose blood samples are found to be repeatedly reactive to markers of TTIs during donation shall be counselled and further managed.

14.1 Post-Donation Counselling

- 14.1.1 During a post-donation counselling, a new blood sample shall be taken from the donor for confirmation testing. Risk factors related to the TTI concerned shall be elicited. Details of the counselling sessions shall be fully documented.
- 14.1.2 The donors shall NOT be informed of the screening test results from the donation until the results have been confirmed.

14.2 Managing Blood Donor

Donations that are repeatedly reactive may be confirmed as being of negative, inconclusive or positive status:

- 14.2.1 A negative conclusion on confirmatory testing indicates that the donor is not infected with the specific infection. However, a donor showing repeatedly reactive results on screening and negative results on confirmatory testing should be counselled and temporarily deferred until screen non-reactive on follow-up. The donor can then be accepted for future donations.
- 14.2.2 An inconclusive outcome is usually due to non-specific reactivity not related to the presence of the infectious agent. It is also known as a Biologically False Reactive (BFR) result. The donor should be counselled, deferred for blood donation and followed-up for further investigations.
- 14.2.3 A positive conclusion confirms that the donor is infected and should be deferred from future blood donation, counselled and referred for appropriate medical care. The case shall be notified to the nearest Public Health Officer responsible within 1 week from the date of confirmation, regardless of whether the donor turns up for the post-donation counselling. Details of all confirmed positive donations and particulars of the implicated donor shall be registered without delay into a central registry (*Sistem Pengumpulan Maklumat untuk Pusat Kutipan & Pusat Saringan (SUKUSA)*).

15.0 Management of Seroconverted Donors and Recipient

The management of sereconvert donors and recipients is an important obligation of both the blood transfusion service and the clinicians who ordered the transfusion.

15.1 Seroconverted Donor

A seroconverted donor is one who is confirmed positive for a particular TTI in his current donation but was negative in the previous donation.

- 15.1.1 All donors found to be seroconverted with HIV, Hepatitis B, Hepatitis C or Syphilis shall first be informed and counselled by the doctors at the blood centre, and then referred to the appropriate physician for further management. Refer Appendix 16 for the flowchart on management of seroconverted donor.
- 15.1.2 Upon confirmation of seroconversion of a donor, the blood centre, shall take the following actions concurrently for donor and blood products management:
 - a. Counsel and permanently defer the donor from donating.
 - b. Register the donor in SUKUSA.
 - c. Conduct look back procedure for the last negative donation and donation(s) in the six (6) months period prior to the last negative donation.
 - d. Recall blood component that has not been used.
 - e. Inform the hospital(s) supplied with the previous last negative donation of the seroconverted donor.
 - f. Details of look back investigations of seroconverted donor should be compiled in Seroconvert Donor Notification Form (BTS/SC/1/2016, refer Appendix 22) and kept in each blood centre. A copy of Part 1 of the form shall be completed and sent to NHCC within a month after the donor came for counselling. Upon completion of all investigations, send a copy of the completed form (both Part 1 and Part 2) to the NHCC within a month.

15.1.3 Each hospital shall develop and implement a system for managing recipients that received blood or blood product from seroconverted donor.

Upon notification of a seroconverted donor the hospital blood bank shall:-

- a. Trace transfusion record of recipient/s of the implicated donation/s and inform treating clinician to contact recipient/s for further counseling and testing.
- b. Trace any blood component that are still in their inventory and return to the blood centre immediately.

15.1.4 The team involved in counselling recipients should include at least the treating specialist/consultant and may include a transfusion medicine specialist.

15.1.5 First counselling session with recipient should be carried out as follows (pre-test counselling):

- a. Inform recipient the reason for consultation.
- b. Inform and explain that the blood or blood component transfused was from a donor who recently seroconverted. As a precautionary measure, the recipient needs to be tested to ascertain whether he/she is infected following the transfusion of a possible window period donation. Explain that “window period” IS NOT a laboratory error.
- c. Assess the risk factors of the recipient with respect to the TTI concerned. Try to identify risk factors other than blood transfusion.
- d. Explain about the TTI concerned, including its mode of transmission and potential complications.
- e. Explain about tests available and the interpretation of the results.
- f. Take samples of blood for the implicated infection, and reassure the recipient that the probability of being infected through transfusion is low.
- g. Inform about the precautions to be taken while waiting for the test results. This is to prevent potential transmission from the recipient to others.
- h. Discuss with the recipient the probability of the tests outcome.

15.1.6 Second counselling session should be carried out as follows (post-test counselling):

- a. If test results is negative
 - i. Inform recipient and explain.
 - ii. Reassure the recipient.
 - iii. If necessary, retest after 6 months or implement any follow-up.
- b. If test result is positive to the TTI
 - i. Inform the recipient and explain.
 - ii. Further assess the risk factors other than blood transfusion. If none, explain to blood he or she received was tested negative at the time of donation.
 - iii. Reassure and discuss about the treatment options.
 - v. Refer the recipient to an infectious disease physician. Report transfusion-related adverse event to NHCC using form BTS/HV/3/2016.

15.2 Seroconverted Recipient

A seroconverted recipient is one who is confirmed positive for a particular TTI marker(s) after receiving blood transfusion, but who was negative for that infection prior to the transfusion.

- 15.2.1 Recipients of a transfusion may develop HIV, Hepatitis B, Hepatitis C, Syphilis infection or other possible TTI agent infection resulting from:
 - a. Transfusion of blood that was donated within the window period of the infection, or
 - b. other sources not related to the blood transfusion.
- 15.2.2 However, it is recommended that donors of the blood that has been transfused to the patient in the 12 months period prior to the detection of the infection be contacted for testing. The hospital blood bank shall be informed to identify the blood donors and their status determined (refer Appendix 17).
- 15.2.3 If a blood donor is identified as the source of infection, other recipients of his or her blood should be traced and investigated.

15.3 Investigation and Reporting

- 15.3.1 Blood sample are taken for the suspected infectious disease marker based on the following table:

TYPE OF INFECTION	TEST FOR RECIPIENT
Syphilis	RPR TPPA
Hepatitis B	HBsAg Neutralization (Other supportive test for e.g. Molecular)
Hepatitis C	AntiHCV Line Immunoassay (Other supportive test for e.g. Molecular)
HIV	AntiHIV Particle Agglutination Line Immunoassay (Other supportive test for e.g. Molecular)

- 15.3.2 Investigations and reporting of seroconversions of both donors and recipients shall be carried out as described in Section 18.0 below (Haemovigilance in Blood Transfusion).

16.0 Quality Management in Blood Transfusion Services

16.1 Quality Management System

All blood centres, hospital blood banks and collection centres must establish and implement a quality management system guided by requirements of established standards, guidelines and principles such as MS ISO 15189 and current good manufacturing practice (cGMP). The system must cover all aspects of its activities carried out in all its facilities.

16.2 Essential Elements of Quality

The quality management system must address the following elements of quality:

16.2.1 Management Responsibility

The management of the hospital blood bank must:

- a. Give full commitment and support to the establishment and implementation of its quality management system.
- b. Clearly define its quality policy and quality goals.
- c. Provide adequate resources for all activities within the scope to enable objectives to be met effectively and efficiently.

16.2.2 Organizational Structure and Responsibilities

- a. The organizational structure must be well defined. Lines of authority and responsibility must be clearly spelt out.
- b. A suitably qualified person possessing the necessary skills and expertise should be appointed as a quality manager.
- c. Where feasible, a quality assurance unit should be set up, whose primary function is to coordinate and monitor all quality activities of the organization.

16.2.3 Documents and Records

- a. All relevant processes, procedures and instructions must be adequately documented. These documents and references must be made readily available at the places of work. It is the responsibility of the management to ensure that all staff understand and implement the

- processes, procedures and instructions as documented.
- b. All documents must be duly authorized, and regularly reviewed to ensure they remain current.
 - c. Records of work carried out must be adequately maintained. These records should contain details of work done, the personnel who execute the work and the dates on which the work was carried out.
 - d. An effective system for the control of documents and records must be established and implemented.
 - e. Policies and systems for the archiving of documents and records must be established and implemented. The policies must be in compliance with current regulations and laws.

16.2.4 Personnel and Training

It is the responsibility of the management to ensure that:

- a. Each personnel have a clear job description which includes lines of authority and responsibility.
- b. Each personnel is adequately trained and assessed to be competent in the specified task before being allowed to carry out the task independently.
- c. Each personnel is regularly trained and assessed to ensure continuous competency.
- d. Records of training and assessment of competency are established and systematically maintained.

16.2.5 Premises (Work Environment)

- a. The work environment must be designed and maintained accordingly to facilitate effective and efficient operations.
- b. The work environment must not give rise to any detrimental impact on the quality and safety of products and services
- c. Areas for donation, laboratory tests and processing of blood must be effectively separated from each other.
- d. Access to working areas must be effectively delineated and limited to relevant authorized personnel only.
- e. Effective housekeeping of the work environment must be maintained at all times.

16.2.6 Equipment

- a. All critical equipment that has impact on the quality of tests or blood component prepared must be operated within their defined specifications.
- b. Each blood centre, hospital blood banks and collection centres must have:
 - i. Documented procedure for the purchase of equipment.
 - ii. Procedure for validation and qualification to confirm fitness for purpose which must be performed:-
 - When commissioning new equipment, where full validation data from the manufacturer and approved results of the installation qualification (IQ), operational qualification (OQ) and performance qualification (PQ) must be made available.
 - According to validation plan (e.g. by using risk assessment) after being put in use.
 - Following repairs and relocation, and after a pre-determined period after being put in use (e.g. every 5 years).
 - iii. Effective documented maintenance programs to ensure that all equipments are functioning optimally at all times.
 - iv. Procedures and manuals for the operation and maintenance of all equipment available on site.

16.2.7 Material: Apparatus, Reagents and Chemicals

- a. Materials used in laboratory tests and processing must be appropriately validated by the manufacturer and endorsed by reputable authorities.
- b. Notwithstanding the above, all materials must be first verified/ validated by the blood centres and hospital blood banks before being put into use.
- c. All materials must be stored under appropriate storage conditions as to maintain their integrity.
- d. Procedures for the inspection, acceptance and rejection of materials must be established and implemented.
- e. Records of inventory of materials must also be maintained.

16.2.8 Supplier

Suppliers of materials and services having impacts on the quality of laboratory tests or blood must be periodically evaluated and monitored.

16.2.9 Validation of Processes and Procedures

- a. A policy on validation must be established, and it must clearly define the scope, process and purpose of validation.
- b. The process of validation should commence from the time the decision is made to implement a particular system, process, procedure or test method, or to use a particular facility, equipment or material.
- c. Validation should be carefully planned and conducted in compliance with the established standards, guidelines and principles such as MS ISO 15189 and cGMP.
- d. Data and information generated during the validation and the outcome of the validation must be adequately documented.

16.2.10 Change Control

Change control is a formal process used to ensure that changes to a system, equipment or processes are introduced in a controlled and coordinated manner. It reduces the possibility of unnecessary changes being introduced to the system without forethought, introducing faults into the system or undoing changes made by other units within the organization. The goals of a change control procedure would include minimal disruption to services, reduction in back-out activities, and cost-effective utilization of resources involved in implementing change.

Changes may result from a planned change in a laboratory process or input, a systematic review of a procedure, audit findings, incidents or from complaints. Some laboratory changes e.g. using new equipment of the same type, or relocating a work process may not require any alteration to documented procedures but should still be subjected to change control. However, minor amendments to documented procedures may not need to be subjected to change control but should still be managed through the documented control process.

The blood centres, hospital blood banks and collection centres, must establish a formal procedure for implementing change control:-

- a. The unit or person responsible for the change must initiate the process of change control.

- b. The relevant change should be planned. As the change may involve several stages, adequate records of activities leading to the successful outcome of each stage should be maintained.
- c. After successful completion of all the stages involved, it must be duly reviewed and approved by designated person(s) before the change is implemented.

16.2.11 Internal Audits

- a. Regular internal audits to monitor compliance to the quality management system, current policies and regulatory requirements must be planned and carried out.
- b. Internal auditors should possess good knowledge of the quality system, and should have been trained in auditing.
- c. Wherever feasible, the auditors should audit an area different from where he or she is currently working.
- d. Findings from the internal audits and any actions taken must be documented, analyzed and presented to management for quality improvement.

16.2.12 Continual Quality Improvement

The effectiveness of the quality system and the extent of compliance to the system by the blood centres and hospital blood banks must be regularly reviewed. At the very least, one review meeting is to be conducted each year.

16.2.13 Safety

The blood centres, hospital blood banks and collection centres must establish policies and procedures on safety and security. Relevant committees should be set up to maintain and continually improve safety and security in the organization.

17.0 Hospital Transfusion Committee

The role of a Hospital Transfusion Committee is to ensure safe and appropriate transfusion practices within the hospital. The Hospital Transfusion Committee shall be authorized to take necessary actions to improve transfusion practices within the hospital.

17.1 Members of the Committee

Members of the committee shall include the following:

Chairman	:	Hospital Director
Members	:	Heads of relevant clinical disciplines Representative of the blood centre Head of nursing services or designee
Secretariat	:	Hospital blood bank

17.2 Terms of Reference

17.2.1. Principal Responsibilities:

The Hospital Transfusion Committee shall:

- i Promote best practices in the hospital based on current policies, guidelines and directives.
- ii. Proactively and regularly review transfusion practices of various disciplines in the hospital.
- iii. Promote/organize and/or conduct education and training of all clinical, laboratory and supporting staff involved in blood transfusion.
- iv. Organize regular transfusion audits on the transfusion service to ensure compliance to policies, guidelines and directives.
- v. Ensure all transfusion adverse events such as errors in transfusion process, donor and recipient seroconversion are investigated, analysed and reported.
- vi. Monitor the hospital haemovigilance unit activities. Refer 18.1.2.
- vii. Implement corrective and preventive actions.

- viii. Monitor the use of blood to ensure adequate supply.
- ix. Establish and ensure implementation of contingency plans to cope with periods of shortages of blood, and or unexpected increases in demand for blood such as during disasters.

17.2.2. Meetings:

The committee shall meet at least twice a year. Copies of minutes of the meetings shall be forwarded to its State Transfusion Committee.

18.0 Haemovigilance in Blood Transfusion

Haemovigilance is a surveillance programme covering adverse events occurring during the entire blood transfusion chain from the donation of blood to the follow-up of patients receiving transfusion. The ultimate goal of haemovigilance is to improve patient and donor safety through the detection, reporting, analysis of information on unexpected or undesirable effects, and implementation of corrective and preventive actions.

Transfusion safety must be ensured in every stage, starting from the donor at the time of donation, blood sampling from the patient for pre-transfusion tests as well as blood administration at patient's bedside during time of transfusion and their follow up.

18.1 Hemovigilance Reporting

- 18.1.1 All adverse events relating to blood collection, processing, testing, transfusion processes and outcome of the transfusion including near misses must be reported. Incident related to products and equipment should be included.
- 18.1.2 Each hospital should have a mechanism to collect, compile and analyzedata of all adverse events and deviations relating to collection, processing, testing and transfusion of blood, including near misses.
- 18.1.3 Regular reports shall be submitted to respective Hospital Transfusion Committee (HTC), the State Transfusion Committee (STC) (if applicable) and National Haemovigilance Coordinating Centre (NHCC).
- 18.1.4 The HTC and the STC shall take corrective and preventive actions, and facilitate allocation of adequate resources both at the hospital and at the state level for improving transfusion safety.
- 18.1.5 The National Blood Centre shall act as the NHCC for the Ministry of Health.
- 18.1.6 Confidentiality of reporting to NHCC will be maintained and the identities of the donor, patient and the reporter of the incident and the institution shall not be disclosed to a third party.

18.2 Patient Haemovigilance

Transfusion process involves many important steps that are critical for patient safety. Patient haemovigilance is a surveillance system that monitors the transfusion processes in the clinical area. The process of reporting adverse events shall be as follows:

- 18.2.1 The treating doctor shall send a request for transfusion reaction investigation using the Request Form for Transfusion Reaction Investigation (BTS/TR/2/2016) (Appendix 18) to the hospital blood bank.
- 18.2.2 The hospital blood bank shall then carry out relevant laboratory investigation using the Worksheet for Investigation of Transfusion Reaction (BTS/TRW/2/2016) (Appendix 19). The findings shall be reported to the treating doctor concerned.
- 18.2.3 The treating doctor shall provide a detailed report using the Reporting Form for Transfusion-Related Adverse (BTS/HV/3/2016) (Appendix 20). The report shall include information such as clinical findings, laboratory investigations, personnel involved and corrective actions taken if any (refer to page 3 of 4 and 4 of 4 of the form). This report shall be forwarded to the hospital blood bank within two weeks of the occurrence.
- 18.2.4 It shall be the responsibility of the hospital blood bank concerned to follow up with the ward and doctor concerned to ensure that the transfusion-related adverse event report is delivered within a month to the relevant authorities. Copies of the report shall be sent to the HTC, the STC, and the NHCC. Refer Appendix 21 for flowchart for reporting adverse transfusion event.
- 18.2.5 For Incorrect Blood Component Transfused (IBCT) and Near Miss a detailed report should be submitted to NHCC with root cause analysis together with implemented corrective and preventive action.

18.3 Donor Haemovigilance

Donor haemovigilance is a surveillance system for tracking adverse events associated with blood donation with a view to improve the safety of the donation process. This system allows the collection centres to monitor the prevalence of adverse donor

events, patterns and trends, and find ways to improve blood donation process, which will result in quality donor care and safety thus better donor return.

18.3.1 All unintended reactions related to blood donation, and cases of seroconverted donors shall be reported.

18.3.2 Reporting of adverse donor events shall be as follows:

- a. The medical personnel attending to the donor with adverse donor reaction shall investigate and report the event in the Reporting Form for Adverse Donor Reaction (BTS/DV/2/2016) (Appendix 4). The doctor in charge of the collection centre shall retain this report. Appendices 5 and 6 provide guidance for the description of complications and the grading of severity of donor reactions.
- b. A copy of Reporting Form for Adverse Donor Reaction shall be forwarded to the NHCC, HTC and STC at the end of each month and the original copy will be retained at the collection centre. (Refer Appendix 23 for flowchart for reporting adverse donor reaction).
- c. All seroconverted donors shall be documented using Seroconvert Donor Notification Form (BTS/SC/1/2016) (Appendix 22).
- d. The Seroconvert Donor Notification Form (BTS/SC/1/2016) has to be retained at the respective hospital blood banks. A copy of Part 1 of the form shall be forwarded to NHCC within a month after donor came for post-donation counselling, while a copy of the completed form (Part 1 and Part 2) shall be forwarded to NHCC within a month after the whole investigation is completed. (Refer to 15.1.2.f)

18.4 National Haemovigilance Coordinating Centre

The National Haemovigilance Coordinating Centre shall:

- 18.4.1 Manage the notification of adverse events reports from all hospitals.
- 18.4.2 Prepare annual report with recommendation of appropriate interventions for continual improvement to KKM.
- 18.4.3 Monitor effectiveness of corrective and preventive action taken.

Appendix 1: Guidelines for the Acceptance and Deferral of Donors

Condition	Acceptance Or Deferral Criteria
Abortion	Defer for 6 months.
Acne Medication	Retin A cream - Accept Isotretinoin (Roaccutane®) - Defer for 28 days after last dose Acitretin (Neotigason®) - Defer for 3 years after last dose Etretinate (Tigasone®) - Defer permanently
Acupuncture	Defer for 6 months from date of procedure.
Age limits for blood donation	17 to 70 years old. Accept up to 60 years old for first time donor. May accept regular donor up to 70 years old with annual medical check-up which includes chest X-ray, ECG, LFT, Renal Profile, Fasting Blood Sugar and Full Blood Profile or letter from physician stating that donor is fit to donate. For donors aged 17 years old, written parental/guardian's consent is compulsory.
Alcohol intake	Defer 24 hours if intoxicated. Accept if no intoxication.
Allergy	Accept if mild or symptom free. Defer permanently - History of anaphylaxis - Severe debilitating autoimmune disorders such as systemic lupus erythematosus, dermatomyositis or severe rheumatoid disease - Immunosuppression due to congenital or acquired hypogammaglobulinaemia or immunosuppressive medication (Also see "Immunological diseases")
Anaemia	Accept if past history of iron deficiency anaemia, with a known cause not a contraindication to donation, when treatment completed and fully recovered. Accept individuals with Thalassaemia traits, provided they are well and meet the minimum haemoglobin level for blood donation. Accept if vitamin B12 or folate deficiency when fully recovered and on maintenance treatment. Defer permanently if chronic anaemia of unknown cause or associated with systemic disease.

Condition	Acceptance Or Deferral Criteria
Anaphylaxis	Defer permanently.
Ankylosing spondylitis	Defer permanently.
Arthritis	Accept if osteoarthritis and donor able to climb on and off donation couch without assistance. Defer permanently if systemic diseases affecting joints such as • Rheumatoid disease • Psoriatic arthropathy • Ankylosing spondylitis
Asthma	Accept if asymptomatic, even if on medication other than oral or injected steroid. Defer for 14 days after full recovery from acute exacerbation. Defer for 14 days after completion of a course of oral or injected steroid. Defer permanently if severe asthma requiring regular medication.
Babesiosis	Defer permanently.
Biopsy	Defer for 6 months from date of procedure.
Bleeding disorders	Accept if only family member is affected and donor has no history of prolonged bleeding. (Also see "Coagulation disorders".)
Blood pressure	Accept if within the following range: • Systolic: 100-150 mmHg • Diastolic: 70-100 mmHg
Blood transfusion	Defer for 6 months after transfusion with blood or blood component. Defer for 6 months after immunoglobulin (IVIg) therapy. Defer permanently if on regular treatment with plasma-derived coagulation factors. Defer permanently if ever received a transfusion or injection of blood or blood components while in England, Scotland, Wales, Northern Ireland or the Isle of Man from 1st January 1980 onwards.
Body piercing	Defer for 6 months from date of procedure.
Bronchitis	Defer for 14 days after full recovery from acute attack and completion of treatment.
Brucellosis	Defer permanently.
Burns	Accept if fully healed.

Condition	Acceptance Or Deferral Criteria
Campylobacter	Defer for 28 days after full recovery.
Cancer	See “Malignant diseases”.
Cardiovascular diseases	Accept for surgically corrected simple congenital cardiac malformation with no residual symptoms. Accept for asymptomatic disorder: e.g. functional murmurs, mitral valve prolapsed. Defer permanently all other conditions (e.g. angina pectoris, arrhythmia, coronary artery disease, heart failure).
Central nervous system diseases	Defer permanently: • Epilepsy or history of seizure • Dementia or neurodegenerative disease due to any cause • Multiple sclerosis or other demyelinating diseases
Cerebrovascular diseases	Defer permanently.
Chagas disease (American trypanosomiasis)	Defer permanently.
Chancroid	Defer permanently.
Chickenpox	Defer for 14 days after full recovery from infection. Defer for 21 days after last day of close contact with individual with the disease.
Chikungunya virus	Defer for 6 months after full recovery.
Childbirth	Defer for 6 months post-delivery. (Also see “Pregnancy”)
Cholecystitis	Accept after fully recovered.
Coagulation disorders	Defer permanently if coagulation factor deficiencies whether inherited or acquired.
Coeliac disease	Accept if fully treated .
Colitis	Accept if irritable bowel syndrome without debility. Defer any active inflammatory bowel disease unless well and in long-term remission.
Common cold	Defer for 7 days after full recovery.
Cosmetic treatment (invasive)	Defer for 6 months from date of procedure. (Also see “Injection”)

Condition	Acceptance Or Deferral Criteria
Creutzfeldt-Jakob disease (CJD)	Defer permanently sporadic and familial CJD and first-degree relatives. Defer permanently if history of treatment with pituitary-derived human growth hormone, human gonadotrophin, dura mater graft, corneal transplantation, neurosurgery. (Also see "Variant CJD")
Crohn's disease	Defer if active disease. Accept if well and in-long term remission.
Cupping (Bekam)	Defer for 6 months from date of procedure for wet cupping (bekam darah). Accept if dry cupping or fire cupping.
Dementia	Defer permanently.
Dengue fever	Defer for 6 months after full recovery.
Dental treatment	Defer for 24 hours after simple procedures. Defer for 7 days after extraction or endodontic procedures. Defer for 6 months after dental surgery.
Depression	Accept if feeling well. (Also see "Psychiatric disorders")
Dermatitis	See "Skin diseases".
Dermatomyositis	Defer permanently.
Diabetes mellitus	Accept diabetes mellitus controlled by diet or oral medication provided no history of orthostatic hypotension and no evidence of infection, neuropathy or vascular disease. Defer permanently if requires insulin treatment or has complications with multi-organ involvement.
Diagnostic procedures	Defer following minor diagnostic procedure including rigid endoscopy until normal activity resumed. Defer for 6 months after invasive diagnostic procedure using flexible endoscopy.
Diarrhoea	Accept 14 days after full recovery and completion of therapy, including antibiotics. Accept for chronic diarrhoea due to irritable bowel syndrome without debility; otherwise defer. Defer for 28 days if symptoms suggestive of Yersinia enterocolitica.
Diverticular disease	Accept if well and asymptomatic.

Condition	Acceptance Or Deferral Criteria
Drug use	Injecting drug use: - Defer permanently individuals with history of drug use by injection Non-injected drug use: - Defer for 6 months from last in-take of the substance.
Eczema	Accept if lesions not infected and venepuncture site unaffected.
Epilepsy	Defer permanently.
Epstein-Barr virus	Defer for 28 days after full recovery.
Erythrocytosis	See "Polycythemia".
Essential thrombocythaemia	Defer permanently.
Fever (non-specific)	Defer for 14 days after full recovery.
Foreigner	Defer for 12 months after entry into Malaysia and after re-entry following prolonged (>1 month) travel outside of Malaysia.
Fracture	Defer until plaster is removed and mobility returns to normal.
Gastritis	Accept if well and asymptomatic.
Gallstones	Accept if well and asymptomatic.
Gastroenteritis	Defer for 28 days after full recovery.
Gastro-oesophageal reflux	Accept mild cases, if well and asymptomatic.
Gonorrhoea	Defer permanently.
Gout	Defer for 7 days after acute attack.
G6PD deficiency	Accept if no history of haemolysis Red cells however are not to be used. Defer permanently if there is history of haemolysis.
Haemochromatosis	Accept if well and asymptomatic.
Haemoglobin level	Accept if haemoglobin level is between 13.5 to 18.0 g/dl for male and 12.5 to 18.0 g/dl for female.
Haemoglobinopathies	Defer permanently if thalassaemia major, thalassaemia intermedia or sickle cell disease, including sickle cell trait.
Haemophilia	Defer permanently.

Condition	Acceptance Or Deferral Criteria
Hepatitis A, hepatitis E and hepatitis of unknown origin	Defer for 12 months after full recovery.
Hepatitis B	Defer permanently individuals who are Chronic Hepatitis B carrier or has been diagnosed with Occult Hepatitis B Infection (OBI). <u>Recovered from Hepatitis B infection:</u> • Accept 12 months after full recovery (i.e. negative for HBsAg) with anti-HBs of >100mIU/ml and blood is screened by NAT. • Current sexual partner may also be accepted 12 months after full recovery. <u>Living with person with active Hepatitis B infection:</u> • Defer while still living in the same home. • Accept if immunised for Hepatitis B with anti-HBs >100mIU/ml and negative for anti-HBc. • Former household may be accepted 6 months after last contact. <u>Family history of Hepatitis B (siblings, father, mother):</u> • Permanent deferral if new donor. • Accept repeat donor if negative for both HBsAg and anti-HBc, or if anti-HBc positive must have anti-HBs >100mIU/ml. <u>Sexual contact:</u> • Defer current sexual contact. • Current sexual partner may be accepted 12 months after full recovery. • Former sexual partner may be accepted 12 months after last sexual contact.
Hepatitis C	Defer permanently. <u>Recovered from Hepatitis C infection:</u> • Permanent deferral. <u>Living with person with Hepatitis C:</u> • Accept. <u>Family history of Hepatitis C (siblings, father, mother):</u> • Accept. <u>Sexual contact:</u> • Defer current sexual partner. • Defer 12 months since last sexual contact for former sexual partner.
Herpes viruses	Defer for 28 days after full recovery (except HHV8 infection). Defer for 28 days for contacts of symptomatic individuals (except HHV8 infection). Defer permanently individuals with HHV8 infection, and current or former sexual contacts of individuals with HHV8 infection.

Condition	Acceptance Or Deferral Criteria
Hiatus hernia	Accept mild cases, if well and asymptomatic.
High-risk behaviours	Defer permanently: • Men who have sex with men (MSM). • Individuals who make or receive payment in exchange for sex, including sex workers and their clients. • Drug users by injections (IVDUs), including body building drugs. • Live the lifestyle of having casual sex or having multiple sexual partners.
HIV/AIDS	Defer permanently. <u>Living with person with HIV:</u> • Accept <u>Sexual contact:</u> • Defer permanently current and former sexual partners
HTLV	Defer permanently individuals with evidence of HTLV infection. <u>Living with person with HTLV infection:</u> • Accept. <u>Family history of HTLV (mother or maternal grandmother):</u> • Defer permanently. <u>Sexual contact:</u> • Defer permanently current and former sexual partner.
Hypertension	Accept if stable and uncomplicated hypertension controlled by medication. Defer if recently started on or changed anti-hypertensive medication until 28 days after blood pressure stabilized. Defer permanently if • Complicated with heart or renal disease. • On ACE Inhibitor (ACE inhibitor is potentially teratogenic [teratogenic drugs-defer 6 months after last dose]).
Hypogammaglobulinaemia	Defer permanently.
Immunisation	Accept • Toxoids and non-live vaccines (e.g. Diphtheria, Polio, Pneumococcal, Rabies, Tetanus and Typhoid) – if well and asymptomatic. Defer • 48 hours for recombinant virus vaccines (e.g. HBV, HPV, H1N1 vaccines, influenza). • 14 days for attenuated virus (live) vaccine such as HBV vaccine. • 28 days for Rubella vaccine. • 12 months for Rabies vaccine (post-exposure).

Condition	Acceptance Or Deferral Criteria
Immunological diseases	Accept individuals with mild conditions, such as vitiligo or mild rheumatoid arthritis without systemic symptoms. Defer permanently individuals with: - Severe debilitating autoimmune disorders such as systemic lupus erythematosus, dermatomyositis or severe rheumatoid disease. - Immunosuppression due to congenital or acquired hypogammaglobulinaemia or immunosuppressive medication, with the exception of individuals with IgA deficiency. - History of anaphylaxis. (Also see "Allergy")
Infections (acute bacterial)	Accept 14 days after full recovery and completion of antibiotic treatment. Defer for 28 days following full recovery and completion of treatment if symptoms suggestive of infection with salmonella, campylobacter, streptococcus or staphylococcus. (Also see "Medical conditions")
Influenza	Accept asymptomatic individuals with no close contact with those having active infection. Defer asymptomatic close contacts for 7 days after last day of contact. Defer for 14 days after full recovery and cessation of any therapy. Defer for 48 hours after influenza vaccination.
Injection	Defer for 6 months after any injection for cosmetic purposes such as Botox, Vitamin C and Collagen injection. Defer for 6 months for case of needle stick injury.
Interval between donations	Between whole blood donations - Minimum 8 weeks from last donation date. - Maximum of 6 WB donation per year for male and 4WB donation per year for female. Between apheresis (platelet, plasma) donations - Minimum 2 weeks after last donation date. - Not exceeding 15 liters/year. Between whole blood to apheresis donation - Minimum 8 weeks from last donation date. Between apheresis to whole blood donation - Minimum of 2 weeks from last donation date. Following apheresis donation with red cell loss - Defer for 8 weeks if more than 100ml loss. Apheresis donor who did not donate for more than 6 months - Accept as whole blood donor first before resuming apheresis donation.

Condition	Acceptance Or Deferral Criteria
Iron deficiency	See “Anaemia”.
Irritable bowel syndrome	Accept, if well and without debility.
Lactating women	Defer during lactation.
Leishmaniasis	Defer permanently individuals who have ever been diagnosed with leishmaniasis. Defer for 12 months individuals who have spent extended periods in endemic areas.
Leukaemia	Defer permanently.
Lyme disease	Defer for 28 days after full recovery and completion of treatment, whichever is longer.
Lymphoma	Defer permanently.
Malaria	Defer for 6 months after completion of treatment and full recovery whenever is longer. Defer for 4 weeks after completion of malarial prophylaxis.
Malabsorption syndromes	Defer permanently except treated coeliac disease.
Malignant diseases	Defer permanently.
Medical conditions	Abscess/ Boils - Defer for 28 days after full recovery. Bronchitis - Defer for 14 days after full recovery. Chickenpox - Defer for 14 days after full recovery. - Defer close contacts for 21 days after last day of contact. Cystitis - Defer for 14 days after full recovery. Dengue fever - Defer for 6 months after full recovery. Diphtheria - Defer for 3 months after full recovery. Dysentery - Defer for 28 days after full recovery. Emphysema - Permanent deferral. Encephalitis - Defer for 6 months after full recovery.

Condition	Acceptance Or Deferral Criteria
Medical conditions	Gastroenteritis - Defer for 28 days after full recovery. Hay fever - Defer for 28 days after full recovery. H1N1 - Defer for 28 days after full recovery. - Defer close contacts for 14 days after last day of contact. Infectious mononucleosis (Glandular fever) - Defer for 6 months after full recovery. Measles - Defer for 14 days after full recovery. - Defer close contacts for 21 days after last day of contact. Meningitis - Defer for 6 months after full recovery. Migraine - Defer until fully recovered. - Defer permanently if severe or frequent. Mumps - Defer for 14 days after full recovery. - Defer close contacts for 21 days after last day of contact. Osteomyelitis - Defer for 6 months after full recovery. Pancreatitis - Defer for 6 months after full recovery. Phlebitis - Defer for 6 months after full recovery. Pneumonia - Defer for 6 months after full recovery. Pneumothorax - Defer for 6 months after full recovery. Poliomyelitis - Defer for 6 months after full recovery. Pyelitis - Defer for 3 months after full recovery. Raynaud's disease - Defer permanently. Rubella - Defer for 14 days after full recovery. - Defer close contacts for 21 days after last day of contact. Scarlet fever - Defer for 28 days after full recovery. Schistosomiasis - Defer for 6 months after full recovery.

Condition	Acceptance Or Deferral Criteria
Medical conditions	Sore throat - Defer for 7 days after full recovery. Tetanus - Defer for 6 months after full recovery. Thyphus - Defer for 6 months after full recovery. Tonsillitis - Defer for 14 days after full recovery. Toxoplasmosis - Defer for 14 days after full recovery. Trypanosomiasis (African) - Defer for 14 days after full recovery. Typhoid - Defer for 6 months after full recovery. Yersinia enterocolitica - Defer for 28 days after full recovery.
Medications	Take account of indication for treatment. Allopurinol - Accept. Antibiotics - Defer for 2 weeks after last dose. - Defer permanently if on prophylactic antibiotics following splenectomy. Anticoagulants (other than warfarin) - Defer for 1 week after last dose. Anti-depressants - Accept. Anti-histamines - Accept. Anti-malarial prophylaxis - Defer for 4 weeks after last dose. Anti-platelets (e.g. aspirin, clopidogrel, ticlopidin) - Defer for 2 weeks after last dose. - May be accepted but not for platelet preparation. Glucosamine - Accept. Hormone replacement therapy - Accept if taken for menopausal symptoms, osteoporosis prevention or fertility treatment. - Defer permanently if human-derived hormone, for replacement of adrenal steroid hormones or for treatment of malignancy. Hypnotics - Accept.

Condition	Acceptance Or Deferral Criteria
Medications	NSAIDs - Defer for 24 hours after last dose. Paracetamol - Accept (subject to reason for taking medication). Statins - Accept. Steroids - Defer for 1 week after last dose of oral or parenteral medication. - Accept if inhaled or used topically. Supplements - Accept, unless known side-effect. Teratogenic drugs - Defer for 6 months after last dose. Tigasono - Defer permanently. Topical/locally applied medication (e.g. eye drops, ear drops, nasal spray) - Accept.
Menstruation	Defer for first 3 days. Accept from 4th day onward.
Mucosal splash with blood	Defer for 6 months from the time of exposure.
Multiple sclerosis	Defer permanently.
Musculoskeletal disorders	Accept acute or chronic mild disorders (e.g. mild rheumatoid arthritis, back pain, sciatica, frozen shoulder, osteoarthritis) if the individual's mobility unaffected. Defer permanently if systemic disease affecting joints: e.g. severe rheumatoid arthritis, psoriatic arthropathy, ankylosing spondylitis. (Also see "Arthritis")
Myelodysplastic syndrome	Defer permanently.
Nephritis	Lower urinary tract infections - Defer for 14 days after full recovery and completion of treatment. Acute nephritis - Defer until fully recovered and renal functions returned back to normal. (Also see "Renal disease")
Operation	See "Surgery".
Peptic ulcer	Accept if asymptomatic with or without maintenance therapy. Defer if symptomatic or if still under investigation. Defer permanently if associated with underlying malignancy.

Condition	Acceptance Or Deferral Criteria
Platelet disorders	Defer permanently if cause is unknown or associated with long term haematological or systematic disorders.
Polycythaemia	Secondary polycythaemia Accept if the secondary cause does not lead to deferral. Defer permanently if polycythaemia rubra vera.
Pregnancy	Defer during pregnancy and 6 months following delivery or termination. See also “Childbirth”.
Prisons and penal institutions	Defer inmates of prison and penal institutions. Acceptance of individuals with history of imprisonment requires close assessment of risk of transfusion transmitted infection.
Prostate problems	Accept if benign prostate hyperplasia (BPH) not on treatment. Defer if on treatment: - Dutasteride: defer for 6 months after stopping. - Finasteride: defer for 28 days after stopping. Defer permanently if associated with malignancy.
Psoriasis	Accept individuals with mild psoriasis provided lesions not infected, no systemic symptoms, venepuncture site not affected, or not receiving immunosuppressive or retinoid therapy. Otherwise defer. (See also “Skin disease”)
Psoriatic arthropathy	Defer permanently.
Psychiatric disorders	Accept anxiety disorder and mood (affective) disorder such as depression provided in generally good health and able to answer questionnaire and give informed consent. Defer permanently psychotic disorder (e.g. bipolar, schizophrenia) requiring treatment.
Red cell membrane defects	Accept if no history of haemolysis. Defer permanently if history of haemolysis. (Also see “G6PD deficiency”)
Renal diseases	Acute self-limiting condition (e.g. acute nephritis) - Accept when fully recovered and renal function normal. Chronic renal disease - Defer permanently.

Condition	Acceptance Or Deferral Criteria
Respiratory diseases	Acute respiratory infection - Defer for 14 days following full recovery and completion of therapy, including antibiotics. Defer permanently - Breathlessness at rest or minimal exertion or if cyanosed. - Severe obstructive airways disease (including if on long-term oral steroid therapy). - Chronic or recurrent respiratory infection.
Rubella infection	Defer for 14 days after full recovery. Close contacts Defer for 21 days after last day of close contact.
Salmonella infection	Defer for 28 days following full recovery.
Sarcoidosis	Defer permanently.
Scleroderma	Defer permanently.
Seizure	Defer permanently.
Severe Acute Respiratory Syndrome (SARS)	Defer for 28 days after full recovery. Close contacts Defer for 14 days after last day of contact with individual diagnosed with SARS or suspected to have SARS.
Shingles	Defer permanently.
Sexual activity	Defer permanently sexual partner to: - Men who have sex with men (MSM). - Individuals who make or receive payment in exchange for sex, including sex workers and their clients. - Drug users by injections (IVDUs), including body building drugs. - Individuals who live the lifestyle of having multiple sexual partners. - Individuals diagnosed with HIV/ AIDS, HTLV, HHV8. Defer - Current sexual partner to individuals with HIV, hepatitis B, hepatitis C or syphilis. - For 12 months from date of sexual contact following change of sexual partner. - For 12 months from date of sexual contact with the new wife in a polygamous marriage. Accept - Former sexual partner to individuals with hepatitis B, hepatitis C or syphilis 12 months after last sexual contact.

Condition	Acceptance Or Deferral Criteria
Sickle cell disease	Defer permanently, including sickle cell trait.
Skin diseases	Accept mild common skin disease (e.g. acne, eczema, psoriasis) if lesions not infected and venepuncture site is not affected. Defer if generalized skin disease and on systemic medication. Defer if contagious skin disease. Defer permanently if systemic disease affecting skin (e.g. scleroderma, systemic lupus erythematosus, dermatomyositis, systemic cutaneous amyloidosis).
Snake bite	Accept after fully recovered. Defer for 6 months if given anti-venom.
Streptococcus infection	Defer for 28 days following full recovery. Defer for 14 days following full healing of superficial but significant wounds.
Stroke	Defer permanently.
Surgery	Defer for 6 months following minor or major surgery. Defer permanently following neurosurgical procedure, dura mater graft or corneal transplant.
Syphilis	Defer permanently if ever been diagnosed with syphilis. Sexual contact - Defer current sexual partner. - Defer 12 months since last sexual contact for former sexual partner.
Systemic lupus erythematosus	Defer permanently.
Tattoos	Defer for 6 months from date of procedure.
Thalassaemia	Accept thalassaemia trait provided well and haemoglobin above required lower limit. Defer permanently for thalassaemia major and thalassaemia intermedia. (Also see “Haemoglobinopathies”).
Thrombocytopenia	Accept past history of acute autoimmune thrombocytopenia (ITP) more than 5 years previously, if well and not on treatment. Defer permanently if thrombocytopenia of unknown cause or associated with long-term haematological or systemic disease.
Thrombophlebitis	Accept if had only a single episode in the last 12 months, otherwise well and off treatment for at least 7 days. Defer permanently - Affects the upper limb. - Two or more episodes in the last 12 months.

Condition	Acceptance Or Deferral Criteria
Thrombosis	Defer permanently.
Thyroid disorders	Accept if benign disorder and euthyroid (with or without treatment). Defer if under investigation for thyroid disease, if hyper- or hypo-thyroid, or with a history of malignant thyroid tumours. Defer permanently if history of thyrotoxicosis due to Graves' disease.
Transient cerebral ischaemic episodes	Defer permanently.
Transplantation	Defer for 12 months after full recovery following transplantation of allogeneic tissues. Defer permanently if transplanted with allogeneic cells or tissue sourced since 1980 from a country at risk of vCJD. Defer permanently following stem cell or organ transplantation, dura mater graft, corneal transplant or xenograft.
Tuberculosis	Defer for 5 years following confirmation of cure.
Ulcerative colitis	Defer if active disease. Accept if well, in long-term remission and meet the minimum haemoglobin level of blood donation.
Urinary tract diseases	Accept lower urinary tract infections 14 days after full recovery and completion of treatment.
Variant Creutzfeldt-Jakob disease (vCJD)	Defer permanently if ever suspected or diagnosed with variant Creutzfeldt-Jakob disease (vCJD). Defer permanently if ever visited or lived in the United Kingdom (England, Northern Ireland, Ireland, Wales, Scotland, the Isle of Man, the Channel Island) or the Republic of Ireland for a cumulative period of 6 months or more between 1st January 1980 to 31st December 1996. Defer permanently if ever visited or lived in the following European countries* for a cumulative period of 5 years or more between 1st January 1980 until now. (*Austria, Belgium, Denmark, Finland, France, Germany, Greece, Holland, Italy, Liechtenstein, Luxembourg, Norway, Portugal, Spain, Sweden and Switzerland.)
Vitiligo	Accept.
Weight	Accept for whole blood donation if weight is 45kg or more. Accept for apheresis donation if weight is 55kg or more.

Condition	Acceptance Or Deferral Criteria
West Nile virus (WNV)	Individuals who have known WNV infection or symptoms suggestive of WNV. • Defer for 6 months from date of full recovery. Defer for 28 days following return from visit to endemic area and asymptomatic.
Yersinia enterocolitica infection	Defer for 28 days following full recovery if recent abdominal symptoms, particularly diarrhoea, suggestive of Y. enterocolitica infection.

Appendix 2

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 **BORANG PENDAFTARAN PENDERMA DARAH**
PERKHIDMATAN TRANSFUSI DARAH
KEMENTERIAN KESIHATAN MALAYSIA



Nama : _____

No. KP Baru : [] [] [] [] [] [] - [] [] - [] [] [] []

No. KP Polis/Askar : [] [] [] [] [] []

Tarikh Lahir : [] [] / [] [] / [] [] [] []

Umur : [] [] Tahun

Bangsa : ☐ Melayu ☐ Cina ☐ India ☐ Lain-lain (nyatakan) _____
☐ Iban ☐ Kadazan ☐ Melanau
☐ Murut ☐ Bidayuh ☐ Bajau

Status Perkahwinan : ☐ Bujang ☐ Berkahwin ☐ Duda/Janda/Bercera

Pekerjaan : _____ E-mel : _____

No. Tel. Rumah : _____ No. HP : _____

No. Tel Pejabat : _____ Faks : _____

Alamat Rumah : _____

Sekarang/Semasa : _____

Negeri : _____ Poskod : _____

Alamat Surat Menyurat : _____

Negeri : _____ Poskod : _____

PERHATIAN : ADAKAH DARAH ANDA SELAMAT UNTUK DIDERMAKAN?

Terima kasih kerana dengan sukarela tampil untuk menderma darah anda. Darah yang anda dermakan dapat membantu menyelamatkan nyawa.

Kami sentiasa berusaha memastikan darah yang diberi kepada pesakit adalah selamat. Untuk itu semua darah yang didermakan akan diuji untuk mengesan jangkitan Hepatitis B dan C, HIV dan Sifilis. Walaupun bagaimanapun, ada kalanya ujian-ujian ini gagal mengesan darah yang baru sahaja dijangkiti. Akibatnya darah yang dijangkiti ini mungkin akan diberi kepada pesakit tanpa disedari.

Oleh sebab itu, bagi membantu kami memastikan darah yang didermakan adalah selamat untuk digunakan, anda diminta untuk membaca dengan teliti kenyataan di bawah sebelum anda menderma darah.

Anda DIMINTA UNTUK TIDAK MENDERMA DARAH jika anda:

- tahu atau syak diri anda dihidapi HIV, penghidap/pembawa Hepatitis B atau Hepatitis C, atau dijangkiti Sifilis atau Penyakit Kelamin yang lain.
- mengamal atau pernah mengamalkan gaya hidup BERTUKAR-TUKAR PASANGAN SEKS
- lelaki yang pernah melakukan hubungan seks dengan lelaki lain (HOMOSEKSUAL/BISEKSUAL)
- pernah membayar atau menerima bayaran untuk hubungan seks
- pernah melakukan hubungan seks dengan pekerja seks komersil (pelacur)
- pernah mengambil dadah terlarang secara suntikan
- pernah melakukan hubungan seks dengan sesiapa daripada mana-mana golongan di atas

Anda juga diminta supaya **JANGAN** menderma darah dengan tujuan untuk menguji darah anda. Ujian darah boleh dilakukan di mana-mana Klinik Kesihatan yang berhampiran. Jika anda mempunyai sebarang soalan, sila bertemu Pegawai Perubatan bertugas untuk bantuan.

"DARAH YANG SELAMAT BERMULA DENGAN SAYA"

SOALSELIDIK KELAYAKAN PENDERMA DARAH

"Mana-mana penderma darah yang didapati memberikan pengakuan yang tidak benar berkaitan dengan tingkah laku gaya hidup mereka yang berisiko tinggi, akan didakwa di Mahkamah mengikut undang-undang yang sedang berkuatkuasa"

Sebelum anda teruskan dengan soalselidik ini, sila baca dan fahamkan kenyataan di muka hadapan. Jawab soalan-soalan berikut dengan menanda 'x' di kotak jawapan yang bersesuaian.

	Ya	Tidak
1. Adakah anda berasa sihat hari ini?	☐	☐
2. Adakah anda menderma untuk menguji darah anda untuk HIV, Hepatitis dan/atau Sifilis?	☐	☐
3. Pernahkah anda menderma darah sebelum ini? Jika ya, pernahkah anda hadapi masalah semasa atau selepas menderma? Jika ya, sila nyatakan _____	☐	☐
4. Dalam tempoh seminggu yang lepas, pernahkah anda: a) Mengambil sebarang ubat-ubatan? Jika ya, sila nyatakan _____ b) Menghidap demam, selsema dan/atau batuk? c) Diserang sakit kepala atau migrain? d) Mendapatkan rawatan doktor untuk sebarang masalah kesihatan? Jika ya, sila nyatakan _____	☐	☐
5. Adakah anda sedang menghidap / pernah menghidap / sedang dirawat / pernah dirawat untuk sebarang masalah kesihatan berikut?	Ya	Tidak
• Sakit kuning / Jaundis • Hepatitis B atau Hepatitis C • HIV • Penyakit Kelamin / Sifilis • Malaria • Sakit Buah Pinggang • Asma / Lelah	☐	☐
* Jika ya, sila nyatakan _____		
6. Adakah sesiapa di dalam keluarga anda pernah menghidap atau sedang dirawat untuk penyakit Hepatitis B atau Hepatitis C? Jika ya, sila nyatakan hubungan anda dengan beliau _____	☐	☐
7. Dalam tempoh 6 bulan yang lalu, pernahkah anda: a) Menjalani sebarang rawatan pembedahan? b) Menerima pemindahan (transfusi) darah? c) Mendapat kecederaan akibat tusukan jarum tanpa sengaja?	☐	☐
8. Pernahkah anda menerima suntikan imunisasi atau sebarang bentuk suntikan untuk kecantikan (cth: botox, kolagen) dalam tempoh 4 minggu yang lepas? Jika ya, sila nyatakan jenis dan/atau tujuan _____	☐	☐
9. Pernahkah anda mendapat rawatan pergigian dalam tempoh 24 jam yang lepas?	☐	☐
10. Pernahkah anda bertindik di mana-mana bahagian badan (body piercing), bertatu (tattooing), berbekam atau menjalani akupunktur dalam tempoh 6 bulan yang lepas?	☐	☐
11. Adakah di dalam tempoh 24 jam yang lepas anda telah mengambil minuman beralkohol sehingga memabukkan?	☐	☐
12. Pernahkah anda menerima rawatan: a) Suntikan hormon tumbesaran manusia (human growth hormone)? b) Pemindahan (transplantasi) kornea? c) Pemindahan (transplantasi) selaput otak (duramater)? d) Pemindahan (transplantasi) sum-sum tulang atau sel stem (stem cell)?	☐	☐

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13. Risiko jangkitan variant Creutzfeldt-Jakob Disease (vCJD)
- | | Ya | Tidak |
|---|--------------------------|--------------------------|
| a) Pernahkah anda melawat atau menetap di United Kingdom (England, Ireland Utara, Wales, Scotland, Isle of Man, Channel Island) atau Republik Ireland untuk tempoh terkumpul 6 bulan atau lebih di antara 1hb Januari 1980 hingga 31hb Disember 1996? | ☐ | ☐ |
| b) Pernahkah anda menerima transfusi atau suntikan darah atau produk darah sewaktu berada di United Kingdom di antara 1hb Januari 1980 hingga sekarang? | ☐ | ☐ |
| c) Pernahkah anda melawat atau menetap di negara-negara Eropah berikut* untuk tempoh terkumpul 5 tahun atau lebih di antara 1hb Januari 1980 hingga sekarang?
(*Austria, Belanda, Belgium, Denmark, Finland, Greece, Jerman, Itali, Liechtenstein, Luxembourg, Norway, Perancis, Portugal, Sepanyol, Sweden dan Switzerland) | ☐ | ☐ |

14. Demi keselamatan pesakit, soalan-soalan berikut PERLU dijawab dengan JUJUR, walaupun ia hanya melibatkan anda sekali sahaja. Anda dikehendaki menjawab soalan-soalan berikut di hadapan doktor atau pegawai KKM yang menemuduga anda.

- | | Ya | Tidak |
|---|--------------------------|--------------------------|
| a) Jika anda lelaki, pernahkah anda melakukan hubungan seks dengan lelaki lain? | ☐ | ☐ |
| b) Pernahkah anda melakukan hubungan seks dengan pekerja seks komersil (pelacur)? | ☐ | ☐ |
| c) Pernahkah anda membayar atau menerima bayaran untuk seks? | ☐ | ☐ |
| d) Pernahkah anda mempunyai lebih daripada seorang pasangan seks? | ☐ | ☐ |
| e) Adakah anda mempunyai pасаhаn seks baru dalam tempoh 12 bulan yang lalu? | ☐ | ☐ |
| f) Pernahkah anda menyuntik diri anda dengan dadah yang terlarang, termasuk dadah bina badan? | ☐ | ☐ |
| g) Adakah pasangan seks anda tergolong di dalam mana-mana kategori di atas? | ☐ | ☐ |
| h) Adakah anda atau pasangan seks anda pernah diuji positif untuk HIV? | ☐ | ☐ |
| i) Adakah anda rasa anda atau pasangan seks anda mungkin dijangkiti HIV? | ☐ | ☐ |

Saya, nama seperti di borang ini, mengesahkan bahawa saya faham SEMUA soalan di atas seperti yang DIJELASKAN kepada saya dan saya MENGAKU bahawa saya telah menjawabnya dengan BENAR dan JUJUR.

(Tandatangan Penderma)

(Nama & Tandatangan Penemuduga)

Tarikh : _____

Tarikh : _____

15. Untuk dijawab oleh penderma wanita sahaja
- | | Ya | Tidak |
|---|--------------------------|--------------------------|
| a) Adakah anda sedang kedatangan haid sekarang? | ☐ | ☐ |
| b) Adakah anda mengandung atau mungkin mengandung? | ☐ | ☐ |
| c) Adakah anda mempunyai anak yang masih menyusu-badan? | ☐ | ☐ |
| d) Pernahkah anda melahirkan anak atau keguguran dalam tempoh 6 bulan yang lepas? | ☐ | ☐ |

PENGAKUAN DAN KEBENARAN PENDERMA

(untuk ditandatangani di hadapan doktor atau pegawai KKM yang menemuduga anda)

Saya, nama seperti di borang ini:-

- Mengaku bahawa jawapan untuk SEMUA soalan di atas adalah benar.
- Sedar bahawa saya tidak boleh menderma darah saya jika saya tergolong di dalam mana-mana kumpulan individu yang berisiko untuk dijangkiti HIV/Hepatitis/Sifilis (rujuk PERHATIAN di muka 1).
- Dengan sukarela membenarkan pengambilan darah / komponen darah saya dan penggunaannya bagi ujian untuk HIV, Hepatitis B, Hepatitis C dan Sifilis, dan untuk tujuan lain yang difikirkan perlu oleh Pusat Perkhidmatan Darah, Hospital dan Kementerian Kesihatan Malaysia.
- Faham bahawa semua maklumat yang diberi dan keputusan ujian adalah sulit.

(Tandatangan Penderma)

(Nama & Tandatangan Penemuduga)

Tarikh : _____

Tarikh : _____

Mukasurat 3 / 4

UNTUK DIISI OLEH KAKITANGAN KKM BERTUGAS

Nombor Pengenalan Pendermaan (Barkod) : _____

Jenis Penderma : ☐ Penderma Baru
☐ Penderma Tetap/Berulang
☐ Penderma Lama (*Lapsed*)
☐ Penderma Autologus

Tarikh Akhir Pendermaan : / /

Jumlah Pendermaan : _____

Status Kelayakan Penderma (cth. SUKUSA, BBIS) :

☐ Layak ☐ Tidak Layak

Tarikh Pendaftaran : / /

Didaftarkan Oleh : _____
 (Nama & T/Tangan Kakitangan)

Pemerhatian / Ujian	Keputusan	Nama & T/Tangan Kakitangan
Berat Badan (kg)		
Kumpulan Darah		
Paras Hb (g/dL) (*sila nyatakan jika berkenaan)	☐ ≥ 12.5 g/dL ☐ < 12.5 g/dL *Nilai Hb : _____ g/dL	
Kiraan Platelet Pra-pendermaan (pendermaan platelet aferesis)	_____ $\times 10^9$ /L	
Tekanan Darah (mmHg)		

Individu yang namanya seperti di borang ini telah ditemuduga, diperiksa dan diuji, dan didapati:
 (sila tandakan $\checkmark$)

☐ LAYAK UNTUK MENDERMA

☐ TIDAK LAYAK UNTUK MENDERMA

☐ Darah Utuh ☐ Aferesis
☐ Triple Bag ☐ Plasma
☐ Double Bag ☐ Platelet
☐ Single Bag ☐ Lain-lain (nyatakan)
☐ Filter Bag

Sebab : _____

Status Tidak Layak :

☐ Kekal
☐ Sementara

Tempoh : _____

Isipadu : ml

Nama & T/Tangan Kakitangan : _____

Proses Pendermaan Darah		Nama & T/Tangan Kakitangan
Venepuncture Dilakukan Oleh :		
Ubat Pelali Diberi? :	☐ Ya ☐ Tidak	
Masa Pendermaan Bermula :	Masa	
Sampel Diambil? :	☐ Ya ☐ Tidak	
Masa Pendermaan Berakhir :	Masa	
Baki Barkod (Pengenalan Pendermaan) :	Jumlah : _____	
Nota / Komen (jika ada) :		



**BLOOD DONOR REGISTRATION FORM
BLOOD TRANSFUSION SERVICE
MINISTRY OF HEALTH MALAYSIA**

PDN 3/2014



Name	_____														
New IC No.	_____ - _____ - _____	For Non-Citizen Only Passport No : _____ Country : _____													
Police/Army IC No.	_____														
Date of Birth	____/____/____														
Age	____ Years Old	Gender :	☐ Male ☐ Female												
Ethnicity	<table border="0"> <tr> <td>☐ Malay</td> <td>☐ Chinese</td> <td>☐ Indian</td> <td>☐ Others (specify) _____</td> </tr> <tr> <td>☐ Iban</td> <td>☐ Kadazan</td> <td>☐ Melanau</td> <td></td> </tr> <tr> <td>☐ Murut</td> <td>☐ Bidayah</td> <td>☐ Bajau</td> <td></td> </tr> </table>			☐ Malay	☐ Chinese	☐ Indian	☐ Others (specify) _____	☐ Iban	☐ Kadazan	☐ Melanau		☐ Murut	☐ Bidayah	☐ Bajau	
☐ Malay	☐ Chinese	☐ Indian	☐ Others (specify) _____												
☐ Iban	☐ Kadazan	☐ Melanau													
☐ Murut	☐ Bidayah	☐ Bajau													
Marital Status	☐ Single ☐ Married ☐ Widowed/Divorced														
Occupation	_____	E-mail	_____												
Home Tel. No.	_____	H/P No.	_____												
Office Tel No.	_____	Fax	_____												
Current Home Address	_____														
	State : _____ Postcode : _____														
Postal Address	_____														
	State : _____ Postcode : _____														

ATTENTION : IS YOUR BLOOD SAFE TO BE DONATED?

Thank you for volunteering to donate your blood. The blood that you donate could help save lives.

We always strive to ensure that the blood given to patients is safe. For that, all donated blood is tested for evidence of infections by Hepatitis B and C, HIV and Syphilis. However, occasionally these tests are unable to detect blood that has only recently being infected. As a result, the infected blood may unknowingly end up being given to patients.

Therefore, in order to help us ensure that the blood donated is safe for transfusion, you are requested to carefully read the statement below before donating your blood.

You are **ASKED NOT TO DONATE BLOOD** if you:

- know or suspect you may have HIV, suffering from/carrier of **Hepatitis B** or **Hepatitis C**, or being infected with **Syphilis** or other **Sexually Transmitted Disease (STD)**
- lead or had led a life style involving **CHANGING MULTIPLE SEXUAL PARTNERS**
- are a man who have had sex with another man (**HOMOSEXUAL/BISEXUAL**)
- have ever made payment or received payment for having sex
- have had sex with commercial sex worker (prostitute)
- have had taken illegal drugs intravenously
- have ever had sex with anyone from any of the above group

You are also asked **NOT TO** donate just to test your blood. Blood test can be performed at any nearby Health Clinic. If you have any questions, do not hesitate to ask our Medical Officer on duty for help.

"SAFE BLOOD BEGINS WITH ME"

BLOOD DONOR ELIGIBILITY QUESTIONNAIRES

"Any blood donor who is found to make false declaration pertaining to his or her high risk lifestyle behaviours will be prosecuted in Court under the existing laws"

Before you proceed with the questionnaires, please read and understand the statement on the front page. Answer the following questions by ticking ☐ in the appropriate boxes.

	Yes	No
1. Are you feeling healthy and well today?	☐	☐
2. Are you donating today to test your blood for HIV, Hepatitis and/or Syphilis?	☐	☐
3. Have you donated blood before?	☐	☐
If yes, have you had any problem during or after the donation?	☐	☐
If yes, please specify _____		
4. In the past one week, have you:		
a) Taken any medication?	☐	☐
If yes, please specify _____		
b) Suffered from fever, cold and/or cough?	☐	☐
c) Suffered from headache or migraine?	☐	☐
d) Seek treatment from a doctor for any health problem?	☐	☐
If yes, please specify _____		
5. Are you suffering from / have ever suffered from / undergoing treatment for / had been treated for any of the following health problems?		
	Yes	No
• Jaundice	☐	☐
• Hepatitis B or Hepatitis C	☐	☐
• HIV	☐	☐
• STDs / Syphilis	☐	☐
• Malaria	☐	☐
• Renal Disease / Renal Failure	☐	☐
• Asthma	☐	☐
• Tuberculosis	☐	☐
• Diabetes	☐	☐
• Hypertension	☐	☐
• Heart Disease	☐	☐
• Mental illness	☐	☐
• Epilepsy	☐	☐
• Others*	☐	☐
*If yes, please specify _____		
6. Has anybody in your family been diagnosed with or currently being treated for Hepatitis B or Hepatitis C?	☐	☐
If yes, please state your relationship with him/her _____		
7. In the last 6 months, have you :		
a) Underwent any surgical procedure or operation?	☐	☐
b) Received any blood transfusion?	☐	☐
c) Had any accidental needle stick injury?	☐	☐
8. Have you received any immunisation injection or any type of injection for beauty (e.g. botox, collagen) within the past 4 weeks?	☐	☐
If yes, please specify type and/or purpose _____		
9. Have you had any dental treatment in the past 24 hours?	☐	☐
10. Have you had any body piercing, tattooing, blood-letting / cupping (berbekam) or acupuncture done within the past 6 months?	☐	☐
11. In the past 24 hours, have you taken any alcoholic drink until you were drunk or intoxicated?	☐	☐
12. Have you ever received:		
a) Injection with human growth hormone?	☐	☐
b) Cornea transplant?	☐	☐
c) Brain membrane (duramater) transplant?	☐	☐
d) Bone marrow or stem cell transplant?	☐	☐

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13. Risk of infection with variant Creutzfeldt-Jakob Disease (vCJD)
- | | Yes | No |
|---|--------------------------|--------------------------|
| a) Have you ever visited or lived in the United Kingdom (England, Northern Ireland, Ireland, Wales, Scotland, the Isle of Man, the Channel Island) or the Republic of Ireland for a cumulative period of 6 months or more between 1st January 1980 and 31st December 1996? | ☐ | ☐ |
| b) Have you ever received a transfusion or injection of blood or blood product while in the United Kingdom between 1st January 1980 until now? | ☐ | ☐ |
| c) Have you ever visited or lived in the following European countries* for a cumulative period of 5 years or more between 1st January 1980 until now?
(*Austria, Belgium, Denmark, Finland, France, Germany, Greece, Holland, Italy, Liechtenstein, Luxembourg, Norway, Portugal, Spain, Sweden and Switzerland) | ☐ | ☐ |

14. For patient safety, the following questions SHALL be answered HONESTLY, even if you were only involved in it once. You are required to answer the following questions in front of the assigned doctor or officer from MOH who interviews you.

- | | Yes | No |
|---|--------------------------|--------------------------|
| a) If you are a man, have you ever had sex with another man? | ☐ | ☐ |
| b) Have you ever had sex with commercial sex worker /prostitute? | ☐ | ☐ |
| c) Have you ever paid or received payment in exchange for sex? | ☐ | ☐ |
| d) Have you ever had more than one sexual partner? | ☐ | ☐ |
| e) Have you had any new sexual partner(s) within the past 12 months? | ☐ | ☐ |
| f) Have you ever injected yourself with illegal drugs, including drugs for body building? | ☐ | ☐ |
| g) Does your sexual partner belong to any of the above categories? | ☐ | ☐ |
| h) Have you or your sexual partner ever been tested positive for HIV? | ☐ | ☐ |
| i) Do you think you or your sexual partner may be tested positive for HIV? | ☐ | ☐ |

I, name as stated on this form, hereby confirm that I understand ALL the above questions as EXPLAINED to me and I DECLARE that I have answered them TRUTHFULLY and SINCERELY.

(Donor's Signature)

(Interviewer's Name & Signature)

Date : _____

Date : _____

15. To be answered by female donors only
- | | Yes | No |
|--|--------------------------|--------------------------|
| a) Are you having your menstrual period? | ☐ | ☐ |
| b) Are you pregnant or may be pregnant? | ☐ | ☐ |
| c) Do you have a child that is still breast-feeding? | ☐ | ☐ |
| d) Have you given birth or had a miscarriage in the past 6 months? | ☐ | ☐ |

DONOR DECLARATION AND CONSENT

(to be signed in front of the MOH's doctor or staff who interviews you)

I, name as stated on this form:-

- Declare that the answers to ALL of the above questions are true.
- Realise that I shall not donate my blood if I belong to any of the groups of individuals at risk of contracting HIV/Hepatitis/Syphilis (refer to ATTENTION on page 1).
- Voluntarily give permission for my blood/blood component to be withdrawn and used in testing for HIV, Hepatitis B, Hepatitis C and Syphilis, and in what other manner deemed appropriate by the Blood Service Centre, Hospital and the Ministry of Health, Malaysia.
- Understand that all information given and the test results will be kept confidential.

(Donor's Signature)

(Interviewer's Name & Signature)

Date : _____

Date : _____

TO BE FILLED IN BY MOH'S STAFF ON DUTY

Donation Identification Number (Barcode): _____

Type of Donor : ☐ New Donor
☐ Regular/Repeat Donor
☐ Lapsed Donor
☐ Autologous Donor

Last Donation Date :

Total Donation : _____

Donor Eligibility Status (e.g. SUKUSA, BBIS) :

☐ Eligible ☐ Not Eligible

Registration Date : / /

Registered By : _____
 (Staff's Name & Signature)

Observation / Tests	Results	Staff's Name & Signature
Body Weight (kg)		
Blood Group		
Hb Level (g/dL) (*please state where appropriate)	☐ ≥ 12.5 g/dL ☐ < 12.5 g/dL *Hb value : _____ g/dL	
Pre-donation Platelet Count (apheresis platelet donation)	_____ $\times 10^9$ /L	
Blood Pressure (mmHg)		

The individual named on this form has been interviewed, examined and tested, and is found to be:
 (please mark $\checkmark$)

☐ ELIGIBLE TO DONATE

☐ NOT ELIGIBLE TO DONATE

☐ Whole Blood ☐ Apheresis
☐ Triple Bag ☐ Plasma
☐ Double Bag ☐ Platelet
☐ Single Bag ☐ Others (specify) _____
☐ Filter Bag

Reason : _____

Deferral Status :

☐ Permanent

☐ Temporary

Duration : _____

Volume : ml

Staff's Name & Initial : _____

Blood Donation Process		Staff's Name & Signature
Venepuncture Performs By :		
Anaesthetic Given? :	☐ Yes ☐ No	
Time Donation Start :	Time Start :	
Sample Taken? :	☐ Yes ☐ No	
Time Donation End :	Time End :	
Remaining Barcodes (Donation Identification) :	Total : _____	
Notes / Comment (if any) :		

Appendix 3 - Management of Adverse Reactions in Blood Donors

(a) Mild Vasovagal Reaction

- Discontinue the donation process.
- Raise the donor's legs and lower the head to improve the blood circulation to the brain (Trendelenburg Position).
- Alert the doctor in charge as soon as possible for further management.
- Loosen any tight fitting clothing and keep the donor cool and provide sufficient ventilation.
- Check donor's blood pressure, pulse rate and respiratory rate.
- After sufficient period of rest and improvement, encourage oral fluid intake.
- Observe the donor till full recovery.
- Reassure the donor and explain to the donor what has occurred.
- Advise the donor that if symptoms persist, they should contact the blood bank for further consultation.

(b) Moderate Vasovagal Reaction without Convulsions

Institute all the steps as in (a) for mild vasovagal reaction, following which additional management steps should be taken as follows

- Check the blood pressure, pulse rate and respiratory rate every 5 minutes until donor recovers.
- Maintain privacy of the donor.
- Administer intravenous fluids (e.g. normal saline or 5% dextrose saline infusion) if hypotension is prolonged.
- Health personnel should remain with the donor during this period.
- Advise the donor not to donate blood in future.

(c) Moderate or Severe Vasovagal Reactions with Convulsions

Institute all the steps as in (a) for mild vasovagal reaction, following which additional management steps should be taken as follows:

- Alert the doctor in-charge immediately for further management.
- Turn the donor to a lateral position and maintain a clear airway.

- Check the blood pressure, pulse rate and respiratory rate every 5 minutes until donor recovers.
- Gently restrain the donor to prevent any injury.
- Maintain privacy of donor.
- When the seizure aborts spontaneously, take blood samples for the following investigations:
 - Random Blood Sugar.
 - Renal Profile.
 - Serum Calcium, Magnesium, Phosphate.
 - Full Blood Picture.
- If the convulsion last longer than 5 minutes (status epilepticus), this is a medical emergency.
 - At a collection centre, intravenous valium may be given by the doctor in-charge.
 - At the mobile unit, the donor shall be sent to the nearest hospital immediately, accompanied by the doctor.
 - Referral to a neurologist may be necessary.
- Allow sufficient amount of period for rest and provide refreshments before allowing the donor to leave the premise.
- The donor shall be referred to the nearest hospital if there is any evidence of poor or slow recovery.
- Advise the donor not to donate blood again (permanent deferral).
- Advise the donor and/or family member that if convulsion reoccurs at home, the donor shall be taken to the nearest hospital for further management.
- Follow up with the donor the next day and arrange for an appointment to assess the condition of the donor and for review of the blood investigation results.

(d) Haematoma

- Release the tourniquet pressure immediately and discontinue the donation process.
- Apply firm pressure on the venepuncture site.
- Apply a cold compression over the haematoma.
- Apply a local analgesic gel over the affected area to reduce the swelling and bruising, and which is to be continued to be applied at home.

- Prescribe oral analgesic for moderate discomfort.
- Advise the donor to refrain from lifting any heavy objects till haematoma resolves.
- Advise donor that if the area becomes unduly painful they should contact the blood bank doctor immediately.

(e) Local Nerve Injury

- Release the tourniquet pressure immediately and discontinue the donation process.
- Observe for any haematoma as it could be one of the causative factors.
- Prescribe oral analgesic if the pain is severe and/or persistent.
- Advise the donor to refrain from lifting any heavy objects till symptoms resolve.
- Local nerve injury is almost always transient. However advise the donor to return to the blood bank if the symptoms persist or worsen as referral to a neurologist may be indicated.

(f) Arterial Puncture

- Release the tourniquet pressure immediately and discontinue the donation process.
- Apply firm pressure on the venepuncture site after the withdrawal of the needle and maintain the compression pressure for a minimum of 15 minutes.
- Raise the affected limb above the level of the heart.
- When the bleeding has stopped, apply a compression bandage and instruct the donor to keep it on for 6 hours.
- Prescribe oral analgesic for moderate discomfort.
- Advise the donor to refrain from lifting any heavy objects till symptoms resolve.
- Advise donor that if the area becomes unduly painful they should contact the blood bank doctor.
- If the arterial bleeding is suspected to be continuing, the donor shall be referred to nearest hospital.
- Follow up with the donor the next day to assess the condition of the donor.

(g) Citrate Toxicity (In Apheresis Donation)

- Evaluate the level of severity by assessing the symptoms.
- Reduce the ACD level by decreasing the ratio of ACD flow into machine if the symptoms are mild.
- Encourage oral fluid intake.
- Observe the donor for 10 minutes.
- If symptoms persist or worsen, alert the doctor in-charge for assessment of the level of severity and further management.
- Give more fluid and prescribe 2 tablets of calcium lactate 500 mg to be taken immediately.
- Terminate the apheresis procedure if necessary.
- Take blood samples for the following investigations:
 - Renal profile
 - Liver function test
 - Serum calcium, magnesium, phosphate
- The donor shall be sent to the nearest hospital for further management, accompanied by a doctor if there is no improvement after instituting the above measures.
- Arrange for an appointment to assess the condition of the donor and to review the blood investigation results.

(h) Delayed Adverse Reaction

- If the donor develops an adverse donor reaction within the premise of the blood collection centre or mobile unit, the donor shall be managed accordingly as above (refer (a) to (g)).
- If the adverse donor reaction occurs away from the premise of blood donation, advise the donor to go to the nearest clinic or hospital for further management.

Appendix 4

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REPORTING FORM FOR ADVERSE DONOR REACTION

IMPORTANT INFORMATION

1. Every adverse event related to blood or blood component donation shall be managed, investigated and documented accordingly.
2. The blood collection personnel shall fill up this form **immediately** after any adverse donor reaction. The head of the blood collection centre shall ensure that this form is filled up correctly.
3. Completed original form shall be retained at the respective blood collection centre and a copy to be sent to the National Haemovigilance Coordinating Centre, National Blood Centre every month.

SECTION A: DONOR DETAILS

Name :	NRIC / Passport No:
Gender : ☐ Male ☐ Female	Telephone:
Weight (kg):	Barcode:
Date of donation:	Number of previous donations:
Place of donation:	
Collection centre:	State:

SECTION B: DONATION DETAILS

Type of donation : ☐ Whole Blood ☐ Apheresis Machine: ()	
Time start:	Time end:
Time of Reaction:	Time of recovery:
Volume collected :	Donation terminated early: ☐ Yes ☐ No
Previous history of reactions: ☐ Yes ☐ No	
If yes, please describe:	

SECTION C: TYPE OF REACTION (Tick ✓ where applicable)

Type of Reactions*			Grading of Severity*		
			Mild	Moderate	Severe
Local Symptoms	Blood Outside Vessels		Haematoma		
			Arterial Puncture		
			Delayed Bleeding		
	Arm Pain	Specified as	Nerve irritation		
			Nerve injury		
		or not specified	Other Arm Pain		
	Localised infection/ inflammation of vein or soft tissue		Thrombophlebitis		
			Cellulitis		
	Other Major Blood Vessel Injury		Deep Vein Thrombosis (DVT)		
			Arteriovenous Fistula		
			Compartment Syndrome		
			Brachial Artery Pseudoaneurysm		
Generalised symptoms	Vasovagal Reaction		Immediate		
			Immediate with injury		
			Delayed		
			Delayed with injury		
Related to Apheresis Donation			Citrate reaction		
			Haemolysis		
			Air embolism		
Allergic Reactions			Local Allergic Reaction		
			Generalized (anaphylactic) reaction		
Other Serious Complications Related to Blood Donation			Acute Cardiac symptoms (other than Myocardial Infarct or cardiac arrest)		
			Myocardial Infarct		
			Transient Ischemic Attack (TIA)		
			Cerebrovascular accident		
Others					

Table adapted from Standard for Surveillance of Complications Related to Blood Donation by the Working Group on Complications Related to Blood Donation, International Society of Blood Transfusion and Working Party on Haemovigilance, European Haemovigilance Network (2014)

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SECTION D: MANAGEMENT (To be filled if necessary)

Vital Sign	Pre Donation	During Reaction	Post Recovery
BP (mmHg)			
Pulse (/ min)			

SECTION E: INVESTIGATIONS (for citrate toxicity, moderate/severe vasovagal reactions)

(e.g.: Sodium, Potassium, Calcium, Phosphate & Magnesium Level, RBS, RP and LFT)

RESULTS
☐ Normal ☐ Abnormal

If abnormal please specify: _____

SECTION F: DONOR OUTCOME

G1. Recovered with no ill effects ☐

G2. Recovered with illness ☐ specify if any: _____

G3. Death ☐

SECTION G: FOLLOW UP

Reported by :	Verified by
Designation :	Designation
Date :	Date:

Appendix 5 - Description of Adverse Events

A. Complications Mainly with Local Symptoms

These complications are directly caused by the insertion of the needle. Some of these are mainly characterized by occurrence of blood outside vessels, whereas others are mainly characterized by pain.

A1. Complications Mainly Characterized by the Occurrence of Blood Outside the Vessels

Haematoma (bruise)

Definition: A haematoma is an accumulation of blood in the tissues outside the vessels.

Mechanism: The symptoms are caused by blood flowing out of damaged vessels and accumulating in the soft tissues. For apheresis procedures, haematomas may also be caused by infiltration of the soft tissues by red cells during the return phase of the procedure. Large haematomas, particularly those in deeper layers of the forearm, put pressure on surrounding tissues and may contribute to other complications such as nerve irritation and injury and more rarely compartment syndrome.

Signs and symptoms: Bruising, discolouration, swelling and local pain. Accumulation of blood in deeper tissues may result in more serious pain and pressure syndromes listed below.

Arterial puncture

Definition: Arterial puncture is a puncture of the brachial artery or of one of its branches by the needle used for bleeding the donor.

Mechanism: Because of the rapid blood flow, the risk of a large haematoma is increased and thereby risks of more serious pain and pressure syndromes listed below.

Signs and symptoms: A lighter red colour than usual of the collected blood can be seen. The needle and tubing may appear to pulsate; the blood bag fills very quickly. There may be weak pain localized to the elbow region.

Delayed bleeding (re-bleeding)

Definition: Leakage of blood from the venepuncture site after the initial bleeding has stopped.

Mechanism: Re-bleeding may be related to pressure not being applied to the correct location or for an adequate duration, or premature removal of the bandage. After the donor has left the clinic, re-bleeding may be related to heavy lifting or strain to the donor's arm. Donors on certain medications, such as autologous donors on anticoagulants, may be at higher risk to re-bleed.

Signs and symptoms: Spontaneous recommencement of bleeding from the venepuncture site, after pressure has been applied and the initial dressing has been removed, or leaking through the dressing.

A2. Complications Mainly Characterized by Pain

Nerve injury/irritation

Definition: Injury or irritation of a nerve.

Mechanism: A nerve may be hit directly by the needle at insertion or withdrawal, or there may be pressure on a nerve due to a haematoma or inflammation of the soft tissues. Include medically diagnosed cases, as well as cases reported on the basis of documented 'nerve' type symptoms.

Signs and symptoms: Radiating, often 'electrical' sharp pain moving away from the venepuncture site, and/or paraesthesias such as tingling, burning sensations in the hand, wrist or shoulder area but away from the venepuncture site. Symptoms may arise immediately when the needle is inserted or withdrawn. In cases associated with a haematoma, pain may not be apparent at the time and may start when the haematoma has reached a sufficient size, some time after insertion of the needle. Symptoms may be worse in certain positions or with certain arm motions. Rarely, weakness of the arm may develop.

Other painful arm

Definition: Pain in the arm is the primary symptom, without the characteristics of nerve irritation outlined above, or the presence of a large hematoma or other defined complications that may be painful.

Mechanism: Pain may be related to tissue injury, possibly due to hematoma in the deeper tissues.

Signs and symptoms: Pain in the arm, without characteristics of nerve irritation. May be described as an ache or heaviness in the arm, similar to that experienced after vaccination. Include all cases where arm pain is the main symptom, unless a diagnosis of nerve injury/irritation is suspected in the presence of nerve type symptoms recognised by trained staff.

A 3. Localised Infection/Inflammation

Localised infection/inflammation

Definition: Inflammation along the course of a vein, which may progress to localised infection several days after phlebotomy. There may be clotting in the vein.

Mechanism: Tissue damage and introduction of surface bacteria into the deeper tissues with venepuncture. The superficial vein itself (thrombophlebitis) or the surrounding subcutaneous tissue (cellulitis) may be predominantly affected.

Signs and symptoms: Warmth, tenderness, local pain, redness and swelling at the site of phlebotomy. The site and the vein may feel tender, firm, and warm to the touch. Fever may be present.

Thrombophlebitis: The redness, swelling, and tenderness extend along the course of the vein.

Cellulitis: The redness, swelling and tenderness affect the soft tissues, and are not localised to the course of the vein.

A4. Other Major Blood Vessel Injury

These rare, serious conditions must always be medically diagnosed.

Deep venous thrombosis (DVT)

Definition: Thrombosis of a deep vein in the donor's phlebotomy arm.

Mechanism: Superficial venous thrombosis may progress into the deeper veins of the donor's arm. DVT may also rarely occur without previous signs and symptoms of superficial thrombosis. An additional risk factor for thrombosis, in particular, the use of oral contraceptives, may be present in these donors.

Symptoms and signs: Swelling and pain in the upper arm. May be accompanied by symptoms of superficial inflammation and thrombosis (see above).

Arteriovenous fistula

Definition: Acquired connection between the vein and artery due to venepuncture lacerations.

Mechanism: A channel forms between the lacerated vein and artery immediately post-venepuncture, or in the healing process. May be related to arterial puncture.

Signs and symptoms: Pulsating mass with a palpable thrill and associated bruit. The affected area may be warm, and the distal part of the arm may be cool if significant shunting of blood is present. The distal veins may be dilated and may pulsate.

Compartment syndrome

Definition: Increased intracompartment pressure leading to muscle and soft tissue necrosis.

Mechanism: Blood may accumulate in the frontal deep areas of the forearm, closing small blood vessels and resulting in muscle and nerve tissue necrosis. May be related to arterial puncture.

Signs and symptoms: Painful arm, particularly on movement; swelling, paresthesias and partial paralysis.

Brachial artery pseudoaneurysm

Definition: Collection of blood outside an artery, contained by adventitia or the surrounding tissues alone.

Mechanism: After a traumatic arterial puncture, blood may leak out of the artery and accumulate in the surrounding space.

Signs and symptoms: Pulsating mass in the arm. May be accompanied by pain and paraesthesias. May be preceded by a large hematoma following arterial puncture.

B. Complications mainly with generalized symptoms: vasovagal reactions

Definition: A vasovagal reaction (VVR) is a general feeling of discomfort and weakness with anxiety, dizziness and nausea, which may progress to loss of consciousness (faint). It is the most common acute complication related to blood donation.

Mechanisms: Both physiologic and psychological factors may be important. The reaction is generated by the autonomic nervous system and further stimulated by psychological factors and the volume of blood removed, relative to the donor's total blood volume.

Signs and symptoms: Usually several of the following: discomfort, weakness, anxiety, light-headedness/dizziness, nausea, chills, sweating, vomiting, pallor, hyperventilation, rapid or a slow pulse.

Hypotension and loss of consciousness (LOC) may occur and can be accompanied by loss of bladder or bowel control or convulsive movements. Reactions may occur before phlebotomy (rare), during phlebotomy or immediately after phlebotomy,

when the donor stands up, in the refreshment area, or after the donor has left the collection site. Most reactions occur within 12 hours of phlebotomy. Reactions accompanied by LOC carry a risk of injury, particularly if they occur once the donor has left the collection site (delayed vasovagal reactions).

Vasovagal reactions are divided in two main subgroups:

With injury - Injury caused by falls or accidents in donors with a vasovagal reaction

Without injury

Location of reaction:

Immediate: On collection facility* - Symptoms occurred before donor has left the donation site

Delayed: Outside collection facility - Symptoms occurred after donor has left the donation site

*in area within which staff can observe the donor and be responsible for the care of donors with complications

C. Complications Related to Apheresis

Citrate reaction

Definition: Neuromuscular hyperactivity related to reduced ionized calcium levels.

Mechanism: Infusion of citrate anticoagulant during apheresis causes a fall in ionised calcium levels, leading to neuromuscular hyperactivity. If untreated, symptoms may progress to tetany and severe cardiac arrhythmias, including cardiac arrest. Operator error with mix up of saline and citrate bags may occur with some apheresis equipment, and lead to rapid citrate infusion.

Symptoms and signs: Numbness or tingling of lips, feelings of vibrations, numbness or tingling in the fingers, metallic taste, chills, shivering, light-headedness, feeling of tightness, muscle twitching, rapid or slow pulse, shortness of breath.

Symptoms may progress to carpopedal spasms and vomiting, and in severe reactions, to generalised muscle contractions (tetany), shock, irregular pulse and cardiac arrest.

Haemolysis

Definition: Donor red cells may be damaged, releasing haemoglobin.

Mechanism: There may be malfunctioning valves, kinks or obstruction of the tubing, incorrect installation of equipment, or other equipment failures affecting the extracorporeal circuit. Incompatible replacement fluids, such as dextrose D5W, may be used in error.

Signs and symptoms: Pink or red plasma, blood in lines or filter may appear dark. The donor may notice pink or red urine after collection.

Air embolism

Definition: Air bubble introduced into the donor's circulation.

Mechanism: Air may enter into the lines due to incomplete priming of lines, as a result of a machine malfunction or defective collection kits or through incorrect manipulation by staff. Air in the donor's pulmonary circulation may occlude the pulmonary arteries in the lung and cause cardiopulmonary symptoms. Air may pass to the arterial circulation through an atrial septal defect, and reduce blood flow to the brain.

Signs and symptoms: Bubbling sound or feeling at the venipuncture site. Cough, dyspnea, apprehension, sweating, chest pain, confusion, tachycardia, hypotension, nausea and vomiting.

D. Allergic reactions

Allergy (local)

Definition: Red or irritated skin at the venipuncture site.

Mechanism: Reaction caused by allergens or irritants in solutions used for disinfection of the arm (such as iodine or chlorhexidine) or in manufacture of the collection set. Irritation may also occur due to application of the adhesive bandage (bandage adhesive dermatitis). An allergic reaction to latex that may be in supplies such as gloves may also occur.

Signs and symptoms: Itching and redness at the venepuncture site, the bandage site, or the entire skin disinfection area. In a true allergic reaction, there may be a raised rash or hives in these areas that may expand to cover a larger area of the arm. The reaction may occur soon after donation or in the hours to days post-donation.

Generalised allergic reaction (anaphylactic reaction)

Definition: Anaphylactic type reactions usually starting soon after the procedure is begun and may progress rapidly to cardiac arrest.

Mechanism: Extremely rare reactions, attributed to donor sensitivity to ethylene oxide gas used to sterilize some collection kits.

Signs and symptoms: Apprehension, anxiousness, flushing, swelling of eyes, lips or tongue, cyanosis, cough, wheezing, dyspnea, chest tightness, cramps, nausea, vomiting, diarrhoea, tachycardia, hypotension, and altered mentation.

E. Other Serious Complications Related to Blood Donation

Major cardiovascular event (MCE)

Acute cardiac symptoms (other than myocardial infarction or cardiac arrest).

Myocardial infarction.

Cardiac arrest.

Transient Ischemic Attack.

Cerebrovascular accident.

Death.

Reporting is encouraged of MCE or death from any cause up to 24 hours after donation, with an assessment of imputability. Only cases with definite, probable or possible imputability should be included in international reporting. Major cardiovascular events, including death, may occur in the hours after attending the collection centre for blood donation. This can occur without any relation to the donation (for deaths, this is described by the term actuarial deaths).

F. Other Complications

Other systemic reactions or complications that do not fit into the above, such as chest pain that may have been investigated as angina, but was actually musculoskeletal, or transmission of infection to a donor through erroneous re-use of equipment.

Appendix 6 - Grading of Complication Severity and Imputability

Grading of Severity

Life-threatening complications and long-term disability are thankfully extremely rare after blood donation. Grading of severity for donor reactions does not easily fit into grading systems used for adverse reactions in patients. Use of this grading system is therefore optional. The criteria for classification of a reaction as serious (severe) as derived from these systems are:

Hospitalization: If it was attributable to the complication. The criterion of hospital admission is applicable if a donor is kept in hospital overnight. Cases where a donor is seen, examined, and in some cases given treatment (e.g. suturing, IV fluids, treatment of a fracture) but discharged home are not automatically classified as serious.

Intervention: To preclude permanent damage or impairment of a body function or to prevent death (life-threatening).

Symptoms: Causing significant disability or incapacity following a complication of blood donation and persisted for more than a year after the donation (Long term morbidity).

Death: If it follows a complication of blood donation and the death was possibly, probably or definitely related to the donation.

Types and Definitions of Reactions:

Certain complications of donation are by their nature mild or severe.

Local reactions - Most local reactions (hematoma, arm pain syndromes) would not be considered severe.

Severe consequences are separate reaction types: deep venous thrombosis, arteriovenous fistula, and compartment syndrome.

Nerve injury may rarely result in long term donor signs and symptoms. This may be captured by the duration of symptoms (optional split in nerve pain category).

Systemic reactions - Vasovagal reactions are characterised as those with or without LOC. There are two optional additional characteristics: LOC can be characterised as having additional symptoms (convulsions, loss of bowel or bladder control and/or duration of ≥ 60 seconds). Reactions can be categorised as resulting in injury or not.

Complications that are by their nature severe include generalised allergic (anaphylactic) reactions, and all major cardiovascular events.

Grading of Imputability

The strength of relation between donation and complication is:

Definite or certain: When there is conclusive evidence beyond reasonable doubt for the relation.

Probable or likely: When the evidence is clearly in favour of a relation.

Possible: When the evidence is indeterminate for attributing the complication to the donation or an alternative cause.

Unlikely or doubtful: When the evidence is clearly in favour of attributing the complication to other causes.

Excluded: When there is conclusive evidence beyond reasonable doubt that the complication can be attributed to causes other than the donation.

Imputability should only be reported for cardiovascular events leading to hospitalization or death post-donation, and only cases with imputability of possible, probable or definite should be captured.

Adapted from: Standard for Surveillance of Complications Related to Blood Donation by the Working Group on Complications Related to Blood Donation, International Society of Blood Transfusion and Working Party on Haemovigilance, European Haemovigilance Network (2014).

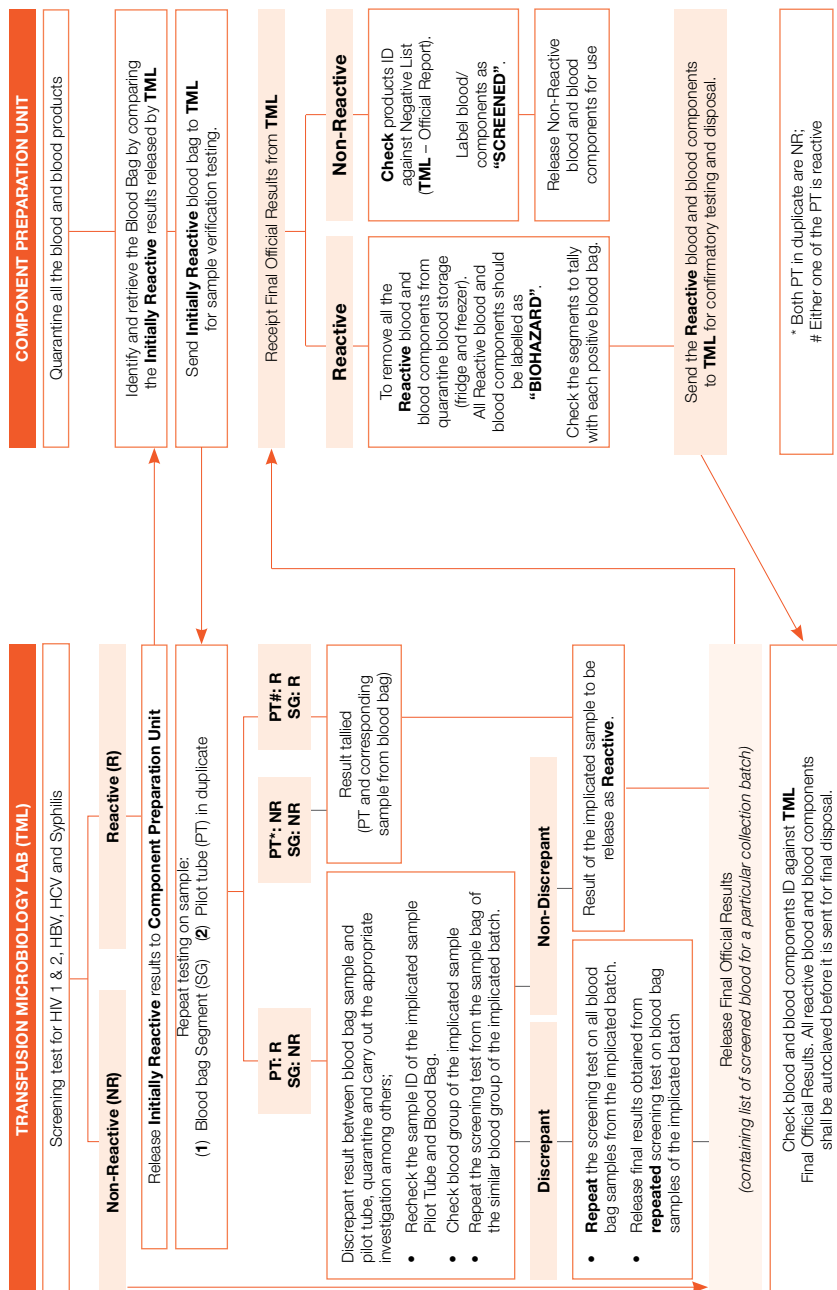
Appendix 7

CRITERIA FOR SETTING UP TRANSFUSION MICROBIOLOGY LABORATORIES IN THE MINISTRY OF HEALTH, MALAYSIA

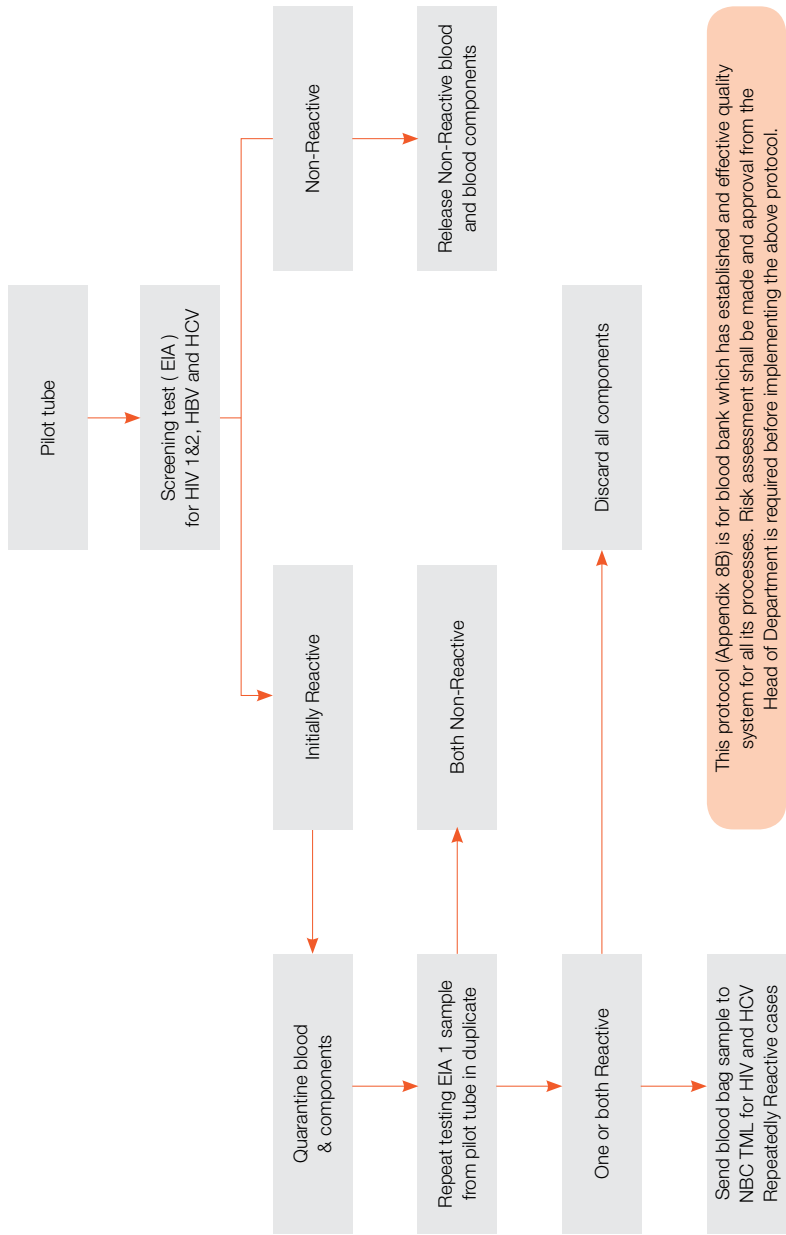
The laboratory shall:

- a. Have a comprehensive and effective quality management system incorporating elements of GMP in place.
- b. Have an annual workload of blood collection of at least 40,000 donations.
- c. Have infrastructure, resources and equipment that are appropriate for the function :
 - proper facility for screening transfusion transmitted infection in compliance to GMP or other quality systems
 - partial or full automation system;
 - adequate budget.
 - adequate number of personnel of at least 2 Microbiologists and 4 Medical Laboratory Technologist dedicated for the screening laboratory.
- d. Participate in external quality assessment programmes at national or international level.
- e. Obtain a written approval from Kementerian Kesihatan Malaysia.

Appendix 8A: Blood Screening and Blood Release Flow Chart



Appendix 8B: Blood Screening and Blood Release Flowchart



Appendix 9

BTS/TC/2/2016

CONSENT FORM FOR BLOOD OR BLOOD COMPONENT TRANSFUSION

Patient's Name:

Age:

Identity Card No.:

Sex: ☐ Male ☐ Female

--	--	--	--	--	--	--	--	--	--	--	--	--	--	--

Address:

Attending Medical Practitioner: Dr.

Identity Card No.

I, the above-named/parent/guardian/spouse/next of kin of the above-named*, have been informed of the need for a blood transfusion of the patient. The attending medical practitioner has explained to me the risk and benefits involved in the transfusion as well as answering all my inquiries satisfactorily. I understand that despite testing and screening on the blood/blood components for HIV, Hepatitis B, Hepatitis C and Syphilis according to established standard, there are still risks of developing the disease. I also understand that unavoidable complications of transfusion may also occur.

I fully understood the above and hereby agree to the blood/blood component transfusion.

Signature of the patient/
parent/guardian/spouse/next of kin*

Signature of Attending
Medical Practitioner

Name of parent/guardian/spouse/next of kin**:

Identity Card No. of the above :

I was present while the above matter was explained to the patient/parent/guardian/spouse/next of kin* whose signature appears above. In my opinion, the person referred to has understood the contents of this form and agreed to the transfusion willingly.

Signature of witness*

Name of witness :

Identity Card No.:

* delete appropriately

** if necessary

BTS/TC/2/2016

BORANG PERSETUJUAN PEMINDAHAN DARAH ATAU KOMPONEN DARAH

Nama Pesakit:

Umur:

No. Kad Pengenalan:

Jantina: ☐ Lelaki ☐ Perempuan

--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--

Alamat:

Pengamal Perubatan Yang Merawat: Dr.

No. Kad Pengenalan

Saya, seperti nama tersebut di atas/ibu bapa/penjaga/suami/isteri/saudara kepada pesakit seperti nama di atas*, telah dimaklumkan bahawa pesakit memerlukan pemindahan darah atau komponen darah. Pengamal Perubatan yang merawat telah memberi penjelasan kepada saya tentang risiko dan kebaikan pemindahan darah dan saya berpuas hati dengan semua jawapan yang diberikan kepada soalan-soalan yang saya kemukakan. Saya faham dan sedar, meskipun darah atau komponen darah itu telah menjalani ujian saringan untuk HIV, Hepatitis B, Hepatitis C dan Sifilis mengikut standard yang telah ditetapkan, namun risiko jangkitan penyakit menerusi pemindahan darah masih boleh berlaku. Saya juga faham dan sedar bahawa komplikasi pemindahan darah yang lain yang tidak dapat dielakkan juga mungkin berlaku.

Saya benar-benar faham kenyataan diatas dan saya bersetuju untuk menerima pemindahan darah atau komponen darah.

Tandatangan pesakit/ibu bapa/
penjaga/suami/isteri/saudara terdekat

Tandatangan Pengamal
Perubatan Yang Merawat

Nama ibu bapa/penjaga/suami/isteri/saudara terdekat**:

No. Kad Pengenalan:

Saya memperakui makluman di atas telah diterangkan kepada pesakit/ibubapa/penjaga/suami/isteri/saudara terdekat yang tanda tangannya tertera di atas. Pada hemah saya penama yang dirujuk telah memahami kandungan borang ini dan telah bersetuju untuk menerima pemindahan darah atau komponen darah secara sukarela.

Tandatangan Saksi*

Nama saksi:

No. Kad Pengenalan saksi:

* potong yang tidak berkaitan

** jika perlu

PER-SS-BT 105
(Pind. 1/2016)

(Mesti dipenuhi dalam dua salinan. Tulis dengan pen mata bulat dan sila tandakan $\surd$ dalam petak yang berkenaan.)

[illegible]

Appendix 11: Examples of Rejection Criteria

No.	Reasons for Rejection of GXM/GSH request
1.	Sample sent in wrong container.
2.	Patient's name on sample tube does not tally with request form.
3.	Patient's identity card number on sample tube does not tally with request form.
4.	Patient's registration number on sample tube does not tally with request form.
5.	No patient's identity card number written.
6.	No patient's diagnosis written.
7.	Date and time of sample collected not written.
8.	No doctor's signature in the request form.
9.	Illegible handwriting on request form or tube label.
10.	No/ wrong request form used.
11.	Form sent has no carbon copy.
12.	Double label on sample tube.
13.	Sample tube labelled with pre-printed label.
14.	Sample tube not labelled.
15.	No patient's blood sample sent.
16.	Patient's blood sample sent in wrong container.
17.	Insufficient blood sample sent.
18.	Blood sample lysed.
19.	Blood sample clotted.

Appendix 12: Instructions on Proper Handling of Blood and Blood Components in the Ward

	Whole blood/Red Cell	Platelet Concentrate	Plasma components
Supply	- After Crossmatch	- Group Specific/ Compatible - No Crossmatching Required	- Group Specific - No Crossmatching Required - Should be thawed
Collection	- Blood Box with Ice	- Blood Box without Ice	Blood Box with Ice
Use	- As Soon As Possible (After Reaching The Ward)	- Transfuse Immediately	- Transfuse Immediately
Storage	+2°C to +6°C	Room Temperature + 20°C to + 24°C on Agitator Do Not Store in Fridge	Should Not Be Stored or Kept in The Wards
Return of Unused Blood to Hospital Blood Bank	Return Immediately	Return Immediately	Return Immediately
After Use	Fill Up PPDK 1 and Return Together with Empty Bag to Blood Bank As Soon As Possible	Fill Up PPDK 1 and Return Together with Empty Bag to Hospital Blood Bank As Soon As Possible	Fill Up PPDK1 and Return Together with Empty Bag to Blood Bank As Soon As Possible

Appendix 13: Example of Transfusion Checklist

HKL/ BPK/ 027

BAHAGIAN PERKHIDMATAN KEJURURAWATAN HOSPITAL KUALA LUMPUR

BLOOD / BLOOD PRODUCT TRANSFUSION CHECKLIST

III. PATIENT DATA

NAME :		
RN :		
NEW I/C NO :		
WARD :		
DATE TRANSFUSION :		
NAME OF CONSULTANT :		

IV. ADMINISTRATION OF BLOOD

E) Verify Blood / Blood Product (S) Supplied Are Compatible By Checking

i. Patient's Name ii. RN iii. IC Number IV. Blood Bag Number With:

1	Patient's case notes	Yes	No
2	Compatibility label, blood group & expiry date	Yes	No
3	Blood request form	Yes	No
Name of Doctor			
Signature			

F) Ascertain Patient Receiving Blood / Blood Product Is Correct By Checking

i. Patient's Name ii. RN iii. IC Number IV. Blood Bag Number With:

		DOCTOR		NURSE / AMO	
		Yes	No	Yes	No
1	Patient's case notes				
2	Asking patient / relative				
3	Compatibility label, blood group, & expiry date				
4	Blood request form				

NB: DATA IN II (B) TO BE COMPLETED BY TWO PERSON

First verifier (Doctor)	*Name	
	Signature	
Counter checked by second verifier (Nurse/AMO)	*Name	
	Signature	

G) TRANSFUSION PROCEDURE

Time of commencement	
Time of completion	
Any reaction	Yes No
If yes, state reaction and report to blood bank medical officer no. tel : 26955542 until 9pm, public holiday 8am- 12pm	
Monitor vital signs at baseline, 15 minutes, 30 minutes and every hour until completed transfusion. Record in observation chart.	Name Signature

H) VITAL SIGNS

FREQUENCY	TIME	PULSE	B/P	T°	FREQUENCY	TIME	PULSE	B/P	T°
Baseline					Hourly				
15min					Hourly				
30min					Hourly				
Hourly					Hourly				

NB: Form are to be filled in duplicate. Put a tick (✓) in the appropriate box.

* Please fill in block letters

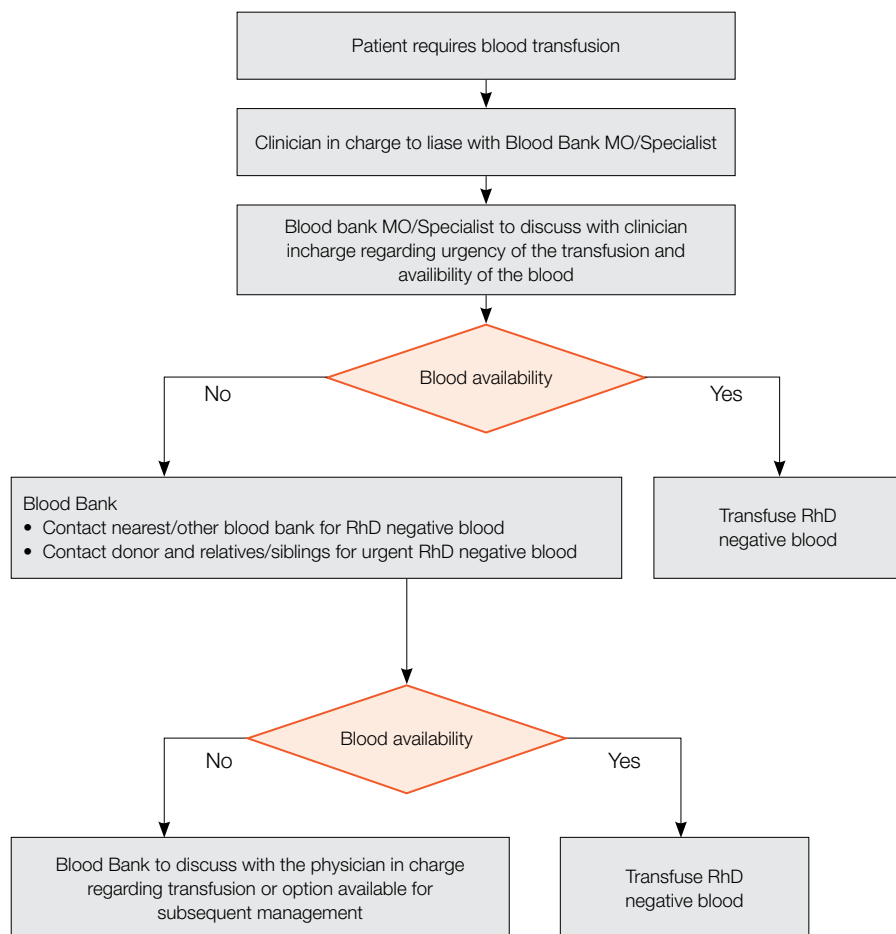
Original copy is to be kept in the patient's notes

Duplicate copy is to be kept in a ward file and

Each ward to send monthly analysis to the Head of Department and Unit Pengurusan Kualiti, HKL.

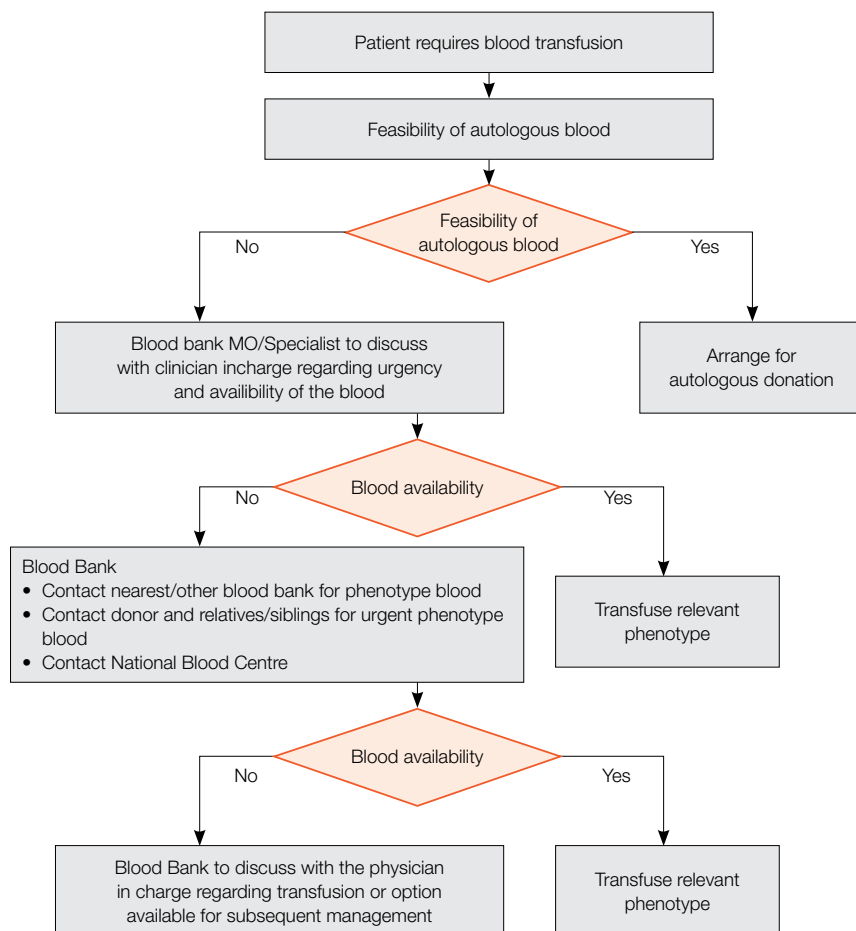
K020(BPK)/Revised 2015

Appendix 14: Flowchart for Transfusion of RhD Negative Patients



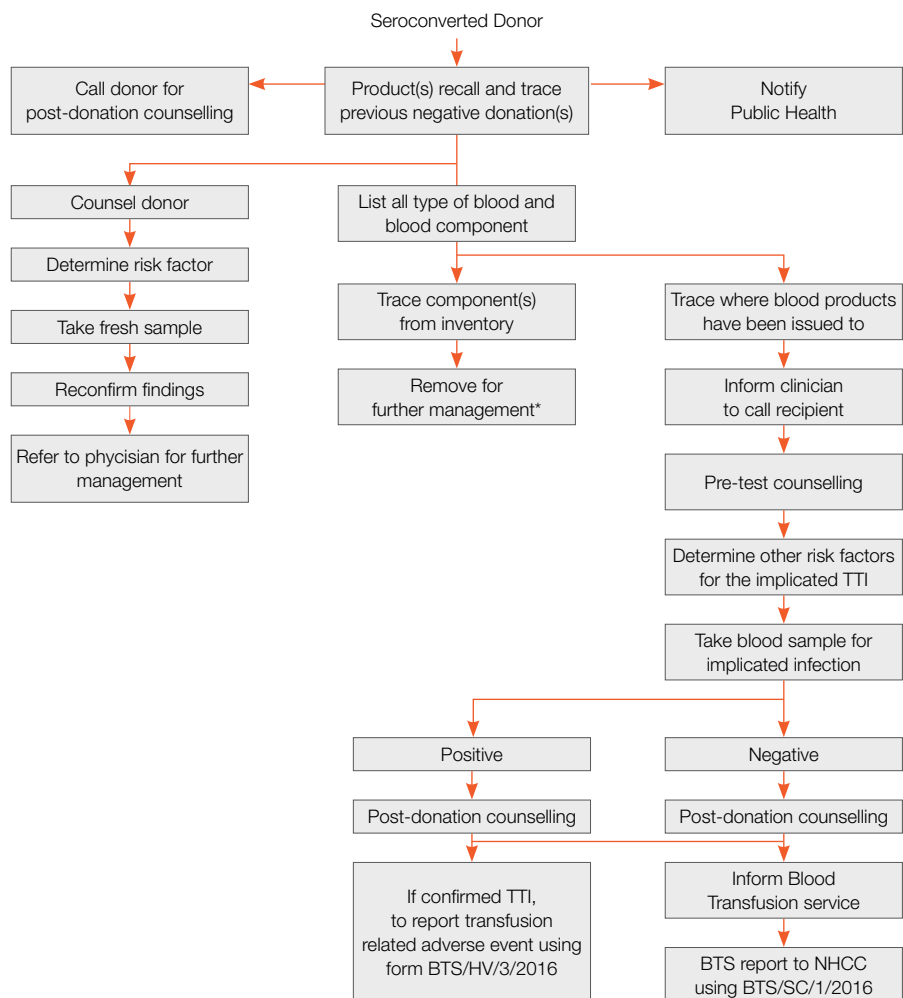
* For any queries please contact local Hospital blood bank.

Appendix 15: Flowchart for Transfusion in Patients with Rare Phenotype Blood

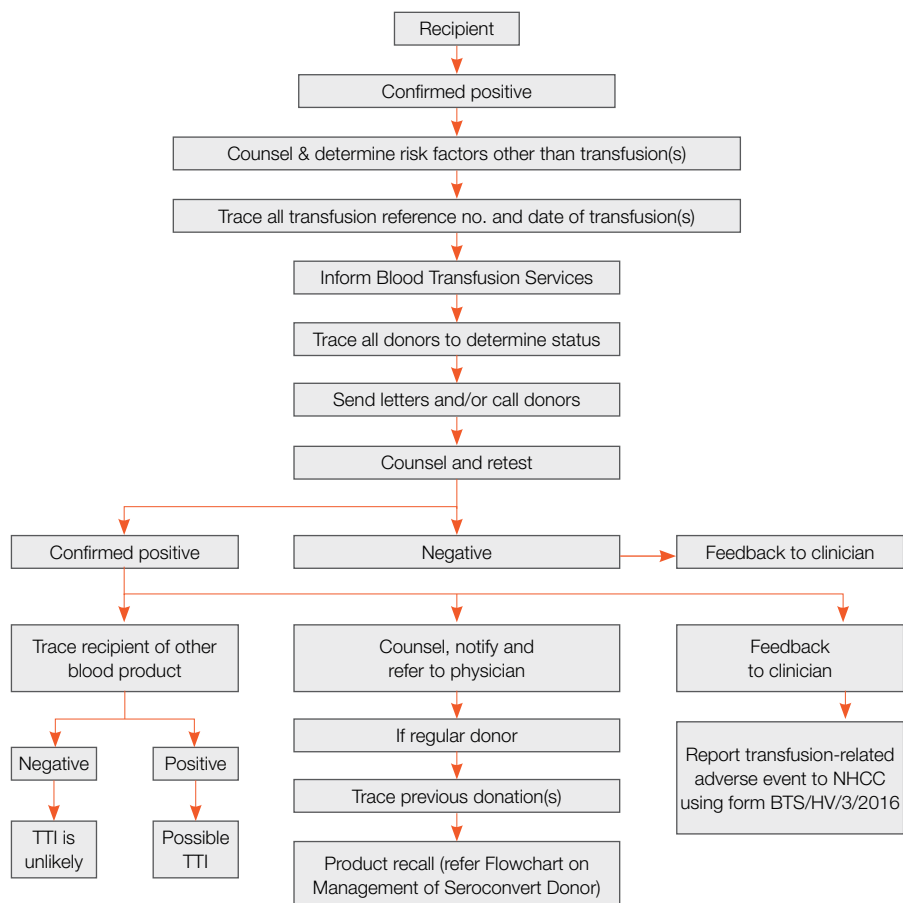


* For any queries please contact local hospital blood bank.

Appendix 16: Flowchart on Management of Seroconverted Donor



Appendix 17: Flow Chart on Management of Seroconverted Recipient



Appendix 18

BTS/TR/2/2016

BTS/TR/2/2016

REQUEST FORM FOR TRANSFUSION REACTION INVESTIGATION (BLOOD AND BLOOD COMPONENTS)

1. When a patient has an adverse reaction to any blood or blood component, **STOP** transfusion immediately. **URGENTLY** inform the doctor in charge of the patient and the Blood Bank.
2. Report all reactions and do the following:
 - 2.1 Preserve the blood bag and giving set with all attached labels. Seal it securely and send immediately to the Blood Bank.
 - 2.2 Send the following samples for transfusion reaction investigation to the Blood Bank or relevant laboratory.
 - a. Post-transfusion sample 1 (immediately)
 - I. 10 mls of blood in EDTA bottle
 - II. 10 mls of urine for haemoglobinuria
 - b. Post-transfusion sample II (after 24 hours)
 - I. 10 mls of blood in EDTA bottle
 - II. 10 mls of urine for haemoglobinuria
 - 2.3 Please send for other appropriate investigations if necessary.
 - 2.4 Please refer to Section 10: Adverse effect of transfusion in Handbook on Clinical Use of Blood for details.

Hospital: Ward/Clinic:

Patient's name: IC/Passport No:

Race: Age: Sex:

Diagnosis.....

- i. Date and time transfusion started
- ii. Date and time of onset of reaction
- iii. Blood/ Blood Component Serial No.
- iv. Volume Blood/ Blood Component transfused
- v. Blood Pressure: Before transfusion After transfusion
- vi. Temperature: Before transfusion After transfusion

BTS/TR/2/2016

vii. Nature of Reaction: Tick off (✓) the positive symptoms/signs.

Fever	☐	Shock	☐	Haematuria	☐
Chills /Rigors	☐	Jaundice	☐	Haemoglobinuria	☐
Urticaria	☐	Dyspnoea	☐		
Pain	☐	(Location of pain if present.....)			

viii. Solution used for starting IV drip: - N.Saline / 5% Dextrose / Others

ix. History of previous transfusion: Yes / No

Date of last transfusion:

x. History of previous transfusion reaction if any:

.....

.....

xi. Medication (If any, please specify):

.....

.....

xii. Applicable for female patients ONLY:

History of pregnancy: Yes / No No. of pregnancies:

History of abortion: Yes / No No. of abortions:

xiii. History of transplant:

Date of transplant:

Date:

Signature:

Name:

**PLEASE SEND THIS FORM TO THE BLOOD BANK WITH ALL
REQUIRED SAMPLES FOR INVESTIGATION**

Appendix 19

BTS/TRW/2/2016

BTS/TRW/2/2016

WORKSHEET FOR INVESTIGATION OF TRANSFUSION REACTION

Patient's name : _____
Ward : _____
Date reaction was noted : _____

Reg. No. : _____
No. of returned blood packs : _____
Date blood was returned : _____

I. RECHECK OF BLOO GROUPING	ANTI SERA				CELL				ANTI SERA	GROUP	Rh
	A	B	AB	AC	A	B	O	D			
Patient :-											
1. Pre-Transfusion Sample											
2. Post-Transfusion Sample I											
3. Post-Transfusion Sample II											
Donor :-											
1. Blood from Segment											
II. CHECK FOR SENSITIZATION AND ATYPICAL ANTIBODY	DIRECT COOMBS TEST ON CELLS	ANTIBODY SCREENING USING SCREENING CELLS									
		RT			37°C/ LISS / ALBUMIN			AHG			
		I	II	III	I	II	III	I	II	III	
1. Pre-Transfusion Sample											
2. Post-Transfusion Sample I											
3. Post-Transfusion Sample II											
Donor											
III. RECHECK OF CROSSMATCHINGS:-				RT		37°C/ LISS / ALBUMIN		AHG			
1. Pre-Transfusion Sample with Donor Blood											
2. Post-Transfusion Sample I with Donor Blood											
3. Post -Transfusion Sample II with Donor Blood											
IV. URINE:-				HAEMOGLOBIN							
1. Post-Transfusion Sample I											
2. Post-Transfusion Sample II											
V. BLOOD CULTURE.		DATE SENT		BACTERIOLOGICAL REPORT							
1. From Blood Bag											

CONCLUSION :

Signature : _____
Name : _____
Date : _____

Appendix 20

BTS/HV/3/2016

BTS/HV/3/2016

**REPORTING FORM FOR TRANSFUSION-RELATED ADVERSE EVENT
TRANSFUSION MEDICINE SERVICE
KEMENTERIAN KESIHATAN MALAYSIA**

IMPORTANT INFORMATION

1. Every adverse event related to transfusion of blood or blood component shall be managed, investigated and documented accordingly.
2. The form must be completed and returned to the blood bank within 2 weeks of the incident.
3. The blood bank shall retain the completed form and send a copy to the State Transfusion Committee and the National Haemovigilance Coordinating Centre (NHCC), Pusat Darah Negara within a month.

Reported by:

Name:	Designation:
Email:	Tel. No:
Date:	Fax No:

SECTION A: PATIENT DETAILS

Name of Patient:		
NRIC/ Passport No:	Age:	Hospital:
Barcode:	Gender:	Ward:
		Department:

SECTION B: TYPE OF ADVERSE EVENTS

- B1. TRANSFUSION REACTION ☐ (Fill up section C-J)
- B2. ERROR IN TRANSFUSION PROCESS ☐ (Proceed to SECTION K1 for 'NEAR MISS' on page 4)
- a) INCORRECT BLOOD COMPONENT TRANSFUSED ☐ (Proceed to SECTION K2 for 'INCIDENT' on page 4)
- b) NEAR MISS
- c) INCIDENT

Near Miss: Any error that has occurred but did not cause any adverse event as it was detected prior to blood transfusion.

SECTION C: ONSET OF ADVERSE EVENT

- C1. IMMEDIATE (within 24 hours of transfusion) ☐
- C2. DELAYED (after 24 hours of transfusion) ☐

SECTION D: BLOOD COMPONENTS IMPLICATED IN THE ADVERSE EVENT

- | | | | | | |
|-----------------------------------|--------------------------|-------------|----------|-----------------------|----------|
| D1. Whole blood | ☐ | Irradiated: | YES / NO | Filtered: | YES / NO |
| D2. Packed Cells | ☐ | Irradiated: | YES / NO | Filtered: | YES / NO |
| D3. Apheresis Platelet | ☐ | Irradiated: | YES / NO | Pathogen Inactivated: | YES / NO |
| D4. Random Platelet | ☐ | Irradiated: | YES / NO | | |
| D5. Fresh Frozen Plasma | ☐ | | | | |
| D6. Cryoprecipitate | ☐ | | | Pathogen Inactivated: | YES / NO |
| D7. Cryosupernatant/ Liver plasma | ☐ | | | | |
| D8. Others (please specify) | _____ | | | | |

SECTION E: DETAILS OF ADVERSE EVENTS

- E1. Date of transfusion: (DD/MM/YY) / /
- E2. Time transfusion started: am/pm
- E3. Time reaction occurred: am/pm
- E4. Volume transfused: ml / unit

SECTION F: RELEVANT CLINICAL HISTORY

- F1. Patient's primary / provisional diagnosis: _____
- F2. Indication for transfusion: _____
- F3. History of pregnancy / miscarriage (if applicable): ☐ YES ☐ NO
- F4. a) History of previous transfusion: ☐ YES <3 mths ☐ YES >3 mths ☐ NO ☐ UNKNOWN
- b) If YES, component transfused: _____
- c) Reaction towards transfusion: ☐ YES ☐ NO
- d) If YES, please describe: _____
- F5. Other relevant medical and/or surgical history: _____
- F6. Emergency crossmatch (immediate spin) ☐ YES ☐ NO
- F7. Transfusion with safe "O" or uncrossmatched group specific blood ☐ YES ☐ NO

SECTION G: SIGNS AND SYMPTOMS [Tick all that apply (✓)]

- G1. General: ☐ Chill ☐ Rigors ☐ Fever ☐ Nausea ☐ Haemorrhage
☐ Restlessness / Anxiety ☐ Vomiting ☐ Cyanosis
☐ Others (specify) _____
- G2. Cardiovascular: ☐ Chest pain ☐ Palpitation ☐ Others (specify) _____
- G3. Skin: ☐ Oedema ☐ Flushing ☐ Hives ☐ Itching ☐ Pallor
☐ Jaundice ☐ Urticaria ☐ Petechiae ☐ Rash
- G4. Pain: ☐ Infusion site pain ☐ Abdominal pain ☐ Chest pain
☐ Flank pain ☐ Headache ☐ Back pain
☐ Other pain (specify) _____
- G5. Renal: ☐ Oliguria ☐ Anuria ☐ Dark coloured urine
- G6. Respiratory: ☐ Cough ☐ Hypoxia ☐ Dyspnoea
☐ Wheezing ☐ Others (specify) _____
- G7. Patient's baseline observations prior to reaction: Temperature: ____ °C, BP: ____ Pulse rate: ____ RR: ____ SPO₂ ____
- G8. Patient's baseline observations at time of reaction: Temperature: ____ °C, BP: ____ Pulse rate: ____ RR: ____ SPO₂ ____

SECTION H: RELEVANT INVESTIGATIONS

- H1. Chest X-ray findings (specify): _____
- H2. Relevant **pre-transfusion** laboratory investigation results:
 Full blood count: _____
 Liver Function: _____
 Coagulation Test: _____
- H3. Relevant **post-transfusion** laboratory investigation results:
 Full blood count including Reticulocyte count: _____
 Liver Function: _____
 Coagulation Test: _____
 Red cells antibodies: _____
 Haptoglobin: _____
 Blood C&S Patient: POS/ NEG Organism: _____
 Blood C&S Donor: POS/ NEG Organism: _____
 Urine FEME: _____
☐ Haemoglobinuria ☐ Hematuria
- H4. State other relevant investigations if any: _____

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SECTION I: PATIENT OUTCOME FROM THE ADVERSE EVENTI1. Recovered with no ill effects ☐I2. Recovered with illness (morbidity) ☐

Time frame of recovery _____

Specify the morbidity _____

I3. Death ☐I4. a) Unlikely related to transfusion ☐b) Probable related to transfusion ☐c) Possible related to transfusion ☐**SECTION J: TYPE OF ADVERSE EVENTS: [Tick where applicable]**

Section	Events	✓	*
J1	Incorrect Blood Component / Product Transfused (Proceed to SECTION K for 'IBCT' on page 4)		*
	J1.1. Acute Immune Haemolytic Anaemia		*
	J1.1a. ABO incompatible		*
	J1.1b. Other red cell incompatibility (e.g. Rh positive given to Rh negative)		*
	J1.2 Blood is compatible but meant for another patient		*
	J1.3. Others :		
	J1.3a. Special requirement not met (e.g. irradiated, filtered, phenotyped)		*
	J1.3b. Inappropriate transfusion (e.g. wrong component)		*
J2	Delayed Haemolytic Transfusion Reaction		*
J3	Non-immune hemolytic reaction (due to mechanical factor, osmotic, heat, cold, etc)		*
J4	Febrile Non- Haemolytic Transfusion Reaction (FNHTR)		
J5	Allergic Reaction		
	a) Mild (Rash / Urticaria)		
	b) Moderate (Anaphylactoid)		*
	c) Severe (Anaphylactic Transfusion Reaction)		*
J6	Transfusion-Related Acute Lung Injury (TRALI)		*
J7	Transfusion-Associated Circulatory Overload (TACO)		*
J8	Transfusion-Associated Dyspnoea (TAD)		*
J9	Transfusion-Associated Graft-versus-Host Disease (TA-GvHD)		*
J10	Post-Transfusion Purpura (PTP)		*
J11	Post-Transfusion Infection : Virus (please specify) _____		*
J12	Post-Transfusion Infection : Bacteria (please specify) _____		*
J13	Post-Transfusion Infection : Parasite (please specify) _____		*
J14	Handling and storage error		*
J15	Equipment related (e.g. faulty waterbath, transfusion set, etc)		*
J16	Others , please specify :		*

* Please send detailed report for all transfusion reaction except for FNHTR & mild allergy.

SECTION K: ERRORS AND INCIDENTS IN TRANSFUSION PROCESS [Tick all that apply (✓)]

K1. IBCT AND NEAR MISSES IN TRANSFUSION PROCESS.

No	CLASSIFICATION OF ACTUAL ERRORS / NEAR MISS	
1.	ERROR IN WARD	
	a) Sampling error at time of blood taking	
	b) Labelling error at time of blood taking	
	c) Cause cannot be determined	
2.	TESTING (BLOOD BANK)	
	a) Technical error	
	b) Transcription error	
	c) Blood issued meant for another patient	
3.	BLOOD ADMINISTRATION IN THE WARD	
	a) Failure to check the blood against patient's full identity.	
	b) Others (please specify)	

**K2. OTHER INCIDENTS RELATED TO TRANSFUSION PROCESS.
(Tick ✓ where applicable)**

a)	Sharing same ID (IC, UNHCR, Passport)	
b)	Possible blood grouping error in other hospitals / clinics	
c)	Error in previous admission	
d)	Others (please specify)	

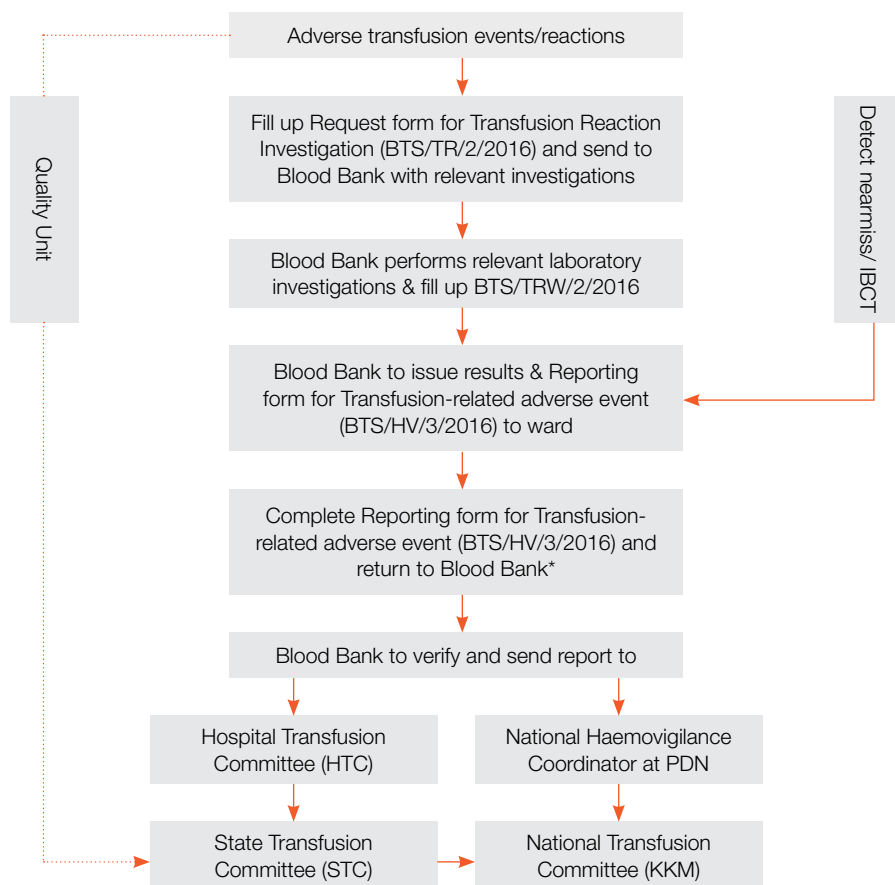
K3. ERROR/ INCIDENT DISCOVERED (Tick ✓ where applicable)

- ☐ Pre-Transfusion
☐ During Transfusion
☐ Post-Transfusion

Please describe in detail how error was discovered (additional pages to be filled if necessary):

Please send root cause analysis (RCA) report for all IBCTs and Near Misses.

Appendix 21: Flowchart for Reporting Transfusion-Related Adverse Events



*BTS/HV/3/2016 should be completed within 2 weeks after the event and sent back to Blood Bank for compilation.

Note:

1. Every case of adverse reaction must be reported.
2. If the case of adverse reaction involves a seropositive recipient, a lookback and recall procedure must be carried out.

Appendix 22

BTS/SC/1/2016

BTS/SC/1/2016

SEROCONVERT DONOR NOTIFICATION FORM

IMPORTANT INFORMATION

PART 1

1. Every case of seroconverted donor shall be managed, investigated and documented accordingly.
2. Please complete Part 1 of this form and send a copy within ONE (1) month following donor counselling to the National Haemovigilance Coordinating Centre, National Blood Centre.
3. Completed original form shall be retained at the respective blood centre.

DONOR DETAILS

Name :	IC / Passport No :
Gender : Male ☐ Female ☐	Barcode :
Date of donation :	Number of previous donations :
Reported by :	Designation :
Collection centre :	Date of reporting :

1. Infectious markers implicated

- HIV HBV HCV Syphilis Others (please specify) : _____
- a. Screening (Specify method) : _____
 - b. Confirmation (Specify method) : _____
 - c. Date of confirmation (Seroconversion) : _____

2. Risk Factors

- c High Risk Sexual Behaviour (Specify) : _____
- c Body piercing / Tattoo/ Acupuncture (Please circle the appropriate one)
- c History of blood transfusion (Date & Hospital involved) : _____
- c Intravenous drug use
- Others (please specify) : _____

IMPORTANT INFORMATION**PART 2**

1. Please fill up the following for the last negative donation and donation(s) in the six (6) months period prior to the last negative donation.
2. Upon completion of Part 2, please resend the complete form to National Haemovigilance Coordinating Centre, National Blood Centre.
3. Completed original form shall be retained at the respective blood centre.

PREVIOUS DONATION RECORDS

Barcode NO: _____

Date (DD/MM/YY) ____ / ____ / ____

Donation Centre/ Hospital: _____

Type of Product:	Whole blood	Packed cells	FFP	Platelet	Cryoppt/sup	Others (.....)
Date Issued:						
Issued to Hospital/ward:						
Patient's name:						
Patient ID:						
Ward :						
Patients current status(dead/ alive/ result status) :						
Patient's Diagnosis :						

Barcode NO: _____

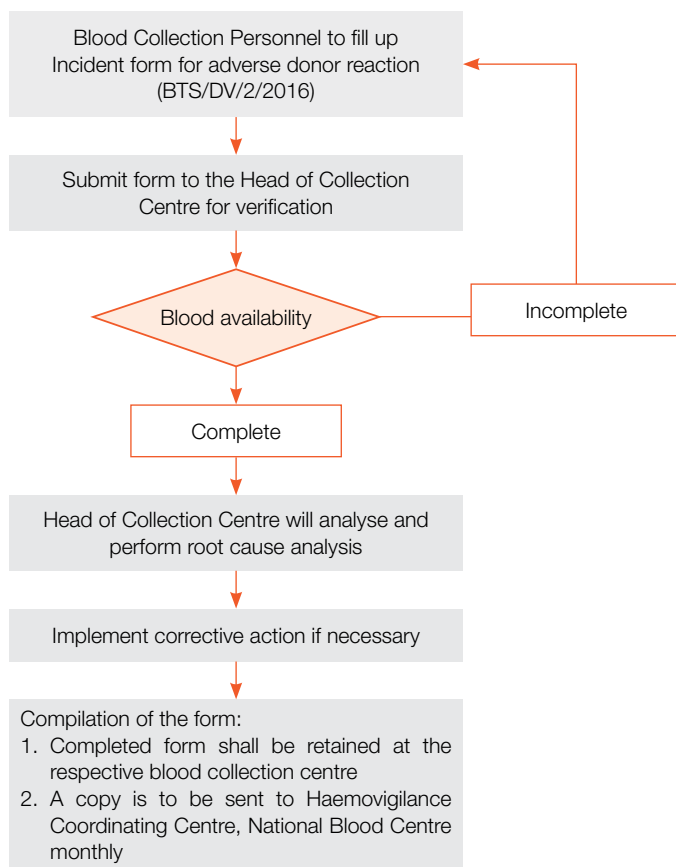
Date (DD/MM/YY) ____ / ____ / ____

Donation Centre/ Hospital: _____

Type of Product:	Whole blood	Packed cells	FFP	Platelet	Cryoppt/sup	Others (.....)
Date Issued:						
Issued to Hospital/ward:						
Patient's name:						
Patient ID:						
Ward :						
Patients current status(dead/ alive/ result status) :						
Patient's Diagnosis :						

*additional pages to be filled if necessary

Appendix 23: Flowchart for Reporting of Adverse Donor Reaction



Glossary

Additive solution	Solution specifically formulated to maintain beneficial properties of cellular components during storage.
Adverse event	Any untoward occurrence whether it is incidence, accident or deviation from Standard Operating Procedure (SOP) associated with the collection, testing, processing, storage, distribution and administration of blood and blood components that might lead to an adverse reaction in patient who received blood transfusion or blood donors.
Adverse reaction	Unintended response in donor or in patient associated with the collection or transfusion of blood or blood components
Anticoagulant	Solution that prevents blood from clotting.
Apheresis	Procedure of obtaining one or more blood components by machine processing of whole blood in which the residual components of the blood are returned to the donor during or at the end of the process.
Autologous donors	Individuals who donate blood for their own use. If the need for blood can be anticipated and a donation plan developed.
Blood components	Blood components are prepared from whole blood through centrifugation. Therapeutic components of blood (red cells, white cells, platelets, plasma) that can be prepared by centrifugation, filtration, and freezing using conventional blood bank methodology.
Buffy coat (BC)	BC is the layer of white cells and platelets that is seen between the red cells (at the bottom) and the plasma (at the top) of anticoagulated blood.
Confidential unit exclusion	The removal and disposal of a unit of blood after donation following information obtain from donor.
Crossmatch	One of the compatibility procedure involving mixing of patient's plasma and donor's red cells.
Cryopreserve	A process employed to prolong the storage life of blood components by freezing.
Cryoprotectant	A solution (eg: glycerol), used in long term storage of materials in frozen state (e.g. red cell).
Donor	A person in normal health with a good medical history who voluntarily gives blood or components for therapeutic use.
Donor deferral	Suspension of the eligibility of an individual to donate blood or blood components, either on permanent or temporary basis.
Emergency O blood	Group O RhD positive whole blood with low titres of Anti-A and Anti-B (titre $\leq 1/16$), and negative for haemolysin.

Fractionation	A process of isolating and separating plasma proteins which include albumin, immunoglobulin (gamma globulin) and clotting factors.
Haemovigilance	Organized surveillance procedures related to adverse or unexpected events or reactions in donors and recipients.
Incorrect blood or blood component transfused (IBCT)	Where a patient is transfused with blood/blood components that does not meet the appropriate requirements or which is intended for another patient.
Lapsed donor	A blood donor who has donated before but the last donation was more than 24 months in the same blood centre.
Near miss event	An error which if undetected could result in the determination of a wrong blood group, or issue, collection or administration of an incorrect, inappropriate or unsuitable blood or blood component, but which was recognized before the erroneous transfusion took place.
Phenotype	Observable expression of the gene inherited by a person and reflects the biologic activity of the gene.
Phlebotomist	Health personnel who is trained in drawing blood for testing or donation.
Phlebotomy	The process of inserting a needle into the vein.
Pyrogens	Endotoxins produced as a result of the metabolism of gram negative bacteria which are heat stable.
TTI	Infections agents that can be transmitted through transfusion of blood and blood products.
Reactive donors	A blood donors who was found to be reactive during screening for TTI.
Regular donor	A blood donor who has donated minimum of two times within 24 months in the same blood centre.
Safe O	Group O RhD positive packed cell that is used in life threatening condition without crossmatching.
Self-deferral	The decision by a potential donor to defer himself/herself from donating blood.
Validation	A process of confirming that a process, equipments, product or service meets or exceeds a predefined set of criteria.
Voluntary non-remunerated blood donor	A person who donates blood of his/her own free will and receives no payment for it, either in the form of cash, or in kind which could be considered a substitute for money.
Window period	The time interval that elapses between infection and the appearance of detectable antibodies or antigens by the laboratory testing methods.



NATIONAL BLOOD CENTRE

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