DEPARTMENTAL OPERATIONAL POLICIES

BLOOD TRANSFUSION SERVICE

KANOWIT HOSPITAL

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KANOWIT HOSPITAL

BLOOD TRANSFUSION SERVICE OPERATIONAL POLICIES

REVISED:

THAN MIN YIK
JURUTEKNOLOGI MAKMAL PERUBATAN U29
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MEDICAL LABORATORY TECHNOLOGIST

JULY 2023

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HOSPITAL DIRECTOR

JULY 2023

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1. INTRODUCTION

Kanowit Hospital Blood Transfusion Service (Blood bank) is located at the end of building next to Pathology Unit (General Laboratory) and Radiology Unit.

1.1 Vision And Mission

a. Vision

To provide adequate and safe blood based on quality system for patient's right.

b. Mission

Providing quality service through teamwork, well-trained & educated staffs.

To give a well-care on blood donors and cooperation between the other organization in the society.

c. Objectives

i. To provide a comprehensive range of safe blood and its related products.

ii. To provide 24 hours services, including safe adequate supply of blood or blood products for quality patient's care.

iii. To ensure a good laboratory service is rendered by adhering to the code of professional conduct for the Medical Laboratory Technologist and the other related ethical standard.

d. Roles And Activities

i. Provide one of the clinical supporting services – Blood transfusion service

1.2 Scope of Services

Since year 2011, Kanowit Hospital Blood Transfusion Service has two distinct sections which are Bleeding room and Cross-matching room.

1.2.1 Cross-matching room

- Cross-matching, ABO Grouping and Antibody screening
- Screening of HIV, Hepatitis B, Hepatitis C, and VDRL are screened at screening Centre (Sibu Hospital Transfusion Microbiology Laboratory).

1.2.2 Bleeding room

- Recruit new blood donors.
- Blood donation campaigns.

2. ORGANIZATION & MANAGEMENT

2.1 Hospital Director

The Hospital Director is responsible for the overall management of the hospital, supported by the heads of the clinical and non-clinical departments/units of the hospital.

2.2 Heads of Departments

The Blood Transfusion Service headed by a Scientific Officer, a Senior Medical Laboratory Technologist and two Medical Laboratory Technologists

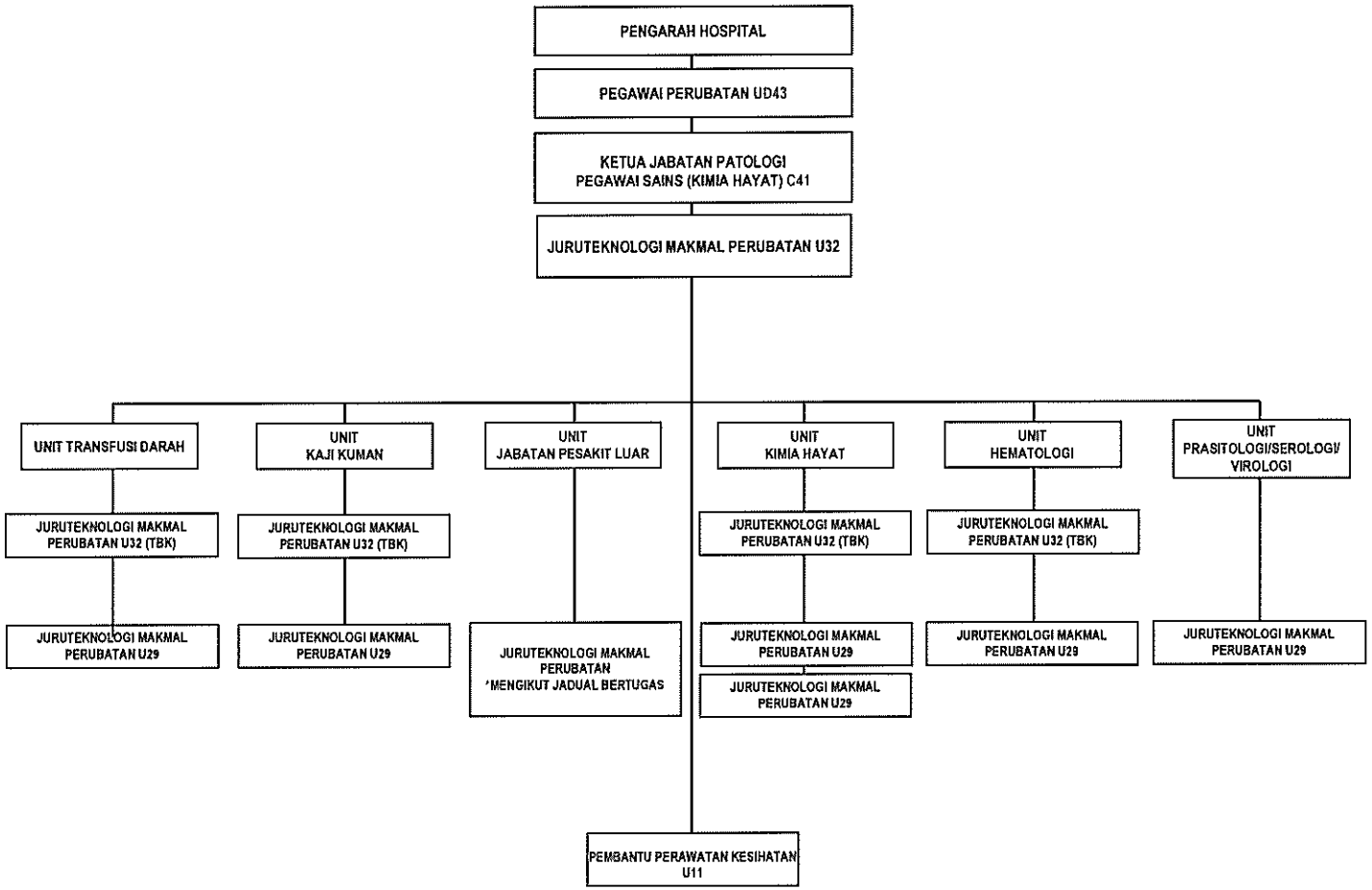
2.2.1 The Scientific Officer shall be responsible for overall operation of the Blood Transfusion Service and review the external quality control (e.g. NEQABB) from Pusat Darah Negara 3 monthly in a year. Scientific Officer will monitor the internal quality control done by the Medical Laboratory Technologists.

2.2.2 The Senior Medical Laboratory Technologists will headed all section in Blood Transfusion Service and be responsible to:

- Make sure quality controls are practiced
- Adequate blood stock and reagents at all time
- Responsible to inform any plan of actions, emergencies and problems to Scientific Officer, thus discuss and solve matters together.

2.3 Overall Organization

The overall organization of the Blood Transfusion Service is shown in the organization chart below.



3. OPERATIONAL POLICY

3.1 Operation time

i. The Blood Transfusion Service will operate on full strength during the office hours:

Day	Working Hours
Monday- Thursday	0800hrs-1300hrs 1400hrs-1700hrs
Friday	0800hrs-1145hrs 1415hrs-1700hrs

ii. After Office Hours (On call):

Day	Working Hours
Monday- Friday	1700 hrs - 0800hrs (The following days)
Saturday, Sunday, Public Holidays	0800 hrs - 1700 hrs (The following days) 1700 hrs - 0800 hrs (The following days)

iii. Services offered after office hours are ABO blood grouping, antibody screening, cross-matching, issuing of blood (packed cells or whole blood) and blood component (fresh frozen plasma) for transfusion.

3.2 Procurement of Blood

3.2.1 Blood shall be procured only from voluntary non-remunerated blood donors.

3.2.2 The blood procurement team shall manage the blood collection activities.

a) Blood Procurement Team

The blood procurement team should comprise of the following personnel:

- Medical Officer(s) or Assistant Medical Officer(s)
- Medical Laboratory Technologist(s).
- Health Attendant(s) (Pembantu Perawatan Kesihatan).
- Driver(s).

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.
- Maintenance of records, data and information pertaining to its activities for traceability, reference and quality improvement.

b) Promotion and Recruitment

- The blood procurement team shall creating public awareness on blood donation.
- The blood procurement team shall recruit new organizers and blood donor through donation campaigns.

3.2.3 Identification of Blood Donor

a) 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 (Photostatted copy must be verified by relevant authority e.g. employer).

b) 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.

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

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

a) Age

- Between **17 to 70 years** old.
- **Donors at 17 years** of age - a written consent form the parents/ guardians is compulsory.
- **First time donor** can be accepted **up to the age of 60 years** old.
- **Donors at 60-65 years** of age - requires a yearly medical checkup 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 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

- Persons involved in any activities that put oneself at high risk of being infected with Transfusion Transmissible Infections shall not be allowed to donate and shall be permanently deferred from future donation.
- 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 Behaviours

a. Persons involved in any activities that put oneself at high risk of being infected with Transfusion Transmissible Infections (TTIs) shall not be allowed to donate and shall be permanently deferred from future donation.

- Sexual Relationship with HIV or Hepatitis B, Hepatitis C, Syphilis infected person.
- Multiple sex partners
- Intravenous drug users
- Homosexuals or bisexuals
- Prostitutes or exposure to prostitutes

b. 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

a. The blood collection centre must not allow blood donation for the purpose of replacement or directed to specified recipient.

b. Exceptions however are applicable subject to the approval by the medical officer or specialist in-charge or in special circumstances.

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:

a. Has resided in Malaysia for at least 12 months.

b. Able to provide a residential or postal where the donor is contactable.

c. Must be able to read and understand Bahasa Malaysia or English.

3.3 Frequency of Donation

3.3.1 The interval between the last donations of whole blood should not be less than 3 months and not less than 2 weeks for plasma or platelet donation. Note: If the donor donates regularly every 3 months, iron stores should be checked at least annually.

3.3.2 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.

3.4 Pre-Donation Questionnaire

3.4.1 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.

3.4.2 Appropriate assistance may be provided to those who are unable to read or understand the questionnaire (applicable only to Malaysian citizen).

3.4.3 Consent for the donation must be clearly indicated on the Blood Donor Registration Form.

3.4.4 All potential donors are interview by the Blood Transfusion Service personnel before donation. A safe donor could be checked through SUKUSA. This is to ensure the exclusion of persons with high risk behaviors that exposed them to infectious diseases.

3.5 Pre-Donation Interview

3.5.1 Pre-donation interview must be conducted in privacy by a doctor or nurse who has been trained and qualified in blood donation process.

3.5.2 The interviewer must explain to the prospective donor about the blood donation process.

3.5.3 There must be adequate assessment made of the health status of the prospective donor.

3.5.4 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.

3.5.5 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.

3.5.6 The interviewer must explain to the prospective donor about high risk behaviours that expose oneself to Transfusion Transmitted Infections (TTIs), and assess if the prospective donor has or is suspected to have any of these high risk behaviours.

3.5.7 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).

3.5.8 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.

3.6 Donor Deferral or Acceptance criteria

3.6.1 Conditions Necessitating Permanent Exclusion/ Deferral

a) Having lived at United Kingdom from 1980-1996 for a period of 6 months or longer.

b) Having lived in Europe from 1980 to the present for a period of 6 months or longer.

Refer Transfusion Practice Guidelines for Clinical and Laboratory Personnel 4th Edition 24th Edition 2016.

3.7 Blood Collection

3.7.1 Donor Identification

a) The identity of the donor must be asked and checked against the record in the Blood Donor Registration Form.

b) Check (expiry date and any physical defect) and identify the type of blood bag and the volume to be collected.

c) All blood bags and containers should be labeled with blood group sticker and barcode at the bedside before performing the venipuncture.

3.7.2 Venipuncture

a) Preparation of venipuncture site must be strictly following the standard operation procedure.

b) The standard operating procedure must be strictly adhered to during the venipuncture process.

c) In the event of an unsuccessful venipuncture at the first attempt, use a new set at a different venipuncture site/arm subject to consent of the donor.

3.7.3 Mixing of donated whole blood need for successful venipuncture and proper mixing the blood.

a) The personnel attending to a donation must ensure that blood flows uninterrupted into the bag at an acceptable rate.

b) 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 throughout the whole collection period.

3.7.4 Duration of bleeding for whole blood donation

a) Ideal bleeding time should not take more than 10 minutes.

3.7.5 Collection of blood samples and handling of blood containers

a) The collection of the blood samples and the labelling of the samples must be carried out at the bedside.

b) Samples of blood for laboratory testing must be collected from the pouch of the blood collection set or directly from the donor venipuncture tubing at the end of the donation.

c) Tubes or containers should be checked before and after donation for any defect.

d) 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.

3.7.6 Blood donation identification

a) 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.

b) 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.

c) All information relating to the blood donor shall be kept confidential and records of donors and donations shall be traceable to the blood donation identification.

3.7.7 Confidential Unit Exclusion

a) The prospective donor must be made to understand fully about confidential unit exclusion.

b) Confidential unit exclusion is the act of the donor notifying the blood bank/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.

c) Upon such notification, Sibu Hospital Transfusion Service shall be immediately informed and the blood or any blood component(s) prepared from this donor shall be immediately removed and disposed of. Records of this event shall be maintained.

3.7.8 The Privilege Leave (1 day) for donor is eligible for Kanowit Hospital's staff only. The Medical Laboratory Technologists is responsible to paste the blood bags sticker on the form.

3.7.9 Donors are treated with refreshments after the donation.

3.8 Adverse Reactions in Donors

3.8.1 Donors should be managed with high standards of care to assure them safe during blood donation process.

3.8.2 Management of Adverse Reaction in Donors

a) Special attention shall be given to donors in whom an adverse reaction associated with blood donation is identified.

b) Any ADR should be attended immediately. The donor shall be referred as soon as possible to the doctor in-charge for further management.

c) The necessary treatment measures shall be instituted as soon as possible and investigations shall be carried out to identify the cause of the reaction.

d) Donors shall be explained about the adverse reaction and reassurance shall be given.

e) Appropriate preventive and corrective measures shall be implemented.

f) 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.

Please refer to Transfusion Practice Guidelines for Clinical and Laboratory Personnel 4th for a ***guide to the management of specific adverse donor reactions.***

3.8.3 Documentation of Adverse Reactions in Donors

a) The doctor in charge and/ or health personnel shall fully document the incident, treatment and outcome of all adverse donor reactions.

b) All adverse reactions shall be documented in a dedicated incident reporting form for donor reaction.

3.9 Registry

3.9.1 Registries of whole blood donors and donors with positive makers to Transfusion Transmitted Infection (TTIs) shall be maintained.

3.9.2 Registries of permanently deferred donors (due to reasons other than positivity to TTIs) and temporarily deferred donors should be established.

3.9.3 Record Keeping

a) 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).

3.9.4 Destruction of records

a) Destruction of records should be supervised by an officer.

b) National Archives should be consulted first before any destruction of any records including electronic data.

c) There is no active or pending litigation and audit for the records.

d) The records are no longer required under any other legislation, and all statutory and regulatory requirements are fulfilled.

e) 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.

f) The destruction of all records must be documented, so that it is able to determine whether a record has been destroyed.

4. BLOOD COMPONENT

4.1 All blood components used in Kanowit Hospital Blood Transfusion Service shall be prepared in adherence to the principles of Good Manufacturing Practice (GMP), and any other applicable regulatory requirements in the blood processing centre at Sibu Hospital Blood Transfusion Service.

4.2 Blood cold chain shall be monitored and maintained from the time of collection to processing, including during transportation.

4.3 Each blood component shall be uniquely identified by a unique barcode number to allow for full traceability to the donor and the collection.

4.4 Each unit of component shall be labelled, at the minimum, with the following information:

i. Unique barcode number.
ii. Date of collection.
iii. Date of expiry.
iv. ABO and RhD grouping.
v. Name of the blood component.
vi. Volume of the blood component.
vii. The name of the blood processing centre.
viii. The word SCREENED.
ix. Additional component information e.g. Irradiated, Phenotype.

4.5 **All UNSCREENED** blood and blood components shall be quarantined in storage compartments distinctly separate from storage compartments used for screened blood. Any **UNSCREENED** blood or blood components **SHALL NOT** be used for transfusions.

4.6 Storage temperatures shall be controlled and appropriate for the blood or blood components stored and temperature monitoring shall be carried out and documented.

4.7 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.

4.8 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.

4.9 Discard of unsuitable units of blood shall be fully recorded to ensure full traceability and the chain of custody.

5. BLOOD SUPPLY MANAGEMENT

5.1 Stock Forecasting

5.1.1 Data on blood collected, blood supplied, and usable blood stock-in- hand shall be systematically recorded and analyzed.

5.1.2 Information derived from the data can be used, among others, to forecast blood stock, predict impending shortages and plan blood procurement.

5.2 Optimal Inventory

5.2.1 The optimal, minimum and the maximum stock levels of blood component of each ABO and RhD group shall be estimated and Sibu Hospital blood processing centre should be notified.

5.3 Minimum and Maximum Stock of Red Blood Cells

5.3.1 The minimum level of red blood cells should be between 2 to3 days of stock.

5.3.2 The maximum level of red blood cells should be between 7 days of stock.

5.3.3 Both 5.3.1 and 5.3.2 are depend on decision made by the Sibu Hospital Blood Transfusion Service referred to the minimum and maximum stock levels established by Kanowit Hospital Blood Transfusion Service.

5.4 Return of Unused blood to Sibu Hospital Blood bank

5.4.1 All unused blood or blood components shall be returned to Sibu Hospital Blood bank at least two (2) weeks before expiry date.

5.4.2 Appropriate records of the movement of the blood or blood components shall be maintained.

5.5 Storage

5.5.1 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.

5.5.2 FIFO may not be followed in cases which require fresh blood.

5.6 Safe O

5.6.1 Kanowit Hospital Blood Transfusion Service shall make available Safe O (that is Group O RhD positive packed cells) for managing emergencies.

5.6.2 Appropriate records of the use and movement of Safe O shall be maintained.

5.7 RhD Negative Blood Stock

5.7.1 Any transfusion require RhD Negative blood and components shall be first consult with a transfusion specialist (from Hospital Sibu or Sarawak General Hospital).

5.7.2 RhD Negative blood and components shall be supplied by Hospital Sibu Blood bank.

5.8 Storage of Blood

5.8.1 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 Transfusion Practice Guidelines for Clinical and Laboratory Personnel 4th Edition 24th Edition 2016.

5.9 Cold Chain

5.9.1 The blood cold chains shall be maintained during storage and transportation.

Refer Transfusion Practice Guidelines for Clinical and Laboratory Personnel 4th Edition 24th Edition 2016 ***for Blood Storage and Transportation Temperatures.***

5.10 Containers for Transporting Blood

5.10.1 Containers (re-useable or disposable) for transporting blood shall be adequately insulated, robust, tamper proof and clearly labelled for easy identification.

5.10.2 The containers and the ratios of coolant to blood and component shall be validated.

5.10.3 Records of validation shall be maintained.

5.11 Disposal of Blood and Blood Components

5.11.1 Expired/Unsuitable

a) All expired blood and blood components shall be autoclaved before it is sent for final disposal.

b) The disposal of the blood shall be fully documented to ensure audit trail.

5.11.2 Reactive blood and blood components

a) All blood and its component that have been informed reactive by the screening Centre (Hospital Sibu Transfusion Microbiology Laboratory) shall be immediately retrieve for discard.

b) All reactive blood and blood components shall be autoclaved before it is sent for final disposal.

c) The disposal of the reactive blood shall be fully documented to ensure audit trail.

5.12 Crossmatch to Transfusion (CT) ratio and expiry rate shall be monitored closely.

6. TRANSFUSION MICROBIOLOGY LABORATORY

The primary function of the Transfusion Microbiology Laboratory is to screen blood for Transfusion Transmitted Infections (TTIs).

All donated blood in Kanowit Hospital Blood Transfusion Unit will be send to Transfusion Microbiology Laboratory Sibu Hospital for TTIs screening.

6.1 Samples

6.1.1 All donated blood and samples shall be correctly identified by barcoded and eye-readable numbers which can be linked to their donor.

6.2 Scope of Screening

6.2.1 All donated blood MUST screen for TTIs:

a) Human Immunodeficiency Virus (HIV)

b) Hepatitis B Virus

c) Hepatitis C Virus

d) Syphilis

6.2.2 Blood collected in areas with high risk of malaria infection should be screened for malaria parasites.

6.3 Quality In Screening Of Donated Blood

6.3.1 To ensure quality in screening of donated blood in Transfusion Microbiology Laboratory Sibu Hospital, the following measures should be in place.

a) Use only assays and standard methods approved by the Ministry of Health.

b) Test methods shall be strictly adhered to at all times.

c) Modifications to the standards methods are not allowed.

d) Rapid test **SHALL NOT BE USED** for screening of donated blood.

6.3.2 To ensure quality in screening of donated blood, the Transfusion Microbiology Laboratory in Sibu Hospital shall, at the minimum:

a) Perform daily internal quality control monitoring for both reagents and techniques.

b) Participate in external quality assessment/proficiency programs.

6.4 Confidentiality

6.4.1 All test results and donor particulars shall be kept confidential.

7. BLOOD GROUPING

7.1 Blood Grouping of Donors at the Donation Site

7.1.1 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.

7.1.2 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.

7.2 Blood grouping of donors in the laboratory

7.2.1 Shall employ full ABO and RhD blood grouping.

7.2.2 An investigation shall be carried out if any discrepancy happened in blood grouping.

7.2.3 Any blood donor found to be RhD negative shall be confirmed with a further test (weak-D test, direct antihuman globulin (DAT) and RhD phenotype (only done in Sibu Hospital Bloodbank)).

Please refer to Transfusion Practice Guidelines for Clinical and Laboratory Personnel 4th ***for Blood Grouping for Patients Scheduled for Transfusion.***

7.3 Blood Grouping for Medical or Antenatal Check Up

7.3.1 The blood grouping shall be performed using a full grouping procedure.

7.3.2 All RhD negative cases shall be subjected to further tests for confirmation (see 7.4 above).

7.4 Methods for Blood Grouping

7.4.1 The methods recommended to be used in blood grouping are as follows:

a) 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) 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.

8. ORDERING BLOOD FOR TRANSFUSION

Only registered medical practitioner are authorized to prescribe and request for blood transfusion and should discuss with transfusion specialist when necessary.

The clinician managing the patient shall be responsible for prescribing blood for that patient.

8.1 Consent for Transfusion

8.1.1 The patient must give written informed consent prior to transfusion.

8.1.2 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.

8.1.3 The patient should be given an opportunity to ask questions. The decision of the patient regarding which therapy to take shall be clearly documented.

8.1.4 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.

8.1.5 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.

Please refer to Transfusion Practice Guidelines for Clinical and Laboratory Personnel 4th ***for a sample of consent form.***

8.2 Positive Patient Identification

Positive patient identification is a process to correctly identify patients thus avoiding medical error.

8.2.1 The phlebotomist shall ensure that the patient is correctly identified by:

i. 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?"

ii. Check the answers given against the information stated on the patient's identification wristband and/or case notes.

8.2.2 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.

8.3 Taking and Labelling Patient's Blood Sample

8.3.1 The above procedure shall be carried out as one process by one person at the bedside.

8.3.2 Only one patient shall be attended to at any one time till completion.

8.3.3 The phlebotomist shall clearly and accurately label the blood sample at the patient's bedside immediately after blood taking.

8.3.4 Information on the label shall include, at the minimum, the patient's full name, hospital registration number (or Identity Card (IC) number or Passport number), the date and time of collection and the initial of the phlebotomist.

8.4 Blood Samples for Red Cells Transfusion

8.4.1 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.

8.4.2 Repeated red cell transfusion

a) 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.

b) 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.

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

8.5.1 A new request for blood component other than red cells shall be accompanied by a blood sample taken in EDTA tube.

8.5.2 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.

8.5.3 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.

8.6 Request Forms

8.6.1 The clinician shall ensure that each request form is completed.

8.6.2 Must be completed with patient information such as full name (in capital letter), Identity Card (IC) number or Passport number.

8.6.3 The clinician shall sign, and clearly state his name in block letters on the request form.

8.6.4 Name and signature of staff performed the blood sampling and labeling shall be written in the transfusion form.

8.7 Type of Request

8.7.1 Group and Crossmatching (GXM)

i. GXM consists of checking ABO & RhD grouping and antibody screening for the patient's sample and crossmatching patient and donor unit for compatibility.

ii. GXM shall be requested for cases with high certainty for transfusion at that time.

iii. The full procedure takes about 2 hours to be completed. **However in emergency situation blood can be issued out as described in section 13.1.**

8.8 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.

8.9 Receiving Requests

8.9.1 All requests for transfusion shall be registered.

8.9.2 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.

8.10 Rejection of Requests

8.10.1 The samples are inadequately labeled, insufficient, lysed or in the wrong sampling tube.

8.10.2 There are any discrepancies between the information on the sample label and the transfusion request form.

8.10.3 The request form is filled with insufficient patient's information.

8.10.4 However in **LIFE THREATENING SITUATIONS**, 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.

8.10.5 Rejection of requests shall comply with local policies and procedures.

Please refer to Transfusion Practice Guidelines for Clinical and Laboratory Personnel 4th ***for an example of rejection criteria.***

9. PRE-TRANSFUSION TESTING

Pre-transfusion testing in the laboratory should include ABO and RhD grouping, antibody screening and crossmatching.

9.1 Registration of Request for Transfusion

9.1.1 All requests for transfusion shall be registered.

9.2 Determination of ABO and RhD Group

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

i. 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.

ii. 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.

iii. Blood can be released only if the results of both the two groupings are identical.

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

9.3 Antibody Screening

9.3.1 Antibody screening is mandatory for all requests for transfusion.

9.3.2 Antibody screening shall be performed by using tube method or other standard methods (e.g. column agglutination technology) manufacturer's recommendations shall be followed.

9.4 Records of Previous Transfusions

9.4.1 Records of previous transfusions shall be traced.

9.4.2 Any discrepancy between current and previous blood group shall be fully investigated and documented.

9.5 Antibody Identification

9.5.1 Whenever the antibody screening test is positive, and/ or incompatible crossmatch is detected, antibody identification shall be carried by referring the cases to Sibu hospital Blood Transfusion Service (reference laboratory) for further investigation with the followings:

a) 10ml of blood in EDTA tube and 10ml blood in plain tube accompanied by a duly completed request form.

9.5.2 Initial laboratory findings shall be provided to the reference laboratory.

9.5.3 Reference laboratory shall be notified before sending the sample.

9.6 Crossmatching

9.6.1 Red cell unit selected for crossmatching shall be of the same ABO and RhD type as that of the patient.

Please refer to Transfusion Practice Guidelines for Clinical and Laboratory Personnel 4th Edition 24th Edition 2016 ***in special circumstances.***

9.6.2 Crossmatching shall be performed by using tube method or other standard methods (e.g. column agglutination technology) manufacturer's recommendations shall be followed.

9.6.3 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 9.5.1, Sibu Hospital Blood Transfusion Service (reference laboratory) should provide blood that is antigen negative after investigation.

9.6.4 Where fully compatible blood is not available, and the patient needs urgent transfusion, the clinician in charge of the patient should discuss with transfusion specialist (from Hospital Sibu or Sarawak General Hospital) 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.

9.6.5 Crossmatched samples shall be retained securely under appropriate storage conditions for a minimum of 7 days.

9.6.6 Crossmatched blood that has not been issued shall be released into general stock after 48 hours.

9.7 Selection of Non Red Cell Components

9.7.1 Plasma and platelet concentrates selected for transfusion shall be compatible and preferably of the same ABO group.

Please refer to Transfusion Practice Guidelines for Clinical and Laboratory Personnel 4th Edition 24th Edition 2016 for the ***Selection Recommendations of Plasma and Platelets***

9.7.2 The clinician in charge of the patient should discuss with transfusion specialist (from Hospital Sibu or Sarawak General Hospital) if different ABO group non red cells components are selected.

9.8 Transfusion Records

9.8.1 All transfusion records, in the form of hard or soft copies or both, shall be archived for not less than 20 years.

10. ISSUE AND TRANSPORT OF BLOOD TO THE WARD

Blood shall be kept at appropriate temperature and condition at all times before transfusion.

10.1 Issue and Collection of Blood

10.1.1 Only authorized hospital blood bank personnel (Medical Laboratory Technologists) shall be allowed to issue blood.

10.1.2 The person collecting the blood must being documentary proof of the patient identity.

10.1.3 The ward personnel (doctor, nurse, assistant medical officer) collecting the blood shall bring documentary proof of the patient's identity.

10.1.4 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 Rh (D) blood group of patient.

e) Unique pack number (donation barcode number) of the blood product.

f) Date of issue.

g) Type of component.

10.1.5 The authorized hospital blood bank (Medical Laboratory Technologists) and ward personnel shall verify that the particulars of patient match those of the blood to be issued.

10.1.6 The authorized hospital blood bank personnel (Medical Laboratory Technologists) shall record the dates and times of issue and collection, the name of person issuing and the name of the person collecting the blood.

10.1.7 The lab personnel must record the date, time of issue and collection, and the personnel who issued and who collected the blood.

10.2 Storage and Transport

10.2.1 The ward personnel shall transport the issued blood to the ward or returned blood to the hospital blood bank without delay in order to maintain the blood "cold chain". Transportation shall be carried out in an appropriate temperature using a proper cooler box.

10.2.2 Unused blood must be returned to blood bank as soon as possible. **NEVER** keep the blood in the ward.

10.2.3 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.

11. TRANSFUSION PROCESS

11.1 Identification Check Prior to Transfusion - FINAL BEDSIDE CHECK

11.1.1 Each ward shall establish procedure for carrying out identification checks, to prevent any error occurring at this final stage before transfusion commenced.

11.1.2 The check shall include the blood bag label, blood compatibility label, request form, and the patient's identification.

11.1.3 Each unit of blood supplied by the hospital blood bank shall be appropriately labelled and accompanied by a blood compatibility label.

11.1.4 Prior to transfusion, personnel in charge shall perform a positive patient identification.

11.1.5 A check shall be conducted to ensure that the patient's information on the blood compatibility label match those on the:

a) Blood bag label.

b) Patient's wristband.

c) Patient's blood request form.

d) Case notes.

11.1.6 The blood shall also be checked to ensure that it has not expired and that it conforms to the following in appearance:

a) No change in colour.

b) Absence of clots.

c) No foamy appearance.

d) No leakage.

Please refer to Transfusion Practice Guidelines for Clinical and Laboratory Personnel 4th Edition 24th Edition 2016 for the ***Identification Check Prior to Transfusion - FINAL BEDSIDE CHECK.***

11.1.7 A competent personnel (doctor or paramedic) shall perform all the steps in 11.1.2 to 11.1.6 above, and a second person (doctor or paramedic) shall countercheck that the steps mentioned have been carried out correctly.

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.

11.1.8 Blood bank shall be immediately informed in the event of any discrepancy in the identification check of intended recipient, blood compatibility label, request form and blood component. The implicated blood shall be immediately returned to the blood bank for appropriate measures to be taken. The chain of custody shall be documented.

11.1.9 **DO NOT** transfuse if there is any non-compliance to any of the requirements stated in 11.1.2 to 11.1.6 above.

11.2 Monitoring Of Patient

11.2.1 The patient shall be closely observed and monitored during blood transfusion.

11.2.2 Parameters to be monitored shall include:

i. Blood pressure.

ii. Pulse rate.

iii. Temperature.

iv. Clinical features of acute transfusion reactions.

11.2.3 The vital signs shall be monitored and recorded:

i. Before starting transfusion.

ii. 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).

iii. After completion of transfusion.

11.3 Record Keeping

11.3.1 The following information for each transfusion shall be recorded into the patient's case note:

i. Type of product transfused.

ii. Identification of product transfused (donation barcode number).

iii. Times transfusion starts and ends.

iv. Date of transfusion.

v. Adverse transfusion reaction, if any.

11.3.2 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.

11.4 Duration for Transfusion of Blood

11.4.1 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.

11.4.2 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.

11.4.3 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.

11.5 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.

11.6 Microaggregate filters shall be used to retain degenerating platelets, fibrin strands and clumps of red cells of 20-40 micron but not be used for routine blood administration.

11.7 Leukocyte filters shall be used to decrease the incidence of febrile non-haemolytic transfusion reactions, HLA alloimmunization, platelet alloimmunization and decrease the incidence of CMV transmission but not to be used for granulocyte transfusions.

11.8 Blood warmers shall be validated and maintained regularly before use and only be used under certain indication e.g. exchange transfusion, massive or rapid transfusion and cold agglutinin syndrome.

11.9 Medications or solutions, other than 0.9% NaCl, **SHALL NOT** be administered through the same tubing used for blood transfusion.

11.10 Each ward that performs blood transfusions shall establish procedure referring to the *Transfusion Practice Guidelines for Clinical and Laboratory Personnel.*

Refer Transfusion Practice Guidelines for Clinical and Laboratory Personnel 4th Edition 24th Edition 2016.

11.11 Discontinued Transfusion

11.11.1 Any blood remaining from a discontinued transfusion **SHALL NOT** be used.

11.11.2 Remnants of blood shall be clearly labelled as **USED BLOOD** and returned to the hospital blood bank immediately

11.11.3 The details of the transfusion and the reason for discontinuing the transfusion must be stated on the Recipient card attached to the bag.

11.11.4 Details and reasons for discontinuing the transfusion shall be clearly documented in the patient's case notes.

11.12 Return of Used Blood Bags

11.12.1 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.

11.12.2 The ward shall correctly and completely fill up a compatibility card/ label.

11.12.3 The compatibility card/ label shall contain at least the following information:

i. Name of hospital.

ii. Ward.

iii. Full name of recipient.

iv. Identity card/passport number of recipient/hospital registration number of recipient.

v. Recipient's blood group (ABO and RhD), age and gender.

vi. Date of transfusion.

vii. Time transfusion starts and ends.

viii. Volume transfused.

ix. Adverse transfusion reaction, if any.

x. Name and signature of staff.

11.12.4 The used blood bags shall be kept in a refrigerator duly marked and designated for this purpose, for 7 days after transfusion.

11.13 Disposal of Used Blood Bags

11.13.1 ALL used blood bags shall be autoclaved before it is sent for final disposal.

11.13.2 The disposal of the used blood bags shall be fully documented to ensure audit trail.

11.14 Return of Untransfused Blood

The ward shall return all untransfused blood immediately to the hospital blood bank. *Refer Transfusion Practice Guidelines for Clinical and Laboratory Personnel 4th Edition 24th Edition 2016.*

11.14.1 Untransfused blood that is returned to the blood bank shall be discarded unless it is kept in an appropriate condition and temperature.

11.14.2 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.

11.15 The clinician managing the paediatric patient shall consult with transfusion specialist (from Hospital Sibu or Sarawak General Hospital) in case of paediatric transfusion needed.

12. PAEDIATRIC TRANSFUSION

12.1 Any paediatric transfusion shall refer to the *Transfusion Practice Guidelines for Clinical and Laboratory Personnel.*

12.2 Ward that performs paediatric transfusions shall establish procedure referring to the *Transfusion Practice Guidelines for Clinical and Laboratory Personnel.*

Refer Transfusion Practice Guidelines for Clinical and Laboratory Personnel 4th Edition 24th Edition 2016.

13. TRANSFUSION IN SPECIAL CIRCUMSTANCES

13.1 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.

13.1.1 The choice of blood for transfusion in cases of life threatening bleeding:

i. **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

a) 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.

b) The requesting doctor shall clearly state the reasons for the transfusion in the patient's records and in the request form and sign it.

c) 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.

d) Full group and cross-matching procedures must be undertaken immediately even though emergency blood has been released for use.

e) Problems encountered during the cross-matching must be notified to the doctor concerned immediately to enable timely patient intervention.

ii. **Uncrossmatched group specific packed cells**

If the blood group of the patient is known, uncrossmatched group specific blood maybe given.

iii. **Emergency crossmatch**

Blood that are found to be compatible at immediate spin after 5 minute incubation at room temperature may be issued, compatibility testing and antibody screening shall be proceed to completion. Any incompatibility detected shall be immediately informed to the clinician concerned for appropriate action.

13.1.2 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.

13.1.3 All requests for emergency crossmatch should be accompanied by a phone call to the hospital blood bank to facilitate the process.

13.1.4 Details of the communication shall be documented, including the names of the caller and the receiver.

13.2 Any transfusion involves RhD negative patients, Antibody cases, Rare red cell phenotypes, the clinician managing the patient shall consult with transfusion specialist

(from Hospital Sibu or Sarawak General Hospital) in any case of transfusion including emergency situation.

13.3 Massive Hemorrhage and Massive Transfusion

Massive hemorrhage is defined as blood loss of 150ml/min or 50% blood volume within 3 hours or loss of total volume in 24 hours.

Massive Transfusion is defined as infusion of ≥10 units of red cells within 24 hours or a transfusion of blood and blood component equivalent to/or more to the patient's total blood volume if less than 24 hours or replacement of 50% or more of the estimated blood volume within 3 hours.

13.3.1 Massive Hemorrhage and Massive Transfusion Protocol

a) Massive Hemorrhage and Massive Transfusion protocol is used to identified and manage patient at risk of bleeding episode. It specified the responsibilities of the clinical team, pathology laboratory and the blood bank. It defines communication and information to be relayed.

b) **Early communication** with the Transfusion Specialist is required. **Medical officer who manages the patient should consult with Transfusion Specialist in Sibu Hospital or Sarawak General Hospital.**

c) In emergency situation, blood samples for blood grouping and cross matching should be taken accompanied by a duly completed request form prior to transfusion of 'safe O' blood. **Only 'safe O' will be supplied** due to the limitation of services and facilities in Kanowit Hospital Blood Transfusion Service.

13.4 Transfusion in Thalassemia patients

13.4.1 Medical officer who manages the patient should consult with Transfusion Specialist in Sibu Hospital or Sarawak General Hospital.

13.4.2 Blood samples for blood grouping and cross matching should be taken accompanied by a duly completed request form and will be sent to Sibu Hospital

Blood bank for cross matching. Specific phenotype and filtered blood should be considered and supplied to Kanowit Hospital Blood bank for transfusion.

14. 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.

14.1 All transfusion reactions shall be investigated and reported.

Refer guideline *Refer Transfusion Practice Guidelines for Clinical and Laboratory Personnel 4th Edition 24th Edition 2016.*

14.2 All personnel involved in ordering and administering transfusions shall be trained and assessed their competency in recognizing the signs and symptoms of transfusion reactions, and management of transfusion reactions.

14.3 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.

14.4 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 :-
b) Repeat ABO/Rh grouping.
c) Repeat crossmatching.
d) Direct and indirect antihuman globulin test (Coombs).
e) Urine examination for haemoglobin and red cell.

14.5 These specimens shall be accompanied by a request form for investigation of transfusion reaction.

Refer Transfusion Practice Guidelines for Clinical and Laboratory Personnel 4th Edition 24th Edition 2016.

14.6 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)

14.7 The "Report of Reaction to Blood or Plasma Transfusion" form must be completed.

14.8 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.

14.9 Once the Transfusion Adverse Event investigation is complete, fill up the transfusion adverse event form in duplicate and sent to the blood bank. Send a copy of the document to Pusat Darah Negara.

14.10 All the transfusion reaction reports should be discussed at the hospital transfusion committee meeting and appropriate measures implemented.

15. MANAGEMENT OF DONORS WITH REACTIVE TRANSFUSION TRANSMITTED INFECTIONS (TTIS) MARKERS

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

15.2 Post-Donation Counselling

15.3 During a post-donation counselling, a new blood sample shall be taken from the donor for confirmation testing. Risk factors related to the TTIs concerned shall be elicited.

15.3.1 Details of the counselling sessions shall be fully documented.

15.3.2 The donors shall NOT be informed of the screening test results from the donation until the results have been confirmed.

15.4 Managing Blood Donor

15.4.1 Donations that are repeatedly reactive may be confirmed as being of negative, or inconclusive after confirmatory testing being done and shall be counselled, temporarily deferred and followed-up for further investigations. The donor can then be accepted for future donations if screened non-reactive on follow-up.

15.4.2 A positive conclusion confirms that the donor is infected and should be deferred from future blood donation, counselled and referred for appropriate medical care.

15.4.3 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.

15.4.4 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)) by the screening centre (Hospital Sibu Transfusion Microbiology Laboratory).

16. MANAGEMENT OF SEROCONVERTED DONORS AND RECIPIENT

16.1 Seroconverted Donors

A seroconverted donor is one who is confirmed positive for a particular Transfusion Transmitted Infections (TTIs) in his current donation but was negative in the previous donation.

16.1.1 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 donation centre, and then referred to the appropriate physician for further management.

16.1.2 Upon confirmation of seroconversion of a donor, the donor shall be counselled and permanently deferred from donating. Further action shall be taken.

16.1.3 Details of look back investigations of seroconverted donor should be compiled and kept in bloodbank and a copy of report should be send to NHCC.

16.1.4 Upon notification of a seroconverted donor by the screening centre (Sibu Hospital Transfusion Microbiology Laboratory) transfusion record of recipient/s of the implicated donation/s shall be traced and the treating clinician shall contact recipient/s for further counseling and testing.

Refer Hospital safety policies and Laboratory standard precaution and safety guidelines.

16.2 Seroconverted Recipient

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

16.2.1 Donors of the blood that has been transfused to the patient in the 12 months period prior to the detection of the infection to be contacted for testing.

The hospital blood bank shall be informed to identify the blood donors and their status determined.

Refer Transfusion Practice Guidelines for Clinical and Laboratory Personnel 4th Edition 24th Edition 2016.

16.2.2 If a blood donor is identified as the source of infection, other recipients of his or her blood should be traced and investigated.

16.3 Investigation and Reporting

16.3.1 Investigations and reporting of seroconversions of both donors and recipients shall be carried out.

Refer Transfusion Practice Guidelines for Clinical and Laboratory Personnel 4th Edition 24th Edition 2016.

17. QUALITY MANAGEMENT IN BLOOD TRANSFUSION SERVICES

17.1 Organizational Structure and Responsibilities

a) The organizational structure must be well defined. Lines of authority and responsibility must be clearly spelt out.

17.2 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. All staff should 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) The policies for the archiving of documents and records must be in compliance with current regulations and laws.

17.3 Personnel and Training

a) Each personnel shall have a clear job description which includes lines of authority and responsibility.

b) Each personnel shall adequately trained and assessed to be competent in the specified task before being allowed to carry out the task independently.

c) Each personnel shall regularly trained and assessed to ensure continuous competency.

d) Records of training and assessment of competency shall be established and systematically maintained.

17.4 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.

17.5 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) Effective documented maintenance programs to ensure that all equipment shall functioning optimally at all times.

c) Procedures and manuals for the operation and maintenance of all equipment shall be available on site.

17.6 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) All materials must be first verified/ validated before being put into use.

c) All materials must be stored under appropriate storage conditions as to maintain their integrity.

d) Records of inventory of materials must also be maintained.

17.7 Validation of Processes and Procedures

a) 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.

b) Validation should be carefully planned and conducted in compliance with the established standards, guidelines and principles.

17.8 Audits

a) Regular internal/external (auditors from Sibu Hospital Blood Transfusion Service) audits should be planned and carried out.to monitor compliance to the quality management system, current policies and regulatory requirements

b) Findings from the internal audits and any actions taken must be documented, analyzed and presented to the management for quality improvement.

17.9 Continual Quality Improvement

a) Regularly review on the effectiveness of the quality system shall be done.

17.10 Safety

a) All personnel shall determine the potential hazards and use appropriate safety precautions before beginning any operation.

b) All personnel shall be familiar with the location of emergency equipment such as fire alarms, fire extinguishers, emergency eyewash, and shower stations and know the appropriate emergency response procedures.

c) Distracting or startling other workers when they are handling hazardous materials shall be avoided.

d) Always be alert to unsafe conditions and actions and call attention to them so that corrective action can be taken as quickly as possible.

e) Appropriate skin, eye and face protection must be wear before beginning any operation.

Refer Hospital safety policies and Laboratory standard precaution and safety guidelines.

18. HOSPITAL TRANSFUSION COMMITTEE

Hospital Transfusion Committee is to ensure safe and appropriate transfusion practices within the hospital.

18.1 The Hospital Transfusion Committee shall be authorized to take necessary actions to improve transfusion practices.

18.2 The Hospital Transfusion Committee shall:

18.2.1 Promote best practices in the hospital based on current policies, guidelines and directives.

18.2.2 Proactively and regularly review transfusion practices of various disciplines in the hospital.

18.2.3 Promote/organize and/or conduct education and training of all clinical, laboratory and supporting staff involved in blood transfusion.

18.2.4 Organize regular transfusion audits on the transfusion service to ensure compliance to policies, guidelines and directives.

18.2.5 Ensure all transfusion adverse events such as errors in transfusion process, donor and recipient seroconversion are investigated, analyzed and reported.

18.2.6 Monitor the hospital haemovigilance unit activities.

18.2.7 Implement corrective and preventive actions.

18.2.8 Monitor the use of blood to ensure adequate supply.

18.2.9 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.

18.2.10 The committee shall meet at least twice a year.

19. HAEMOVIGILANCE IN BLOOD TRANSFUSION

19.1 Haemovigilance Reporting

19.1.1 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.

19.1.2 Regular reports shall be submitted to respective Hospital Transfusion Committee (HTC) and National Haemovigilance Coordinating Centre (NHCC).

19.1.3 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.

Refer Transfusion Practice Guidelines for Clinical and Laboratory Personnel 4th Edition 24th Edition 2016.

19.2 Patient Haemovigilance

19.2.1 The treating doctor shall send a request for transfusion reaction investigation.

19.2.2 The hospital blood bank shall then carry out relevant laboratory investigation. The findings shall be reported to the treating doctor concerned.

19.2.3 The treating doctor shall provide a detailed report include information such as clinical findings, laboratory investigations, personnel involved and corrective actions taken. This report shall be forwarded to the hospital blood bank within two weeks of the occurrence.

19.2.4 Blood bank shall 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 and the NHCC.

19.2.5 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.

Refer Transfusion Practice Guidelines for Clinical and Laboratory Personnel 4th Edition 24th Edition 2016.

19.3 Donor Haemovigilance

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

19.3.2 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. The doctor in charge of the collection centre shall retain this report.

b) A copy of Reporting Form for Adverse Donor Reaction shall be forwarded to the NHCC and HTC.

Refer Transfusion Practice Guidelines for Clinical and Laboratory Personnel 4th Edition 24th Edition 2016.