NATIONAL GUIDELINES ON BLOOD DONOR ASSESSMENT AND SELECTION PROCEDURES

2016



Blood Safety Program, Health Care and Diagnostic Division Department of Medical Services Ministry of Health Thimphu, Bhutan

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FOREWORD

National Blood Transfusion Service is an important part of the national health and medical services. Over the years, many improvements have been seen in this service under the umbrella of the Blood Safety Programe. The service is responsible for collecting blood from low risk donors and for ensuring the safety and sufficiency of blood in the country.

Blood safety has become an integral component of many programs in the Ministry of Health namely National HIV/AIDS Control Program; Disaster Management Program; Mother and Child Health Program and other Non-Communicable Disease Control Programs.

The safety and availability of blood and blood products for transfusion requires the recruitment and selection of voluntary non-remunerated blood donors, qualityassured screening of all donated blood and safe and rational clinical use of blood. The publication titled "National Guidelines on Blood Donor Assessment and Selection Procedures" embodies the knowledge and experiences to assess the suitability of a potential blood donor to donate blood. These criteria should be consistently applied in every blood donation setting on each occasion of donation irrespective of whether the donor is a voluntary non-remunerated donors or family/replacement or a directed donor.

These guidelines should be used in conjunction with the National Blood Policy, National Standards for Blood Transfusion Service and Blood and Blood Products Regulations, Bhutan to be most meaningful.

I would like to thank the entire national and district blood center personnel for their efforts and enthusiasm in drafting the chapters for this edition.

I hope this publication will be useful, informative and guide the health personnel in recruiting and selecting voluntary, non-remunerated blood donors to ensure quality and safety of blood.

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ACKNOWLEDGEMENT

The Blood Safety Program, Ministry of Health, Royal Government of Bhutan would like to appreciate and thank the valuable contribution and hard work put in by the national technical advisor for the program, Dr. Mahrukh Getshen in spearheading the development of this document.

The Ministry of Health acknowledges the national and all the district blood center personnel for their efforts and enthusiasm in reviewing the chapters for this edition.

The Ministry of Health is also grateful to the WHO country office for facilitating the development of this document and would like to extend its appreciation and sincere thanks to our financial partner OPEC Fund for International Development (OFID) Project for providing the necessary funds for the printing of this publication.

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1. Introduction

The National Blood Transfusion Service (NBTS) and each blood center in the country have a primary responsibility to supply safe and sufficient blood and blood products to the hospitals and blood storage centers in a timely manner.

In fulfilling this responsibility, the blood centers must ensure that the act of blood donation is safe and causes no harm to the donor and that the products derived from donated blood are clinically effective to the recipient, with a minimal risk of any infection that could be transmitted through transfusion.

The findings of the audits and visits to the blood centers indicate that significant variations exist between blood centers to which the national blood donor selection criteria set in the current National Standards for Blood Transfusion Service (NSBTS) are followed. This leads to unnecessary deferrals of safe and healthy donors or acceptance of unsuitable individuals. In addition, the donor screening process for suitability to donate blood has also been different at different blood centers in the country.

Therefore, in-order to establish uniformity among blood centers, these guidelines have been developed.

2. Objectives

- To enable the blood center staff to conduct the assessment of the intending blood donors visiting their centers or during mobile blood donation camps in a uniform manner.
- To screen and select only those individuals that are suitable to donate blood.
- To appropriately defer the unsuitable individuals without hurting their sentiments at the same time encouraging them to re-visit the center after completion of deferral period.
- To maintain uniform records of donor selection and deferral procedures.

3. Scope

These guidelines relate only to whole blood collection of healthy volunteer donors. This document shall guide the staff in the decision making process during blood donor screening, however in the end, the staff will have to apply their knowledge, skills and experience to ultimately decide on suitability of a potential donor on an individual case by case basis. The drafting team has been conscious of the unique situation in the country wherein at majority of blood centers, blood donor selection and screening process is being carried out not by medical officers or nursing staff but by laboratory technicians and/or technologists who have minimal knowledge on clinical conditions and diseases. Therefore, additional advice on suitability of donors with health issues should be obtained from medical officers or specialists of that particular health facility.

While conducting blood donor screening and blood collection at mobile donation camps, such medical advice or emergency medical support will not be available, the staff can therefore defer unsuitable donors when in doubt and request them to visit the blood center at a later date. Common examples of health issues encountered by staff include persistently high or low blood pressure recordings, gastro-intestinal problems, intake of long-term medications, use of traditional medicines or treatment, for which guidance is provided in following chapter on donor history.

4. Target Audience:

- NBTS personnel: doctors, laboratory technologists and technicians working in blood centers and blood storage centers.
- Clinicians: clinical officers, medical officers and specialists in health facilities.
- Personnel in the Blood Safety Program, and other relevant programs such as National HIV /AIDS Control Program, Hepatitis Prevention and Control Program, Nutrition, Non-Communicable Diseases Program, Disaster Management Program in Ministry of Health.
- Blood /Drug Regulatory Authority staff involved in blood regulations.
- Institutions and agencies involved in organizing blood donations, donor motivators, and donor recruiters.

The guidelines are based on findings of analysis of the current national data (Annual Blood Bank report 2015) on blood donors, prevalent transfusion transmissible infections (TTIs), evidence obtained from published literature on defined physiological conditions, diseases and risk behaviors in relation to suitability of individuals for blood donation. Where published evidence is lacking, the document recommends best practices followed internationally.

The guidelines shall be valid until following five years and the Blood Safety Program, Ministry of Health shall be responsible to initiate the review process. The guidelines shall be updated in response to any emerging infections, technology advancements and new evidence or medical information available through published literature.

5. General principles

The code of ethics for blood donors, blood donation and for NBTS personnel included in the current NSBTS shall be followed.

Only persons in good health and healthy lifestyles shall be accepted as blood donors.

An intending donor's medical history must be evaluated on the day of donation by a qualified staff of blood center who has been trained in the National Guidelines on Blood Donor Assessment and Selection Procedures.

If there is any doubt about the suitability of a donor, donation should not be taken and the donor referred to the supervisor/in-charge of the donor management area who is competent to do further evaluation and decision making.

Patients referred for therapeutic venesection shall not be accepted as blood donors and blood collected shall not be considered as blood donation or used for clinical transfusion.

The head of the blood center shall ensure that all staffs are appropriately trained in blood donor assessment and selection process and national standards and specific SOPs are followed. Care should be taken to ensure that undue pressure is not put on persons to donate blood.

Assistance shall be given by staff to donors with special needs, including illiterate donors.

6. National System for blood donor selection

The National Blood Policy 2007 has stated in its mission statement that the blood and blood products shall be safe and quality assured. The Policy has been supported by the National Regulation on Blood and Blood Products -2016 that upholds the protection of the health and safety of the blood donors and blood recipients.

The strategic objective no. 3 of the National Blood Policy expresses 'Promotion of Voluntary Blood Donor Recruitment Program' to achieve 100% voluntary blood donations and has four defined strategies to collect safe and adequate blood in the country.

The National Standards for Blood Transfusion Service includes an entire chapter no. 3 on Blood Donor Management.

The national guidelines and criteria set in this document for blood donor selection have been developed in compliance with the national standards and regulatory requirements and after a review of the international guidelines and best practices.

Current national data on blood donor assessment including hemoglobin, weight, risk factors, donor deferral reasons and prevalent transfusion transmissible infections have been taken into consideration during the drafting process.

7. Assessment of blood donor suitability

The intending blood donor must be in good health on the day of donation and to the best of the knowledge free of any infection that can be transmitted from the donation to the blood recipient. Therefore each blood center shall have an established donor screening or assessment process to evaluate the suitability of all individuals visiting the center with the intention to donate blood before they are actually permitted to donate blood. The screening and decision making shall be done on the day of blood donation only.

Such a screening process has three objectives:

Firstly, to ensure that the donor's health does not come to any harm through the donation act.

Secondly, to ensure that the donor's blood has the quality requirements to be clinically effective to the blood recipient.

Thirdly, to ensure the blood recipient does not have any adverse event during or after transfusion.

The steps involved in the assessment process before blood donation must include:

- 1. Donor reception and registration
- 2. Blood donor provided with pre-donation information
- 3. Completion of 'Donor Questionnaire and Consent form'
- 4. Donor interview and counseling
- 5. Physical checkup and Hb estimation
- 6. Informed consent
- 7. Deferral of unsuitable donors

It is important that all the above steps are followed for assessment of each intending donor by the blood center staff to ensure safe blood donation process and outcomes.

The following information provides details into each step.

1. Donor Registration

The first step of donor registration is to capture personal details such as:

- ✓ Full name
- ✓ Age or date of birth and gender
- ✓ Contact details like address, telephone number or email address
- ✓ Citizenship Identification number or identity number
- ✓ Unique donor registration number in case of repeat or regular donors.

Such a registry can provide some information on the average attendance of donors to the blood centers. It is useful for follow-up, recall, retention and for donation records. The details can be recorded on a 'Blood Donor Registration Sheet' (Annexure 1).

2. Pre Donation information

The pre-donation information step is an opportunity to educate the intending donor to allow him/her to self decide whether to go ahead to next step or self–exclude and exit from the center. It is important that staff provide a chance to clarify any doubts or answer any questions posed by the donor. Also the staff must be vigilant to identify individuals seeking HIV testing and results under the pretext of blood donation.

The pre-donation information should educate the donor on:

- \checkmark The purpose of the blood donation and the use of the products.
- \checkmark A description of the procedure and its likely duration.
- ✓ Options to withdraw from blood donation before, during or after donating blood.
- ✓ A description of the common risks and discomfort involved in the phlebotomy procedure such as vaso-vagal reactions, or haematoma formation and how these can be prevented.
- ✓ The tests conducted on donor and donated unit and consequences of abnormal test results.
- ✓ Assurance of confidentiality in entire process.
- ✓ Informed consent.

The above information can be provided verbally by the blood center staff if donors visiting are in small numbers. For mobile sessions or during high turnover, it can be through printed brochures, posters, audio-visual or online materials. Keep the information simple, use common spoken or local language with minimal technical words. Blood Safety Program shall be responsible to develop and make available IEC materials containing such pre-donation information to all blood centers.

3. Completion of 'Donor Questionnaire and Consent Form'

Once the donor decides to donate, he/she must complete a 'Blood Donor Questionnaire and Consent Form' (Annexure 2). It is a tool to screen an intending donor through a set of questions that elicit responses relating to the general health, lifestyles, travel history, past medical/surgical and medication history. For female donors, questions on their reproductive history are also included. It is essential that the donors are made aware of the importance of this form, significance of each question in the form and providing honest answers. Staff must spend more time explaining the first time donors; at the same time reminding the regular donors to be careful while answering. The questionnaire can be paper-based or computerized. Any affirmative answer can be further elaborated during the next step of donor interview.

4. Donor interview and counseling

This step involves a face to face confidential interaction between the staff and the donor to review the answers in the questionnaire form, clarify doubts or obtain further information on positive answers. During interview session, donor is counseled on high-risk behavior and its implications on blood safety and also given a chance to provide honest answers or change the response to any question made early in the form.

Steps 3 and 4 can be combined especially for donors who are unable to read and write. Unsuitable donors identified during the session can be deferred with appropriate advice for further medical attention if needed. Details are provided in Step7.

Paper based forms have to be signed by all donors to imply that he/she has provided the accurate information to the blood center to the best of his/ her knowledge and also be signed by the staff interviewing. The success to effective communication is to use simple understandable language with confidence and sensitivity so that the donor feels comfortable and confident in providing honest answers to very private questions such as any unsafe sex practices or unhealthy lifestyles.

It may not be always possible to provide a similar private environment in a donation camp during this step, nevertheless a specific area away from the crowded place should always be identified and if situation arises donor taken to that area for a private conversation and counseling.

5. Physical checkup and Hb estimation

This step is to evaluate general health of a donor by observing for:

- ✓ ill health, obvious mal-nutrition
- ✓ pallor
- ✓ jaundice
- \checkmark skin rashes or infection on arms
- ✓ tattoos, body piercing marks
- ✓ signs of alcohol intoxication or intra-venous drug abuse

It also includes physical examination such as:

- ✓ weight
- ✓ body temperature for fever
- ✓ blood pressure
- ✓ In addition, quick hemoglobin estimation has to be carried out to screen for anemia.
- 6. Informed consent

It is a voluntary agreement on the part of the donor consenting for blood donation, blood testing for TTIs, transfusion of his/her blood /blood products to patients and for any additional purposes. It must be obtained by a trained person, fully conversant with the procedure.

Each donor must sign the 'Donor Questionnaire And Consent Form' before donation. Donors who are unable to write should be provided with options of obtaining thumb impression in place of signature.

Consent of the parents/legal guardians of young donors between 16 and 17 age groups must be obtained.

7. Deferral of unsuitable donors

On completion of step 1 through step 5, the staff shall now come to a conclusion on the suitability or unsuitability of the donor based on national selection criteria. When a donor is not suitable for donation he/she shall be deferred with:

- Explanation in a clear and understandable language on the reason for deferral.
- ✓ Information whether the deferral is temporary or permanent. If temporary, the donor must be encouraged to visit after the deferral period is completed.

- ✓ Referral to a doctor for consultation if required
- ✓ Reassurance and opportunity to ask questions or clarify any doubts
- ✓ Filled 'Blood Donor Deferral Form' shall be handed to deferred donor (Annexure 3)

The staff must be aware that the possibility of a deferred donor returning after deferral period shall highly depend on how the staff interacted with him/her when found unsuitable and on the clarity of the deferral explanation provided. It can have a negative impact on donor return if staffs are not sensitive and polite while deferring.

All records of deferred donors with reasons for deferral shall be maintained on a 'Blood Donor Deferral Sheet' by the blood center. (Annexure 4). Periodic analysis of data on the donor deferrals can provide insight on the major reasons of deferral, effectiveness of donor information & education, compliance to national guidelines and training needs of the staff. Records can help in the donor recall or donor re-entry or in permanent deferral decisions.



Fig.1 shows the flow process in the blood donor assessment and selection

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8. Criteria for blood donor selection

The decision as to whether an individual is suitable to donate blood is based upon few general criteria and few specific criteria based upon findings of health history, physical examination and tests done during donor screening process.

8.1. The general selection criteria shall be:

8.1.1 Age or date of birth: The information on age is to ensure that donors are not too young or too old to donate. The age limit shall be between 18 and 65 years.

18 years is the legal age of consent however young individuals of 16-17 years can be permitted to donate blood provided they fulfill the physical and hemoglobin criteria set and appropriate consent from parents / guardians is obtained. The age of 16 must be an absolute lower limit for blood donation to ensure the health and safety of these young donors.

The upper age limits for regular donors is set at 65 years and for first time donors at 60 years, provided they do not suffer from any medical illnesses especially cardio-vascular diseases and a screening is done by a medical practitioner.

8.1.2 Donation interval: Since the donors are donating whole blood, iron lost in a donation is not restored quickly. Therefore for male donors an interval of three months and for female donors an interval of four months is set. As a general rule, frequency must not be more than four times in one year. Female donors who are menstruating must defer themselves temporarily.

8.1.3 Occupation: Donors who are from professions such as construction workers, long distance drivers, crane operators, athletes or pilots must be extra cautioned after donation because delayed fainting after donation may present which can be hazardous to them or to others.

8.1.4 Last meal taken: The donor should have eaten something in the last 4 hours and had 5 hours sleep. If not, offer the donor some refreshment or atleast 500ml of drinking water before donation. Heavy fatty meals should be discouraged to avoid lipaemic plasma in donation unit. It is recommended that all donors are offered some drinking water or other form of fluids just before donating blood in addition to post-donation fluid supplements.

8.2. The specific selection criteria shall include:

8.2.1 Body Weight: Low body weight and low blood volume can lead to donor adverse reactions such as vaso-vagal reactions. Therefore minimum acceptable body weight shall be 45 kg for 350ml and 50 kg for 450ml blood collection. There is no defined upper limit of body weight for blood donation but obesity can make veins difficult to access. In any case, blood volume collected should not exceed 10ml/kg body weight. Low body weight is one of the reasons of temporary deferral especially among high school or college students but the period of deferral cannot be pre-determined. Caution must be taken if the donor gives history of sudden weight loss even though he/she is within acceptable weight range.

8.2.2 Body temperature: Fever or body temperature of more than 37.5°C could be a sign of infection or a medical condition in a donor. Donor may present as being unwell and with other associated symptoms or taking medications. Such donors should be deferred indefinitely till complete treatment and recovery is made.

8.2.3 Blood Pressure(BP): BP is one of the physical examination carried out for donor screening. However donor anxiety, errors due to non-calibrated or non-validated blood pressure equipment and inappropriate skills of staff can lead to temporary elevated BP reading. Therefore rechecking BP after 10 to 15 minutes of rest is advisable. Donors with H/o hypertension is discussed in following chapter.

Acceptable BP levels for donation shall be:

- ✓ Systolic reading between 90 mmHg and 180mmHg
- ✓ Diastolic reading between 50 mmHg and 100mmHg

8.2.4 Hemglobin (Hb) level: Hemoglobin screening prevents anemic individuals from donating blood and detects if regular donors are suffering from donation induced iron deficiency state. In addition, it prevents collection of anemic blood that shall compromise the clinical effectiveness to patient receiving such transfusions. Minimum acceptable hemoglobin level must be 12.0 gm% for females and 13gm% for males. Anyone below this threshold shall be deferred. Blood centers may supplement mild anemic(Hb=9 to 12gm%) donors with iron tablets for a month along with dietary advice, whereas all moderate to severely anemic donors(Hb less than or equal to 8gm%) must be referred to a physician for further management. Donor with H/o anemia is discussed in following chapter.

The upper level for Hb must not exceed 17gm%.

In addition to above criteria, the prospective donor must be free from any skin diseases at the phlebotomy area, mentally alert on the day of donation and not a jail inmate or a drug/ alcohol addict and no obvious lymph node enlargement.

8.2.5 Pregnancy, child birth and lactation. All female donors shall be asked to provide information on current pregnancy, child birth in last one year and breast feeding. Donors shall be deferred temporarily based on their response to each criterion. Menstruation is not an absolute criterion for deferral, but female donors with heavy menstrual flow or anemia shall be deferred temporarily.

9. Donor History

9 A. Medical History

Having checked for donor suitability based on above criteria, medical history using the donor questionnaire and while conducting interview session must be obtained. The aim is to detect any medical or surgical condition in a prospective donor that can pose harm to the donor or to the patient. The donor shall be made to elaborate any condition identified or declared during this session.

Staff must ask questions such as:

- ✓ When was the condition identified?
- ✓ Was it diagnosed by a doctor or self-identified?
- ✓ Any treatment taken from a doctor?
- ✓ Any prescriptions or documents available?
- ✓ What are current symptoms or on-going complaints in relation to the condition?

Points to remember

✓ Whenever in doubt, conditions posing threat to the donor or recipient shall be discussed or brought to the notice of the head of the blood center or to a clinician in the health facility. This shall prevent unnecessary deferrals of donors who would have been suitable for blood donation.

- ✓ All donors should be made aware that recipients are at risk from transfused blood, and therefore donors shall report to the blood center of any illness that develops after and within 14 days of donation.
- ✓ The staff carrying out the donor assessment must confirm they have done the assessment by signing the donor questionnaire.
- ✓ Information about either the donor or the donation which becomes available after the blood has been issued or transfused, should also be reported to the patient's physician and in charge of the blood storage center.

Discussed below are the common conditions identified at the blood centers during donor history taking and recommendations on deferral and deferral periods.

T-1.1. 1

FA.I Alielilla Table I		
Accept donor if	An iron deficiency anemia, treatment is completed & Hb level is acceptable as in the selection criteria.	
	Anemia is due to folate or B12 deficiency, donor has recovered fully and taking medications like Vitamin B12 or folic acid	
Defer temporarily if	Symptomatic or Hb level not acceptable as per the selection criteria.	
	Currently under management for anemia.	
Defer permanently if	Chronic anemia of unknown cause or other kidney, cardio-vascular or respiratory problems present.	

9A.1 Anemia

9A.2 High Blood Pressure: The measurement of BP is recommended on the basis that uncontrolled hypertension can be a risk factor for cardiovascular or non-communicable diseases. Although high or low blood pressure readings or history of hypertension is a concern for the staff as it can lead to increased adverse reactions, literature evidence in this area is found to be limited. More-so donor anxiety may result in the temporary elevation of systolic BP. Therefore, recommendations are:

Table 2	2
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Accept donor if	BP is controlled with medication and no heart, kidney or other complications of hypertension present.
Defer temporarily for a month if	Medications for hypertension are recently started or BP is not under control even with medications.
Defer permanent- ly if	Suffering from heart or renal or other systemic dis- eases secondary to hypertension.

9A.3 Renal or urinary tract diseases: It's important to prevent the risk of bacterial infection which may enter the bloodstream through donated blood and to safe guard the health of a donor with such disease.

Table 3

Defer temporar-	Suffering from lower urinary tract infections. Defer for 14 days or till full recovery and completion of treatment.
IIY II	H/o nephritis. Defer for as long as 5 years after full recovery even if renal functions are back to normal.
Defer permanent- ly if	H/o chronic renal disease causing ill-health, anemia, or associated with chronic or recurrent infections.

9A.4 Gastrointestinal diseases: For GI diseases it is important to obtain history of any acute or chronic blood loss, any GI related infections or cancers or acute or chronic diarrhea or dysentery.

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Accept donor if	 Presents with any of the following diagnosis: irritable bowel syndrome, cholecystitis recovered from acute attack, gallstones, mild gastro-oesophageal reflux, peptic ulcer syndrome or peptic ulcer but with no blood loss or other symptoms 	
Defer temperarily if	Active peptic ulceration: defer until completion of treatment and full recovery.	
Delet temporarity if	Active inflammatory bowel disease (ulcerative colitis or Crohn's disease).	
Defer permanently if	Individuals with mal-absorption syndromes.	

9A.5 Diabetes: Important to obtain treatment history and check for recent blood sugar results.

Table 5		
Accept donor if	Diabetes well controlled sugar levels with diet or oral hypoglycemic drugs. There are no signs of infection, or organ complication.	
	Diabetes requiring Inj. insulin.	
Defer permanently if	Complications of diabetes with multi organ involvement.	

9A.6 Thyroid disease: Important to obtain treatment history and check for recent thyroid function results.

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lable 6		
Accept if	Asymptomatic goiter	
	Euthyroid with thyroxin medication	
Defer temporarily if	Under investigation for thyroid disease	
	Hyper- or hypo-thyroid	
Defer permanently if	Suffering from thyrotoxicosis	

9A.7 Respiratory diseases: It's important to prevent the risk of bacterial infection which may enter the bloodstream through donated blood and to safe guard the health of a donor with such diseases.

Table 7

Accept if	Asymptomatic asthma controlled with non- steroidal medications.	
	Asthmatics with acute attacks.	
	Acute respiratory infections like bronchitis, on antibiotics	
Defer temporarily if	Pulmonary TB on anti-TB treatment	
	TB treated individuals, defer for 5 years after completing full course of treatment	
	Chronic or recurrent respiratory infections or diseases	
Defer permanently if	Asthmatics on steroids	
	Lung cancers	

Table 5

9A.8 Skin diseases: Consider deferral if the skin problem is a manifestation of a systemic disease

Table 8		
Accept if	Diagnosed as a c/o eczema, acne or psoriasis. Donor must not be on antibiotics, steroids and venepuncture site should not be affected.	
Defer temporarily if	Diagnosed as a c/o psoriasis with infected wounds Receiving steroids or antibiotics Venepuncture site is affected Having generalized skin disease(s) Having acne/pimples and on oral antibiotics Contagious skin diseases such as scabies and ringworm until cleared	
Defer permanently if	Skin manifestation is a manifestation of a par- ticular systemic disease.	

9A.9 Cardio vascular diseases: Defer permanently all individuals with any cardiovascular diseases.

9A.10 Beeding disorders: Defer permanently if h/o unexplained blood loss, easy bruising prolonged time in controlling bleeding after minor cuts. Examples are diagnosed cases of thrombocytopenia, hemophilia, or other clotting disorders.

9A.11 Epilepsy

Table 9

Accept if	Epilepsy in childhood and adulthood is seizure-free
Defer permanently if	History of epilepsy or seizure disorder, on anti-epileptic drugs. They are generally deferred because of concerns that adverse reaction like va- sovagal syncope associated with blood donation may precipitate an epileptic seizure

9A.12 Muscular diseases

Table 10		
Accept if	 back pain sciatica frozen shoulder osteoarthritis 	
Defer temporarily if	H/o fractures until plaster or external fixation is removed and they are fully mobile	
Defer permanently if	Suffering from systemic diseases affecting joints, such as: rheumatoid disease, psoriatic arthropathy or ankylosing spondylitis	

9A.13 Psychiatric diseases: Defer if diagnosed with a psychiatric disorder or on anti-psychiatric treatment

9A.14 Surgeries: Find out the cause of surgery. The cause itself could be a reason for deferral.

- ✓ Defer for 3 to 6 months for minor surgeries like tonsillectomy, appendicectomy, gall stone removal procedures and till they have resumed normal activity.
- ✓ Defer for 12 months major surgeries like hip replacements, for major bone fractures, hysterectomy etc.
- ✓ Defer for 72 hours for dental procedures like tooth extraction and up to 7 days following root canal therapy or till antibiotic treatment is completed.

9A.15 Hematological diseases: Individuals with hereditary haemochromatosis which is an inherited condition of iron overload through excessive iron absorption of dietary iron are treated by phlebotomy. Such individuals who are otherwise healthy and meet all other donor selection criteria may be accepted as blood donors and donation used for transfusion.

Polycythemia Vera: Individuals with this disease should not be taken as blood donors and their blood unit should be discarded.

9A.16 Medications and vaccines: Donor deferral for most medications is based on the underlying illness suffered by the donor (e.g. cardiovascular disease, diabetes, anaemia and malignancies) rather than on the properties of the drug itself. Since, in general, traces of medicinal drugs in blood and blood components are believed to be harmless to patients, many people taking medications – even when prescribed – are acceptable as blood donors as long as the reason for which the medication is taken is acceptable.

Antimicrobials or antibiotics: Since they are administered for treatment of infections, deferral is made till full recovery and not just completion of therapy.

If the donor has taken drugs affecting platelet function (e.g. aspirin) within last 3 days, the donation can be done but donation shall not be used for preparing platelet concentrates.

Sporadic self-medication with some drugs (e.g. vitamins, aspirin, sleeping tablets or oral contraceptive pills) need not prevent a donation being accepted, as long as the donor is in good health.

Other drugs or tablets may be acceptable. However, the taking of some drugs may indicate a disease that would automatically make a donor ineligible.

9A.17 Vaccination History

Vaccines	Deferral period
Vaccines with live bacteria or viruses ex. BCG, rubella, measles, oral polio, mumps, typhoid fever vaccine or chol- era vaccine	Four weeks
Vaccines with killed bacteria or inacti- vated viruses ex cholera, typhoid, polio or influenza	Defer for one day
Toxoids	Defer for one day
Hepatitis B vaccine	• Defer for one day if taken without any h/o of contact or exposure to disease
	• Defer for one year if there is
	h/o of contact, or exposure to positive or suspected positive HBsAg individual
Rabies vaccine	Defer for one year if taken after exposure to a dog bite

Table 11

9A.18 Blood Transfusion history: Defer for a period of 12 months due to the possibility of the donor getting a TTI through the blood transfused even if it was screened negative for the infectious markers. The 12 month deferral period covers the window period of most of the TTIs.

9A.19 Alternative and traditional medicine: Any therapy involving skin penetration (e.g. acupuncture or scarification) may cause blood-borne infection unless sterile techniques are used. Donor with h/o traditional medicine must be asked regarding the medical problem for which he/she is taking treatment and about these procedures if undertaken, to decide accordingly.

9 B. Life style and sexual history

The staff interviewing the intending donor should have the knowledge and understanding of the infectious diseases that are transmissible through blood and blood products to the recipient and therefore every effort is made to prevent the transmission of disease by careful and appropriate selection of donors. As mentioned earlier, this includes providing the donor with clear, understandable information and pre-donation counseling on the mode of transmission and eliciting any positive response to exposure to any risk of acquiring a transfusion-transmissible infections.

It would be worthwhile to remember that the infectious agent be it a virus, bacteria or protozoa have to be present in the blood/ blood products for a long period and in infectious form; they have to be stable and alive at the temperatures at which blood/blood products are stored; have long incubation periods before the symptoms are known or they cause mild nonspecific symptoms missed out during history taking session. Due to these reasons, the donor may think he/she is healthy enough to donate blood and the screening of the donation for TTIs may not detect the infection marker because of the window period.

Prospective donors should be asked relevant questions to assess any history, signs or symptoms indicative of current or past infections, specific high-risk behaviours or activities, travel history, contact with infectious diseases and possible exposure to infection as result of the profession or environmental factors.

Individuals who have engaged in behaviours that pose a high risk for HIV, HBV and/or HCV infection should be deferred for an interval that covers the window period of these infections. Such a deferral must be done with counseling in confidential, sensitive and non-judgmental manner.

Transfusion Transmissible Infections: Hepatitis B and hepatitis C, HIV/AIDS, syphilis and malaria are considered as transmissible infections associated with blood transfusion.

The following are the recommendations:

9B.1 Hepatitis B and C: The donor must be asked for h/o of jaundice, hepatitis, positive test result for Hepatitis, unsafe sex practices, sharing sharp objects for drug abuse, tattoos or close contact with an individual with hepatitis or told by doctor or blood center staff not to donate blood earlier.

All donors may not understand the term 'jaundice' or hepatitis and so the question asked would be " Did you or your close contacts like spouse or others in same house suffer from yellow discolouration of eyes, with yellow coloured urine, loss of appetite, vomiting or upper abdominal pain?"

Accept donor if	 H/o of Viral Hepatitis/Jaundice before puberty (before age of 11 years). 12 months have passed since last contact with a hepatitis positive sex partner or close contact with household member
Defer donor for 6 to12 months if	 Had recent sexual contact with a hepatitis positive partner Had recent close contact with hepatitis positive household member. H/o unprotected, casual sex, or had sex in return for payment or sex with multiple partners (male or female). Health worker with accidental needle stick or mucosal injury recently. H/o tattoo, skin piercing done with unsterile needles
Defer donor permanently if	Has or had HBV or HCV infections

Table 12

9B.2 HIV/AIDS: With the emergence of HIV/AIDS, donor population with sexually transmitted diseases or high risk behaviours is not safe to donate blood and must be deferred.

The following individuals should be excluded permanently or for 12 months since the last unsafe act:

- a. Intravenous drug users or individuals sharing sharp injectable objects
- b. Persons with multiple sex partners
- c. Commercial sex workers
- d. Persons who had paid, casual or unsafe sex
- e. Individuals with homosexual behaviors
- f. Sex partners of all the above
- g. Recipients of regular blood and blood products' transfusions
- h. Persons suffering from HIV/AIDS or with confirmed Positive HIV testresults

Techniques for identifying and excluding high risk individuals:

- ✓ Direct questioning focusing on sexual practices during pre-counseling session and prior reading of information materials by donor. Also elicit history of un-explained fever or sudden weight loss, chronic diarrhea and look for swollen glands
- ✓ Physical examination for search of any puncture marks or intravenous drug abuse.
- ✓ Discouragement of persons tempted to donate blood so as to obtain HIV test results. Such persons must be directed to Voluntray Counselling and Testing Centers(VCTs) and excluded to donate blood.
- ✓ Informing donors about confidentiality in the procedures; donor and donation records is very important to build confidence among donors to share sensitive and private answers.

Follow the recommendations in the table below:

Accept donor if	12 months have passed since last contact with a HIV positive sex partner or close contact with household member		
Defer donor for 6 months if	 H/o unprotected, casual sex, or had sex in return for payment or sex with multiple partners (male or female). Health worker with accidental needle stick or mucosal injury recently H/o tattoo, skin piercing done with unsterile needles 		
Defer donor for 12 months if	 Had recent sexual contact with a HIV positive partner or Had recent close contact with HIV positive household member. 		
Defer donor permanently if	Has HIV infection clinically or with laboratory evidence		

Table 13

9B.3 Syphilis and other Sexually Transmitted Infections (STIs): Donors with history of syphilis, gonorrhea or other STIs must be deferred for 12 months after treatment. Such a deferral is necessary to prevent any HIV transmission as having an STI is an indication of high risk behavior.

9 C. Travel history

Increased and rapid travel of the population may lead to asymptomatic people donating infectious blood. A clear and detailed travel history must be obtained from all donors to minimise the risk of transmission of malaria, dengue and emerging diseases such as Ebola or Chikangunya or Zika virus.

For Ebola, Chikengunya or Zika virus infections, the blood centre personnel must follow the advice and notifications by the Ministry of Health.

9C.1 Malaria:

Endemic areas: In addition to asking donors for history of malaria infection or treatment, in endemic areas declared by MoH, all intending blood donors must be tested for malaria antigen or for malarial parasite(MP) by smear microscopy. Also ask on the use of malaria control measures like use of bed nets, mosquito repellant etc.

Defer for 6months if	If suffered from malaria or taken anti-malarial treatment
Defer permanently if	Tested positive for malarial antigen/s or for MP on microscopy
Accept if	No history of malaria or treatment and malarial antigen test or microscopy test result is negative

Non-endemic areas: Ask for history of recent travel to endemic areas, history of malaria or febrile illness.

Table 15

Defer for 6-12 months if	Travelled from non-endemic to endemic areas with or without history of febrile symptoms on return.
Defer permanently or for 3 years	If diagnosed with malaria and treatment received

10. Special considerations and emergency situations

10.1 Donors of pre-deposit autologous donations: Pre-deposit autologous donations must be collected according to the same requirements as allogeneic donations but the deferral criteria may vary. These donations must be clearly identified and kept separate from allogeneic donation. Autologous donations must be done in consultation with the treating physician.

Criteria for deferral-

- Presence of bacterial infection
- Positive screening results for TTIs.
- H/o epilepsy , uncontrolled hypertension, cardio-vascular disease
- Pregnancy with impaired placental flow or intra uterine growth retardation
- Children

10.2 Directed blood donors: Directed donations must be collected according to the same requirements as allogeneic donations. In addition the ABO/Rh blood group of the directed donor must be the same as that of the directed recipient.

10.3 Mobile donor sessions: Notwithstanding the fact that premises used for mobile donor sessions may often be accepted, as the only local venue available, they must be of sufficient size, construction and location to allow proper operation, cleaning and maintenance. Availability of a written plan of action appropriate to different venues would be beneficial to the blood center team and to the organizers. Care must be taken to avoid disturbances of other activities or work within the venue if it is being shared with a work place. Account must be taken of the following activities/requirements when selecting a venue:

- ✓ registration of donors and all other necessary data entry or management
- ✓ appropriate facilities to assess the fitness of individuals to donate
- ✓ sufficient seating (tables and chairs, cots)should be provided for donors and staff, with allowance made for possible queues during busy periods
- \checkmark withdrawal of blood from donors without risk of contamination or errors
- \checkmark social and medical care of donors, including those who suffer reactions
- ✓ storage of equipment, reagents and disposables and collected blood units
- ✓ access to an adequate electrical supply to support all electrical equipment used for the session (optional), availability of water.
- ✓ Adequate space for post –donation care and refreshments.
- ✓ Organizers and blood center staff must keep in mind the work load or donor turn over to make adequate arrangements at each step of donor screening and blood collection.

10.4. Emergency situations such as disasters or natural calamities.

During a disaster, natural calamity or a disease outbreak, the donor selection criteria and any specific measures relating to donor deferral may need a careful review for temporary amendments, to ensure donor and patient safety, while minimizing the risk of blood shortages during such urgent and high blood demanding situations.

Effective coordination among blood centers, hospitals, blood donor organizations; and officials from MoH is crucial.

Some of the questions that blood center will have to be thoughtful about before any relaxation in criteria is made are:

- \checkmark Is there a real high medical need for blood at that particular time?
- ✓ Can transportation of blood from one blood center to another be facilitated?
- ✓ What are the measures to communicate a common message to the blood community and the public about the status of the blood supply in the disaster-affected area and the nation?
- ✓ How can the public enthusiasm and blood collections in excess of medical need be controlled in a sensitive manner?
- Can additional supplies be arranged much ahead during the warning period?
- ✓ Can routine blood transfusions be stopped to preserve the blood stocks?

The relaxation of the donor selection criteria will then depend upon answers to many of these questions. In times of an epidemic outbreak, it is important to ensure that blood is only collected from healthy donors who are not considered at risk of that disease. Deferral periods will need to be reviewed as new evidence or information on the outbreak is made available from Public Health department of MoH. Blood Safety Program shall have to co-ordinate and seek directives from Drug Regulatory Authority for any amendments and the time period during which relaxation in criteria are necessary.

11. Quality management in donor selection

Essential quality elements of a donor selection process are similar to those in quality management of blood transfusion service/center.

11.1. There shall be a defined organization structure with identified in-charge who shall be delegated with overall responsibility and supervision for donor selection and care in the donor management section of the center.

In addition to having basic required qualification, all staff working in the donor selection area must be trained and be skilled in performing all the steps to assess donor suitability for blood donation. They shall be reporting to the in-charge and in-charge shall be accountable to or shall consult the head of the blood center. The in-charge shall maintain an adequate staffing level who are properly trained to conduct donor selection, collection procedures and manage donor adverse reactions appropriately both at the fixed and mobile sites. A suitably trained doctor must be immediately available to attend to the donor with especially serious reactions such as epileptic seizures or arterial damage.

11.2. SOPs for each procedure must be developed and strictly followed by all involved. Use of standard forms, worksheets and record formats must be in use.

11.3. Donor and donation records must be maintained either electronically or manually for traceability. This shall include filled donor questionnaire, result of health checks done, Hb results, donor deferrals, donor adverse reactions.

11.4. Training and competency assessment results of all staff must be documented.

11.5. Quality control test results, calibration and validation records of the equipment used such as weighing scale, thermometer, BP equipment, hemoglobin meter, blood collection machines. This also applies to supplies such as blood bags, skin disinfectants, hemocue cuvettes and ABO and Rh testing reagents.

11.6. Premises: While arranging the facility for donor selection, smooth flow of donor from one step to another must be looked into. Provision of privacy and a conducive environment to maximize positive donor experience must be at the core of each facility. Facilities for the provision of refreshments for donors and staff should be separated from the other activities of a donor session whenever possible. Adequate facilities must be available for the disposal of waste. This shall contribute in retention of donors.

11.7. Donor hemovigilance(DHV): All adverse events and reactions in donors should be identified, documented and reported to the incharge of donor area. Such data generated must be studied monthly by the head and quality manager of the center. This is called donor hemovigilance. DHV can help in improving donor, product and patient safety by putting in appropriate corrective and preventive actions in the entire donor selection process. Information gathered over time through DHV can signal the need for certain policy changes in the donor selection criteria or process.

12. Monitoring and Evaluation

Each blood center should maintain data on the following indicators to monitor and for submission of annual reports to BSP.

- 12.1 Number and percentage of donor deferrals, by types of deferral:
 - a. Temporary deferral
 - b. Permanent deferral
- 12.2 Number and percentage of deferrals, by reasons for deferral:
 - a. Low haemoglobin
 - b. Low weight
 - c. Medical/surgical conditions
 - d. High-risk behaviour
 - e. Travel
 - f. Other reasons
- 12.3 Number of adverse donor reactions, by types of reaction
 - a. Vaso-vagal reaction
 - b. Hematoma or bruising
 - c. Nerve injury
 - d. Arterial puncture
 - e. Seizures
 - f. Any other serious adverse reaction
- 12.4 Prevalence (Number and %) of TTI markers by types of donations: a.HIV
 - b. Hepatitis B (HBV)
 - c. Hepatitis C (HCV)
 - d. Syphilis
 - e. Others
- 12.5 Number and percentage of confirmed positive donations that were HIV screened reactive.
- 12.6 Total number of whole blood donations collected annually
- 12.7 Number and percentage by types of donation:
 - a. Voluntary non-remunerated donations from first time donors
 - b. Voluntary non-remunerated donations from repeat donors
 - c. Voluntary non-remunerated donations from regular donors
 - d. Donations from replacement / family donors

12.8 Number of blood donations collected from:

- a. Male donors
- b. Female donors
- 12.9 Number of blood donations collected from donors:
 - a. Under 18 years
 - b. 18 to 24 years
 - c. 25 to 44 years
 - d. 45 to 64 years
 - e. 65 years or older
- 12.10 Number of pre-deposit autologous blood donations.
- 12.11 Number of directed blood donations.

				NI IVIT CINTU VINION ANNTA		
Sr.No	Date	Name of donor	Age / Sex	CID no., mobile no, email id and physical address.	Unique Donor number(from donor card or computer generated)	Donated or not (<i>For BB Staff</i>)

ANNEXURE 1 BLOOD DONOR REGISTRATION SHEET

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ANNEXURE 2 BLOOD DONOR QUESTIONAIRRE AND CONSENT FORM

BLOOD BANK, JDW, NR HOSPITAL DONOR QUESTIONNAIRE

(Please go through the questions and give us the <u>correct information</u> to ensure yours and the recipient's safety. In doubt you may contact the staff for any clarification).

Pointion Transver	S	
QUESTIONS	YES	NO
1) Have you been feeling well today?		
2) Have you taken any medicines like aspirin, antibiotics or for any drugs in the last three days?		
3) Have you had jaundice in the last one year or been in close contact with anyone having jaundice?		
A) Has your blood been tested "POSITIVE" for Hepatitis B / C or for Sexually Transmitted Disease?		
5) Have you had malaria or taken treatment for malaria in the last three years or visited malaria risk area in last 6 months?		
6) Have you suffered from major disease of the heart, lungs ,kidney, thyroid, skin, liver or epilepsy or had any operation?		0
7) Have you had any tooth extraction in the last three days?		-
B) Have you taken any vaccines like Tetanus toxoid (TT) or Hopatilis B or rabies vaccine in last 24 hours?		
9) Have you had a tattoo, acupuncture, or ear piercing done in the Last one year?		
10) Have you suffered from any bleeding tendency like easy bruising or heavy blood loss after minor cuts?		
11) Is one you are a warman are you program to read feeding or had on		
abortion in the last three months?	1 1	
11) In case you are a woman are you pregnant, beest recently of ned an abortion in the last three months? 12) Did you have unsafe, paid sex or sex in last one year? 13) The consent of consent: 1, the undersigned have understood the importance and have given the correct answers to the best of my live consent to screen my blood for infections like HIV, Hepatitis B and C and syphilis. Houd donor's signature:	knowledge.	I also
Information Note (To be given to the donor)	knowledge.	I also
Information Note (To be given to the donor) Name of the donor: , Age /Sex:	knowledge.	I also
12) Did you have unsafe, paid sex or sex in last one year? 12) Did you have unsafe, paid sex or sex in last one year? 12) Did you have unsafe, paid sex or sex in last one year? 13) The provided of the prov	knowledge.	I also
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	knowledge.	I also
If y in case you are a worman are you pregnant, breast record you have an abortion in the last three months? 12) Did you have unsafe, paid sex or sex in last one year? Information Note (To be given the correct answers to the best of my give consent to screen my blood for infections like HIV, Hepatitis B and C and syphilis. Blood donor's signature: Information Note (To be given to the donor) Name of the donor:	knowledge.	I also
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ANNEXURE 3 BLOOD DONOR DEFERRAL FORM

|--|

(Please retain this form with you and produce it to the staff when you visit next to blood center) Name:_____

Age/Sex:_____

Date of deferral:

Date of deferral:_____ Reason for deferral:_____ Needs consultation with a doctor: Yes/No

Any further investigations/treatment /counseling required:

Needs	follow-u	n after	investiga	tion/	treatment.
TICCUS	10110 w -u	p anor	mvesuge	iii011/	treatment.

Can visit blood center after

Name of staff	 Name of Blood center:
Signature:	 _

Date:_____

Can come Others | after : travel to malaria region H/0Reason for deferral(tick appropriate column) Unsafe Permanent behavior deferral problem Med Low Low wt Hb 1 deferral Date of Total of each reason of donor deferral Age / Grand total of deferred donors= sex Name & contact details of donor Month/Year: Sr.

ANNEXURE 4. BLOOD DONOR DEFERRAL SHEET

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ANNEXURE 5

	Name of BB staff managing DAR/E						
DETAILS OF BLOOD DONOR ADVERSE EVENT/REACTION (DAR/E)	Management /Remarks						
	Type of DAR/E (Tick in appropriate box)	Convulsion					
		Arterial /Nerve injury					
		Bruise/ hematoma					
		VasoVagal					
	Date of DAR/E						
	Name of the donor / donation unit number						
YEAF		Sr. No					

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GLOSSARY

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

Blood centre: refers to a structure, facility or body that is responsible for any aspect of donor recruitment, donor screening and selection, blood collection, testing, processing, storage, release and/or distribution of human blood or blood components when intended for transfusion to a recipient. It is also responsible for pre-transfusion tests on patient blood samples and issue of blood and blood products for clinical transfusion as well as investigating and reporting adverse transfusion reactions.

Blood Collection: refers to a procedure whereby a single donation of blood is collected in an anticoagulant solution

Blood Donor: refers to a person who gives whole blood or one of its components

Blood donor counseling: A confidential dialogue between a blood donor and a counsellor about issues related to the donor's health and the donation process, provided before, during and after blood donation

Blood Products: refers to any therapeutic constituent of blood that is separated by physical or mechanical means (e.g. red cells, platelets and plasma). It is not intended to capture plasma derived products (e.g. albumin and Factor VIII).

Blood Storage Centre: refers to a center that is involved only in the functions of receiving and storing screened blood and blood products from an authorized blood center, performing pre-transfusion tests on patient blood samples and issue blood for clinical transfusion as well as investigating and reporting adverse transfusion reactions.

Donor deferral The non-acceptance of a potential blood donor to donate blood or blood components, either temporarily or permanently, based on general health or medical condition, or the risk of exposure to pathogens

Directed donation: A donation that is given specifically for transfusion to a named patient

Donor selection The process of assessing the suitability of an individual to donate blood against defined selection criteria

Disaster: refers to any domestic disaster or act of terrorism that suddenly requires a much larger amount of blood than usual **OR**

Temporarily restricts or eliminates a blood collector's ability to collect, test, process, and distribute blood

OR

Temporarily restricts or prevents the local population from donating blood, or restricts or prevents the use of the available inventory of blood products and thus requires immediate

replacement or resupply of the region's blood inventory from another region **OR**

Creates a sudden influx of donors, requiring accelerated drawing of blood to meet an emergent need elsewhere

Donor haemovigilance: A set of surveillance procedures for the monitoring, reporting and investigation of adverse donor reactions and events which are designed to prevent their occurrence or recurrence

'First time' blood donor: any individual who has never donated blood before

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

Intending donor: Any individual who expresses willingness to donate blood

Mobile Site: refers to a unit or site used for collection of blood and / or blood components operating temporarily or at movable locations off-site from a permanent collection site, under responsibility of a blood center except the blood centers

Prevalence: The proportion of a specific population that is infected with an infectious agent at any particular time

Quality system: Organizational structure, processes, procedures and resources needed to implement quality requirements

Donor reactions: refers to an unexpected response to a during or after blood donation, manifested by signs and/or symptoms in the donor that could be mild or severe.

Recipient: refers to someone who has been transfused with blood or blood components

Record (noun): refers to information captured in writing or through electronically generated media that provides objective evidence of activities that have been performed or results that have been achieved, such as test records or audit results. Records do not exist until the activity has been performed and documented.

Repeat donor: A blood donor who has donated in the past but not on a regular time frame

Regular donor: A blood donor who has been donating blood at defined donation intervals.

Risk: refers to chance or possibility of danger, loss or injury. This can relate to the health and well-being of staff and the public, property, reputation, environment, organizational functioning, financial stability, market share and other things of value.

Risk behavior: Behaviour that exposes a person to the risk of acquiring a transfusion-transmissible infection.

Self-deferral: The decision by a potential donor to defer himself/herself from the donation of blood until a condition that makes him/her unsuitable is resolved.

Self-exclusion: the decision by a potential donor not to give blood because he/she has engaged in riskk behavior or because of the state of his/her own health.

Serious donor adverse reactions: refers to an undesirable response or effect in a donor associated with blood donation that is fatal, life –threatening, disability or incapacitating condition or which results in or prolongs hospitalization or morbidity

Standard operating procedure: Written instructions for the performance of a specific procedure in a standardized manner

Transfusion-transmissible infection(s): An infection that is potentially capable of being transmitted by blood transfusion

Unit: refers to a defined quantity of blood or blood products in one container as prescribed by clinician.

Validation: refers to an action of proving that any operational procedure, process, activity or system leads to the expected results. The validation work is normally performed in advance according to a defined and approved protocol laying out tests and acceptance criteria.

Vasovagal reaction: is a general feeling of discomfort and weakness with anxiety, dizziness and nausea, which may progress to loss of consciousness (faint).

Voluntary non-remunerated donation: refers to donation given by an altruistic donor who gives blood freely and voluntarily without receiving money or any other form of payment.

Whole blood: refers to a single blood collection, collected in an anticoagulant solution with or without additives.

Window period: refers to time period between the on-set of infection till the detection of the antibodies

Five Simple Steps to Donate Blood





Printed at Lhazeen Press