

No. S-12016/5/2016 – NACO (NBTC)
Government of India
Ministry of Health & Family Welfare
National Aids Control Organization
(National Blood Transfusion Services)

9th Floor, Chandralok Building,
36, Janpath, New Delhi-110 001.
Dated : 11th October, 2017

To,

The Director/Member Secretaries of
All State Blood Transfusion Councils

Subject: Guidelines for Blood Donor Selection & Blood Donor Referral.

Sir/Madam,

It is informed that uniform guidelines for Blood Donor Selection and Blood Donor Referral have been approved by the Governing Body of NBTC in its 26th meeting which was held on 1st June, 2017. The guideline document is enclosed for your reference and necessary action.

This issues with the approval of AS & DG, NACO and President, NBTC.

Yours sincerely,

(Dr. Shobini Rajan)

Director, National Blood Transfusion Council

Copy to:

1. The Project Directors of all SACS
2. Website of NACO.

Encl: Guidelines of 29 pages on Blood Donor Selection & Blood Donor Referral.

Guidelines
for
Blood Donor Selection
and
Blood Donor Referral

NATIONAL BLOOD TRANSFUSION COUNCIL
NATIONAL AIDS CONTROL ORGANIZATION
MINISTRY OF HEALTH AND FAMILY WELFARE
GOVERNMENT OF INDIA

NEW DELHI
OCTOBER 2017



Introduction

The primary responsibility of a Blood Transfusion Service is to provide a safe, sufficient and timely supply of blood and blood components to those in need. In fulfilling this responsibility the BTS should ensure that the act of blood donation is safe and causes no harm to the donor. It should build and maintain a pool of safe, voluntary non-remunerated blood donors and take all necessary steps to ensure that the products derived from donated blood are efficacious for the recipient, with a minimal risk of any infection that could be transmitted through transfusion.

The donor selection criteria detailed in these guidelines apply to donors of whole blood, red cells, platelets, plasma and other blood components, donated as whole blood or through apheresis, including plasma for fractionation.

These guidelines are designed to promote best practise in Blood Transfusion Services to ensure the collection of donations from the lowest risk donors possible and also to ensure that every probable TTI reactive blood donor is referred for proper diagnosis and management of the infection and if confirmed, remains excluded from the donor pool.

Donor Engagement

The key to safe blood transfusions is having safe and healthy donors.

In order to ensure this, blood bank should follow these basic principles:

- Blood should be accepted only from voluntary, non-remunerated, low risk, safe and healthy donors. Replacement donors should be phased out.
- Efforts should be directed towards encouraging and retaining adequate numbers of healthy repeat donors.
- Donors should be appropriately recognised and thanked for their contribution.

Donor motivation is usually done by volunteers from the community using various communication materials and methods to draw prospective donors to come to the blood bank or to a blood donation camp. The minimum criteria for blood donation are verbally screened at this stage, i.e., age between 18-65 years, weight atleast 45 Kg and a Haemoglobin of atleast 12.5 grams. This activity is a bit different from the counselling, which is offered once the prospective donor reaches the blood bank or blood donation camp with the intention to donate. Once recruited, all first time donors should be encouraged to become regular repeat donors and retained with the Blood Transfusion Service through constant engagement through different communication media. The role of community organizations, civil society bodies and NGOs plays a critical role in these activities.

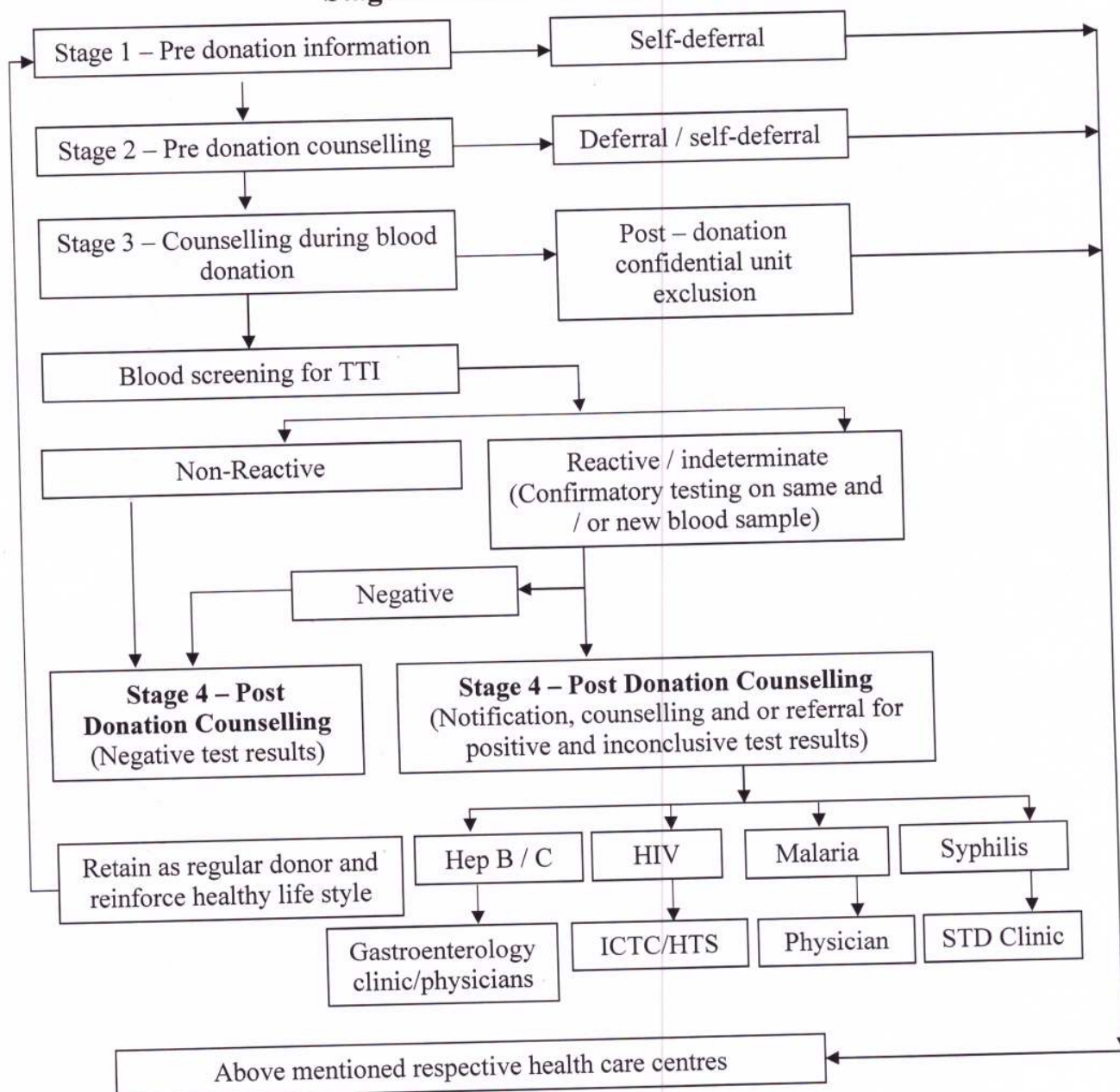
Donor Selection and Counselling

Once a prospective donor reaches the blood bank or blood donation camp, the following steps should be followed:

1. Pre-donation information
2. Pre-donation counselling
3. Donor Questionnaire and Health check up
4. Counselling during blood donation
5. Post-donation counselling

Counselling is to be provided by trained blood donor counsellors maintaining privacy and confidentiality. All blood banks may also train their donor organizers/paramedical staff/ medical officers to undertake counselling, in case a dedicated manpower is not available. Medical officer with minimum MBBS qualification should be responsible for reviewing the donor's health conditions and performing physical examination of the donor. Final call on donor selection is taken by the medical officer.

Stages of Blood Donor Counselling



Pre-donation information should include information about:

- Nature and use of blood and its components and the importance of maintaining healthy lifestyles
- Eligibility for blood donation
- Rationale for the donor questionnaire and pre-donation health assessment
- Options for the donor to withdraw or self-defer at any time before, during or after donation
- Blood donation process and potential adverse donor reactions
- Common TTI, modes of transmission and window period
- Basic information on tests performed on donated blood
- Possible consequences for donors and donated blood in the case of abnormal TTI test results

Donors should be educated regarding the possible risks of blood donation and possible risks of transmission of transfusion transmissible infections and encouraged to share his medical history and details to enable appropriate deferral. This is an opportunity to talk to, dispel doubts and answer questions from donors. It can be done as a one-on-group and integrated with the activities undertaken for donor recruitment and retention and supported with simple IEC material and job aids like leaflets, posters etc.

Pre-donation Counselling should focus on the donor and preferably be done one-on-one.

The objectives include:

- Understanding of Donor Questionnaire to enable correct responses
- Reiterate understanding of TTI testing and the disclosure of results
- Clarify any misunderstanding about donor selection, blood donation and blood screening
- Explain self-deferral
- Explain temporary and permanent deferral
- Familiarize donor to process of blood donation
- Obtain donor's Informed consent

Donor Questionnaire and Health Check-up is administered to every prospective donor to enable a quick history taking, limited physical examination and blood test. Questionnaire should be prepared in English and Local languages which is simple and easy to understand to be answered by the donor. For donors who are illiterate, assistance should be given by counsellor/ donor registration staff.

Demographic details of the donor, date and time of donor selection and donation should be registered. Informed consent should be obtained in writing from the donors on the questionnaire.

Prior to blood donation, the consent of the donor should be obtained in writing with donor's signature or thumb impression after the procedure is explained and the donor is informed regarding testing of blood for all mandatory tests for safety of recipients. The donor should be provided an opportunity to ask questions and refuse consent. Efforts should also be made to obtain the correct contact details of the blood donors so that he can be contacted by the blood bank in future. Blood bank can ask to see a photo-identity but it should not be made mandatory to donate blood.

Every prospective blood donor should be subjected to a basic health check up by a Medical Officer through history taking, limited physical examination and Hb test to determine eligibility to enrol as a blood donor. In case a donor is to be temporarily or permanently deferred, he should be explained the reasons in understandable terms.

Donor consent should be taken for the following understanding that:

1. Blood donation is a totally voluntary act and no inducement or remuneration has been offered.
2. Donation of blood/ components is a medical procedure and that by donating voluntarily, I accept the risk associated with this procedure.
3. My donated blood and plasma recovered from my donated blood may be sent for plasma fractionation for preparation of plasma derived medicines, which may be used for larger patient population and not just this blood bank.
4. My blood will be tested for Hepatitis B, Hepatitis C, Malarial parasite, HIV/AIDS and Syphilis diseases in addition to any other screening tests required to ensure blood safety.
5. I would like to be informed about any abnormal test results done on my donated blood
Yes/No

Counselling during donation must be aimed at

- Ensuring that donors feel conformable during blood donation, including the venepuncture.
- Reducing donor anxiety and minimizing the risk of any adverse donor reactions such as fainting
- Giving post donation advice, including care of the venepuncture site
- Fostering donor trust and confidence for donor retention
- Thanking the donor for his valuable contribution

Post-donation interaction includes

- Brief instructions on self-care
 - Plenty of fluids
 - No heavy work
 - No smoking or driving immediately post donation
 - Remove bandage after 6 hours
 - Contact details of blood bank in case of discomfort following donation
- Information about what to do in case of specific adverse donor reactions
- Message on healthy lifestyle and regular blood donation
- Donor feedback
- Issuance of donor card, donor certificate or a memento
- Reiteration for recalling of blood donor for abnormal test results

Blood Donor Selection Criteria

<u>General Criteria</u>		
S.No.	Criteria	Recommendations
1.	Well being	The donor shall be in good health, mentally alert and physically fit and shall not be inmates of jail or any other confinement. “Differently abled” or donor with communication and sight difficulties can donate blood provided that clear and confidential communication can be established and he/she fully understands the donation process and gives a valid consent.
2.	Age	Minimum age 18 years Maximum age 65 years First time donor shall not be over 60 years of age, for repeat donor upper limit is 65 years. For aphaeresis donors 18-60 years
3.	Whole Blood Volume Collected and weight of donor	350 ml- 45 kg 450ml- more than 55 kg Apheresis- 50 kg
4.	Donation Interval	For whole blood donation, once in three months (90 days) for males and four months (120 days) for females. For apheresis, at least 48 hours interval after platelet/ plasma – apheresis shall be kept (not more than 2 times a week, limited to 24 in one year) After whole blood donation a plateletpheresis donor shall not be accepted before 28 days. Apheresis platelet donor shall not be accepted for whole blood donation before 28 days from the last platelet donation provided reinfusion of red cell was complete in the last plateletpheresis donation. If the reinfusion of red cells was not complete then the donor shall not be accepted within 90 days. A donor shall not donate any type of donation within 12 months after a bone marrow harvest, within 6 months after a peripheral stem cell harvest.
5.	Blood Pressure	100-140mm Hg systolic 60-90 mm Hg diastolic with or without medications. There shall be no findings suggestive of end organ damage or secondary complication (cardiac, renal, eye or vascular) or history of feeling giddiness, fainting made out during history and examination. Neither the drug nor its dosage should have been altered in the last 28 days.

6.	Pulse	60- 100 Regular
7.	Temperature	Afebrile;37°C/98.4°F
8.	Respiration	The donor shall be free from acute respiratory disease.
9.	Haemoglobin	>or =12.5g/dL Thalassemia trait may be accepted, provided haemoglobin is acceptable.
10.	Meal	The donor shall not be fasting before the blood donation or observing fast during the period of blood donation and last meal should have been taken at least 4 hours prior to donation. Donor shall not have consumed alcohol and show signs of intoxication before the blood donation. The donor shall not be a person having regular heavy alcohol intake.
11.	Occupation	The donor who works as air crew member, long distance vehicle driver, either above sea level or below sea level or in emergency services or where strenuous work is required, shall not donate blood at least 24 hours prior to their next duty shift. The donor shall not be a night shift workers without adequate sleep.
12.	Risk behaviour	The donor shall be free from any disease transmissible by blood transfusion, as far as can be determined by history and examination. The donor shall not be a person considered "at risk" for HIV, Hepatitis B or C infections (Transgender, Men who have sex with men, Female sex workers, Injecting drug users, persons with multiple sexual partners or any other high risk as determined by the medical officer deciding fitness to donate blood).
13.	Travel and residence	The donor shall not be a person with history of residence or travel in a geographical area which is endemic for diseases that can be transmitted by blood transfusion and for which screening is not mandated or there is no guidance in India.
14.	Donor Skin	The donor shall be free from any skin diseases at the site of phlebotomy. The arms and forearms of the donor shall be free of skin punctures or scars indicative of professional blood donors or addiction of self-injected narcotics.
<u>Physiological Status for Women</u>		
15.	Pregnancy or recently delivered	Defer for 12 Months after delivery
16.	Abortion	Defer for 6 months after abortion
17.	Breast feeding	Defer for total period of lactation
18.	Menstruation	Defer for the period of menstruation

<u>Non-specific illness</u>		
19.	Minor non-specific symptoms including but not limited to general malaise, pain, headache	Defer until all symptoms subside and donor is afebrile
<u>Respiratory (Lung) Diseases</u>		
20.	Cold, flu, cough, sore throat or acute sinusitis	Defer until all symptoms subside and donor is afebrile
21.	Chronic sinusitis	Accept unless on antibiotics
22.	Asthmatic attack	Permanently Defer
23.	Asthmatics on steroids	Permanently Defer
<u>Surgical Procedures</u>		
24.	Major surgery	Defer for 12 months after recovery. (Major surgery being defined as that requiring hospitalisation, anaesthesia (general/spinal) had Blood Transfusion and/or had significant Blood loss)
25.	Minor surgery	Defer for 6 months after recovery
26.	Received Blood Transfusion	Defer for 12 months
27.	Open heart surgery Including By-pass surgery	Permanently defer
28.	Cancer surgery	Permanently defer
29.	Tooth extraction	Defer for 6 months after tooth extraction
30.	Dental surgery under anaesthesia	Defer for 6 months after recovery
<u>Cardio-Vascular Diseases (Heart Disease)</u>		
31.	Has any active symptom (Chest Pain, Shortness of breath, swelling of feet)	Permanently defer
32.	Myocardial infarction (Heart Attack)	Permanently defer
33.	Cardiac medication (digitalis, nitro-glycerine)	Permanently defer
34.	Hypertensive heart disease	Permanently defer
35.	Coronary artery disease	Permanently defer
36.	Angina pectoris	Permanently defer
37.	Rheumatic heart disease with residual damage	Permanently defer
<u>Central Nervous System/ Psychiatric Diseases</u>		
38.	Migraine	Accept if not severe and occurs at a frequency of less than once a week
39.	Convulsions and Epilepsy	Permanently defer
40.	Schizophrenia	Permanently defer
41.	Anxiety and mood disorders	Accept person having anxiety and mood (affective) disorders like depression or bipolar disorder, but is stable

		and feeling well on the day regardless of medication-
<u>Endocrine Disorders</u>		
42.	Diabetes	Accept person with Diabetes Mellitus well controlled by diet or oral hypoglycaemic medication, with no history of orthostatic hypotension and no evidence of infection, neuropathy or vascular disease (in particular peripheral ulceration) - Permanently defer person requiring insulin and/or complications of Diabetes with multi organ involvement- Defer if oral hypoglycaemic medication has been altered/dosage adjusted in last 4 weeks
43.	Thyroid disorders	Accept donations from individuals with Benign Thyroid Disorders if euthyroid (Asymptomatic Goitre, History of Viral Thyroiditis, Auto Immune Hypo Thyroidism) Defer if under investigation for Thyroid Disease or thyroid status is not known Permanently defer if: 1) Thyrotoxicosis due to Graves' Disease 2) Hyper/Hypo Thyroid 3) History of malignant thyroid tumours
44.	Other endocrine disorders	Permanently defer
<u>Liver Diseases and Hepatitis infection</u>		
45.	Hepatitis	Known Hepatitis B, C- Permanently defer Unknown Hepatitis- Permanently defer Known hepatitis A or E; Defer for 12 months
46.	Spouse/ partner/ close contact of individual suffering with hepatitis,	Defer for 12 months
47.	At risk for hepatitis by tattoos, acupuncture or body piercing, scarification and any other invasive cosmetic procedure by self or spouse/ partner	Defer for 12 months
48.	Spouse/ partner of individual receiving transfusion of blood/ components	Defer for 12 months
49.	Jaundice	Accept donor with history of jaundice that was attributed to gall stones, Rh disease, mononucleosis or in neonatal period.
50.	Chronic Liver disease/ Liver Failure	Permanently defer
<u>HIV Infection/AIDS</u>		
51.	At risk for HIV infection (Transgender, Men who have Sex with Men, Female Sex Workers,	Permanently defer

	Injecting drug users, persons with multiple sex partners)	
52.	Known HIV positive person or spouse/ partner of PLHA (person living with HIV AIDS)	Permanently defer
53.	Persons having symptoms suggestive of AIDS	Permanently defer person having lymphadenopathy, prolonged and repeated fever, prolonged & repeated diarrhoea irrespective of HIV risk or status
<u>Sexually Transmitted Infections</u>		
54.	Syphilis (Genital sore, or generalized skin rashes)	Permanently defer
55.	Gonorrhoea	Permanently defer
<u>Other Infectious diseases</u>		
56.	History of Measles , Mumps, Chickenpox	Defer for 2 weeks following full recovery
57.	Malaria	Defer for 3 months following full recovery.
58.	Typhoid	Defer for 12 Months following full recovery
59.	Dengue/ Chikungunya	In case of history of Dengue/Chikungunya: Defer for 6 Months following full recovery. Following visit to Dengue/Chikungunya endemic area: 4 weeks following return from visit to dengue endemic area if no febrile illness is noted.
60.	Zika Virus/ West Nile Virus	In case of Zika infection: Defer for 4 months following recovery. In case of history of travel to West Nile Virus endemic area or Zika virus outbreak zone: Defer for 4 months.
61.	Tuberculosis	Defer for 2 years following confirmation of cure
62.	Leishmaniasis	Permanently defer
63.	Leprosy	Permanently defer
<u>Other infections</u>		
64.	Conjunctivitis	Defer for the period of illness and continuation of local medication.
65.	Osteomyelitis	Defer for 2 years following completion of treatment and cure.
<u>Kidney Disease</u>		
66.	Acute infection of kidney (pyelonephritis)	Defer for 6 months after complete recovery and last dose of medication
67.	Acute infection of bladder (cystitis) / UTI	Defer for 2 weeks after complete recovery and last dose of medication
68.	Chronic infection of kidney/ kidney disease/ renal failure	Permanently defer
<u>Digestive System</u>		
69.	Diarrhoea	Person having history of diarrhoea in preceding week particularly if associated with fever: Defer for 2 weeks after complete recovery and last dose of medication
70.	GI endoscopy	Defer for 12 months.

71.	Acid Peptic disease	Accept person with acid reflux, mild gastro-oesophageal reflux, mild hiatus hernia, gastro-oesophageal reflux disorder (GERD), hiatus hernia: Permanently defer person with stomach ulcer with symptoms or with recurrent bleeding:
Other diseases/ disorders		
72.	Autoimmune disorders like Systemic lupus erythematosus, scleroderma, dermatomyositis, ankylosing spondylitis or severe rheumatoid arthritis	Permanently defer
73.	Polycythaemia Vera	Permanently defer
74.	Bleeding disorders and unexplained bleeding tendency	Permanently defer
75.	Malignancy	Permanently defer
76.	Severe allergic disorders	Permanently defer
77.	Haemoglobinopathies and red cell enzyme deficiencies with known history of haemolysis	Permanently defer
Vaccination and inoculation		
78.	Non live vaccines and Toxoid: Typhoid, Cholera, Papillomavirus, Influenza, Meningococcal, Pertussis, Pneumococcal, Polio injectable, Diphtheria, Tetanus, Plague	Defer for 14 days
79.	Live attenuated vaccines: Polio oral, Measles (rubella) Mumps, Yellow fever, Japanese encephalitis, influenza, Typhoid, Cholera, Hepatitis A	Defer for 28 days
80.	Anti-tetanus serum, anti-venom serum, anti-diphtheria serum, and anti-gas gangrene serum	Defer for 28 days
81.	Anti-rabies vaccination following animal bite, Hepatitis B Immunoglobulin, Immunoglobulins	Defer for 1 year
Medications taken by prospective blood donor		
82.	Oral contraceptive	Accept
83.	Analgesics	Accept
84.	Vitamins	Accept
85.	Mild sedative and tranquillizers	Accept
86.	Allopurinol	Accept

87.	Cholesterol lowering medication	Accept
88.	Salicylates (aspirin), other NSAIDs	Defer for 3 days if blood is to be used for Platelet preparation
89.	Ketoconazole, Antihelminthic drugs including mebendazole,	Defer for 7 days after last dose if donor is well
90.	Antibiotics	Defer for 2 Weeks after last dose if donor is well
91.	Ticlopidine, clopidogrel	Defer for 2 Weeks after last dose
92.	Piroxicam, dipyridamole	Defer for 2 Weeks after last dose
93.	Etretinate, Acitretin or Isotretinoin. (Used for acne)	Defer for 1 month after the last dose
94.	Finasteride used to treat benign prostatic hyperplasia	Defer for 1 month after the last dose
95.	Radioactive contrast material	8 weeks deferral
96.	Dutasteride used to treat benign prostatic hyperplasia	Defer for 6 months after the last dose
97.	Any medication of unknown nature	Defer till details are available
98.	Oral anti-diabetic drugs	Accept if there is no alteration in dose within last 4 weeks.
99.	Insulin	Permanently defer
100.	Anti-arrhythmic, Anti-convulsions, Anticoagulant, Anti-thyroid drugs, Cytotoxic drugs, Cardiac Failure Drugs(Digitalis)	Permanently defer
Other conditions requiring Permanent deferral		
101.	Recipients of organ, stem cell and tissue transplants Donors who have had an unexplained delayed faint or delayed faint with injury or two consecutive faints following a blood donation.	Permanently defer

Recall and Referral Mechanism for Initial Sero-reactive Blood Donors

Information of test results

- Donors who have consented to be contacted by the blood bank in case of an abnormal test result should be recalled to the blood bank so as to inform them about initial sero-reactive result of transfusion transmitted infection (TTI).
- Donors should be provided post-donation counselling prior to referring to appropriate medical services for confirmation of diagnosis, follow up and treatment whenever necessary.
- Adequate efforts must be made by the Blood Bank staff to contact the initial sero-reactive blood donors for recall-referral and the process should be documented on record.
- Result seeking blood donors, even if non sero-reactive, should also be informed of their TTI status with reiterated counselling to remain negative and continue to donate blood.
- State AIDS Control Societies shall make available updated list of ICTC along with contact details of counsellors to all licensed blood banks.

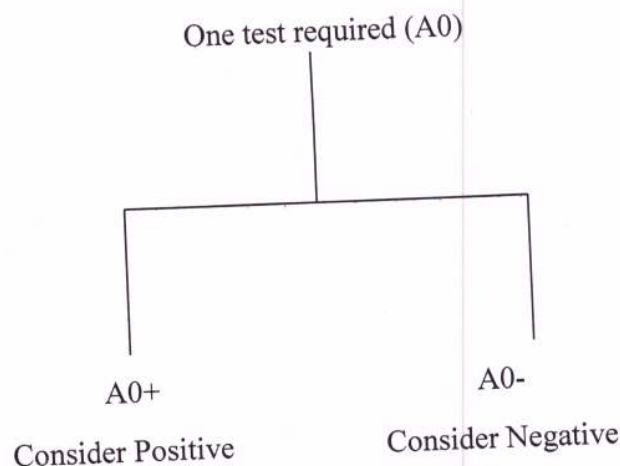
Duties of a Blood Bank:

- Consent of the Blood Donor shall be obtained for performing the screening tests and to be informed of the results thereof at the time of blood donation.
- It is not the primary duty of the Blood Bank or Blood Transfusion Service to confirm the diagnosis of any of the TTI screened for.
- Blood Bank shall repeat the test using the same technique using the pilot tube/ sample from blood bag prior to labelling the donor as initial sero-reactive and recalling for referral.
- All initial sero-reactive blood units shall continue to be discarded as per standard operating protocol of blood bank and compliance to Biomedical Waste Management Rules 2016.
- All initial sero-reactive donors shall be recalled, offered post donation counselling and referred to appropriate facility for further counselling, confirmation and management.
- Results shall not be informed over the telephone.
- A standard referral format for the same shall be used and Blood Bank shall maintain all records of recall and referral.
- Signatures of the blood donor shall be obtained on the consent form attached to the referral format so as to avoid litigation due to discordant results of screening at blood banks and confirmatory tests of reference centre.
- In case, the initial sero-reactive donor does not return to blood bank despite three consecutive weekly attempts, the list of HIV sero-reactive blood donors should be shared with the linked ICTC under shared confidentiality under guidance from State AIDS Control Society.

Testing Strategy for HIV at Blood Banks

Testing Strategy used in the Blood Banks for HIV is "Strategy I" and the test done in the blood bank is considered to be a test of triage (A0)

The blood unit is subjected to one test of high sensitivity for HIV reactivity. If non-reactive, the specimen shall be considered free of HIV (negative) and if reactive, the blood unit is considered as HIV positive and discarded. This strategy is focused on ensuring recipient safety and is also used in the setting of screening of organs, tissues, sperm and other donations.



Flow chart of Strategy I

1. Prior consent shall be taken from the donor for both conduction of screening tests and to be informed of result of testing at the time of the donation by the blood bank along with complete contact details and telephone number.
2. All blood donors found to be initial HIV sero-reactive at blood bank shall be referred to Integrated Counselling and Testing Centres (ICTC) for counselling and confirmation.
3. Blood bank shall fill out the referral form as per standard format and send it along with referred donor.
4. Confidentiality shall be maintained at all levels.

Algorithm for Blood Donors referred to ICTC

- All initial sero-reactive donors referred to ICTC from Blood Bank shall be offered HIV pre-test counselling at the ICTC and consent taken to perform the HIV test.
- ICTC shall perform first test (A1). In case first test positive, ICTC shall perform remaining two tests and give a positive result after three sequential reactive tests.
- In case first test is negative, ICTC shall report the result as HIV inconclusive and recall the donor for re-testing after two weeks after thorough counselling for risk perception.
- All blood donors found to be positive for HIV shall be counselled to permanently defer them from the donor pool, in addition to referral for Pre-ART during post-test counselling.
- In addition, the message for all PLHA to permanently defer themselves/ spouses/ partners from donating blood shall be incorporated into the information for all PLHA during post-test counselling.

Testing Strategy for other TTI at Blood Banks

Similar to HIV, the blood unit is subjected to one test of high sensitivity for HBV, HCV, Malaria and syphilis reactivity. If non-reactive, the specimen is to be considered free of infection

(negative) and if reactive, the blood unit is considered as positive and discarded. This strategy is focused on ensuring recipient safety and is also used in the setting of screening of organs, tissues, sperm and other donations.

1. Prior consent shall be taken from the donor for both conduction of screening tests and to be informed of result of testing at the time of the donation by the blood bank along with complete contact details and telephone number.
2. All blood donors found to be sero-reactive at blood bank for HBV, HCV, Syphilis and Malaria shall be referred to clinicians in the Out Patient Department of associated hospitals or others for assessment and re-testing.
3. Blood bank shall fill out the referral form as per standard format and send it along with referred donor.
4. Confidentiality shall be maintained at all levels.

Algorithm for Blood Donors referred to Clinicians

- All initial sero-reactive donors referred to clinicians from Blood Bank. Donor shall be assessed by the clinician with history taking and clinical examination.
- Donor shall be referred to the laboratory for re-testing and confirmation of the test results.
- Donor shall be offered appropriate treatment by the assessing clinician or referred to a higher centre for the same.
- All blood donors found to be positive for HBV, HCV, Malaria and Syphilis should be counselled to defer themselves and their spouses/partners from the donor pool, in addition to appropriate management.

Annexure 1 Sample of Blood Donor Questionnaire

XYZ Blood Bank
Thank you for coming forward to donate blood

To ensure your safety as a blood donor and the safety of the patients who will receive your blood, please read the information leaflet provided and answer this questionnaire correctly. If you have any difficulty in filling this form please ask for help from the Blood Centre Staff. All details given by you will be kept confidential.

Donor's Name: _____

Date of Birth : _____

Address (Resi): _____

Address (Office): _____

	Sex:
	Age:

Contact Nos (Resi): _____ (Office) _____ (Mobile) _____

Email : _____

1. Have you donated Blood previously?

Yes No

1.1 If yes how many times

1.2 Date of last donation:

1.3. Did you experience any ailment, difficulty or discomfort during previous donations?

1.4 What was the difficulty?

1.5 Have you ever been advised not to donate blood?

Yes No

2.1 Are you feeling well today?

2.2 Have you eaten anything in the last 4 hours?

2.3 After donating blood do you have to engage in heavy work, driving heavy vehicle or work at heights today

Yes No

3. Have you had / have any of the following? If yes, discuss with the doctor present:

- | | | | |
|--------------------|------------------|---------------------|----------------------------|
| • Allergy | • Kidney disease | • Endocrine disease | • Leprosy |
| • Cancer | • Mental illness | • Diabetes | • Epilepsy |
| • Fainting attacks | • Amoebiasis | • Syphilis | • Blood/ Bleeding disorder |
| • Heart disease | • Cold/Cough | • Gonorrhoea | • Tuberculosis |
| • Lung disease | • Liver disease | • Skin disease | • Polycythemia |
| • Asthma | • Fever | • High/low BP | • G – 6 PD deficiency |

4. During past 12 months have you had any of the following?

- | | | |
|--|-----|----|
| 4.1 Received blood or blood components? | Yes | No |
| 4.2 Any accidents or operations? | Yes | No |
| 4.3 Received any vaccinations? | Yes | No |
| 4.4 Bitten by any animal, which can result in rabies? | Yes | No |
| 4.5 Had tattooing / ear piercing or acupuncture treatment? | Yes | No |
| 4.6 Have you been imprisoned for any reason? | Yes | No |

5. Have you had jaundice in the last 1 year?

- | | | |
|--|-----|----|
| 5.1 Has your blood ever tested positive for hepatitis B or C? | Yes | No |
| 5.2 Have you had close contact with anyone (family / others) suffering from jaundice in the last 1 year? | Yes | No |

6. Have you had tuberculosis or typhoid during the last year?

Yes No

7. Have you had malaria or taken antimalarial drugs in the last 3 years?

Yes No

8. Have you had any of the following in the last 6 months?

- Dental Procedure
- Measles
- Chicken Pox
- Dengue

Yes	No
Yes	No
Yes	No
Yes	No

9. Have you taken any medicine in the last 7 days especially or antibiotic?

Yes No

10. Do you know that you should not give blood in following conditions?

Yes No

- If you were found to be HIV positive, Hepatitis B, C or Syphilis infections
- If you are having multiple sex partners or have engaged in male to male sexual activity
- If you have ever worked as a sex worker or had sex with a sex worker
- If you have ever injected any drug (esp. Narcotics) not prescribed by a qualified doctor
- If you suspect that you or your partner may have HIV or any other sexually transmitted disease

11. Do you or your sexual partner belong to any of the above or below categories? Yes No

11.1 Do you have any reason to believe that you have been infected by the virus that causes AIDS? Yes No

11.2 In the last 6 months have you had:

Night Sweats	Yes	No
Persistent Fever	Yes	No
Unexplained Weight Loss	Yes	No
Swollen Glands	Yes	No
Persistent Diarrhoea	Yes	No

12. In case you are a woman:

a. Are you pregnant or have you had an abortion in the last 06 months? Yes No

b. Have you a child less than 1 year of age? Are you breast feeding? Yes No

Consent

I understand that:

- Blood donation is a totally voluntary act and no inducement or remuneration has been offered
- Donation of blood/components is a medical procedure and that by donating voluntarily, I accept the risk associated with this procedure
- My donated blood, blood and plasma recovered from my donated blood may be sent for plasma fractionation for preparation of plasma derived medicinal products, all of which may be used for larger patient population and not just this blood bank
- My blood will be tested for Hepatitis B, Hepatitis C, Malaria Parasite, HIV/ AIDS and Syphilis diseases in addition to any other screening tests required ensuring blood safety.
- I would like to be informed about any abnormal test results done on my donated blood: Yes/No

Donor's Signature

Signature of Medical Officer

MEDICAL ASSESSMENT	Name of Medical Officer:	Sign:
Donor's Name: _____ Weight: _____ Kgs Hb Level: $\geq 12.5\text{g/dl}$ $< 12.5\text{g/dl}$		
History Check List	Feeling well/adequate sleep ($> 5\text{hrs}$) / Last meal within 4 hrs Ever Hospitalized Current illness or medications:	
Examination Check List	Unhealthy look/pallor/icterus/ alcohol smell Infected wounds/ Venepuncture site lesions Pulse: beats/min BP:mmHg Heart: Lungs:	
Counselling Points	Post donation instructions/ making a regular donor Need for follow up for TTI purposes How to contact for follow up purposes: By a letter/ By phone/ By e-mail	
Outcome	Donor accepted/ Temporary deferral/ Permanent deferral	
Remarks / Reasons for Deferral:		

REGISTRATION	Name of Medical Officer:	Date
Donor I.D No.	Blood Unit No.	Segment No.
Type of Bag: Single: Double: Triple: Quadruple:		

BLOOD COLLECTION	Name of Phlebotomist:	Sign:
Check: Donor's Name Check Donation No: On Donation record/ Blood Bags/ Specimen Tubes Start time: a.m/p.m Time Taken:..... mins Volume: ml		
Complications: Faint: Fits: Double Prick: Haematoma: Others (please specify):		
Management:		

Annexure 2

REFERRAL SLIP FOR BLOOD DONORS

(To be filled by Blood Bank Staff)

Name and address of the Referring Blood Bank: -

Date of Referral Blood Bank ID No.

Name of Donor.....

Age Gender Phone Number Contact details.....

Name and designation of the referring person

Reason for referral (to be ticked)	Date of testing	Assay used (III gen/ Any other)
Counselling& testing for HIV ☐		
Testing of HBsAg ☐		
Testing of HCV ☐		
Testing of VDRL/RPR ☐		
Testing of Malaria ☐		

Address of referral centre (ICTC/Clinician).....

(Blood Bank seal with contact details)

(To be filled by ICTC/Laboratory and retained in record)

Name of Donor.....Date of performing test.....

PID No. /OPD Regn. No.

Investigation done

Results

(Seal of ICTC /Laboratory with contact details)

-----X-----X-----X-----X-----
(This part is to be filled by ICTC/Laboratory and returned to donor)

Name of the Donor/Department

Donor ID No.

PID No/ OPD Regn. No.

Date of Sample draw.....

Instructions:

Please come for retesting after 2 weeks on

1. Result to be collected on

2. Repeat test at ICTCon

(Seal of ICTC /Laboratory with contact details)

Annexure 3

CONSENT FOR REFERRAL

I understand that

- during blood donation process I have been counseled regarding the importance of safe blood donation and have consented to testing of my blood and be informed of any abnormal test results.
- I understand that these screening tests conducted at blood bank are not diagnostic and may yield false-positive results.
- I understand that any willful misrepresentation of facts could endanger my health or that of patients receiving my blood and may lead to litigation.
- I understand that I have been contacted, counseled and referred by the blood bank for confirmation and management to appropriate facility.

Signature of Referring Blood Bank Staff

Signature of Donor

Place: -----

Date : _____

Annexure 4

DUTIES AND RESPONSIBILITIES OF BLOOD BANK MEDICAL OFFICER

1) Administration, Oversight and Coordination

- a) Overall supervision
- b) Inventory management
- c) Fulfilling regulatory requirements
- d) Recording & reporting
- e) Convening hospital transfusion committee meetings
- f) Fulfilling program requirements
- g) Undergo appropriate training programs
- h) Provide consultation to supervisory and technical personnel on maintaining adequate inventory of all blood components.
- i) In times of limited inventory, provide interface to attending physician and resident staffs on requests for those components in short supply
- j) Evaluate function of blood bank periodically

2) Donor Management

- a) Perform routine donor evaluation and monitoring, including physical examinations and phlebotomy site examination and review of periodic laboratory testing.
- b) Provide consultation to Blood Bank technical and clerical personnel concerning donor selection and acceptability.
- c) Evaluate and manage blood donor reactions.
- d) Evaluate and follow-up donors with abnormal test results, including infectious disease testing.
- e) Evaluation and approval of requests for specific components from specific donors
- f) Selection of donors for specific patients
- g) Evaluation of donor acceptability
- h) Donor monitoring.

3) Camp Management

- a) Medical officer should check the following :
- b) Exact venue ,number of donors, time for the camp, refreshment for donors, furniture, space, mobile vans, appliances for collection and transportation of blood, and emergency box
- c) Record and report the details about the blood camp to the Blood transfusion committee.

4) Testing (IH/ ID)

- a) Provide consultation and support to technical and clerical staff concerning specimen and requisition acceptability.
- b) Review and interpret:
 - i) Blood typing discrepancies
 - ii) Positive antibody screens
 - iii) Antibody panels; prenatal titers
 - iv) Positive direct/ indirect anti-globulin tests

- c) Provide consultation to technical staff concerning additional evaluation of patients with complex serologic problems.
- d) Review clinical significance of serologic findings and decide on additional testing required prior to transfusion.

5) Component Management

- a) Provide consultation to apheresis nursing and technical staff concerning donor selection and acceptability.
- b) Evaluate and manage apheresis donor reactions.
- c) Provide medical direction of component collection via cell separator.
- d) Evaluate and approve requests for selected and specialized blood components, including washed red cells and apheresis derived platelet

6) QMS/QA

- a) Assists with developing, implementing, and maintaining the quality assurance with respect to
 - i) Organisation
 - ii) Personnel
 - iii) Technical
 - iv) Document control
 - v) Infrastructure management
 - vi) Equipment
 - vii) QA
 - viii) Audits
- b) Perform the initial review of the Quality Control records with the quality manager
- c) Ensure staff and departmental compliance with all regulatory, safety, and institution policies and procedures.
- d) Ensure that all work is done according to the required standards
- e) Ensure the SOP is followed at all critical steps of process flow like donor screening , phlebotomy site cleaning, phlebotomy, temperature maintenance during blood transport, calibrated centrifuge and trained technical staff in component lab
- f) Ensure the application of Good Manufacturing Practices (GMP),/Good lab practices(GLP)/Good Clinical Practices(GCP).

7) Training

- a) Cross training of different levels of staff
- b) Competency management
- c) Plans and Helps in Conduction of the refresher and regular training program of the staff in the blood bank
- d) Helps in evaluating the knowledge of the new staff and arrange for the training programs.

8) Clinical Services

- a) Provide consultation to clinical staff concerning selection and acceptability of donors for autologous transfusion.
- b) Consult with the attending physician and resident staffs as necessary.

- c) Determine risks of transfusion in: patients with complex serologic problems and patients who require transfusion before routine serologic testing can be completed. Provide consultation to attending physician and resident staffs as indicated
- d) Review initial workup of all transfusion reactions reported to the Blood Bank.
- e) Determine additional evaluation required and prepare a written interpretation for review and discussion with the in-charge blood bank and provide consultation to attending physician and resident staffs as indicated.
- f) Provide initial evaluation of patients who are candidates for therapeutic apheresis. This includes: review of patient problem; prepare initial draft of consultation report and review with the Consultant Transfusion Medicine to select appropriate patients for therapeutic apheresis; determine the apheresis protocol to be used; determine methods to be used for evaluating patient response to therapeutic apheresis.
- g) Obtain informed consent for therapeutic apheresis from patients.
- h) Schedule therapeutic apheresis procedures with apheresis personnel.
- i) Complete therapeutic apheresis worksheets and write the detailed orders for the apheresis procedure.
- j) Write daily apheresis orders.
- k) Evaluate patient pre-procedure and document procedure/"SOP" note.
- l) Evaluate and manage patient reactions during therapeutic apheresis.
- m) Monitor and evaluate patient response to therapeutic apheresis.
- n) Participate in Haemovigilance

9) Biosafety & Infection Control

- a) Ensure universal precautions to be followed consistently by all the staff of blood bank
- b) Ensure Infection control practices including BMW management

DUTIES AND RESPONSIBILITIES OF BLOOD BANK NURSE

1) Donor Management

- a) Assist with donor room preparations, prepare and distribute supplies and equipment, maintain drugs & consumables and equipment management.
- b) Assist MO in preparing the patient for phlebotomy procedure.
- c) Assist MO in donor selection.
- d) Provide information related to donor screening & post donation instructions to donors
- e) Perform phlebotomy & manage post donation care
- f) Collect samples in pilot tubes, supervise transportation of pilot tubes & collected blood bags to the respective labs
- g) Maintain documentation related to donor records
- h) Assist in apheresis procedure, donor eligibility and donor care.
- i) Perform duties assigned by the BB MO in charge
- j) Assist in Donor motivation activities

2) Camp Management

- a) Ensure that all the documents and records are made ready before the camp.
- b) Ensure that all the equipment's and furniture's are made available.
- c) Arranges all the apparatus and equipment's required for the mobile blood collection unit.
- d) Assist in storage and transportation of collected blood.

- e) Records the concerns about the blood donation camp

3) Administrative/ Programme management/ Regulatory Aspects

- a) Coordinate activities in blood collection unit, including work flow and work assignments
- b) Coordinate preparation of monthly, quarterly & annual reports to be sent to SACS/SBTC/Drug Control Departments.

4) QMS/QA

- a) Perform quality control of donor related equipment, and maintain records as per D& C act

5) Training

- a) Assist in training new staff.
- b) Instruct new nursing staff in specific tasks and job techniques as required
- c) Training of other clinical department nurses on bedside transfusion practices

6) Clinical Services

- a) Obtain informed consent for therapeutic apheresis from patients.
- b) Help MO in scheduling therapeutic apheresis procedures with apheresis personnel.
- c) Help MO in Completing therapeutic apheresis worksheets
- d) Maintain the records of daily apheresis orders, pre-procedure records and document procedure/"SOP" note.
- e) Maintain the records related to management of patient reactions during therapeutic apheresis.
- f) Maintain records and reports with patient response to therapeutic apheresis
- g) Assist in Haemovigilance

7) Biosafety & Infection Control

- a) Ensure Universal precautions are followed strictly
- b) Ensure Infection control practices including BMW management

RESPONSIBILITIES FOR BLOOD BANK TECHNICIANS

1) Donor Management

- a) Assist in Donor motivation activities
- b) Assist in donor room activities including assisting in apheresis procedures
- c) Identifies and communicates abnormal test reports by alerting supervisory personnel & safe disposal of TTI reactive units as per BMW regulation.

2) Testing

- a) Understands blood bank methods, demonstrates knowledge of testing processes which includes donor screening, blood grouping, cross matching, IH testing, TTI screening.

- b) Organize work by matching blood requests with test tube labelling; sorting samples; checking labelling; logging samples; cross matching and reserving units ready for issue, keeping work surfaces clean and orderly.

3) Component management

- a) Performs blood component separation, labelling, quality control of blood components produced.

4) Administrative/ Programme management/ Regulatory Aspects

- a) Perform duties as assigned by the BB MO
- b) All activities & records to be maintained as per relevant SOP & D&C act.
- c) Document all the necessary information in the required blood bank records in the respective work area
- d) Assist staff nurse & MO in preparation of reports.
- e) Maintains donor/patient confidence by keeping laboratory information confidential.

5) QMS/QA

- a) Assist in preparation of SOPs
- b) Maintains quality results by running standards and controls, verifying equipment function through routine equipment maintenance and advanced trouble shooting; calibrating equipment utilizing approved testing procedures; monitoring quality control measures and protocols.
- c) Perform & maintain records of QC procedures related to reagent, kits & equipment's.

6) Training

- a) Responsible for in house staff training.

7) Clinical Services

- a) Ensures the issue of blood components / units for patient care.

8) Biosafety & Infection Control

- a) Ensure Universal precautions are followed strictly
- b) Ensure Infection control practices including BMW management

TERMS OF REFERENCE FOR THE COUNSELLOR AT BLOOD BANKS

1. Donor Education

- a) To explain the blood donor of the entire blood donation process (sic).
- b) To ensure that the donor understands all questions and responds accurately to the donor questionnaire.
- c) To inform the donor that his/her blood will be tested for blood group serology and markers of TTI and the test results will be given to the donor.

- d) To ensure that the donor is able to give informed consent to donate and recognizes that his/her signature is an affirmation that responses provided to the questionnaire are accurate and the donor is willing to be informed of their test results.

2. Donor Education regarding Blood Donation Process

- a) To ensure that donors feel comfortable during blood donation process, including the venepuncture.
- b) To reduce donor anxiety and minimize the risk of any adverse donor reactions, such as fainting.
- c) To give post-donation advice, including care of the venepuncture site.
- d) To secure donors' cooperation in the confidential unit exclusion or post-donation information process.
- e) To clarify doubts or concerns raised by donors.
- f) To alleviate donors' anxiety.

3. Donor Education regarding TTI Reactivity

- a) To keep the donor informed about the health implications of the positive TTI test results for the donor and the donated blood (discard) and the suitability of the donor for future blood donations.
- b) To guide and help the blood donor with positive screening results in further investigation, management, treatment and care, if necessary.
- c) To encourage donors to provide all relevant information, including the possible source of infection.
- d) To explain the test results, the need for confirmation of the results, the health implications for the donor and the donated blood (discard) and the suitability of the donor for future blood donation.
- e) To provide information on precautions for preventing the transmission of infection to others.

4. Donor Deferral and Preventive Health Education

- a) To explain and clarify of the nature of the deferral (permanent or temporary) Example: Donor with low haemoglobin: refer to a health-care institution for haematological investigation and further management, and provide information on nutrition.
- b) To encourage temporarily deferred donor to return for future blood donations after the defined deferral period.
- c) To keep the donor informed about the donor deferral period: i.e. until screening test is non-reactive on follow-up.
- d) To encourage individuals to self-defer if they are suffering from an infection, disease or health condition that may make them unsuitable to donate blood.

5. Referral and Linkages

- a) To provide information and refer donors for further investigation, management, treatment and care, if necessary.
- b) To organise and scheduling Blood Donation Camps (sic.).
- c) To mobilize communities for blood donation.

- d) To organize and lead mobile blood donations in colleges, workplaces, etc.
- e) To give blood donation lectures at workplaces, schools and voluntary organisations.
- f) To prepare donor cards and certificates to voluntary blood donors.
- g) To maintain effective communication and working relationship with team members, other health workers and clients.
- h) To develop list of prospective donor groups by using organizational, professional, and industrial listings and directories.
- i) To contact prospective donor groups to explain requirements and benefits of participation in blood donor program.
- j) To visit prospective or participating blood donor group to discuss blood program.
- k) To distribute promotional material and use audio-visual aids to motivate groups to participate in blood-donor program.
- l) To arrange specific date of blood collection for blood-donor group and confirm appointment in writing.

6. Donor Identification and Motivation

- a) To identify donors with rare-type blood from blood-bank records, and telephone donors to solicit and arrange blood donation.
- b) To increase donors' trust in the BTS and encourage them to adhere to donor selection criteria while responding to the donor questionnaire.
- c) To foster donor trust and confidence for donor retention.
- d) To reinforce the importance of healthy lifestyles for donors found to be non-reactive on blood screening and encourage regular blood donation.

7. Reporting and Record Keeping

- a) To keep records of organizations participating in program.
- b) To record information for mobile blood-collection unit, such as space available, staffing required, and number of donors anticipated.
- c) To consult blood bank records to answer questions, monitor activity, or resolve problems of blood donor groups.
- d) To prepare reports of blood-donor program and donor recruitment activities.

8. Self-Motivation and Monitoring

- a) Develop and maintain continuing personal and professional development to meet the changing demands in the area of blood donor services.
- b) Monitor own performance against objectives and standards.
- c) Keep up-to-date on job-related issues as appropriate and keep log of own performance and in-service training log for purposes of appraisal.

Annexure 5

Counselling Checklist

Pre-Donation Information

- Use simple language
- Avoid using medical terms
- Avoid using slang language
- Discuss one key idea completely before moving on to the next
- Use the counselling skills of summarizing YOUR OWN explanation to ensure the donor has understood.

Pre-Donation Counselling

- Ensure the donor understands the donor questionnaire and responds accurately to all questions
- Ensure the donor understands that his/her blood will be tested for blood group serology and markers of TTI and the test results will be given to the donor
- Ensure the donor is in a position to give informed consent to donate and recognizes that his/her signature affirms that responses provided to the questionnaire are accurate
- Ensure the donor is willing to be informed of his/her test results

Donor Selection and Health Check (not a counsellor role)

Counselling during Blood Donation

- Ensure that donors feel comfortable during blood donation, including the venepuncture
- Reduce donor anxiety and minimize the risk of any adverse donor reactions, such as fainting
- Give post-donation advice, including care of the venepuncture site
- Secure donor's cooperation in the confidential unit exclusion or post-donation information process
- Foster donor trust and confidence for donor retention

Post-Donation Counselling

- Explain the test results, the need for confirmation of the results, the health implications for the donor and the donated blood (discard) and the suitability of the donor for future blood donation.
- Encourage donors to provide all relevant information, including the possible source of infection.
- Clarify doubts or concerns raised by donors.
- Alleviate donors' anxiety
- Provide information on precautions for preventing the transmission of infection to others.
- Provide information and refer donors for further investigation, management, treatment and care, if necessary

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