Dr. Krishan Kumar
डॉ. कृष्ण कुमार
Sr. CMO (SAG)
वरिष्ठ मुख्य चिकित्सा अधिकारी

सत्यमेव जयते

भारत सरकार
स्वास्थ्य एवं परिवार कल्याण मंत्रालय
स्वास्थ्य सेवा महानिदेशालय
Government of India
Ministry of Health & Family Welfare
Directorate General of Health Services

D.O.No. IM11012/09/2022-NBTC/BTS
Dated, 24th January, 2025

Subject: Revision of Guidelines for Donor Selection and Referral

Dear Sir/Madam,

As approved in the 33rd Governing Body Meeting of the National Blood Transfusion Council (NBTC) held on 19.11.2024, the donor selection and referral criteria guidelines have been revised.

The revised donor selection and referral criteria are in Annexure I for your information and future reference.

This issue is with the approval of the competent authority.

Yours Sincerely,

(Dr. Krishan Kumar)

To,

- All members of the Governing Body of NBTC
- All Members of the Technical Resource Group (TRG) of NBTC
- All Directors State Blood Transfusion Council/PDSACS

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Room No. 342-B, A-Wing, 3rd Floor, Nirman Bhawan, New Delhi-110011
Telephone No.: 011-23062625, Email ID: karishan.kumar31@rmlh.nic.in

Guidelines

for

Blood Donor Selection

and

Blood Donor Referral

NATIONAL BLOOD TRANSFUSION COUNCIL
DIRECTOR GENERAL OF HEALTH SERVICES
MINISTRY OF HEALTH AND FAMILY WELFARE
GOVERNMENT OF INDIA
NEW DELHI
2025

Introduction

The primary responsibility of a Blood Transfusion Service (BTS) is to provide a safe, and sufficient 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 blood donors. Whole blood derived from voluntary blood donors is efficacious for the recipient, with minimal risk of any infection that could be transmitted through transfusion.

The donor selection criteria detailed in these guidelines apply to whole blood donors or apheresis donors (red cells, platelets, plasma, and other blood components).

These guidelines are designed to promote best practices in BTS to ensure the collection of blood/blood components from the lowest risk blood donors and also to ensure that every probable transfusion transmissible infection (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 transfusion is having safe and healthy blood donors.

To ensure this, blood centers 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 an adequate number of healthy repeat donors.
- Blood donors should be appropriately recognized and thanked for their contribution.

Blood 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 centeror a blood donation camp. The blood donors are screened using a donor questionnaire based on donor selection criteria. This activity is a bit different from counseling, which is offered once the prospective blood donor reaches the blood centeror blood donation camp. Once recruited, all first-timeblood donors should be encouraged to become regular repeat donors and retained with the BTS through constant engagement through different communication media. Community organizations, civil society bodies, and NGOs play a critical role in these activities.

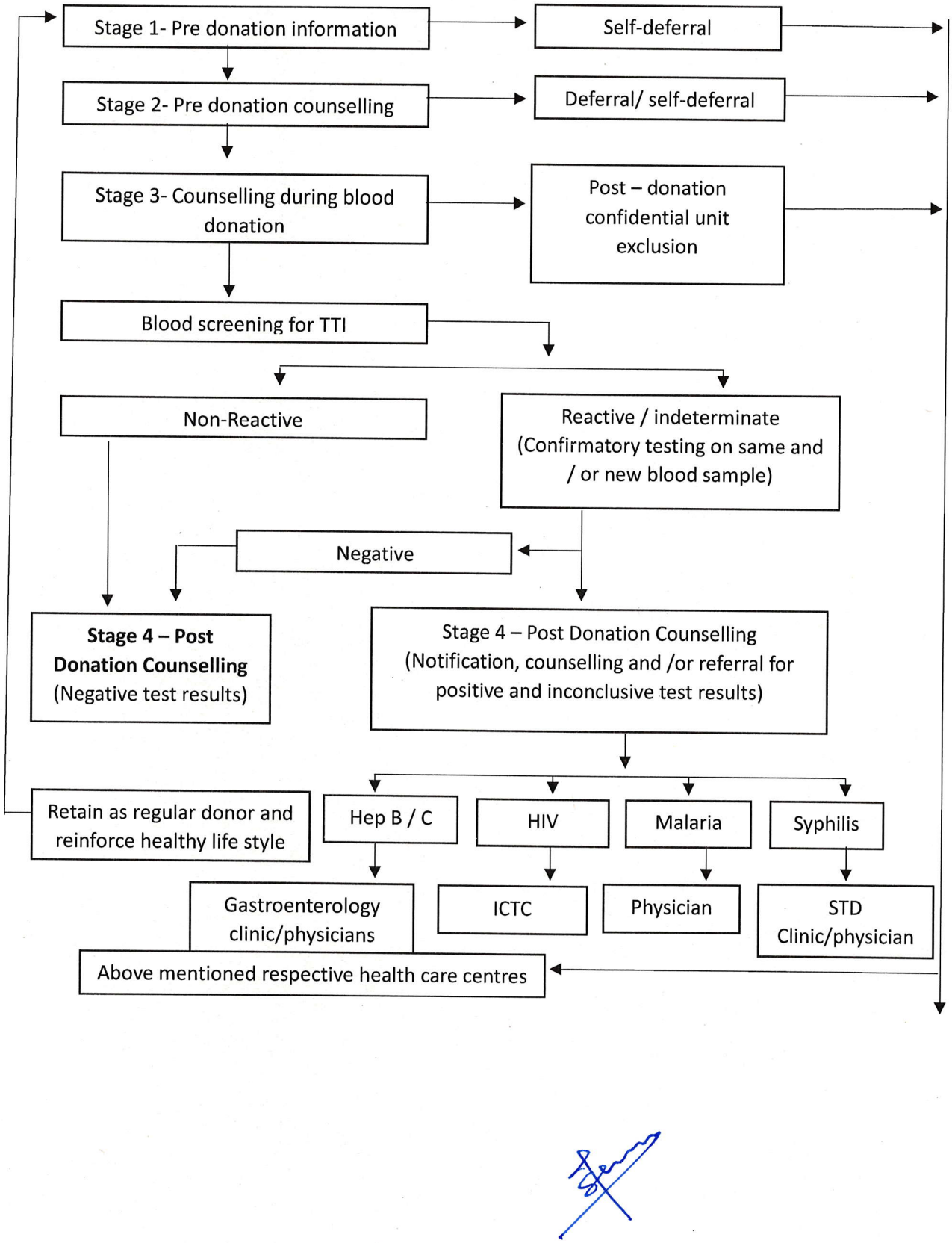
Donor Selection and Counselling

Once a prospective donor reaches the blood centreor 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 centres may also train their paramedical staff/ medical officers to undertake to counsel, in case dedicated manpower is not available. Medical officers with minimum MBBS qualification should be responsible for reviewing the donor's health conditions and performing a physical examination of the donor. The 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 the 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

Blood donors should be educated regarding the possible risks of blood donation and possible risks of transmission of TTI and encouraged to share his/her 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 one-on-one 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 the 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 TTI screening
- Explain self-deferral
- Explain temporary and permanent deferral
- Familiarize donor with to process of blood donation
- Obtain the donor's Informed consent

Donor Questionnaires and Health check-upsare administered to every prospective blood donor to enable quick history taking, limited physical examination, and blood tests. Questionnaires should be prepared in English and local languages which is simple and easy to understand. For blood donors who are illiterate, assistance should be given by the counselor/ 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 blood donors on the questionnaire.

Before blood donation, the consent of the donor should be obtained in writing with the 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 the safety of recipients. The blood 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/she can be contacted by the blood center in the future. Blood centres 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 checkup by a Medical Officer through history taking, limited physical examination, and hemoglobin (Hb)estimation to determine eligibility as a blood donor. In case a donor is to be temporarily or permanently deferred, he/she should explain the reasons in understandable terms.

Donor Consent should be taken for the following understanding:

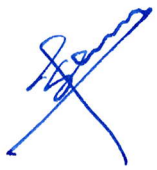
1. Blood donation is a voluntary act and no inducement or remuneration has been offered.
2. Donation of blood/ components is a medical procedure and by donating voluntarily, I accept the risk associated with this procedure.
3. My donated blood and plasma recovered from my donated blood may be sent for plasma fractionation for preparation of plasma-derived medicines, which may be used for the larger patient population and not just this blood center.
4. My blood will be tested for Hepatitis B, Hepatitis C, malariaparasites, 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

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/her valuable contribution

Post-donation interactions include

- 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 the blood centrein case of discomfort following blood donation
- Information about what to do in case of specific donor reactions
- Message on healthy lifestyle and regular blood donation
- Blood 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

S.No.	Condition	Criteria
1	**Well-being**	The donor shall be in good health, mentally alert, and physically fit. Differently-abled donors 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 valid consent.
2	**Age**	Minimum age: 18 years Maximum age: 65 years First-time donors shall not be over 60 years of age. For repeat donors, the upper age limit is 65 years. For apheresis, the donor shall be between 18-60 years of age.
3	**Volume collected and weight of the donor**	For 350ml whole blood: 45kg For 450ml whole blood: more than 55 kg For Single platelet apheresis: 50 Kg For Double platelet apheresis: 60 Kg For Double red cell donation by apheresis: 60 Kg
4	**Donation Interval**	For whole blood donation, once in three months (90 days) for males and four months (120 days) for females. For Single apheresis donation, at least 48-hours interval after platelet /plasma-apheresis shall be kept (not more than 2 times in a week, 4 times in a month, and limited to 24 times in one year). For Double plateletpheresis donation ($6x10^{11}$ per unit), at least 7 days interval shall be kept (not more than 2 times in a month and 12 times in one year). The donor should have a minimum platelet count of more than or equal to $250x10^3/\mu L$. 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 7 days from the last plateletpheresis donation provided reinfusion of red cells was complete in the last plateletpheresis donation.

		If the reinfusion of red cells is not complete, the donor shall not be accepted before 90 days.
5	**Blood Pressure**	100-140mm Hg systolic blood pressure, 60-90mm Hg diastolic blood pressure with or without medications. There shall be no findings suggestive of end-organ damage or secondary complications (cardiac, renal, eye, or vascular) or history of feeling giddiness or 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 for whole blood donation. >or=14g/dL for double Red cell apheresis donation. For higher haemoglobin values, refer to the selection criteria for Polycythemia. 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 the last meal should have been taken at least 4 hours before donation.
11	**Alcohol consumption**	The donor shall not be a person having regular heavy alcohol intake and shall not show signs of intoxication before the blood donation.
12	**Occupation**	The donor who works as an aircrew member, long-distance vehicle driver, either above sea level or below sea level or in emergency services or where strenuous work (including miners and divers) is required, shall not donate blood for 12 hours after duty and shall not resume work for at least 24 hours after blood donation. The donor shall not be a night shift worker without adequate sleep.

13	**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 risk as determined by the Medical Officer deciding fitness to donate blood). The donor shall not be an inmate of a jail or any other confinement.
14	**Travel and residence**	The donor shall not be a person with a history of residence or travel in a geographical area that is endemic for diseases that can be transmitted by blood transfusion and for which screening is not mandated or there are no guidelines in India. Residents of other countries: Accept, if all donor selection criteria are fulfilled. In case of a language barrier, donor screening and examination as well as the process of donation shall be done in the presence of a translator/ witness. The consent shall be taken in the language they understand.
15	**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 to self-injected narcotics.
Physiological Status for Women		
16	**Pregnancy or recently delivered**	Defer for 12 months after delivery.
17	**Abortion**	Defer for 6 months after abortion.
18	**Breastfeeding**	Defer for 12 months after delivery.
19	**Menstruation**	Defer for the period of menstruation.
Non-specific illness		
20	**Minor non-specific symptoms including but not limited to fever, general malaise, pain, headache** **In case of fever with joint pain, rashes, petechiae (diagnosis not specified)**	Defer until all symptoms subside, and the donor is afebrile. Defer for 28 days after symptoms subside.
Respiratory (Lung) Diseases		
21	**Cold, flu, cough, sore throat or acute sinusitis**	Defer until all symptoms subside, and the donor is afebrile.
22	**Chronic sinusitis**	Accept unless on antibiotics.

23	**Asthma**	**Accept:** Individuals with asthma provided they are asymptomatic and/or on a maintenance dose of non-steroid and/or inhaled steroid medication. **Temporary Defer:** Individuals with asthma during an acute exacerbation or on a course of oral or injected steroids to be deferred for 14 days after full recovery **Permanently defer:** Permanently defer individuals with severe obstructive or restrictive respiratory disease.
Surgical Procedures		
24	**Major surgery**	Defer for 12 months after recovery (Major surgery is defined as that requiring hospitalization, anaesthesia (general/spinal), blood transfusion, and/or significant blood loss).
25	**Minor surgery**	Defer following minor surgery for 3 months after recovery.
26	**Received Blood Transfusion**	Defer for 12 months.
27	**Open heart surgery Including Bypass surgery**	Permanently defer
28	**Cancer surgery**	Permanently defer
29	**Dental Procedures**	Defer donor following: - Simple procedure (scaling, filling, etc) for 48 hours. - Endodontic procedure (Root Canal/ Extraction) for 14 days. - Bone/ Graft/ dental reconstruction for 12 months.
Cardio-Vascular Diseases (Heart Disease)		
30	**Has any active symptom (Chest Pain, Shortness of breath, swelling of feet)**	Permanently defer
31	**Myocardial infarction (Heart Attack)**	Permanently defer
32	**Cardiac medication (Digitalis, Nitro-glycerine)**	Permanently defer
33	**Hypertensive heart disease**	Permanently defer
34	**Coronary artery disease**	Permanently defer
35	**Angina pectoris**	Permanently defer
36	**Rheumatic heart disease with residual damage**	Permanently defer

Central Nervous System/Psychiatric Diseases		
37	**Migraine**	Accept if not severe and occurs at a frequency of less than once a week.
38	**Convulsions and Epilepsy**	Accept individuals with a history of convulsion/epilepsy who have been off medication and seizure-free for at least 3 years. Permanently defer if there is an organic cause.
39	**Schizophrenia**	Permanently defer
40	**Anxiety and mood disorders**	Accept a person having anxiety and mood (affective) disorders like depression or bipolar disorder but is stable and feeling well on the day regardless of medication.
Endocrine Disorders		
41	**Diabetes**	Accept a 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). Defer if oral hypoglycaemic medication has been altered/dosage adjusted in the last 4 weeks. Permanently defer a person requiring insulin and/or complications of Diabetes with multi-organ involvement.
42	**Thyroid disorders**	Accept donations from individuals with Benign Thyroid disorders if asymptomatic and euthyroid with medication and no dose adjustment in the last 8 weeks. Permanently defer if - Thyrotoxicosis - History of Malignant thyroid tumours
43	**Polycystic Ovarian Syndrome**	Accept if the donor is well on the day of donation and treatment is acceptable as per the medication list.
44	**Other endocrine disorders**	Permanently defer
Liver Diseases and Hepatitis infection		
45	**Hepatitis**	Permanently defer if a known case of Hepatitis B, C. Unknown Hepatitis: Permanently defer Known case of Hepatitis A or E: Defer for 12 months
46	**Spouse/ partner/ close contact of an individual suffering from hepatitis B and C**	Permanently defer
47	**At risk for hepatitis by tattoos, acupuncture or body piercing, scarification,**	Defer for 12 months.

	and any other invasive cosmetic procedure by self or spouse/ partner	
48	**Spouse/ partner of the individual receiving transfusion of blood/ components**	Defer for 12 months.
49	**Jaundice**	Accept blood donors after one year of having jaundice due to any acute cause that has been adequately treated and resolved
50	**Chronic Liver disease/ Liver Failure**	Permanently defer
HIV Infection/AIDS		
51	**At risk for HIV infection (Transgender, Men who have Sex with Men, Female Sex Workers, Injecting drug users, Persons with multiple sex partners)**	Permanently defer
52	**Known HIV-positive person or spouse/ partner of PLHA (the person living with HIV AIDS)**	Permanently defer
53	**Persons having symptoms suggestive of AIDS**	Permanently defer a person having lymphadenopathy, prolonged and repeated fever, prolonged and repeated diarrhea irrespective of HIV risk or status.
Sexually Transmitted Infections		
54	**Syphilis (Genital sore, or generalized skin rashes)**	Permanently defer
55	**Gonorrhoea**	Permanently defer
Other Infectious diseases		
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/ Zika virus**	In case of diagnosed Dengue/Chikungunya/Zika infection, defer donor for 6 months following full recovery. In case of a history of travel to the Zika virus outbreak zone, defer donor for 28 days.
60	**Tuberculosis**	Defer for 2 years following confirmation of cure.
61	**Leishmaniasis**	Permanently defer
62	**Leprosy**	Permanently defer
Other infections		
63	**Conjunctivitis**	Defer for the period of illness and continuation of local medication.
64	**Osteomyelitis**	Defer for 2 years following completion of treatment and cure.
65	**Acute kidney infection (pyelonephritis)**	Defer for 6 months after complete recovery and last dose of medication
66	**Acute infection (cystitis)/**	Defer for 2 weeks after complete recovery and the last

	UTI	dose of medication.
67	**Chronic infection of kidney/ kidney disease/renal failure**	Permanently defer
Digestive System		
68	**Diarrhea**	In case of a person having a history of diarrhea in the preceding week, particularly if associated with fever, defer donor for 2 weeks after complete recovery and the last dose of medication.
69	**GI endoscopy**	If no sampling is done during the procedure, defer the donor for 7 days (wellness to be ensured). If a sample is taken, then deferral is to be considered based on the report. If Malignant disorder, then permanently defer the donor. If Benign disorder, then defer the donor for 28 days. If any other disorders (like H. Pylori infection) then defer the donor till completion of treatment.
70	**Acid Peptic disease**	Accept person with acid reflux, mild gastro-oesophageal reflux, mild hiatus hernia, gastro-oesophageal reflux disorder (GERD), and hiatus hernia. Permanently defer person with stomach ulcer with symptoms or with recurrent bleeding.
Other diseases/disorders		
71	**Auto immune disorders like Systemic lupus erythematosus, Scleroderma, Dermatomyositis, Ankylosing spondylitis or severe Rheumatoid arthritis**	Permanently defer
72	**Polycythemia Vera**	Primary Polycythemia Vera: Permanently defer. Secondary Polycythemia: Due to high altitude, etc: Accept donors having Hb≤ 18.5 g/dl in males and ≤ 16.5 g/dl in females.
73	**Bleeding disorders and unexplained bleeding tendency**	Permanently defer
74	**Malignancy**	Permanently defer
75	**Allergic disorders**	**Permanently Defer if:** - Donor has an allergy to a substance used in the blood donation process.

		- Donor experiences cold urticaria (red, raised, itchy rashes on the skin after exposure to the cold). - Donor has history of severe allergy. **Temporary defer if** - Donor is on a course of oral or injectable steroids (Accept after 28 days following full recovery and cessation of oral or injectable steroids).
76	**Haemoglobinopathies and red cell enzyme deficiencies with anemia and a known history of haemolysis"**	Permanently defer
Vaccination and inoculation		
77	**Non live vaccines and Toxoid: Typhoid, Cholera, Papilloma virus, Influenza, Meningococcal, Pertussis, Pneumococcal, Polio injectable, Diphtheria, Tetanus, Plague,COVID-19 (non-live) vaccination & Swine Flu vaccination**	Defer for 14 days.
78	**Live attenuated vaccines: Polio oral, Measles Rubella Mumps, Yellow fever, Japanese encephalitis, Influenza, Typhoid, Cholera, Hepatitis A, COVID-19 (Live attenuated)**	Defer for 28 days.
79	**Anti-tetanus serum, anti-venom serum, anti-diphtheria serum, and anti-gas gangrene serum**	Defer for 28 days.
80	**Anti-rabies vaccination following animal bite, Hepatitis B Immunoglobulin, Immunoglobulins**	Defer for 1 year.
Medications taken by prospective blood donor		
81	**Oral contraceptive**	Accept
82	**Analgesics**	Accept
83	**Vitamins**	Accept
84	**A mild sedative and tranquillizers**	Accept
85	**Allopurinol**	Accept
86	**Cholesterol-lowering medication**	Accept for all medication except monoclonal antibody therapy.

87	**Salicylates (aspirin), other NSAIDs**	Defer for 3 days if blood is to be used for platelet component preparation.
88	**Ketoconazole, Antihelminthic drugs including Mebendazole**	Defer for 7 days after the last dose if the donor is well.
89	**Antibiotics**	Defer for 2 weeks after the last dose if the donor is well.
90	**Ticlopidine, Clopidogrel**	Defer for 2 weeks after the last dose
91	**Piroxicam, Dipyridamole**	Defer for 2 weeks after the last dose
92	**Etretinate, Isotretinoin (Used for acne)**	Defer for 1 month after the last dose. Etretinate: Permanent deferral
93	**Finasteride used to treat Benign prostatic hyperplasia**	Defer for1 month after the last dose.
94	**Radioactive contrast material**	Radioactive materials - For non-malignant conditions: Defer for 6 months - For malignant conditions: Permanent deferral
95	**Dutasteride used to treat Benign prostatic hyperplasia**	Defer for 6 months after the last dose.
96	**Any medication of unknown nature**	Defer till details are available.
97	**Oral anti-diabetic drugs**	Accept if there is no alteration in dose within last 4 weeks.
98	**Insulin**	Permanently defer
99	**Anti-arrhythmic, Anti- convulsions, Anticoagulant, Anti-thyroid drugs, Cytotoxic drugs, Cardiac Failure Drugs (Digitalis)**	Permanently defer
100	**Recipients of organ, stem cell and tissue transplants**	Allogenic organ/stem cell: Permanent deferral Autologous organ/stem cell: Permanent deferral **Hair transplant/ PRP therapy/ Skin grafting:** 6 months after the recovery from hair transplant / skin grafting surgery/ PRP therapy and no further treatment/ medication or follow-up is planned. For medication follow the deferral criteria as per the medication list.
101	**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 on test results

- In case of an abnormal test result, blood donors who have consented to be contacted by the blood center should be recalled to inform them about the initial sero-reactive result of TTI.
- Donors should be provided post-donation counseling 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 center staff to contact the initial zero-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 counseling to remain negative and continue to donate blood.
- Updated list of Integrated Counselling and Testing Centres (ICTCs) along with contact details of counselors should be available with all licensed blood centres.

Duties of a Blood centre:

- Consent of the blood donor shall be obtained for performing the TTI 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 centre or BTS to confirm the diagnosis of any of the TTI screening results.
- All initial zero-reactive donors shall be recalled, offered post-donation counseling and referred to an appropriate facility for further counseling, confirmation, and management.
- Results shall not be informed over the telephone.
- A standard referral format for the same shall be used and the Blood centre 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 to avoid litigation due to discordant results of screening at blood centers and confirmatory tests of reference centre.
- In case, the initial zero-reactive donor does not return to the blood centre despite three consecutive weekly attempts, the list of HIV sero-reactive blood donors should be shared with linked ICTC under shared confidentiality.

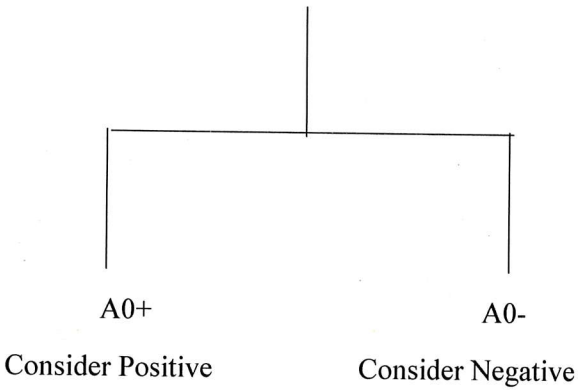
Testing Strategy for HIV at Blood centres

The testing strategy used in the Blood centers for HIV is "Strategy I" and the test done in the blood centre 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



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

Algorithm for Blood Donors referred to ICTC.

- All initial zero-reactive donors referred to ICTC from the Blood centre shall be offered HIV pre-test counseling at the ICTC and consent was taken to perform the HIV test.
- ICTC shall perform the first test (A1). In case the first test is positive, ICTC shall perform the remaining two tests and give a positive result after three sequential reactive tests.
- In case the first test is negative, ICTC shall report the result as HIV is inconclusive and recall the donor for re-testing after two weeks after thorough counseling 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 counseling.
- 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 counseling.

Testing Strategy for other TTI at Blood centres

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 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.

- Prior consent shall be taken from the donor for both the conduction of screening tests and to be informed of the result of testing at the time of the donation by the blood centre along with complete contact details and telephone number.

- All blood donors found to be sero-reactive at blood centre for HBV, HCV, Syphilis, and Malaria shall be referred to clinicians in the Outpatient Department of associated hospitals or others for assessment and re-testing.
- Blood centre shall fill out the referral form per standard format and send it along with the referred donor.
- Confidentiality shall be maintained at all levels.

Algorithm for Blood Donors referred to Clinicians.

- All initialzero-reactive donors are referred to clinicians from the Blood centre. Donors 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 Centre

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 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 many times

   1.2 Date of last donation:

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

   Yes No

   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? Yes No

2.2 Have you eaten anything in the last 4 hours? Yes No

2.3 After donating blood do you have to engage in heavy work, driving heavy vehicle or work at heights today Yes No

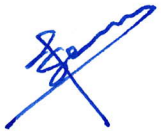
3. Have you had / have any of the following? If yes, discuss with the doctor present:

- Allergy
- Cancer
- Fainting attacks
- Heart disease
- Lung disease
- Asthma
- Kidney disease
- Mental illness
- Amoebiasis
- Cold/Cough
- Liver disease
- Fever
- Endocrine disease
- Diabetes
- Syphilis Blood/Bleeding Disorder
- Gonorrhoea
- Skin disease
- High/low BP
- Leprosy
- Epilepsy
- Tuberculosis
- Polycythemia
- 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?	Yes	No
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	Yes	No
Measles	Yes	No
Chicken Pox	Yes	No
Dengue	Yes	No
9. Have you taken any medicine in 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 been infected by the virus that causes AIDS? Yes No

11.2 In the last 6 months have you had: Yes No

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:

(a) Blood donation is a voluntary act and no inducement or remuneration has been offered.

(b) Donation of blood/components is a medical procedure and that by donating voluntarily, I accept the risk associated with this procedure.

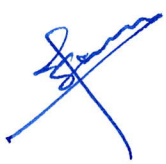
(c) My donated blood, blood and plasma recovered from my donated blood may be sent for plasma fractionation for preparation of plasma-derived medical products, all of which may be used for larger patient population and not just this blood centre.

(d) My blood will be tested for Hepatitis B, Hepatitis C, Malaria Parasite, HIV/ AIDS and Syphilis disease in addition to any other screening tests required to ensure blood safety.

(e) 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: > 12.5g/dl <12.5g/dl		
History Check List	Feeling well/ adequate sleep (> 5hrs) / 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 purpose How to contact for follow up purpose: By a letter/ By phone/ By e-mail	
Outcome	Donor accepted/ Temporary deferral/ Permanent deferral	
Remarks / Reasons for Deferral:		

REGISTRAION	**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

REFERAL SLIP FOR BLOOD DONORS

(*To be filled by Blood Centre Staff*)

Name and address of the referring Blood Centre:-

Date of Referral .....Blood centre 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 centre 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----------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 ICTC on _____

(Seal of ICTC /Laboratory with contact details)

Annexure 3
CONSENT FOR REFERRAL

I understand that

- During the blood donation process I have been counselled 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 a blood centre are not diagnostic and may yield false-positive results.
- I understand that any wilful 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, counselled, and referred by the blood centre for confirmation and management to the appropriate facility.

Signature of Referring Blood Centre Staff

Signature of Donor

Place: ……..

Date: ……



Annexure 4

DUTIES AND RESPONSIBILITIES OF BLOOD CENTRE MEDICAL OFFICER (MO)

1) Administration, Oversight and Coordination

- Overall supervision
- Inventory management
- Fulfilling regulatory requirements
- Recording and reporting
- Convening Hospital Transfusion Committee meetings
- Fulfilling National program requirements
- Undergo appropriate training programs regularly
- Provide consultation to supervisory and technical personnel on maintaining an adequate inventory of all blood components.
- In times of limited inventory, provide the interface to attending physicians and resident staff on requests for those components in short supply
- Evaluate the function of the blood centre periodically

2) Donor Management

- Perform routine donor evaluation and monitoring, including physical examinations and phlebotomy site examination and review of periodic laboratory testing.
- Provide consultation to Blood centre technical and clerical personnel concerning donor selection and acceptability.
- Evaluate, manage and report blood donor reactions to the National program.
- Evaluate and followup donors with abnormal test results, including infectious disease testing.
- Evaluation and approval of requests for specific components from specific donors
- Selection of donors for specific patients
- Evaluation of donor acceptability
- Donor monitoring

3) Camp Management

The Medical officer should check the following:

- Exact venue, number of donors, time for the camp, refreshments for donors, furniture, space, mobile vans, appliances for collection and transportation of blood, and emergency box
- Record and report the details about the blood camp to the Blood transfusion committee.

4) Testing (IH/ID)

- Provide consultation and support to technical and clerical staff concerning specimen and requisition acceptability.
- Review and interpret:
    - Blood typing discrepancies
    - Positive antibody screens
    - Antibody panels; prenatal titters
    - Positive direct/ Indirect anti-globulin tests

- Provide consultation to technical staff concerning additional evaluation of patients with complex serological problems.
- Review the clinical significance of serological findings and decide on additional testing required before transfusion.

5) Component Management

- Provide consultation to apheresis nursing and technical staff concerning donor selection and acceptability.
- Evaluate and manage apheresis donor reactions.
- Provide medical direction of component collection via cell separator.
- Evaluate and approve requests for selected and specialized blood components, including washedred cells and apheresis-derived platelets.

6) Quality Management System/Quality Assurance

a) Assists in developing, implementing, and maintaining the quality assure with respect to
   - Organisation
   - Personnel
   - Technical
   - Document control
   - Infrastructure management
   - Equipment
   - Quality Assurance
   - Audits

b) Perform the initial review of the Quality Control records with the Quality Managerto ensure staff and departmental compliance with all regulatorypolicies, procedures, safety,and institution policies and procedures.

c) Ensure that all work is done according to the required standards.

d) Ensure the standard operating procedure (SOP)has been 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 the component lab.

e) Ensure the application of Good Manufacturing Practices (GMP)/Good lab practices(GLP)/Good Clinical Practices(GCP).

7) Training

- Cross-training of different levels of staff
- Competency management
- Plan and help in the conduction of the refresher and regular training program of the staff in the blood centre.
- Help in evaluating the knowledge of the new staff and arrange for the training programs.

8) Clinical Services

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



- Determine risks of transfusion in patients with complex serological problems and patients who require transfusion before routine serological testing can be completed. Provide consultation to attending physician and resident staff as indicated
- Review the initial workup of all transfusion reactions reported to the Blood Centre. Determine additional evaluation required for a clinical scenario and prepare a written interpretation for review and discussion with the in-charge blood centre and provide consultation to attending physician and resident staff as indicated.
- Provide Clinical consultation to the primary clinical team for patients requiring chronic transfusions.
- Provide initial evaluation of patients who are candidates for Therapeutic apheresis. This includes reviewing patient problems, preparing an initial draft of the consultation report and reviewing with the Consultant Transfusion Medicine to select appropriate patients for therapeutic apheresis, determine the apheresis protocol to be used, and determine methods to be used for evaluating patient response to therapeutic apheresis.
- Obtain informed consent for Therapeutic apheresis from patients.
- Schedule Therapeutic apheresis procedures with apheresis personnel.
- Complete Therapeutic apheresis worksheets and write the detailed orders for the apheresis procedure.
- Write daily apheresis orders.
- Evaluate patient pre-procedure and document procedure/"SOP" note.
- Evaluate and manage patient reactions during Therapeutic apheresis.
- Monitor and evaluate patient response to Therapeutic apheresis.
- Participate and report in the National Hemovigilance Programme of India.

9) Biosafety & Infection Control

- Ensure universal precautions are followed consistently by all the staff of the blood centre
- Ensure Infection control practices, including biomedical waste management rules, are followed for disposal of waste from the blood centre.

DUTIES AND RESPONSIBILITIES OF BLOOD CENTRE NURSE

1) Donor Management

- Assist with donor room preparations, prepare and distribute supplies and equipment, maintain drugs and consumables and equipment management.
- Assist MO in preparing the patient for the phlebotomy procedure.
- Assist MO in donor selection.
- Provide information related to donor screening & post donation instructions to donors.
- Perform phlebotomy & manage post-donation care.
- Collect samples in pilot tubes, supervise the transportation of pilot tubes and collected blood bags to the respective labs.
- Maintain documentation related to donor records.
- Assist in apheresis procedure, donor eligibility and donor care.
- To manage and maintain the availability of emergency drugs.
- To identify and manage donor adverse reactions.
- Perform duties assigned by the MO in-charge.
- Assist in donor motivation activities.

2) Camp Management

- Ensure that all the documents and records are made ready before the camp.
- Ensure that all the equipment and furniture are made available.
- Arrange all the apparatus and equipment required for the mobile blood collection unit.
- Assist in the storage and transportation of collected blood.
- Record the concerns about the blood donation camp.

3) Administrative/ Programme Management/ Regulatory Aspects

- Coordinate activities in the blood collection unit, including workflow and work assignments.
- Coordinate preparation of monthly, quarterly & annual reports to be sent to SBTC/E-Raktkosh/ Drug Control Department.

4) QMS/QA

- Perform quality control of donor-related equipment, and maintain records as per the D& C Act.

5) Training

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

6) Clinical Services

- Obtain informed consent for Therapeutic apheresis from patients.
- Help MO in scheduling Therapeutic apheresis procedures with apheresis personnel.
- Help MO in completing Therapeutic apheresis worksheets.
- Maintain the records of daily apheresis orders, pre-procedure records and document procedure/"SOP" notes.
- Maintain the records related to the management of patient reactions during Therapeutic apheresis.
- Maintain records and reports with patient response to Therapeutic apheresis
- Assist in the National Hemovigilance Programme of India.

7) Biosafety & Infection Control

- Ensure Universal precautions are followed strictly.
- Ensure Infection control practices including biomedical waste management rules, are followed for the disposal of waste from the blood centre.

RESPONSIBILITIES FOR BLOOD CENTRE TECHNICIANS

1) Donor Management

- Assist in donor motivation activities.
- Assist in donor room activities including assisting in apheresis procedures.
- Identify and communicate abnormal test reports by alerting supervisory personnel & safe disposal of TTI reactive units as per biomedical waste regulation.

2) Testing

- Understand blood centre methods, and demonstrates knowledge of testing processes which includes donor screening, blood grouping, cross-matching, IH testing, TTI screening
- Organize work by matching blood requests with test tube labelling, sorting samples, checking labelling, cross-matching, inventory management and reserving units ready for issue, and keeping work surfaces clean and orderly.

- Transfusion reaction workup under the guidance of MO.

3) Component management

- Perform blood component separation, labelling, and quality control of blood components produced.

4) Administrative/ Programme Management/ Regulatory Aspects

- Perform duties as assigned by the MO.
- All activities, equipment maintenance, and blood centre records are to be maintained as per relevant SOP and D&C Act.
- Document all the necessary information in the required blood centre records in the respective work area.
- Assist staff nurse and MO in the preparation of reports.
- Maintain donor/ patient confidence by keeping laboratory information confidential.

5) QMS/QA

- Assist in the preparation of SOPs.
- Maintain quality results by running standards and controls, verifying equipment function through routine equipment maintenance and advanced troubleshooting, calibrating equipment using approved testing procedures, and monitoring quality control measures and protocols.
- Daily temperature verification and troubleshooting of storage equipment.
- Perform and maintain records of QC procedures related to reagents, kits & equipment.

6) Training

- Responsible for in-house staff training.

7) Clinical Services

- Ensure the issue of blood components/units for patient care as per the demand.

8) Biosafety & Infection Control

- Ensure Universal precautions are followed strictly
- Ensure Infection control practices including biomedical waste management rules are followed for disposal of waste from the blood centre.

TERMS OF REFERENCE FOR THE COUNSELLOR AT BLOOD CENTRE

1. Donor Education

- To explain the blood donor of the entire blood donation process.
- To ensure that the donor understands all questions and responds accurately to the donor questionnaire.
- 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.
- 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 the Blood Donation Process

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

3. Donor Education regarding TTI Reactivity

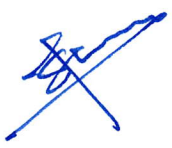
- To keep the donor informed about the health implications of the positive TTI test results for the donor and the donated blood (discard) and the suitability of the donor for future blood donations.
- To guide and help the blood donor with positive screening results in further investigation, management,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

4. Donor Deferral and Preventive Health Education

- To explain and clarify the nature of the deferral (permanent or temporary) Example: Donor with low haemoglobin: refer to a healthcare institution for haematological investigation and further management, and provide information on nutrition
- To encourage temporarily deferred donors to return for future blood donations after the defined deferral period.
- To keep the donor informed about the donor deferral period: i.e. until the screening test is non-reactive on follow-up.
- 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

- To provide information and refer donors for further investigation, management, treatment and care, if necessary.
- To organise and schedule Blood Donation Camps.
- To mobilize communities for blood donation.
- To organize and lead mobile blood donations in colleges, workplaces, etc.
- To give blood donation lectures at workplaces, schools and voluntary organisations.
- To prepare donor cards and certificates for voluntary blood donors.
- To maintain effective communication and working relationships with team members, other health workers and clients.



- To develop a list of prospective donor groups by using organizational, professional, and industrial listings and directories.
- To contact prospective donor groups to explain the requirements and benefits of participation in the blood donor program.
- To visit prospective or participating blood donor groups to discuss the blood program.
- To distribute promotional material and use audio-visual aids to motivate groups to participate in the blood donor program.
- To arrange the specific date of blood collection for the blood-donor group and confirm the appointment in writing.

6. Donor Identification and Motivation

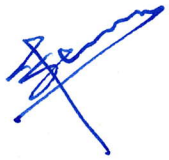
- To identify donors with rare-type blood from blood centre records, and telephone donors to solicit and arrange blood donation.
- To increase donors' trust in the BTS and encourage them to adhere to donor selection criteria while responding to the donor questionnaire.
- To foster donor trust and confidence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

7. Reporting and Record Keeping

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

8. Self-Motivation and Monitoring

- Develop and maintain continuing personal and professional development to meet the changing demands in the area of blood donor services.
- Monitor own performance against objectives and standards.
- Keep up-to-date on job-related issues as appropriate and keep a log of your 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 informed 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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