

No.S.12016/08/2016 - NACO (NBTC)
Government of India
Ministry of Health & Family Welfare
National AIDS Control Organization
(National Blood Transfusion Council)

9th Floor, Chanderlok Building,
36, Janpath, New Delhi - 110 001
Dated 19th June 2017

Office Memorandum

Subject: Minutes of 26th meeting of Governing Body of National Blood Transfusion Council (NBTC)-reg.

This is to inform you that 26th Meeting of Governing Body of NBTC was held on 1st June, 2017 at 3.00 P.M. in the Committee Room of NACO, 6th Floor, Chanderlok Building, 36, Janpath, New Delhi under the Chairpersonship of Additional Secretary, NACO (as President National Blood Transfusion Council). Minutes of the meeting are enclosed for reference and necessary action.

This issues with the approval of President, NBTC.

(Dr. Shobini Rajan)
ADG (Blood Safety) & Director (NBTC)

To

All member of Governing Body of NBTC.

Copy for information to:

1. PPS to Secy(H).
2. PPS to DGHS.
3. PPS to Additional Secretary (NACO).
4. PS to Joint Secretary (Policy).

Minutes of the 26th Governing Body Meeting of National Blood Transfusion Council

The 26th Meeting of Governing Body of the National Blood Transfusion Council was held on 1st June 2017 in the Committee Room, 6th Floor, NACO, Chandralok Building, 36, Janpath, New Delhi under the Chairmanship of Additional Secretary, National AIDS Control Organization & President of National Blood Transfusion Council.

The following members attended the meeting:

1. Dr Arun Kumar Panda, Additional Secretary, National AIDS Control Organization & President, National Blood Transfusion Council New Delhi - in Chair
2. Shri Alok Saxena, Joint Secretary NACO
3. Ms.Vandana Jain, Director IFD, Representing Ms Vijaya Srivastava, Additional Secretary & Financial Advisor, Ministry of Health and Family Welfare, Nirman Bhawan, Delhi
4. Prof A. K. Gadpayle, Addl. Director General and Medical Superintendent Dr RML Hospital, Directorate General of Health Services, Nirman Bhawan, Delhi
5. Dr.Joy Mammen, Professor, Department of Transfusion Medicine and Haematology, Christian Medical College, Vellore
6. Dr.R. N. Makroo, Director Deptt. of Transfusion Medicine, Apollo Hospital, Delhi
7. Dr Nagesh NS, Director, Institute of Gastroenterology Sciences and Organ Transplant, Victoria Hospital, Bangalore
8. Mr Biswaroop Biswas, Secretary, Federation of Indian Blood Donor Organizations, Kolkata
9. Dr K K Aggarwal, President Indian Medical Association
10. Dr.V. G. Somani. Joint Drugs Controller, representating DCG(I), Delhi
11. Ms Vinita Srivastava, National Consultant Blood Cell representing Mr Manoj Jhalani, Joint Secretary (Policy), National Health Mission
12. Dr Alok Ahuja, Member Executive Committee MCI representing Dr. Jayashreeben Mehta, President, Medical Council of India, New Delhi
13. Col.Umesh Kapoor, CO and Head of Armed Forces Transfusion Centre, New Delhi representing DG Armed Forces Medical Services
14. Dr R Sreelatha, Professor and HOD, IHBT Department, Victoria Hospital and BMCRI, BangaloreDelhi
15. Dr.Shobini Rajan, ADG (Blood Safety) NACO, Delhi & Director and Member Secretary NBTC

Attendees/ Invitees from Blood Transfusion Services Division, NACO, CMAI, NIB and CDSCO included

1. Sh. M K Diwaker, Asst. Director, NBTC & Section Officer (BS), NACO Delhi
2. Dr. Shanoo Mishra, PO (QC), NBTC, Delhi
3. Mr Jolly Lazarus, PO (VBD), NBTC Delhi
4. Dr Sunita Upadhyaya, Senior Laboratory Advisor, CDC
5. Mr Lokesh S, Technical Advisor, CMAI
6. Sh. Navneet Pratap Singh, Asstt. Drug Controller, CDSCO, Delhi
7. Dr Akanksha Bisht, Scientist III and Officer I/C Hemovigilance, NIB

The following members could not attend the Meeting or depute any representative for the same:

1. Dr. Neelam Marwah, HOD, Department of Transfusion Medicine, PGIMER, Chandigarh
2. Dr. Bharat Singh, Director, State Blood Transfusion Council, Delhi
3. Dr M Gajjar, HOD, Department of IHBT, BJ Medical College, Ahmedabad
4. Joint Secretary, Indian Red Cross Society, Delhi

The Addl. Secretary, NACO and President of the Governing Body extended a warm welcome to all new members of the Governing Body of NBTC. A power point presentation was made to apprise members of the progress made in strengthening blood transfusion services of India as per approved action plan for 2015-17, also touching on activities conducted through support of CDC CMAI QMBB Project.

The agenda-wise discussions were held and the following decisions were taken in the meeting:

Agenda Item No. 1: Approval of minutes of the 25th meeting of the Governing Body of National Blood Transfusion Council held at New Delhi on 20th January 2014;

The minutes of the 25th Governing Body meeting of NBTC held on 5th August 2015 were approved by the Governing Body.

Agenda Item No. 2: Action Taken Report on proceedings of the 25th Governing Body of NBTC

The Action Taken Report on the minutes of the 25th meeting of the Governing Body of NBTC was noted and accepted by the Governing Body.

Agenda No. 3: Agenda Items for consideration and approval:

The decisions taken on the various agenda items by the Governing Body are as follows:

Agenda Item No. 3.1: Approval of Audit Report 2014-15

The Audited accounts of the Society for 2014-15 were approved.

Agenda Item No. 3.2: Approval of Audit Report for 2015-16

The Audited accounts of the Society for 2015-16 were approved.

Agenda Item No.3.3: Extension of term of existing auditors for FY 2016-17

It was informed that approval of President, NBTC has been accorded for continuing with the existing auditors to carry out the audit work of NBTC for FY 2016-17 as detailed below

1. M/s N. C. Mittal & Co. For Statutory Audit of NBTC @ Rs. 20,000/- per annum (Excl. Of applicable Service tax)
2. M/s L. K. Dhingra & Co. for Internal Audit of NBTC @ Rs. 30,000/- per annum (Incl. Of applicable service tax)

This decision was ratified by the Governing Body.

Agenda Item No.3.4: Financial powers of Director NBTC

The existing financial powers of Director to sanction expenditure of a miscellaneous or contingent nature up to an amount not exceeding Rs 500/- in each case were **enhanced to Rs 50,000** (Rupees Fifty thousand only) with the approval of Governing Body. The rules may be amended accordingly.

Agenda Item No.3.5: Action Plan for NBTC (2017-18 and 2018-19)

The activities proposed as part of the Annual Action Plan (2017 to 2019) were approved by the Governing Body. A total budget of **2000 Lakhs** was projected for the activities as per detailed Work Plan with budget breakup is at **Annexure 1**

It was informed that the actual activities would be tailored to the availability of funds.



Agenda Item No.3.6: Unification and Organizational role allocation of work of Blood Safety and BTS within MoHFW

Members of the Governing Body perused through the agenda notes and the following documents.

1. White paper by a group of experts on "Improving Blood Transfusion Services in India: A Concept Paper on Strengthening National Blood Programme- Way forward" presented to the National Transfusion Services Core Coordination Committee on 29th September 2016.
2. Report of the Mid Term Appraisal (MTA) of NACP IV
3. Recommendations of the High Level Committee (HLC) constituted by the Ministry of Health and Family Welfare on consolidation of the AIDS response based on the Mid Term Appraisal (MTA) of NACP IV

It was decided that there should be there should be a single focal point in the Ministry of Health for all matters pertaining to Blood Transfusion Service and all other entities must work under the overall ambit of National policy guidelines.

It was also informed that the JS (Policy) in NHM has been co-opted as a member in Governing Body of NBTC GB and approval of Hon'ble HFM has been obtained for amendments in the R&R of NBTC.

There was overall agreement towards the recommendation of High Level Committee for take-over of all activities for BTS by NHM including NBTC in a phased manner.

In light of several shortcomings and malpractices continuing in Blood Banks despite regulation and mandatory licensing, the National Blood Policy must be reviewed and its legislation considered with creation of a single authority on lines of NOTTO/SOTTO at National and State level.

As an interim measure, roles and responsibilities of various stakeholders (NBTC/ NACO/ NHM) were demarcated to facilitate the transition of NBTC into NHM and circulated among all members. No comments were received on the document till 15th June 2017. These were deemed approved as detailed in **Annexure 2.**

Agenda Item No. 3.7: Roles of different committees and expert groups constituted under NBTC (GB, EC, Core Committee, Technical Resource Group, Technical Expert Groups, Technical Working Groups)

After review of the composition and TORs of existing committees and expert groups for Blood Transfusion services under NACO and NBTC, the following decisions were taken

- 1.) All Bodies/ Committees for Blood Transfusion Services would be **under aegis of NBTC**.
- 2.) **Governing Body** would be the final authority to take policy decisions on all matters pertaining to Blood Transfusion Services.
- 3.) **Standing Committee** is to be constituted under chairpersonship of Joint Secretary Policy (NHM) to replace the Executive Committee and Core coordination committee with representation from all stakeholders, including few State representatives. This committee would review the functioning of Blood Transfusion Services and Blood Banks every quarter through an online dashboard enabled through e Rakt Kosh and would appraise and inform the Governing Body of NBTC.
- 4.) Matters would be referred for **Technical examination to DGHS or Technical Resource Group** by the Standing Committee as and when required, obviating the need for re-constitution of a separate Technical Resource Group.

This would serve to simplify and make effective the functioning of NBTC.

Agenda Item No. 3.8: Proceedings of the 3rd NTSCCC meeting

The minutes of the Third meeting of National Transfusion Services Core Coordination Committee held on 29th September 2016 under the chairmanship of DGHS were circulated to all the Governing Board members as an attachment for the aforesaid agenda item. During discussion, no objections were raised and the recommendations agreed upon. NBTC stance on Unbanked directed Blood Transfusion is in agreement to the recommendations of NTSCCC.

Agenda Item No. 3.9: Proceedings of the VBD Consultation and way forward for 100% VBD by 2020

National Stakeholder Consultation towards 100% Voluntary Blood Donation by 2020 Workshop was held on 28th January 2016 in Tamarind Hall, India Habitat Center, New Delhi under the Chairpersonship of Shri. N. S. Kang, AS & DG, NACO and proceedings shared with members of Governing Body of NBTC for their information.

The further initiatives taken by NBTC to support Voluntary Blood Donation and creating blood access were also appraised.

- An amendment has been issued to the Drugs and Cosmetics Rules dated 3rd April 2017 indicating that private hospital associated blood banks can conduct blood donation camps, there is no captive consumption clause for set

up of blood storage centres and bulk transfer of blood between blood banks is permitted.

- A proposal has been sent to DoPT to extend the provision of Special Casual Leave for Voluntary Blood Donation to apheresis and enhance the provision to 6 times a year.
- A National Consultative Workshop for development of Communication Strategy for IEC in BTS and material development for 100% VBD by 2020 was held in Vishakhapatnam on 8th and 9th May 2017. It is proposed to develop the requisite materials and launch them on 1st October 2017 on the occasion of National Voluntary Blood Donation Day through a National event.

Agenda Item No. 3.10: Proceedings of review meeting of SBTC and way forward

Review meeting of all State SBTC Directors and SACS representatives was held on 29th of Jan 2016 at India Habitat Center, Delhi under the Chairpersonship of Sh. N.S. Kang, Additional Secretary, NACO & President (NBTC). The meeting was presided over by Prof. Dr.Jagdish Prasad, Director General Health Services, GOI. Proceedings were shared with the members of Governing Body along with a copy of the Compendium of NBTC policy and guidelines disseminated during the meeting for reference and information.

Agenda Item No. 3.11: Approval on Policy and Guidelines for Referral linkages of TTI reactive Blood Donors

National Blood Policy 2002 states that result seeking blood donors shall be referred to a blood testing centre for post donation information and counselling. Action Plan on Blood Safety 2003 describes the process of revealing the status of Transfusion Transmitted Infection status of blood donors.

The policy and guidelines for referral linkages of TTI reactive blood donors were deliberated in a Technical Expert Group meeting held on 5th January 2016 at NACO under Chairpersonship of Dr Neelam Marwaha, HOD Transfusion Medicine, PGIMER Chandigarh. Proceedings of this meeting were shared with the members of NBTC and it was agreed upon that it is desirable to operationalize and strengthen the donor referral linkages for all donors who test sero-reactive for HIV, HBV, HCV, Malaria and Syphilis and that such donors are to be recalled and referred to appropriate facility for confirmation and management.

The guidelines for the same are detailed at **Annexure 3** and summarized below:

1. It is not the primary duty of the Blood Bank or Blood Transfusion Services to confirm the diagnosis of any of the TTI screened for.

2. All initial reactive blood units must continue to be discarded as per protocol.
3. Consent of the Blood Donor is to be obtained for performing the screening tests and to be informed of the results thereof at the time of blood donation.
4. Blood Bank must 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.
5. All initial sero-reactive donors must be recalled, offered post donation counselling and referred to appropriate facility for further counselling, confirmation and management.
6. A standard referral format for the same must be used and Blood Bank must maintain all records of recall and referral.
7. Signatures of the blood donor must also 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.

Matter had already been seen and approved by President NBTC on 5th August 2016, but as per directions of present President NBTC, the guidelines were shared on mail with all the members and no comments were received till 15th June 2017, hence considered approved for circulation to all States and Blood Banks for compliance.

Agenda Item No. 3.12.: NBTC stance on mandatory use of IV generation testing technology for all licensed blood banks

Members of Governing Body went through the minutes of meeting of Technical Resource Group for ICTC held at NACO on 22nd and 23rd December 2015 and Technical Expert Group for Blood Transfusion Services held under chairpersonship of Dr Neelam Marwaha, HOD Transfusion Medicine, PGIMER, Chandigarh on 5th January 2016.

There was a recommendation for use of IV generation assay (Ag/Ab) for screening for HIV in blood banks as it offers a distinct advantage of sero-conversion sensitivity.

National Transfusion Services Core Coordination Committee in its meeting held on 29th September 2016 had also reiterated the stance and recommended for the use of IV Generation ELISA tests for screening blood units at all licensed Blood Banks for HIV, HBV and HCV.

There were discussions and deliberations over the relative merits and advantages with enhancing the technology for screening for TTI at blood banks beyond the mandatory third generation ELISA/Rapid. While it was agreed that NAT and IV generation ELISA offer distinct advantage of reduction of window period vis-à-vis third generation ELISA, but it was not considered appropriate that they be made mandatory at first instance.

The consensus was arrived at

1. NBTC would encourage for the use of IV generation ELISA and NAT to enhance the window of safety of blood for transfusion.
2. NAT would however continue to remain an add on test in addition to performance of ELISA.
3. ICTC would not give out a negative result for HIV with one negative test for initial sero-reactive donors referred from blood banks, but would report it as inconclusive and repeat the test after two weeks to look for sero-conversion.
4. All donors receiving a HIV positive report from the ICTC must be counseled to permanently defer themselves from donating blood or organs.

Agenda Item No. 3.13: NBTC stance on Isolated Plasmapheresis

Permission for Isolated Plasmapheresis for 'Source Plasma' was requested by Plasma Fractionators to fulfil the domestic need for Plasma Derived Medicines and had been deliberated extensively in a multi-stakeholder National Consultation Meeting held under chairpersonship of DGHS on 18th July 2016.

Members of Governing Body after going through the proceedings of this meeting agreed to the following stance, which had also been reiterated in the third meeting of National Transfusion Services Core Coordination Committee held on 29th September 2016.

1. Recovered plasma would continue to remain the main source of raw material for plasma fractionation.
2. While Plasmapheresis is required in our country, it should not be encouraged as 'Standalone plasma collection centers' but 'in collaboration with blood banks with blood component separation units or apheresis'. Piloting could be done with Govt or Pvt Sectors in this regard.
3. Blood donation is a voluntary activity. Plasma donation shall be promoted only through non-remunerated voluntary blood donors. No modality for financial compensation/ recognition beyond what is acceptable by the NBTC in form of badges/ tokens etc shall be admissible.

Agenda Item No. 3.14: NBTC stance on BTS TRG recommendations

It was informed to the Governing Body that all activities being undertaken by NBTC were guided by recommendations of various technical experts and Technical Resource Group for BTS. These activities include conduction of baseline assessment of blood banks of India, roll out of capacity building trainings for blood donor counseling and strengthening Quality Management Systems through a standardized curriculum, assessment of PT providers and plan to roll out of EQAS, study of estimation of blood requirement in India.

Proceedings of BTS TRG meeting held on 19th January 2017 were shared with the members of Governing Body of NBTC wherein the donor selection criteria for the country have been reviewed and standardized for adoption by all the licensed blood banks of the country.

These criteria detailed at **Annexure 4** were approved by the Governing Body. A standard guideline document for Donor selection and Donor Referral prepared by NBTC should be referenced in the Drugs and Cosmetics Act and Rules for compliance by all blood banks.

Agenda Item No. 3.14: Matters for discussion and deliberation

1. Previously approved processing charges for Blood and Blood Components to remain valid for one year (till 31st May 2018), during which time, NBTC would work on revision.
2. NBTC would recommend to the MoHFW for creation of teaching/ non teaching positions for Specialists in Transfusion Medicine through an amendment in CHS Rules.
3. President accorded approval to create a list of NBTC empanelled experts in accordance to set selection criteria for use by the officials of the State FDA which conducting inspections of blood bank license renewals/ issuance. Criteria for selection would also be shared with DCG(I) for use in case of non-availability of NBTC empanelled experts.
4. NBTC requested MCI to remove the anomaly of having differing nomenclature for MD courses having the same curriculum (MD Transfusion Medicine, MD IHBT, MD IHTM). It also requested them to consider the teaching experience of Pathologists valid for starting a PG course in Transfusion Medicine.
5. Armed Forces Medical Services would submit a consolidated monthly report to NBTC for all the blood banks via hard copy, since they do not report on SIMS. They were agreeable to bulk transfer of blood and components with civilian blood banks.
6. IMA was requested to convene a meeting to discuss the course of action for partnership with NBTC for incorporation of informed consent for blood/ component transfusion, improving rational and appropriate clinical use of

- blood and blood components, voluntary blood donation and counseling of blood donors and other areas for cooperation.
7. President directed NBTC to work towards a holistic five year Strategic framework for Blood Transfusion Services.

Agenda Item No. 4: Any other matter with the permission of chair

1. President NBTC directed CDSCO to immediately review the status of pendency in the licensing of blood banks across the country and submit a report within a period of 10 days. He also directed that a central dashboard be created for blood banks on the Sugam/ e Rakt Kosh platform to be accessed by policy makers and regulators for reviewing licence status and monitoring of blood banks. He also asked CDSCO to create a platform through integration of Sugam online with e Rakt Kosh/ other initiatives of CDC QMBB Project and make online reporting mandatory by all licensed blood banks.
2. The relative merits and demerits of a "Hub & Spoke" approach for BTS versus a decentralized blood collection, processing and distributions were deliberated and it was decided to take up the matter with a small group of experts including State representatives to review existing models globally and come up with a realistic approach for the country.
3. The minimum standards prescribed for Blood Banks and Blood Transfusion Services prescribed under the Drugs and Cosmetics Rules must be reviewed and their compliance facilitated and monitored across all Blood Banks to improve quality. Emphasis on and support for accreditation may be however considered for select blood banks.
4. It was pointed out that there were long standing amendments already recommended by NBTC to CDSCO to be made in the Drugs and Cosmetics Rules. Concern was however expressed regarding the long drawn process for the same. NBTC should facilitate summarizing the key bottlenecks required immediately for taking up by CDSCO.
5. NHM was directed to work on creation of a functional network of Blood Storage Units to ensure access to safe blood especially in remote, difficult terrains and along highways. The existing BSU may be mapped out and gaps identified.
6. President NBTC requested for the present status of refreshment money for blood donors through NACO and State Governments be put up to him.

The meeting ended with a vote of thanks.

Action Plan for National Blood Transfusion Council
(2017-18 and 2018-19)

1. Development of Guidelines and Standards:

NACO/NBTC envisions developing and printing the following Guidelines and Standards for Blood Transfusion Services:

- 1.1 National Standards**
- 1.2 Technical & Operational Guidelines**
- 1.3 Communication Strategy for VBD**
- 1.4 Development of National Strategic Framework**
- 1.5 Review and revision of Transfusion Medicine Technical Manual, DGHS, 2nd Edition 2003**

Technical and financial assistance would also be sought from WHO, CDC, Professional Associations for BTS like ISTM, ISBTI, AATM etc for this activity.

*This would be a one-time activity and the Total financial implication for the year 2017-18 and 2018-19 for conduction of expert working group meetings will be around **Rs. 121.00 lakhs***

2. Training Programmes in BTS:

2.1 Strengthening Quality Management Systems in BB-Training of designated 01 Quality Manager and 01 Technical Manager posted in Blood Banks in designated Regional Training Centres (80 batches, Rs.601.6 lakhs)

2.2 Counselling Blood Donors- Training of Counsellors posted in Blood Banks for Counselling Blood Donors at Designated Regional Training Centres (40 batches, Rs. 205.20 lakhs)

Funds would be positioned directly with the training centres for this activity.

*Total financial implication during the year 2017-18 and 2018-19 for conducting Training Programmes in BTS will be around **Rs. 806.80lakhs.***

3. E-Initiatives:

3.1 NBTC Website: Development and maintenance of NBTC Website (Rs.5.00 lakhs)

3.2 Blood Helpline: National Toll Free Blood Helpline for queries related to Blood Banks location and availability of Blood/Blood Components. (Rs. 60.00 lakhs)

Total financial implication for E-initiatives during the year 2017-18 and 2018-19 for will be around **Rs. 65.00 lakhs**

4. External Quality Assurance Programme (EQAP) for Blood Banks:

4.1: Grant-in-aid towards annual subscription charges: @ Rs 4000 per blood bank for enrollment of NACO supported blood banks of the Country in the External Quality Assessment Scheme for Blood Banks in a phased manner. In the year 2017-18, 470 NACO supported Blood Banks to be enrolled in the programme and in the year 2018-19 around 500 NACO supported Blood Banks to be enrolled in the programme.

Total financial implication during the year 2017-18 and 2018-19 for (EQAP) for Blood Banks: will be around **Rs. 38.80 lakhs.**

5. VBD Awareness Activities:

5.1 Observance of Blood Donation Days: Event management/ advertisement/ printing and replication of IEC material, National level activities for 14th June and 1st October each year will be conducted under the aegis of NBTC.

Support would also be extended for this occasion to the various NGOs and organizations involved in promotion of voluntary blood donation to carry out contests, competitions, development of IEC material and felicitation of blood donors, NGOs, government agencies and others supporting the cause of voluntary blood donation. (Rs.200.00 lakhs)

5.2 Round the year Awareness Programme: Awareness programme round the year through multimedia campaigning and nationwide blood drives. Regular spots on radio and TV may be developed which address the youth to volunteer themselves as voluntary blood donors. Programmes should highlight all positive aspect of voluntary blood donation and blood transfusion. These spots may be broadcast/telecast in Hindi as well as regional languages. Social media would also be leveraged (Rs. 200.00 lakhs)

5.3: Development of Standardized Communication Strategy and materials for VBD: National level workshops would be organized to generate a healthy brainstorm among

all stakeholders for VBD and help come up with a communication strategy and standardized prototypes and content for use across States and facilities. Limited quantities of the prototypes would be replicated at National level for dissemination. Thereafter, standardized prototypes would be shared with all the States for replication using their resources. This activity would be conducted with the support from CDC-CMAI QMBB project and outputs disseminated on 1st October 2017 on the occasion of NVBDD. (Rs.120 lakhs)

Total financial implication for VBD Awareness Activities during the year 2017-18 and 2018-19 for will be around **Rs. 520.00 lakhs.**

6. Meetings/ Workshops: It is proposed to organize the following Meetings/ Workshops through NBTC support:

6.1:SBTC Review Meetings: Organizing SBTC Review meeting once every year (Preferably in April)

6.2: NBTC GB Meeting:Organizing Governing Body meeting of NBTC twice every year (preferably in June/ December)

6.3: Regional Training Centres Review Meeting:Organizing Review Meeting for regional training Centres once every year (preferably in February)

6.4: PT Providers Review Meeting:Organizing Review Meeting with PT Providers once every year (after completion of 01 PT cycle)

6.5: Other Meetings:Organizing Meetings of National Core Coordination Committee, Executive Committee, Technical Resource Group, Technical Expert Group, Working Group and any other Meeting.

6.6: Workshops/ Conferences: Organizing/ Supporting/ Attending International/ National Workshops/ Conferences for Strengthening BTS in the CountryOrganizing/ Supporting International/ National Workshops/ Conferences for Strengthening BTS in the Country.

Total financial implication during the year 2017-18 and 2018-19 for conducting Meetings/ Conferences for BTS will be around **Rs. 142.00 lakhs.**

7. Human Resource:

7.1: Remuneration and TA/DA of NBTC officials:

Remuneration towards Salary and TA/ DA of officials posted in NBTC will be paid through NBTC fund.

Existing regular positions and additional contractual positions would be created/ filled to make the NBTC functional and independent.

A fund of **Rs 200.00 Lakhs** will be needed to support staff in NBTC for year 2017-18 and 2018-19.



8. Contingency:

A contingency grant of **Rs. 100.00 lakhs** is to be retained by NBTC to be used as buffer to carry out other expenditure for Legal work, Stationery, IT support and Miscellaneous Activities in the year 2017-18 and 2018-19.

A total budget of Rs. 1993.60 lakhs will be required by NBTC during the year 2017-18 and 2018-19 to carry out the above-mentioned activities as detailed below.

| NATIONAL BLOOD TRANSFUSION COUNCIL AAP 2017-18/ 18-19 | | | | | | | | |
|---|--|-----------|--------------------------|---|----------------------------|-----------|-------|--------------------|
| S.No. | Sub-Component | Cost Head | Unit Cost (Rs. In Lakhs) | Items/ Activities | Targets | | | Allocation |
| | | | | | 2017-2018 | 2018-2019 | Total | DBS (Rs. In Lakhs) |
| 1 | Development of Guidelines/ Standards | One-time | | | | | | |
| 1.1 | National Standards | One-time | | Development & Printing of National Standards for Blood Banks and Blood Transfusion Services | | | | 50.00 |
| 1.2 | Technical & Operational Guidelines | One-time | | Development & Printing of technical & Operational Guidelines for BTS | | | | 50.00 |
| 1.3 | Communication Strategy for VBD | One-time | | Development of Standardized IEC material for promotion of VBD | | | | 1.00 |
| 1.4 | Strategic Framework | One-time | | Development & Printing of National Strategy Document (Vision Document) for BTS | | | | 20.00 |
| 2 | Training programmes in BTS | | per Trng Prgm | | No. of training programmes | | | |
| 2.1 | Strengthening Quality Management Systems in BB | Recurring | 7.52 | Training of 01 Quality Manager and 01 Technical Manager | 30 | 50 | 80 | 601.60 |

| | | | | | | | | |
|----------|--|------------------|----------------------------|--|---------------------------|-----|-----|--------|
| 2.2 | Counselling Blood Donors | Recurring | 5.13 | Training of 01 BB Counsellor | 20 | 20 | 40 | 205.20 |
| 3 | E-Initiatives | | | | | | | |
| 3.1 | NBTC Website | | | Website development and maintenance | | | | 5.00 |
| 3.2 | Blood Helpline | | | National Toll Free Blood Helpline for queries related to Blood Banks location and availability of Blood/Blood Components | | | | 60.00 |
| 4 | External Quality Assurance Programme (EQAP) for Blood Banks | Recurring | Annual subscription | | No. of blood banks | | | |
| 4.1 | Enrolment in EQAP | | 0.04 | Subscription Cost for enrolling Blood Banks for EQA programme | 470 | 500 | 970 | 38.80 |
| 5 | VBD Awareness Activities | Recurring | Per event | | No. of events | | | |
| 5.1 | Observance of Blood Donation Days | Recurring | 50 | Event management/ Advertisement/ Printing and replication of IEC material/ National level activities for 14th June and 1st October | 2 | 2 | 4 | 200.00 |
| 5.2 | Round the year Awareness Programme | Recurring | 100 | Multimedia campaign | 1 | 1 | 2 | 200.00 |
| 5.3 | Printing of NBTC Standardized IEC material | Recurring | | Printing & replication of IEC material for promotion of Voluntary blood donation as per approved Strategy for Communications | | | | 120.00 |
| 6 | Meetings/ Workshops | Recurring | for each meeting | | No. of Meetings | | | |

| | | | | | | | | |
|----------|--|------------------|---|---|------------------|-----|-----|----------------|
| 6.1 | SBTC Review Meetings | Recurring | 5 | Organizing SBTC Review meetings once a year (April) | 1 | 1 | 2 | 10.00 |
| 6.2 | NBTC GB Meeting | Recurring | 3 | Organizing NBTC Governing Body meeting twice every year (June/ December)) | 2 | 2 | 4 | 12.00 |
| 6.3 | Regional Training Centres Review Meeting | Recurring | 5 | Organizing RTC Review Meeting once a year (February) | 1 | 1 | 2 | 10.00 |
| 6.4 | PT Providers Review Meeting | Recurring | 5 | Organizing Review Meeting for PT Providers once a year (after completion of 01 PT cycle) | 1 | 1 | 2 | 10.00 |
| 6.5 | Other Meetings | Recurring | | National Core Coordination Committee, Executive Committee, Technical Resource Group, Technical Expert Group, Working Group, any other Meeting | | | | 50.00 |
| 6.6 | Workshops/ Conferences | Recurring | | Organizing/ Supporting International/ National Workshops/ Conferences for Strengthening BTS in the Country | | | | 50.00 |
| 7 | Human Resource | | | | | | | |
| 7.1 | Salary | Recurring | | Salary, TA/DA for BTS Officials in NBTC | 100 | 100 | 200 | 200.00 |
| 8 | Contingency | Recurring | | | | | | |
| | | | | Fund for Legal work, Stationery, IT support, Miscellaneous expenditures | 50 | 50 | 100 | 100.00 |
| | NBTC (Total Allocation) | | | | 20 crores | | | 1993.60 |

Annexure 2**Roles and Responsibilities of NACO/ NBTC/ NHM**

- Blood Cell (NHM) and BTS Division NACO have distinct roles, but both will work in close coordination with NBTC and overall broad umbrella of NBTC
- Periodic review meetings would be conducted under the chairpersonship of President NBTC (Additional Secretary NACO) to review the progress of all agencies and ensure coordination with all stakeholders including DCG(I) and DGHS

| | NACO | | NHM |
|-------------------------|--|---|---|
| | NBTC | BTS Division | Blood Cell |
| Mandate | <p>Policy and Technical matters Guideline formulation and ensure updatation of standards for BTS and periodic amendments in law/ rules to support the regulation thereof. Coordination mechanism through National/ State Transfusion Core Coordination Committees with DCG(I) and DGHS</p> <p>Overall Guidance to Programmatic Strategy, implementation and Monitoring</p> | <p>Blood Programme under NACP (Safety, Quality)</p> | <p>Blood Programme under NHM (Adequacy, Availability, Access)</p> |
| Purview | <p>All licensed BB in coordination with DCG(I) through SBTC (grant of NOC for Blood Bank license, VBD Camp permission, Grant of RBTC status, Processing Charges etc)</p> | <p>NACO supported Blood Banks in Government and Charitable Sectors through SACS</p> | <p>Blood Banks and Blood Storage Centres (BSC) in Government Sector through State NHM</p> |
| Responsibility | | | |
| Metro Blood Banks | | <p>Establishing Centre of Excellence in Delhi, Mumbai, Kolkata, Chennai and providing funds for the activity, taking approvals, procurement, recruitment etc.</p> | - |
| Plasma Fractionation | | <p>Setting up Plasma Fractionation Centre on PPP modality Providing funds for the activity, taking approvals,</p> | - |

| | | | |
|---|--|---|--|
| | | procurement, recruitment | |
| Monitoring | | Monthly reporting in SIMS | |
| E-initiatives | NBTC website, NHP and centralized helpline | | e-Raktkosh and State level helplines |
| Capacity Building | Training for BB Staff (on BB procedure, QMS, Counselling Blood Donors and others) and Certification thereof | - | Training for BSC Staff |
| QMS and EQAS | Enrolling BB for EQAS, implementation and monitoring | - | - |
| Infrastructure Development | | Metro Blood Banks, PFC, Up gradation of existing tertiary care BCSU to CoE and enhancement of component separation subject to fund allocation | Setting up Blood Banks in district without BB and Blood Storage Centres in Govt. Sector |
| Procurement of BB/ BSC Equipments and their Maintenance | - | Providing equipments to BCSU subject to availability of funds | Providing equipments and AMC/ CMC of the same to BB and BSC |
| Commodity/ Consumables Support | - | Provide Commodity support (75% of the requirement) to NACO supported BB (Blood Bags & Testing Kits) through National procurement | Provide Commodity and Consumables (100% of requirement) to BB & BSC (Reagents, Glass wares, etc) |
| Technical Guidelines/ Specifications for Equipments and Commodities | Defining Standard Technical Specifications for Equipments and commodities to be used in BB/BSC in coordination with DGHS | - | - |
| Promoting VBD Activities | | Fund support to SBTC to conduct VBD Camps, provide donor refreshment, Observe National Voluntary Days and other activities | Funding support for Donor recruitment, retention and motivation |
| Purchase and maintenance of Blood Donation | - | POL, Maintenance of existing Blood Mobile Bus | POL, Maintenance, Recurring expenditure of Blood Collection and Blood |

| | | | |
|--------------------------------------|---|--|--|
| Vehicles | | | transportation vehicles and further procurement and maintenance |
| Human Resource | | Providing Salary to SBTC staff, lab-Technicians, Counsellors, Data Manager, Lab Attendant, Drivers, Bus Attendant, Van Attendant positioned in NACO supported BB/ Blood Mobile Bus/ BTV as per current PoA | Salary to Staff of Blood Cell at National And State level, and manpower positioned in BB through NHM |
| Communication and IEC | Developing Standardized IEC material to augment VBD across the Country to reach the target of 100% by 2020 Observance of National level events | | Printing and distribution of Standardized IEC material developed by NBTC across all BB/BSC to the lowest level of health care delivery through States |
| Blood Disorders & Stem Cell Registry | - | - | All matters related to Blood disorders (Thalassemia, Haemophilia, Sickle-cell anemia and any other blood disorder) and Stem Cell Registry in coordination with Non communicable Diseases programme & NOTTO |
| Research & Development | Assessment of Blood Banks of India, Estimation of Blood requirement, demand and supply , other Operations Research | Providing funds for R&D related to BTS in coordination with Donor partners like WHO, CDC | - |
| Coordination/ Review of Activities | Coordinate with DCGI, DGHS, MCI, AFMS, Other Ministries etc on all matters related to BTS | With States as per Pre-defined areas | With States as per Pre-defined areas |
| Miscellaneous | - | PQ, Grievances, RTI, VIP Reference, Court Cases, Media matters, NHSRC Matters | - |

Recall and Referral Mechanism for 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 sero-reactive result of transfusion transmitted infection (TTI).
- Donors should be provided post-donation counselling prior to referring those 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.

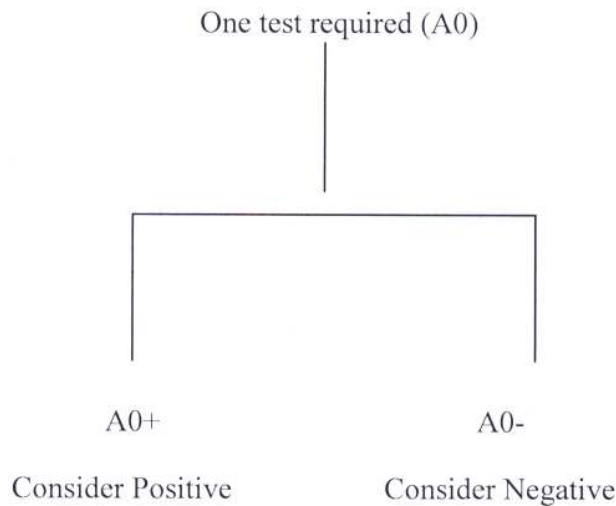
Duties of a Blood Bank:

- It is not the primary duty of the Blood Bank or Blood Transfusion Services to confirm the diagnosis of any of the TTI screened for.
- 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.
- 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.
- 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 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.



Referral Mechanism of HIV Sero-reactive Blood Donors to ICTC:

- 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 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 in annexure 2 and send it along with referred donor.
4. Confidentiality shall be maintained at all levels.

Algorithm for Blood Donors referred to ICTC

- Donor shall be offered HIV pre-test counselling at the ICTC and consent taken to perform the HIV test.
- ICTC shall perform first test. 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.
- 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.

Referral Mechanism of other TTI Sero-reactive Blood Donors to clinicians:

- 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.
 - 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.
1. 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.
 2. Blood bank shall fill out the referral form as per standard format in annexure 2 and send it along with referred donor.
 3. Confidentiality shall be maintained at all levels.

Algorithm for Blood Donors referred to Clinicians

- 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.



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.): _____

| | |
|--|------|
| | Sex: |
| | Age: |

Address (Office) _____

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

E-Mail _____

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 Blood Pressure | • 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 | Yes | No |
| Measles | Yes | No |
| Mumps | Yes | No |
| Chicken Pox | Yes | No |
| Dengue | 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 one 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 diarrhea | Yes | No |

12. In case you are a woman:

a. Are you pregnant or have you had an abortion in the last 6 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: $\geq 12.5\text{g/dl}$ <math><12.5\text{g/dl}</math> | | |
| History Check list | Feeling well / Adequate sleep (>5hrs) / Last meal within 4 hrs Ever hospitalized Current illnesses or medications: | |
| Examination Check List | Unhealthy look / pallor / icterus / alcohol smell Infected wounds / Venopuncture site lesions Pulse:.....beats/min BP:..... mmHg Heart:..... Lungs:..... | |
| Counseling 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: | | |

REFERRAL SLIP FOR BLOOD DONORS

(To be filled by Blood Bank Staff)

Name and address of the Referring Blood Bank: -

Date of ReferralBlood Bank ID No.

Name of Donor.....

Age Gender Phone NumberContact 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 <input type="checkbox"/> | | |
| Testing of HBsAg <input type="checkbox"/> | | |
| Testing of HCV <input type="checkbox"/> | | |
| Testing of VDRL/RPR <input type="checkbox"/> | | |
| Testing of Malaria <input type="checkbox"/> | | |

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-----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 4

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 shallnot be accepted before 28 days. Apheresis platelet donor shallnot 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 |
| 40. | Convulsions and Epilepsy | Permanently defer |
| 41. | Schizophrenia | Permanently defer |
| 42. | 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> | | |
| 43. | 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 |
| 44. | 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 |
| 45. | Other endocrine disorders | Permanently defer |
| <u>Liver Diseases and Hepatitis infection</u> | | |
| 46. | Hepatitis | Known Hepatitis B, C- Permanently defer Unknown Hepatitis- Permanently defer Known hepatitis A or E; Defer for 12 months |
| 47. | Spouse/ partner/ close contact of individual suffering with hepatitis, | Defer for 12 months |

| | | |
|---|--|---|
| 48. | 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 |
| 49. | Spouse/ partner of individual receiving transfusion of blood/ components | Defer for 12 months |
| 50. | Jaundice | Accept donor with history of jaundice that was attributed to gall stones, Rh disease, mononucleosis or in neonatal period. |
| 51. | Chronic Liver disease/ Liver Failure | Permanently defer |
| <u>HIV Infection/AIDS</u> | | |
| 52. | 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 |
| 53. | Known HIV positive person or spouse/ partner of PLHA (person living with HIV AIDS) | Permanently defer |
| 54. | 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> | | |
| 55 | Syphilis (Genital sore, or generalized skin rashes) | Permanently defer |
| 56. | Gonorrhoea | Permanently defer |
| <u>Other Infectious diseases</u> | | |
| 57. | History of Measles , Mumps, Chickenpox | Defer for 2 weeks following full recovery |
| 58. | Malaria | Defer for 3 months following full recovery. |
| 59. | Typhoid | Defer for 12 Months following full recovery |
| 60. | 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. |
| 61. | 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. |
| 62. | Tuberculosis | Defer for 2 years following confirmation of cure |

| | | |
|---|---|--|
| 63. | Leishmaniasis | Permanently defer |
| 64. | Leprosy | Permanently defer |
| <u>Other infections</u> | | |
| 65. | Conjunctivitis | Defer for the period of illness and continuation of local medication. |
| 66. | Osteomyelitis | Defer for 2 years following completion of treatment and cure. |
| <u>Kidney Disease</u> | | |
| 67. | Acute infection of kidney (pyelonephritis) | Defer for 6 months after complete recovery and last dose of medication |
| 68. | Acute infection of bladder (cystitis) / UTI | Defer for 2 weeks after complete recovery and last dose of medication |
| 69. | Chronic infection of kidney/ kidney disease/ renal failure | Permanently defer |
| <u>Digestive System</u> | | |
| 70. | 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 |
| 71. | GI endoscopy | Defer for 12 months. |
| 72. | 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: |
| <u>Other diseases/ disorders</u> | | |
| 73. | Autoimmune disorders like Systemic lupus erythematosus, scleroderma, dermatomyositis, ankylosing spondylitis or severe rheumatoid arthritis | Permanently defer |
| 74. | Polycythaemia Vera | Permanently defer |
| 75. | Bleeding disorders and unexplained bleeding tendency | Permanently defer |
| 76. | Malignancy | Permanently defer |
| 77. | Severe allergic disorders | Permanently defer |
| 78. | Haemoglobinopathies and red cell enzyme deficiencies with known history of haemolysis | Permanently defer |

Vaccination and inoculation

| | | |
|-----|---|-------------------|
| 79. | Non live vaccines and Toxoid: Typhoid, Cholera, Papillomavirus, Influenza, Meningococcal, Pertussis, Pneumococcal, Polio injectable, Diphtheria, Tetanus, Plague | Defer for 14 days |
| 80. | Live attenuated vaccines: Polio oral, Measles (rubella) Mumps, Yellow fever, Japanese encephalitis, influenza, Typhoid, Cholera, Hepatitis A | Defer for 28 days |
| 81. | Anti-tetanus serum, anti-venom serum, anti-diphtheria serum, and anti-gas gangrene serum | Defer for 28 days |
| 82. | Anti-rabies vaccination following animal bite, Hepatitis B Immunoglobulin, Immunoglobulins | Defer for 1 year |

Medications taken by prospective blood donor

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| 83. | Oral contraceptive | Accept |
| 84. | Analgesics | Accept |
| 85. | Vitamins | Accept |
| 86. | Mild sedative and tranquillizers | Accept |
| 87. | Allopurinol | Accept |
| 88. | Cholesterol lowering medication | Accept |
| 89. | Salicylates (aspirin), other NSAIDs | Defer for 3 days if blood is to be used for Platelet preparation |
| 90. | Ketoconazole, Anthelmintic drugs including mebendazole, | Defer for 7 days after last dose if donor is well |
| 91. | Antibiotics | Defer for 2 Weeks after last dose if donor is well |
| 92. | Ticlopidine, clopidogrel | Defer for 2 Weeks after last dose |
| 93. | Piroxicam, dipyridamole | Defer for 2 Weeks after last dose |
| 94. | Etretinate, Acitretin or Isotretinoin. (Used for acne) | Defer for 1 month after the last dose |
| 95. | Finasteride used to treat benign prostatic hyperplasia | Defer for 1 month after the last dose |
| 96. | Radioactive contrast material | 8 weeks deferral |
| 97. | Dutasteride used to treat benign prostatic hyperplasia | Defer for 6 months after the last dose |
| 98. | Any medication of unknown nature | Defer till details are available |
| 99. | Oral anti-diabetic drugs | Accept if there is no alteration in dose within last 4 weeks. |
| 100. | Insulin | Permanently defer |

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| 101. | Anti-arrhythmic, Anti-convulsions, Anticoagulant, Anti-thyroid drugs, Cytotoxic drugs, Cardiac Failure Drugs(Digitalis) | Permanently defer |
| Other conditions requiring Permanent deferral | | |
| 102. | 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 |

