

S12016/08/2015-NACO (NBTC)
Govt of India
Ministry of Health & Family Welfare
Department of AIDS Control
National AIDS Control Organization
National Blood Transfusion Council

9th Floor, Chandralok Building,
36 Janpath, New Delhi - 110001
Dated: 03.09.2015

Office Memorandum

Sub: 25th Meeting of Governing Body of National Blood Transfusion Council held on 05.08.2015-Minutes- reg

The undersigned is directed to forward a copy of the minutes of the meeting of the Governing Body of National Blood Transfusion Council held on 5th August 2015 for information and necessary action.



(V.K Govil)
Assistant Director (NBTC)

To,

1. All Members of Governing Council
2. PPS to AS & President (NBTC)

Minutes of the 25th Governing Body Meeting of National Blood Transfusion Council (NBTC)

The 25th Meeting of Governing Body of the National Blood Transfusion Council was held on 5th August 2015 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. Sh.N. S. Kang, Additional Secretary, National AIDS Control Organization & President, National Blood Transfusion Council New Delhi – in Chair
2. Ms.Vijaya Srivastava, Additional Secretary & Financial Advisor, Ministry of Health and Family Welfare, Nirman Bhawan, Delhi
3. Dr.Sudhir Gupta, Addl. Deputy Director General, Directorate General of Health Services, Nirman Bhawan, Delhi
4. Dr.Neelam Marwah, HOD, Department of Transfusion Medicine, PGIMER, Chandigarh
5. Dr.Sunil Rajadhyaksha, HOD, Transfusion Medicine, Tata Memorial Hospital, Mumbai
6. Dr.R. K. Chaudhary HOD, Deptt. of Transfusion Medicine, SGPGIMS, Lucknow
7. Dr.R. N. Makroo, Director Deptt. of Transfusion Medicine, Apollo Hospital, Delhi
8. Dr.Bharat Singh, Director, State Blood Transfusion Council, Delhi
9. Dr.Viral Kamdar, Director, Deen Dayal Institute of Medical Sciences, Nagpur
10. Dr K K Agarwal, Senior Vice President IMA, representing President IMA
11. Dr.V. G. Somani. Joint Drug Controller, representating DCG(I), Delhi
12. Dr.Vanshree Singh, Director, Blood Bank, Indian Red Cross Society, Delhi, representing Secretary General Indian Red Cross Society
13. Col.Satish Kumar, Head of Armed Forces Transfusion Centre, New Delhi representing DG Armed Forces Medical Services
14. Dr.Shobini Rajan, ADG (Blood Safety), NACO, Delhi
15. Dr. R.S. Gupta, DDG (Blood Safety) NACO, Delhi & Director and Member Secretary NBTC

Attendees from Blood Transfusion Services Division, NACO, CMC Vellore and CDSCO included

1. Dr. Harprit Singh, NPO ((Blood Safety) NACO, New Delhi
2. Dr. Sanjay Kumar Jadhav, National Advisor, BTS, NACO, Delhi

3. Sh. V.K. Govil, Asst. Director, NBTC & Section Officer (BS), NACO Delhi
4. Dr. Aarti Garg, Asst. Director, BTS, NACO Delhi
5. Dr. Shanoo Mishra, PO (QC), NBTC, Delhi
6. Sh. Joy Mammen, Deptt. of Transfusion Medicine, CMC, Vellore
7. Sh. Navreet Pratap Singh, Asstt. Drug Controller, CDSCO, Delhi

The following Ex-officio (representative) Member could not attend the Meeting or depute any representative for the same:

1. Dr. Jayashreeben Mehta, President, Medical Council of India, New 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 and remarked that though this meeting has been convened after a gap of more than one year, future meetings of the NBTC would be held within the timeframe prescribed in the Memorandum of Association of the Council.

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

Agenda Item No. 1: Approval of minutes of the 24th meeting of the Governing Body of National Blood Transfusion Council held at New Delhi on 20th January 2014;

The minutes of the 24th Governing Body meeting of NBTC held on 20th January 2014 were approved by the Governing Body.

Agenda Item No. 2: Action Taken Report on proceedings of the 24th Governing Body of NBTC

The Action Taken Report on the minutes of the 24th meeting of the Governing Body of NBTC was noted 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 Exchange value and guidelines for sending plasma for fractionation;

The Governing Body considered the proposal in the light of recommendations of the meeting of the Expert Group held on 12.01.2015. In view of the prevailing situation, it was felt necessary to prescribe a value at which surplus plasma could be exchanged for various items such as blood bank consumables and plasma

derived products. It was felt that this would help to increase the availability of plasma products which was a dire need in the country. Plasma derived products were currently imported and the proposed move to allow surplus plasma to be used by indigenous fractionators would help to increase availability of these products. The need for the guidelines on the subject was however highlighted. After detailed discussions, on various aspects, the Governing Body approved the proposal with the following guidelines.

1. The fractionators must undertake to fulfill needs of Indian market first and none of products recovered from the Indian plasma should be exported before fulfilling domestic demand. It was decided to request the DCGI to draw up a mechanism to ensure compliance.
2. Uniform exchange value of Rs. 1600/- (Rs. sixteen hundred only) per liter of Plasma was agreed upon.
3. All blood banks must ensure taking of the informed consent of the blood donor for allowing the use of his blood for fractionation, and derivation of essential plasma derived medicines there from.
4. The modalities for use of exchange value would be finalized by the respective State Blood Transfusion Councils and would be primarily directed towards ensuring availability of plasma derived products to patients requiring them. These would include :
 - a) Buy back of plasma derived products of equivalent value for clinical use by needy patients accessing care at the institution where the blood bank exchanging the plasma is located.
 - b) Receipts of equipment or consumables for strengthening of blood banks capacity and improving component recovery, storage and utilization.
 - c) Any other modality approved by NBTC.
5. Blood Component Separation Units would directly enter into an agreement with the fractionators, as per mutually agreed terms and conditions approved by respective SBTC before sending plasma for fractionation.
6. Feedback would be provided by fractionators to NBTC/ respective SBTC in order to provide evidence of the quality of the plasma being fractionated, so as to enable corrective and preventive action.
7. NBTC would review the fractionators periodically so as to prevent any misuse of this strategy.
8. Implementation of this initiative would be reviewed periodically by NBTC.

9. Surplus plasma would be defined as plasma in excess of consumption capacity of the blood bank within a prospective three month period.

Agenda Item No. 3.2: Approval of Audit Report for 2013-14

The Audited accounts of the Society for 2013-14 were approved.

Agenda Item No.3.3: Approval of Selection of auditor for 2014-15 and 2015-16

It was informed by the President, NBTC that auditors to carry out the audit work of NBTC had been selected on file as follows,

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)

These appointments were ratified by the Governing Body.

Agenda Item No.3.4: Annual Action Plan for NBTC (2015-16 and 2016-17)

The activities proposed as part of the Annual Action Plan (2015-16 and 2016-17) were approved by the Governing Body. Though an amount of Rs. 8.00 Crore has been proposed to carry out the above activities, it was informed by President, NBTC said that the actual activities would be tailored to the availability of funds. Shri Viral Kamdar reiterated that NBTC must be strengthened and have an independent office, which was agreed to in principle.

Agenda Item No.3.5: Appraisal for way forward of Metro Blood Bank as Centre of Excellence Project

The matter was discussed and all members agreed that Metro Blood Bank Project would be an important milestone towards centralized and coordinated transfusion services in the country; and suggested that the work on the above project should be started at the earliest for the benefit of making blood available to the needy persons/patients of the country. It was decided that a detailed presentation would be given in the next meeting.

Agenda Item No. 3.6: Approval of Policy on Bulk Transfer of Blood

The proposal to allow bulk transfer of blood was accepted by the members as a welcome step towards ensuring increased availability of blood within the health system. It was noted that the Committee headed by the DGHS had considered the matter in detail in the meeting held on 26.05.15 and had given guidelines on his behalf.

Extensive discussions were held on the question of processing charges to be levied by the recipient blood bank, the responsibility for any adverse reactions and conditions of actual transportation of the blood and blood products.

Though there were various views in the matter, a consensus was finally reached that the system may be put into operation with the following guidelines without further delay and improvements could be incorporated subsequently.

1. Transfers shall be allowed between licensed blood banks in any sector (Public, NGO, Private).
2. Transfer of blood and components in bulk shall be permitted across State borders to also ensure the availability at the point of need.
3. All transfers shall be done at the recommended temperature and as per prescribed storage conditions for whole blood and components. The supplier blood bank shall be responsible for compliance thereof.
4. The recipient blood bank should have the capacity to hold the units requested for, at appropriate temperature till the time of utilization.
5. Broad based donor consent should be incorporated in the standard donor form to ensure that the donor agrees to his blood unit being utilized beyond the blood bank where it is donated.
6. The supplier blood bank can levy the prescribed processing charges on the patient/recipient/recipient blood bank as per NBTC norms. However, the recipient blood bank can levy only processing charging for compatibility testing (cross-matching), in addition to charges levied by the supplier blood bank, from the patient/recipient for such transferred units.
7. Only one transfer shall be allowed, and recipient blood bank cannot further transfer units obtained from another blood bank except to another blood storage centre or a patient/ recipient.
8. Records of traceability shall be retained throughout the process.
9. Supplier blood bank would be responsible for all the complications except for those related to compatibility testing, which will be the responsibility of the recipient blood bank. Recipient blood bank shall report and evaluate all the adverse transfusion reactions, including those happening due to blood that has been transferred from supplier blood bank.
10. Documents accompanying transfer shall include TTI testing report and record of transport in appropriate temperature.

11. Standard format for request and issue formats for bulk transfers shall be developed by NBTC for uniform record maintenance.
12. All recipient blood banks are considered deemed approved to act as functional storage centers for blood and blood components, even though the upper limit of 2000 units utilization per annum is not applicable.
13. All blood banks and storage units be instructed to issue blood to all patients needing transfusion and not restricting blood issue to captive requirements of institution to which they are attached.
14. Blood banks would be informing regarding bulk transfers to SBTC and in case of inter-state bulk transfers to NBTC.

Agenda Item No. 3.7: Approval on policy recommendations made in National Transfusion Services Core Coordination Meeting held on 26th May 2015

The minutes of the 2nd meeting of National Transfusion Services Core Coordination Committee held on 26.05.2015 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 members agreed upon to bring about clarity and uniformity in norms for set up of blood banks, grant of No Objection Certificate (NOC) by SBTC for new blood bank or renewal of blood bank licensure, grant of RBTC status to blood bank and grant of permission for conduction of voluntary blood donation camps by blood banks. It was noted that the Core Coordination Committee had considered the matter and the approved norms were adopted as detailed below:

A. Norms for set up of New Blood Banks

Every district should have atleast one blood bank, but clustering of blood banks in urban/ semi-urban areas should be avoided. New blood banks need to be set up based on geographic location and population demand only.

B. Norms for grant of 'No objection certificate' (NOC) by the SBTC

B1 For New Blood Bank License:

1. A registered voluntary or charitable organizations, which is registered in the territory of Union of India or Union Territory, as the case may be under any such law which is at the time of enforcement of this rule in force.
2. The aforesaid organization must be atleast two years old and should not be a family society or trust.

3. The objectives mentioned in the Memorandum of Association must include the activities related to health care delivery system or blood transfusion services.
4. The activities undertaken by the organization must showcase social accountability and be reflected in the annual Audited Statement of accounts of the last two year (i.e. before the submission of application).
5. The organization should submit undertaking to ensure annual blood collection more than 2000 units per year with nearing 100% contribution from Voluntary blood donor, preferably collected from outdoor blood donation camps.
6. The organization should submit undertaking to appoint Medical Social Worker (MSW) and Counselor with the blood bank for arranging Voluntary Blood Donation (VBD) camps and Pre and Post Test counseling respectively.
7. The organization should submit undertaking to establish blood component separation facility of its own or a storage facility for components within a period of two years from receiving license to operate blood bank.
8. The organization should submit undertaking to abide with the guidelines of SBTC/NBTC issued from time to time, including the guidelines for processing charges for blood and blood components.

Note:

- a. The Organization should submit undertaking on the letter head expressing willingness to abide with aforesaid conditions.
- b. The SBTC should process the application within thirty days from the date of its receipt in the office; failing which NOC shall be deemed granted to the organization.

B2 For Renewal of Blood Bank License:

1. The compliance to point no. 1-4 of norms at B1 (No objection certificate (NOC) for New Blood Bank License) shall be ensured.
2. The organization should submit photocopy of license and application two months before the expiry of validity period of license.
3. The organization should submit Annual blood collection report wherein the total blood collection (Jan- Dec) is shown with voluntary contribution to total collection along with number of blood donation camps conducted. (The annual blood collection should be more than 2000 units per year with nearing

100% contribution from Voluntary blood donor, preferably collected from outdoor blood donation camps. The condition may be relaxed for rural, tribal, hilly region, desert, island and Armed Forces)

4. The organization should submit the proof and details of appointment of Medical Social Worker (MSW) and Counselor with the blood bank for arranging Voluntary Blood Donation (VBD) camps and Pre and Post Test counseling respectively along with the training certificates.
5. The organization should submit Annual report indicating blood component separation facility has been established either of its own or a storage facility, wherein the components were sourced from RBTC approved by SBTC.
6. The organization should submit details of processing charges collected by the blood bank after 12th February 2014. The SBTC should verify, if charges collected are subsidized or at par with guidelines issued by NBTC.

Note :

- a) The Organization should submit undertaking on the letter head expressing willingness to abide with aforesaid conditions.
- b) The SBTC should process the application within thirty days from the date of its receipt in the office; failing which NOC shall be deemed granted to the organization.

C. Norms for grant of 'Regional Blood Transfusion Center' (RBTC) status to blood banks.

RBTC is a blood bank approved by the SBTC taking into consideration the regional needs of blood & blood components and the ability of RBTC in terms of premises, personnel and equipment to cater to the same. A center will be designated as RBTC only after SBTC formally networks it with blood bank/ blood storage centers in the region and establishes two way linkages for exchanges of blood and blood components.

1. The blood bank should be licensed and provide round the clock service.
2. The blood bank should have minimum collection of 2000 per annum with voluntary contribution nearing to 90%. (The criteria for minimum collection may be relaxed in rural, tribal, hilly region, desert, island and Armed Forces).

3. The Blood bank should have component separation facility. Alternatively, Blood bank should provide undertaking to establish component separation facility within two years time frame.
4. The blood bank should have adequate facilities to store and transport blood and blood components at required temperature and ambient conditions.
5. The blood bank should have minimum TTI screening by ELISA facility for atleast 80% collected unit and should be practicing tube method for blood grouping and cross matching. (The criteria for minimum testing may be relaxed in rural, tribal, hilly region, desert, island and Armed Forces).
6. The blood bank should be capable of imparting periodic training to staff attached with Blood Storage Center for blood grouping, cross matching, storage, identifying haemolysis and record keeping.
7. All equipment in the blood bank should be under AMC/CMC and calibrated at the time of applying for RBTC Status and subsequent renewal every year as mandated under Drugs and Cosmetic Act.
8. All records books should be available with the Blood Bank as stipulated in the Drugs and Cosmetics Act 1940 and Rules 1945 there upon.
9. The blood bank should have computer and trained staff to maintain database of donor, blood and products and inventory of demand and supplies made on daily basis.
10. The blood bank must update its stock status of blood availability blood group wise online with NBTC website.

Note:

The RBTC status accorded will be initially for a period of two years only. However, it would be renewed based on the performance and fulfillment of all aforesaid conditions for a further period of five years and at five years interval thereafter.

D. Norms for grant of permission to conduct voluntary blood donation camps:

Drugs and Cosmetics Act, 1940 and rules 1945 thereupon under Schedule F Part XII B has permitted following types of licensed Blood Banks to collect blood by conducting voluntary blood donations camps.

1. Government Blood Bank.
2. Indian Red Cross Society Blood Bank.
3. Regional Blood Transfusion Centers designated by SBTC
4. Blood Banks managed by registered voluntary or charitable trust organizations recognized by SBTC.

However, to ensure 100% blood collection from voluntary non remunerated blood donors in the country, it was decided to permit hospital based private blood banks also to conduct blood donation camps. The DCGI was requested to examine the same and introduce a suitable amendment to the Act.

Agenda Item No. 3.8: Punitive Action on Blood Banks not following NBTC guidelines

Members of the NBTC were of the view that on a number of occasions, the directives and guidelines formulated by the NBTC were not implemented by the Blood Banks, since these guidelines did not have statutory force.

It was therefore decided to request DCGI to examine whether compliance with the directives or guidelines of the NBTC could be made a part of the condition of license, so that defaulter blood banks could be penalized.

Agenda Item No. 3.9.: Approval of proposal of strengthening of NBTC and SBTC and directly routing of funds from NBTC to SBTC for VBD, Quality Management Systems, Monitoring and Training:

The agenda item was not considered to be within the purview of the Governing Body of NBTC, and was hence not discussed.

The meeting ended with a vote of thanks.