

No.S.12016/01/2018 - 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 20th March, 2018

Office Memorandum

Subject: Minutes of 27th meeting of Governing Body of National Blood Transfusion Council (NBTC)-reg.

This is to inform you that 27th Meeting of Governing Body of NBTC was held on 30th January, 2018 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 27th Governing Body Meeting of National Blood Transfusion Council

The 27th Meeting of Governing Body of the National Blood Transfusion Council was held on 30th January 2018 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. Shri. Sanjeeva Kumar, 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, Directorate General of Health Services, Nirman Bhawan, Delhi
5. Dr Mohd Shaukat Usta, Advisor (NCD), Directorate General of Health Services, Nirman Bhawan, Delhi
6. Dr.V. G. Somani. Joint Drugs Controller, representating DCG(I), Delhi
7. Dr. Neelam Marwah, HOD, Department of Transfusion Medicine, PGIMER, Chandigarh
8. Dr M Gajjar, HOD, Department of IHBT, BJ Medical College, Ahmedabad
9. Dr. Joy Mammen, Professor, Department of Transfusion Medicine and Haematology, Christian Medical College, Vellore
10. Dr. R. N. Makroo, Director Deptt. of Transfusion Medicine, Apollo Hospital, Delhi
11. Dr Vanshree Singh, Director Blood Bank IRCS HQ representing Joint Secretary, Indian Red Cross Society, Delhi
12. Dr Nagesh NS, Director, Institute of Gastroenterology Sciences and Organ Transplant, Victoria Hospital, Bangalore
13. Mr Biswaroop Biswas, Secretary, Federation of Indian Blood Donor Organizations, Kolkata
14. Dr R N Tandon, Honorary Secretary General, Indian Medical Association, HQ
15. Dr Sanjay Upreti, Director Technical and Operations, IMA Blood Bank, Dehradun deputed by President IMA
16. Dr Alok Ahuja, Member Executive Committee MCI representing Dr. Jayashreeben Mehta, President, Medical Council of India, New Delhi

17. Major (Dr) Ujjwal Dimri, Armed Forces Transfusion Centre, New Delhi representing DG Armed Forces Medical Services
18. Dr. Shobini Rajan, ADG (Blood Safety) NACO, Delhi & Director and Member Secretary NBTC

Attendees/ Invitees from NACO, Dr RML Hospital, CMAI and CDSCO included

1. Dr S Venkatesh, DDG (TI), NACO, Delhi
2. Dr R S Gupta, DDG (CST), NACO, Delhi
3. Dr Naresh Goel, DDG (IEC & LS), NACO, Delhi
4. Dr Kiran Chaudhary, Head of Blood Bank, PGIMER and Dr RML Hospital, DGHS, Delhi
5. Dr Sufiyan Haider, MO, NBTC, Delhi
6. Sh. M K Diwaker, Asst. Director, NBTC & Section Officer (BS), NACO Delhi
7. Dr Rajesh Rana, National Consultant (IEC and Mainstreaming), NACO, Delhi
8. Mr Jolly J Lazarus, PO (VBD), NBTC Delhi
9. Mr Lokesh S, Technical Advisor, CMAI
10. Dr I S Hura, Asst Drugs Controller, CDSCO
11. Sh Suresh Kalwaniya, Drugs Inspector, CDSCO

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

1. Joint Secretary (Policy), NHM
2. Dr. Bharat Singh, Director, State Blood Transfusion Council, 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 by Programme Officer Voluntary Blood Donation (NBTC) with inputs from Dr Shobini Rajan, Director NBTC to apprise members of the progress made in strengthening blood transfusion services of India as per approved action plan for 2017-19, also touching on activities conducted through support of CDC CMAI QMBB Project and the activities remaining to be done.

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



Agenda Item No. 1: Approval of minutes of the 26th meeting of the Governing Body of National Blood Transfusion Council held at New Delhi on 1st June 2017;

The minutes of the 26th Governing Body meeting of NBTC held on 1st June 2017 were approved by the Governing Body.

Agenda Item No. 2: Action Taken Report on proceedings of the 26th 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.

It was reiterated that the amendments to Drugs and Cosmetics Rules, which were long standing pending would be expedited by CDSCO. CDSCO would also incorporate a clause of making compliance to the guidelines of NBTC for processing charges for blood and blood components a mandatory requirement for licensure.

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 2016-17

The Audited accounts of the Society for 2016-17 were approved.

Agenda Item No. 3.2: Approval of Annual Reports for 2014-17

NBTC being an autonomous society, it is required to submit annual reports to both the Houses of Parliament. The annual reports for the period of 2014 – 17 to be laid before both the Houses of Parliament, were approved as detailed at **Annexure I**. The chair directed that hence forth the annual reports of NBTC be prepared and submitted in a timely fashion.

Agenda Item No.3.3: Extension of term of existing auditors for FY 2017-18 at exiting terms and conditions

Quotations were called for statutory and internal audits to assign the work for FY 2017-18 in July 2017, but could not be finalized due to very high prices quoted in comparison to the present available rates and lack of comparability between the

quotations due to variation. Approval of President NBTC was obtained to continue the same auditors for one more financial year (2017-18) as per quotations called for in 2014-15 as detailed

- 1) M/s N C Mittal & co for statutory audit of NBTC @Rs 20,000 per annum exclusive of service tax
- 2) M/s L K Dhingra & Co for internal audit of NBTC @ Rs 30,000 per annum inclusive of service tax

This decision was ratified by the Governing Body. It was however reiterated that rebidding is done to identify auditors for a three year period.

Agenda Item No.3.4: Appraisal of BTS activities in 2017

A presentation was made to appraise the members of the activities of NBTC conducted in the period of 2016-17 to strengthen Blood Transfusion Services as summarized below:

1. Roll out of EQAS through two PT providers @ 4000 per blood bank per year for 470 blood banks across the country
2. Conduction of Capacity building trainings on blood donor counselling and strengthening QMS through direct funding to Regional Training Centres
3. Dissemination of guidelines for blood donor selection and referral
4. NBTC website preparation and launch
5. Development of IEC material
6. Constitution of a working group for BTS Standards development
7. Constitution of Standing Committee of NBTC under the chairpersonship of JS Policy, MoHFW
8. Support to ISBTI for its National Conference held in Kota on 4th to 6th December 2017.
9. Support to FIBDO for its National Conference held in Phagwara on 11th and 12th November 2017
10. Support for blood drives and VBD activities
11. Dissemination of State-wise assessment reports and National Action Plan to strengthen Blood Transfusion Services of States
12. Completion of Study on Blood Requirement of India

The NBTC website and IEC material prototypes were demonstrated and appreciated by members.

The next steps in accordance to activities proposed as part of the Annual Action Plan (2017 to 2019) were also shared as detailed below:

- Convening of third meeting of Expert Working Group on Manpower norms for Blood Banks and Blood Transfusion Services
- Convening first meeting of Standing Committee of NBTC under the chairpersonship of JS Policy, MoHFW



- Finalization and submission of draft of NBTC standards for BB and BTS Standards by Expert Working Group
- Review and revision of Guidelines for VBD by constituting an expert working group on VBD, which will also look into all the points raised by members during the GB meeting
- Dissemination of Communication Strategy and IEC prototypes for VBD
- Convening of NBTC TRG meeting
- Training Centre and SBTC review meeting to finalize training plan 2018-19 and release of next installment of funds
- Review and monitoring of EQA roll out
- Proposal for Strengthening BTS at Central and State level to be prepared with adequate manpower and resources
- Convene meeting with the Professional Medical Associations working in the field of Transfusion Medicine

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

Agenda Item No.3.5: Report of the Expert Working Group constituted under the Special DGHS for Manpower norms for Blood Banks and Blood Transfusion Services and report submission to NHRC

The broad recommendations made by the Expert Working Group constituted under chairpersonship of Dr BD Athani, Special DGHS and co-chairpersonship of Dr Neelam Marwaha for revision of norms of manpower in blood banks as summarized below and detailed at **Annexure II** was approved by the Governing Body.

1. The present norms of manpower for Blood Banks as per standards laid down in the Drugs and Cosmetics Act and Rules thereof are not adequate to run blood banks efficiently and handle the load of outdoor / in house blood donation / testing and reporting process and provide good quality services round the clock. The Expert Working Group has recommended revisions for norms in accordance to total blood collection, hours of operations and outdoor camp activities.
2. There is no norm for dedicated staff to perform the important function of engagement with the blood donor and promotion of voluntary blood donation to perform tasks including motivation, counseling, recruitment, retention and referral. The Expert Working Group has recommended that every blood bank should have a counselor or social worker for this function.



3. There is also no norm for dedicated staff to look after Quality management systems. In Blood Banks desirous of improving their Quality Management Systems, the Expert Working Group recommended that existing staff may be designated as Quality Manager and Technical Manager to focus on quality issues with overall functioning of the blood banks so as to go ahead for strengthening QMS and accreditation.
4. Transfusion Medicine/ Immunohaematology and Blood Transfusion is an emerging specialty and there are at least 25 Medical Colleges offering the course and around 400 specialists available in the country, with an add-on of approximately 50 per year. They are not being utilized optimally to improve the transfusion services in country due to the absence of a mandatory regulatory requirement for specialists for Blood Bank operations. The Expert Working Group therefore recommended for increasing the minimum standards for blood banks doing blood component separation/ apheresis to an MBBS doctor possessing post graduate degree or diploma in Pathology/ Transfusion Medicine/ Immunohaematology and Blood Transfusion instead of plain MBBS.

The above would be recommended to CDSCO for incorporation in Drugs and Cosmetics Act 1940 and Rules 1945 thereof.


Agenda Item No. 3.6:

Proposal for creating a vertical within MoHFW for Blood Transfusion Services and Cellular Therapies

The proposal for creating a vertical within MoHFW for work related to Blood Banks and Blood Transfusion Services, including Cellular Therapies was discussed by all members. It was agreed that it is high time work related to Blood Banks and Blood Transfusion Services move out of the realm of NACO and the AIDS Control Programme into general health systems, while strengthening a coordination mechanism under the aegis of NBTC with all concerned stakeholders within the Ministry of Health and Family Welfare, which include:

1. NACO
2. NHM
3. Central Drugs Standards Control Organization (CDSCO)
4. DGHS
5. Other control programmes like NCD, Hepatitis etc

The objective would be ***to ensure universal access to safe blood and blood components to those who are in need with optimum quality by strengthening the structure, systems, and services across the country.***



The key strategies towards enhancing availability, accessibility, quality, safety and affordability of blood and blood components for end users as envisaged in the National Strategic Plan of NACO 2017-24 would be

1. Developing a **Nationally coordinated National Blood Transfusion System**: This strategy aims to achieve a National Blood Transfusion System with single decision/policy making body for BTS at National and State level i.e. NBTC –the apex central body and SBTC at the state level, directly under the umbrella of Ministry of Health and Family Welfare. The National Blood Transfusion Service will be working as per guidelines and mandate of NBTC. Strengthening the functioning of NBTC and SBTC in all states through the provision of adequate resources will be emphasized.
2. Taking steps towards **review and legislation of the existing National Blood Policy** and NBTC guidelines to give it the necessary authority to streamline and improve the functioning of Blood Banks
3. Developing **Common national standards for Blood Transfusion Services** and Blood Banks enforceable by law.


In principle all members agreed on creation of a separate vertical in the MoHFW for Blood Transfusion Services and that there should be a single decision / policy making body in the country related to all matters of Blood Transfusion Services at National and State level. States must establish SBTC as separate entities and not a subset of an existing health programme. The NBTC and SBTC should be directly under the umbrella of MOH&FW both at center and at state levels. The Blood Transfusion Service of India should be working as per guidelines and mandate of NBTC implemented through SBTC. All entities would work under the overall ambit of National policy guidelines.

It was also discussed that a funding mechanism should be envisaged to establish direct funding from NBTC to SBTC for strengthening blood banks and blood transfusion services instead of routing funds through NACO and State AIDS Control Societies.

Agenda Item No. 3.7:

Review of National Blood Policy and legislation thereof;

National Blood Policy 2002 requires review and revision to the present context and a strategic framework with resources and action plan is to be developed so as to strengthen the networking between blood banks and get them to function not as



individual blood banks, but part of a service, primarily to cater to the blood needs and demand of the population they cater to.

It was agreed that the process for review of National Blood Policy be initiated through conduction of Stakeholder consultations at National/ Regional levels. Public health being a State subject, it was agreed that States could take a lead in developing a Strategic framework to strengthen the blood transfusion services and allocate adequate resources for their proper functioning in accordance to the policy norms and guidelines of NBTC as adapted and adopted by SBTC. It was also informed that there are multiple sources of funding for blood banks and blood transfusion services, the key being

1. NACO support
2. Support from NHM (with considerable overlap at the level of state programme management structures and district blood banks)
3. State Government support
4. Revenue generation from processing charges and exchange of plasma
5. Donors/ charitable trusts/ private entities and CSR support

The lead taken by the State of Tamil Nadu in preparing a State Blood Policy and created a Strategic framework through pooling all available resources was presented to the members by Dr Joy Mammen, who represented the Project Director TNSACS. Suggestions and comments received from various members, would be incorporated by the State.

Agenda Item No. 3.8

Status of licensure of Blood Banks and Amendments in the Drugs and Cosmetics Rules

A presentation was made by Shri V G Somani, JDC in this regard and informed that CDSCO has devised an online mechanism of license renewal to look into the issue of long standing pendency. It was also informed that CDSCO is reviewing the status with all Zonal offices and State Drug Controllers to ensure that delays do not take place. It was also informed that license for Blood Component Separation at Ramakrishna Mission Hospital, Arunachal Pradesh has been issued and is no longer pending.



Agenda Item No. 3.9**Status of set up of blood banks in 74 districts not having blood banks and access to safe blood in all districts**

There was no representative from NHM to make the presentation and the same had been informed by the Director NHM vide email dated 29th January 2018 to JS NACO.

Agenda Item No. 3.10:**Issues raised by members to be considered by GoI/ NBTC**

Agenda points were sought from various members prior to convening the meeting. Details are given in **Annexure III** and decisions summarized below:

S No	Point	Decision
1.	Agenda points raised by Shri Biswaroop Biswas: Regarding punitive action to be taken in case of non compliance of National Blood policy and NBTC norms, Continued reliance on replacement blood donation by blood banks, Misuse of blood donor cards as credit cards by donors and camp organizers, Development of a policy guideline for Clinical Use of Blood, School blood programme, Rare Blood donor registry, Refreshment money for blood donors Charter of Demands resolute in BLODCON 2017	The issues were presented by Shri Biswas and it was decided to constitute an expert working group to look into the issues and work on review and revision of guidelines for Voluntary Blood Donation. NBTC would request a Professional Association like ISTM to prepare Guidelines for Clinical Use of Blood in coordination with all stakeholders.
2.	Agenda points raised by Dr Joy Mammen 1. National Blood Donor authentication system: Creation of a unique identification number to every blood donor.	1. The proposal of National Blood Donor authentication system was appreciated by members and it was decided that a full fledged proposal for the same would be submitted to the Governing Body for approval with budgetary implications for conducting a pilot prior to scale up. The group could comprise members from NBTC GB

	<p>including Dr Alok Ahuja, Dr Joy Mammen, Dr Sanjay Upreti and Dr M Gajjar.</p> <p>2. Provision of Surplus FFP to Plasma fractionation centres.</p> <p>Issues at the end of State FDA preventing blood banks from giving surplus FFP to Indian plasma fractionation centres</p> <p>3. The Need for creating an experimental model for centralized testing facility</p>	<p>A reiterated clarification would be issued by NBTC to all State Blood Transfusion Council and CDSCO regarding exchange of surplus plasma to indigeneous fractionators at a uniform exchange value as per approved policy of the Ministry of Health and Family Welfare.</p> <p>It was clarified by the representatives of CDSCO that no further permissions or licensing were required at the level of State FDA for licensed Blood Banks to send surplus plasma to existing fractionators.</p> <p>In view of the extant provisions in the Drugs and Cosmetics Act and Rules thereof, wherein each blood bank has to ensure that all collected blood units are screened for all five TTI, making the responsibility lie with each individual blood bank to screen the blood units collected by them, the members of the GB were of the opinion that it would not be appropriate to move ahead with a proposal for centralized testing at this point of time.</p>
3	<p>Agenda points raised by Dr Neelam Marwaha</p> <p>1. Need for Harmonized documents and guidelines 2. Long pending review of DGHS Technical Manual</p>	<p>The matter was discussed at length and few of the members proposed that there should only be one set of standards, ie NABH Standards of Quality Council of India and there was no need to have NBTC Standards. It was however clarified that NABH standards spell out the desirable quality standards that Blood Banks</p>



		<p>aspiring for accreditation and it is over and are above the basic minimum standards, and accreditation is a voluntary and not mandatory. CDSCO representative clarified that accreditation cannot replace licensing, which is mandatory. Also NABH standards cannot be accessed in public domain free of cost.</p> <p>Keeping all this in view, NBTC has taken the initiative to prepare uniform minimum standards fully aligned to the Drugs and Cosmetics Act and Rules to be followed by all blood banks as minimum standards to comply with regulatory provisions. These Standards would be referenced in the Drugs and Cosmetics Act and Rules thereof.</p> <p>A working group has already been constituted and a draft would be submitted for review by the Technical Resource Group of NBTC prior to seeking approval of GB of NBTC.</p> <p>It was also informed that the review of DGHS Technical Manual has been kept in abeyance till such time as these Standards are finalized.</p>
4	<p>Agenda points raised by Dr. M.D Gajjar</p> <ul style="list-style-type: none"> • Involvement of Blood Safety persons of SACS in SBTC • Qualification of Member Secretary of SBTC 	<p>It was informed that an Expert Working Group is constituted to look into manpower norms of the Blood Banks and Blood Transfusion Services and the issues raised would be taken up therein.</p>

Agenda Item No. 3.11 and 3.12:
Proposal from AATM for capacity building of private sector blood banks on Blood Donor Counselling
Matters for discussion and deliberation:

The above agenda items were not discussed in detail, in the interest of time, but the following decisions were taken.



1. AATM proposal to conduct capacity building trainings for Counselors at Blood Banks in collaboration with NBTC was agreed to in principle.
2. There should be no GST on blood bags and testing kits, and NBTC through MoHFW should take it up with the concerned authorities.
3. The matter of sending HIV, HBV and HCV reactive blood bags from licensed blood banks to Kit Manufacturers, PT providers and other Government agencies was considered and it was decided that the matter would be referred to the Technical Resource Group of NBTC to deliberate and prepare detailed norms for the same.
4. MCI has in principle agreed on the convergence in different courses available for Transfusion Medicine/ IHBT, and NBTC would write to the President MCI to expedite the same.
5. Compliance to NBTC guidelines on Processing Charges of Blood and Blood Components by licensed blood banks in the States and prevention of wastage of blood and blood components should be reviewed periodically by respective SBTC and communication reiterating this would be issued by NBTC.
6. Provision for registration of all licensed blood banks of the State is provided in the NBTC website and user id and passwords for respective SBTC would be issued by NBTC.
7. All organizations engaged with conduction of voluntary blood donation camps are to be registered on the NBTC website by the respective SBTC.
8. Blood Banks under DGAFMS are not registered and providing reports on SIMS despite communication from NBTC sharing the reporting format.
9. IMA would continue to support conduction of voluntary blood donation drives and include topics related to Blood Banks and BTS in their CMEs conducted through State Chapters. NBTC would facilitate identification of suitable resource persons through SBTC and other Professional Associations like AATM, ISTM, ISBTI, FIBDO, FBDOI etc.
10. Other individual matters would be taken up with the approval of President NBTC from time to time and put up to Governing Body for ratification.

Meeting ended with a vote of thanks to the chair.