Report of Expert Working Group set up under Chairpersonship of Special Director General Health Services

Review and Recommendations on Manpower Norms for Blood Banks

1. Background:

Blood Transfusion Service (BTS) is an essential part of modern health care system without which medical care is impossible (Pal, Kar, Zaman, & Pal, 2011). The provision of safe and adequate blood and blood products at national level is the responsibility of the government/national health authority of each country (Ramani, Mavalankar, & Govil, 2007).

However, provision of safe and quality blood for a country like India involves a highly complex operation involving various stakeholders and the magnitude and complexity of issues raises several challenges (GoI, 2003). This requires a holistic and comprehensive approach in planning, designing and operationalizing the BTS. It is important to ensure coordination between the Blood Transfusion Services, health services and hospitals, educational institutes, religious, social and industrial organizations, mass media and other stakeholders including general public.

Due to the continuous efforts in India, the availability of safe blood increased from 4.4 million units in 2007 to 10.8 million units by 2016; during this time HIV sero-reactivity also declined from 1.2% to 0.12%; and Voluntary blood donation increased substantially (NACO, 2013). Nevertheless, there are still gaps and challenges in ensuring availability and accessibility of blood to all those are in need. Districts in the country who still do not have government supported blood centers have been reduced to 74; India is making progress towards meeting the annual requirements of 13 million units as per the 1% population norm; overall only around 70% is from voluntary blood donors (Agarwal, 2012); Lack of human resources and lack of adequate quality management systems in the majority of blood banks continue to be areas requiring further attention (Lowalekar & Ravichandran, 2013; Singh, 2007). There are several organizational and management issues hindering the effective service provision in the country (Nanu, 2001).

Objective 6 of the National Blood Policy, 2002 is devoted to strengthen the manpower through human resource development. It talks of encouraging post-graduate degree and diploma courses in Transfusion Medicine and encourage posting of doctors in blood banks for at least 15 days during compulsory rotational internship. States/UT's have also been asked to consider creating a separate cadre for doctors in transfusion medicine. In service training for all categories of staff of blood banks is also reiterated therein.

2. Mandate of Expert Working Group for manpower norms:

An Expert Working Group for Manpower norms for Blood Banks and Blood Transfusion Services has been constituted under the aegis of National Blood Transfusion Council with the following terms of reference:

- To review norms for requirements of technical personnel in Blood Banks and Blood Transfusion Services
- To recommend for revisions in norms thereof for Blood Banks and Blood Transfusion Services, if any

Chairperson:
Dr B.D. Athani, Special Director General of Health Services, Ministry of Health and Family Welfare, GOI

Co-chairperson:
Dr Neelam Marwaha, Head of Department, Department of Transfusion Medicine, PGIMER, Chandigarh

This working group has been constituted on the basis of a complaint made to National Human Rights Commission praying for revision of manpower norms for blood banks.

The working group was originally to submit its report within three months of constitution; however extension of time was sought for the same from NHRC.

The committee held meetings on 31st May 2017 and 27th November 2017 to deliberate and finalize its recommendations.

3. Current norms of staffing pattern of the blood bank as per the Drugs & Cosmetics rules 1945 (as stated in Schedule F, Part XII B)

The following are the pattern and the educational qualifications of the blood bank staff described by the drugs & cosmetics rules1945:

For blood bank/ blood components storage units

Staff: - Every blood bank shall have the following categories of whole time competent technical

(a) Medical Officer, possessing the qualifications specified in condition (i) of rule 122-G.

(b) Blood Bank Technician(s) possessing –

(i) Degree in Medical Laboratory Technology (M.L.T) with six months experience in the testing of blood and/or its components; or

(ii) Diploma in Medical Laboratory Technology (M.L.T) with one year experience in the testing of blood and / or its components, the degree or diploma being from a University / Institution recognized by the Central Government or State Government.

(c) Registered Nurse(s);

(d) Technical supervisor (where blood components are manufactured), possessing-

(i) Degree in Medical Laboratory Technology (M.L.T) with six monthsexperience in the preparation of blood components; or

(ii) Diploma in Medical Laboratory Technology (M.L.T) with one year experience in the preparation of blood components,

The degree or diploma being from a University / Institution recognized by the Central Government or State Government.

S.No	Staff	Qualification	Number
1.	Medical officer	MBBS	1
2.	Lab Technician	DMLT /BMLT	1
3.	Staff Nurse	RNRM	1
4.	Technical supervisor	DMLT/BMLT	1

For Out-door Blood Donation Camps

To collect blood from 50 to 70 donors in about 3 hours or from 100 to 200 donors in 5 hours, the following requirements shall be fulfilled / complied with:

(i) One Medical Officer and two nurses or phlebotomists for managing 6-8 donor tables;

(ii) Two medico social workers;

(iii) Three blood bank technicians;

(iv) Two attendants.

S. No	Staff	Qualification	Number
1.	Medical officer	MBBS	1
2	Lab Technician	DMLT /BMLT	3
3.	Staff Nurse	RNRM	2
4.	Medico Social Worker	MSW	2
5	Attendants		2

For Processing of blood components from whole blood by a blood bank

The full time competent technical staff meant for processing of Blood Components (that is Medical Officer, Technical Supervisor, Blood Bank Technicians and Registered Nurse) shall be as specified under the heading — I. BLOOD BANKS/BLOOD COMPONENTS.

For Collection and storage of plasma for fractionation

(1) Manufacture : The manufacture of blood products shall be conducted under the active direction and personal supervision of competent technical staff, consisting of at least one person who shall be a whole time employee, with one year practical experience in the manufacture of blood products / plasma fractionation and possesses –

(a) Post-graduate degree in Medicine–M.D. (Microbiology/Pathology/ Bacteriology/Immunology/Biochemistry); or

(b) Post-graduate degree in Science (Microbiology); or (c) Post-graduate degree in Pharmacy (Microbiology), from a recognized University or Institution.

Blood Banks are not included within the scope of the Clinical Establishment Act and Rules thereof. However, as per IPHS Standards for District Hospitals (2012), the minimum manpower for blood bank is indicated as detailed below:

Sl No	Cadre	100 beds	200 beds	300 beds	400 beds	500 beds
1	Blood Bank Incharge(Doc tor/ Pathologist)			1	1	1
2	Staff Nurse	3	3	3	3	3
3	Male Female Nursing Attendant	1	1	1	1	1
4	Blood Bank Technician	1	1	1	2	2
5	Sweeper	1	1	1	1	1

4. Current status of manpower in blood banks

Baseline assessment was undertaken during the year 2016 across 2,626 blood banks of which 1,131 were NACO supported and 1,495 were Non-NACO supported and 46 military BBs which were excluded. Among the 2,626 Blood banks 2,493 were considered for analysis (99% NACO supported and 92% Non-NACO BBs). The blood banks were categorised into the following two categories

- Category 1: Blood Banks with component facility
    - Model blood banks - Annual collection of > 10,000 units
    - Blood Component Separation Units – Annual collection of between 5,000 - 10,000 units
- Category 2: Blood Banks without component facility
    - Major blood banks - Annual collection between 3,000 - 5,000 units
    - District Level Blood Banks – Annual collection < 3,000 units

The following table depicts the current staff available across the NACO supported blood banks.

NACO supported BB staff cadre	Category I		Category II		Proportion of staff Cat I : Cat II
	No.of Staff	Average workforce	No.of Staff	Average workforce	
Medical Officer	902	**2.41**	848	**1.33**	1.80
Technical Staff	3822	**8.87**	2106	**3.06**	2.90
Nursing Staff	937	**2.31**	933	**1.56**	1.48
Counsellor	345	**1.14**	174	**0.98**	1.17
PRO/Donor Motivator	261	**1.47**	93	**0.93**	1.58
Administrative Staff	468	**2.36**	121	**1.08**	2.19
Support Staff	1850	**4.29**	743	**1.08**	3.97
TOTAL (approx)		**22**		**10**	

The average annual collection across the Category I blood banks was 11,236 and across Category II blood banks was 3,045. Though the quantum of work load across the category I and II blood banks is in the ratio **3.7 : 1,** the staffing pattern across the category I blood bank cadres doesn't reflect so. The work load of Category I blood banks which are collecting more than 10,000 units is approximately 3.7 times more than the Category II blood banks, which are collecting less than 3,000 units . But the staffing proportion is only between **1.2 to 2.9** times.

There are very few studies across the country and internationally, which has assessed the work load of blood bank staff and suggested recommendations for improving it.

5. Broad Recommendations:

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.
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.
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. It is recommended that existing staff is 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 atleast 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 Banks. The minimum standards for blood banks doing blood component separation/ apheresis should be increased to an MBBS doctor with minimum qualification of post graduate degree or diploma in Pathology/ Transfusion Medicine/ Immunohaematology and Blood Transfusion.
5. There are no norms for manpower and systems for management of Blood Transfusion Services at Central and State level other than the Supreme Court Directions of 1992 and the same should be prepared.
6. As a start, NBTC and SBTC should be strengthened to perform their delegated functions at National and State level. In addition to having Governing Bodies for policy making, additional positions must be created to perform the executive functions of Promoting Voluntary Blood Donation, Advocacy and IEC activities, Strengthening Quality, Reporting, E RaktKosh etc to oversee and manage the blood transfusion services. As a beginning, NACO could consider moving the existing contractual manpower in State AIDS Control Societies to State Blood Transfusion Councils to take a step towards segregating SBTC from SACS.

6. Specific Recommendations for Blood Banks

Modifications were made to earlier recommendations for manpower at blood banks made by an expert working group set up for proposing amendments to the Drugs and Cosmetics Act and Rules thereof by NACO as detailed below:

PERSONNEL

Every Blood Centre shall have following categories of full time competent technical staff. The qualifications are enlisted and numbers based on blood collection and workload are tabulated below:

Qualifications:

1. MEDICAL OFFICER (Whole Blood)

(a) Degree in Medicine (MBBS) having experience of working in a licensed Blood Centre, not less than one year during regular service and also has adequate knowledge and experience in blood group serology, blood group methodology and medical principles involved n the procurement of blood and/ or preparation of its components, or

(b) Degree in Medicine (MBBS) with Diploma in Clinical Pathology or Diploma in Pathology and Bacteriology with six months experience in a licensed Blood Centre, or

(c) Degree in Medicine (MBBS) with Diploma in Transfusion Medicine or Diploma in Immunohaematology and Blood Transfusion with three months experience in a licensed Blood Centre, or

(d) MD Pathology or DNB (Pathology) with three months experience in a licensed Blood Centre, or

(e) Post graduate degree in Transfusion Medicine- MD (Transfusion Medicine)/ MD (Immunohaematology and Blood Transfusion) or DNB (Transfusion Medicine/ IHBT)

The degree or diploma shall be recognized by Medical Council of India or its equivalent.

2. MEDICAL OFFICER (Component Separation)

For Blood Banks with Component Separation, the qualification of Medical Officer should be as below:

(a) Degree in Medicine (MBBS) with Diploma in Clinical Pathology or Diploma in Pathology and Bacteriology with six months experience in a licensed Blood Centre, or

(b) Degree in Medicine (MBBS) with Diploma in Transfusion Medicine or Diploma in Immunohaematology and Blood Transfusion with three months experience in a licensed Blood Centre, or

(c) MD Pathology or DNB (Pathology) with three months experience in a licensed Blood Centre, or

(d) Post graduate degree in Transfusion Medicine- MD (Transfusion Medicine)/ MD (Immunohaematology and Blood Transfusion) or DNB (Transfusion Medicine/ IHBT)

The degree or diploma shall be recognized by Medical Council of India or its equivalent.

3. BLOOD CENTRE TECHNICIAN (Whole Blood)

i. Diploma in Medical Laboratory Technology (DMLT) or Transfusion Medicine or Blood Bank Technology after 10+2 with one year experience in the testing of blood and/ or its components in a licensed Blood Centre
ii. Degree in Medical Laboratory Technology (MLT) or Blood Bank Technology with six months experience in the testing of blood and/or its components in a licensed Blood Centre
iii. B.Sc. Haematology and Transfusion Medicine with six months' experience in the testing of blood or its components in a licensed Blood Centre
iv. M.Sc. Transfusion Medicine with six month's experience in the testing of blood or its components in a licensed Blood Centre
v. PG DMLT/ PG DMLS with six months' experience in the testing of blood and/or its components in a licensed Blood Centre

The degree or diploma shall be from a University / Institution recognized by the Central Government or State Government.

4. BLOOD CENTRE TECHNICAL SUPERVISOR (Component Separation)

For Blood Banks with Component Separation, the qualification of Blood Centre Technical Supervisor should be as below:

i. Diploma in Medical Laboratory Technology (DMLT) or Transfusion Medicine or Blood Bank Technology after 10+2 with two years experience in the preparation and testing of blood components in a licensed Blood Centre
ii. Degree in Medical Laboratory Technology (MLT) or Blood Bank Technology with one year experience in the preparation and testing of blood components in a licensed Blood Centre
iii. B.Sc. Haematology and Transfusion Medicine with two years experience in the preparation and testing of blood components in a licensed Blood Centre
iv. M.Sc. Transfusion Medicine with one year experience in the preparation and testing of blood components in a licensed Blood Centre
v. PG DMLT/ PG DMLS with one year experience in the preparation and testing of blood components in a licensed Blood Centre

The degree or diploma shall be from a University / Institution recognized by the Central Government or State Government

5. REGISTERED NURSE

6. BLOOD CENTRE COUNSELOR/ MEDICAL SOCIAL WORKER:

For Blood Banks conducting Outdoor Blood Donation Camps and Indoor Blood Collection Drives, the qualification of Blood Centre Counselor/ Medical Social Worker should be as below:

i. Master's degree in Social Work, Sociology, Psychology with six months' experience in a licensed Blood Centre
ii. Degree in Science/ Health Science with one year or experience in a licensed Blood Centre
iii. Person with 10+2 having three years of experience in the field of counseling in a licensed Blood Centre

Note: For Blood Centres collecting less than 3000 units per annum, the counselor or medical social worker can be part-time and shared with the institution.

The above extract is to be suitably incorporated in the Rule 122 G and Schedule F Part XII B under Para 1-C of Drugs and Cosmetics Rules 1945.

Staffing pattern and numbers:

For Whole Blood (24 hours operations, blood collection/ processing in routine working hours, cross-match and issue 24/7)

Staff required	Annual blood collection (units)				
	Upto 5,000	Upto 10,000	Upto 20,000	> 20,000	>50,000
Medical Officer In-charge/ Medical Personnel	2	3	5	7	8
Counselor/ Medical Social Worker	1	2	2	2	4
Registered Nurse	1	2	3	4	8
Blood Centre Technician	5	8	11	13	22
Lab. Attendant/ Housekeeping Staff	1	3	4	4	8

For Outdoor Blood Donation Camps/ Blood Mobile Van collection (Additional minimum staff required to collect 50 – 120 blood donors per camp)

Additional Staff required	Numbers
Medical personnel	1
Counselor/ Medical Social Workers	2
Registered Nurse	2
Blood Centre Technician	3
Attendants	2

Note: The Medical Officer / residents undergoing Post Graduate training, having minimum qualification of M.B.B.S. can attend Blood Donation Camps under the supervision of Medical Officer of the blood centre.

For blood component separation

Additional Staff required	Annual blood collection (units)				
	Upto 5000	Upto 10000	Upto 20000	> 20000	>50,000
Blood Centre Technical Supervisor	1	1	1	1	1
Blood Centre Technician	1	2	3	3	4
Lab.Attendant/ Housekeeping staff	0	1	1	1	2

For Apheresis (Additional Minimum Staff required to conduct 20 apheresis per month)

Additional Staff required	
Medical personnel	1
Nurse/Technologist	1

Note: The number of above mentioned staff is the basic minimum and actual numbers of staff will depend upon nature of work and work load of the individual Blood Center. Blood center can recruit additional staff above this norm.