

Health, Medical and Family Welfare Department

3.4 Non-functioning of Blood Component Separation Units

Three Blood Component Separation Units at Gadwal, Mahabubnagar and Tandur could not commence their operations for want of resources and equipment. As a result, the equipment bought at a cost ₹94 lakh remained idle for periods ranging from two to five years

Blood Banks¹⁴⁶ and Blood Component Separation Units¹⁴⁷ (BCSUs) are regulated under the Drugs and Cosmetics Act, 1940 and Rules framed thereunder. As per the Rule 122-G, 122-I and 122-P, adequate accommodation¹⁴⁸, equipment¹⁴⁹, technical/trained staff¹⁵⁰, etc. are required to be provided¹⁵¹ to a BCSU for obtaining licence for its operations. The licence is granted by State Licensing and Central Licensing authorities. The Heads of the Department¹⁵² (HoDs) are required to ensure provision of essential requirements including the licence for the Blood Banks/BCSUs.

Audit scrutinised (January/October 2017) the records of Director, Drugs Control Administration (DCA - State Licensing authority) and three¹⁵³ (out of 27¹⁵⁴) test-checked Blood Banks in the State. The objective was to assess the compliance of the mandatory requirements by the BCSUs proposed to function in the Blood Banks.

For establishing three BCSUs¹⁵⁵ at District Hospital Blood Banks at Gadwal, Mahabubnagar and Tandur, the Department had supplied¹⁵⁶ (January 2013 - September 2017) certain essential equipment costing ₹94 lakh¹⁵⁷.

Audit scrutiny showed that the three proposed BCSUs were not put into operation due to non-provision of various essential equipment¹⁵⁸ and technical/trained staff¹⁵⁹. As a result,

¹⁴⁶ Blood Bank carries out all or any of the operations for collection, apheresis, storage, processing and distribution of Whole Human Blood drawn from donors and/or for preparation, storage and distribution of blood components

¹⁴⁷ Blood Component Separation Unit (as a part of Blood Bank services) carries out separation of whole blood into its constituent components viz., red cells, platelets and plasma for use when these specific components are required

¹⁴⁸ an area of 50 sq. meters for preparation of blood components (in addition to 100 sq. meters for Blood Bank operations)

¹⁴⁹ Air conditioner; Laminar air flow bench; suitable Refrigerated Centrifuge, Plasma expresser; Clipper and clips and/or dielectric sealer; Weighing device; Dry rubber balancing material; Artery forceps, scissors; Refrigerator (to maintain 2°C to 6°C temperature), Platelet agitator with incubator, Deep freezers (to maintain -30°C to -40°C and -75°C to -80°C temperature); Refrigerated Water bath for Plasma Thawing; Insulated blood bag containers; etc.

¹⁵⁰ Whole time Medical Officer, Technical Supervisor, Blood Bank Technicians and Registered Nurses

¹⁵¹ as stipulated in the Schedule F, Part XII B of Drugs and Cosmetics Rules, 1945

¹⁵² Commissioner, TVVP, Director of Medical Education and Director of Public Health and Family Welfare

¹⁵³ District Hospital Blood Banks at Gadwal, Mahabubnagar (Mahabubnagar district) and Tandur (Rangareddy district)

¹⁵⁴ functioning under Government sector

¹⁵⁵ for strengthening hospital services to combat the Dengue and other viral fevers

¹⁵⁶ Through Andhra Pradesh Medical Services and Infrastructure Development Corporation (APMSIDC - now TSMSIDC for Telangana State) and Andhra Pradesh State AIDS Control Society

¹⁵⁷ District Hospitals, **Gadwal** (cost: ₹29.81 lakh/supplied: June - September 2015); **Mahabubnagar** (₹33.44 lakh/January 2013 to September 2017) and **Tandur** (₹30.33 lakh/February 2013 - September 2015)

¹⁵⁸ **BCSU, Gadwal:** 40 Kv Generator; Air Conditioners; Blood Bags Weighing Device; Dry Rubber balancing material; Artery forceps, scissors; Blood Bank Refrigerators, Insulated Blood bag containers, Temperature Recorder System (CMS), Stop Watch/Timer Clock Digital and Electronic/Laboratory Thermometers and **BCSU, Mahabubnagar:** Air Conditioner, Laminar air flow bench, Dry rubber balancing material, Artery forceps, Deep freezers (minus 75 to 80), Blood collection Monitor, Test tube racks, Coagula Meter and Single Donor Platelet

¹⁵⁹ **BCSU, Mahabubnagar:** Technical staff were not provided; **BCSUs, Gadwal:** Professional staff were not sanctioned; and **Tandur:** Technical staff were provided. However, Medical Officer and Lab Technicians were not trained

the entire equipment already supplied (cost: ₹94 lakh) were lying idle for the periods ranging from two¹⁶⁰ to five years in the three Blood Banks.



Refrigerated Centrifuge kept idle at BCSU, Gadwal (October 2017)



Platelet agitator, Refrigerated Centrifuge, and Deep freezer kept idle at BCSU, Mahabubnagar (October 2017)

It was further seen that the District Hospitals¹⁶¹ repeatedly requested for meeting the gaps in equipment and trained staff, but these were not provided by the Department. Thus, procurement of essential equipment and positioning of trained manpower were not simultaneously ensured for commencement of the BCSUs. DCA confirmed (July 2017) non-compliance of the mandatory requirements for the BCSUs.

The DCA/CDSCO¹⁶² had in fact, issued licences to the three BCSUs¹⁶³ for their operations, pending provision of essential equipment, technical/trained staff, etc.

In their reply (September 2017), the Commissioner, Telangana Vaidya Vidhana Parishad (TVVP) and the Government stated (January 2018)¹⁶⁴ that all the three BCSUs were functioning.

Audit conducted (26 to 28 October 2017) joint physical verification of the BCSUs along with hospital authorities concerned. It was, however, found that the BCSUs were still not functioning due to non-provision of certain other essential equipment and trained technical staff. Hence, the reply of the Commissioner/Government was not acceptable.

Thus, due to lack of resources the three BCSUs could not commence their operations. This led to the equipment (cost: ₹94 lakh) already supplied remaining idle for the periods ranging from two to five years. This deprived needy patients of easy access to safe blood/blood components appropriate to their clinical needs. With efflux of time, the equipment may become dysfunctional.

As these findings emerged only from a test-check by Audit, it is unlikely that these findings were confined to the aforementioned BCSUs only. According to DCA (July 2017), certain other Government hospitals also had not provided all the essential requirements for functioning of Blood Banks. In this context, it is recommended that Government review the functioning of all the Blood Banks/BCSUs in the State.

¹⁶⁰ One month in the case of equipment, i.e., 'Cell Counter' which was received in September 2017 in BCSU, Mahabubnagar

¹⁶¹ Gadwal and Mahabubnagar

¹⁶² Central Drugs Standard Control Organisation (Central Licensing authority)

¹⁶³ **Gadwal:** August 2016 (based on the assurance given by the Blood Bank authorities for compliance of mandatory requirements), **Tandur:** September 2016 and **Mahabubnagar:** June 2017

¹⁶⁴ while forwarding the response (20 October 2017) of the Commissioner indicating the status of BCSUs