

Association of Rural Surgeons of India, Jan Swasthya Sahayog, Shaheed Hospital v. Union of India and Ors. (Writ Petition (Civil) No. 211/2020)

1. This Public Interest Litigation petition highlights the absence of access to blood for transfusion purposes for all patients in India whose lives are at risk in emergency health situations. The petition prays *inter alia* for orders to strengthen and regulate blood banks and blood storage units across the nation, especially in the priority districts under Categories A, B and C as identified by the National AIDS Control Programme- III (hereinafter “NACP III”) under the National Aids Control Organization (hereinafter “NACO”).

The Government’s Failure in Providing Ready Access to Blood

Transfusion Services in Rural Areas

2. Health care in our society is deeply unequal. Geography, economic status and dubious public institutions dictate one’s ability to access quality health care and achieve good health. Moreover, availability, cost, quality and safety of health services raise difficult technical and ethical questions which have yet to be adequately resolved.
3. Blood Transfusion Services (BTS) in India are highly decentralized and lack many vital resources needed to make them effective including adequate manpower, infrastructure and financial support. The main issue plaguing blood banking systems however are fragmented management. Standards of care and supplies of blood vary from state to state, city to city and centre to centre. Despite the existence of government health infrastructure, many large hospitals (such as district hospitals) and nursing homes in rural areas lack their own blood banks. This has led to the proliferation of stand-alone private blood banks out of which many

are not registered. The Major failures of blood banks and BTSs in India include:

- i. **The low number of licensed and registered blood banks.** The number of registered and licensed blood banks in India is extremely low with only 1700 (ERAKTKOSH) blood banks across India, which comes to less than 3 blood banks per 10 lakh population. Although the annual blood collection has increased from 2013 – 2014 to 2016 – 2017 by 12%, it is still less than the projected requirement by 15%.
- ii. **Lack of access to blood in rural areas is unaddressed.** The 1996 judgment of the Hon'ble Supreme Court of India in *Common Cause v. Union of India &Ors.* [Writ Petition (Civil) 91 of 1992] regulated the means of blood transfusion and held that blood could *only* be collected, stored and tested, and components made and issued for transfusion, after first being cross matched from a licensed blood bank. This decision of the court brought to a halt the unregulated blood business, rampant profiteering, the practice of poor testing or not testing at all and the practice of encouraging professional donors. However, lack of access to blood was not mentioned because the voluntary sector continued to use blood bags available in the market in the absence of any blood banks in small towns and rural areas. Donors (voluntary or family) were used as donors when the need arose for transfusion.
- iii. **Non-implementation of laws and guidelines for BSUs and First Referral Units.** Lack of access to blood in rural areas was raised when the government, in response to *Common Cause v. Union of India*, announced an amendment to the Drugs and Cosmetics Act, 1940. The amendment required blood storage units to be established in areas where blood banks were not

present and the requirement for blood was likely to be less than 2000 units per year. All First Referral Units (hereinafter FRUs) were mandated to have Blood Storage Units (hereinafter BSUs) and all District Hospitals as per IPHS norms were to have blood banks. Although Guidelines for BSUs were published in 2007, to date only a fraction of FRUs have the infrastructure for BSUs and only a miniscule percentage actually function to any significant extent, approximately transacting and using less than 100 units of blood per yr.

- IV. **High maternal mortality rates in India due to inaccessibility of blood.** Around the world, over 5 lakh women die annually during childbirth. One-third of these deaths happen in India. Obstetric Hemorrhaging (PPH and APH) is by far, the largest cause of these maternal deaths, the situation being compounded by rampant anemia, especially among the rural poor.
- V. **Proximity of facilities to one another.** Nearly 50,000 deaths could have been averted had there been a well-resourced and functioning facility within 50 kms of the health facilities in both public and non-governmental sectors.
- VI. **Strict enforcement of replacement donations even in emergency situations.** Most blood banks, especially those in the public sector (government) rely heavily on ‘replacement’ donations and often refuse issuing blood even in emergency situations where no replacement donor is available.
- VII. **Detrimental reliance on replacement donations.** The NBTC has called for a complete phase-out of replacement donations by 2020. The focus on replacement donations rather than voluntary, non-remunerated donations (VNRDs) means that district hospitals (otherwise known as the mother banks) which are intended to

feed the BSUs underneath them (usually 4 – 5 in number) will never be self-sustaining enough to spare any blood as they themselves have a hand-to-mouth existence. Consequently, most BSUs have hardly any blood units and are non functional.

- VIII. **Lack of functioning blood banks or BSUs.** At least 81 districts across India lack a single functioning blood bank or BSU. A district hospital caters to a population often as large as 25 Lakh spread over hundreds of kilometers and is often the only hope for this population. Such district hospitals, even those sufficiently staffed (having at least one anesthetist, gynecologist, and surgeon) will rightfully refuse to perform caesarean sections or deal with other obstetric or surgical emergencies in the absence of blood. This blood shortage however often results in needless referrals and more complications including the needless deaths of these young women.
- IX. **Unregulated cost of blood processing equipment.** The blood processing equipment is unregulated and the price of being a part of Essential Drugs List needs to be regulated through the drug price control order.
- X. **Shortage of medical specialists. There is a huge shortage trained health professionals in the field of transfusion medicine** (80 – 85% shortage of specialists). There is a need for the government to map these inadequacy and make the Blood Banks functional

PRAYER

1. That by this writ petition the petitioner prays for issuance of an appropriate writ(s)/ order(s)/ direction(s) particularly:

2. To issue orders and directions for setting up of Blood banks in all District Hospitals in compliance with National Blood Policy and the NBTC Guidelines.
3. To issue orders and directions to Union of India and all State Governments to make Blood Banks fully fed through non-remunerative blood donation with monthly calendar with effective propagation of Blood Donation Camps in compliance with NBTC Guidelines, 2007.
4. To issue orders and directions for setting up of Regional Blood Banks in all Divisional Headquarters of the State, mostly Government Medical Colleges, to act as a hub to direct and regular supply of blood to district hospital blood banks and Blood Storage Units.
5. To issue orders, directing rapid upscale of the BSUs in FRUs and even in other CHCs with BSUs being fed from their 'mother' Blood Banks- without need for replacement.
6. To issue orders and directions legalizing Unbanked Directed Blood Transfusion that is well regulated which at present is the only feasible and safe option to meet blood demands in rural areas in our country, because to achieve the target to expand the network of blood banks to improve access to safe blood across the country may take many years.
7. To issue orders and directions to Union of India and all State Governments to make Blood Banks fully fed through non-remunerative blood donation with effective propagation of Blood Donation Camps in compliance with NBTC Guidelines, 2007.
8. To issue orders and directions to Union of India for establishing a separate monitoring body for all purposes relating to blood and blood transfusion services under the Ministry of Health and Family Welfare, Government of India.

9. To issue orders and directions to Union of India for revising and rationalizing the NBTC Guidelines in consultation with the Petitioners.
10. To issue orders and Directions to Union of India for strict enforcement of Notification No. S/12016/01/2012-NACO(NBTC) issued on 12.02.2014 by Ministry of Health and Family Welfare, Government of India by making necessary amendments in the Drugs and Cosmetic Rules, 1945, regulating the price of blood and blood components.
11. To issue orders and directions to Union of India and State Governments to provide free and non- replacement blood in all Government health facilities including district hospitals, CHCs and PHCs.

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