

RIGHT TO HEALTH AS A FUNDAMENTAL RIGHT AND THE AVAILABILITY OF BLOOD TO CITIZENS

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This paper consists of two parts. The first section discusses 'Right to Health' as basic fundamental right existing in India after several judgments decided this in the affirmative. The second section explores the availability of blood to patients with regards to this right. With respect to the first part, 'Right to Health' is now a Fundamental Right in India. However, subjecting the concept of this right to the international arena reflects ambiguity. This is because international treaties and covenants refer to this right as one which should be extended such that the "highest attainable standard" of health is achieved. The uncertainty arises in determining this "highest standard". Bringing developed and developing countries at par is in itself a challenge due to their different economic potential and social systems, which put the citizens of the poorer countries at a relative disadvantage. In the second part, this paper attempts to explore the provisions regarding the availability of blood to its citizens in India. The WHO has also laid down rules for making available safe blood to all patients. Therefore access to blood is important under Right to Health. This implies that availability of safe, affordable blood should concur with the "highest standard" that Right to Health aims to achieve. However, laws relating to blood face considerable limitations in India. Despite the Supreme Court Mpassing guidelines and judgments to ensure access to safe blood for all, there is a significant shortage of blood in terms of quantity and safety. The National Blood Policy aims to provide safe blood transfusion services and has taken steps in this regard; however concrete laws or guidelines for transfusion remain absent. This paper also discusses banning of paid donors, enabling fluidity between blood banks and the efforts of NACO to ensure the efficiency of blood banks.

INTRODUCTION

One of the most prominent features of the Indian Constitution is the Fundamental Rights. These rights are an inseparable part of every individual which helps them live a free, equal, healthy and dignified life. There are six main Fundamental Rights granted to every citizen. Under these, there are several implied rights. Similar is the Right to Health under Right to Life and Personal Liberty as guaranteed under Article 21. Health constitutes an important asset for the economy as it can contribute in increasing the GDP of a country. The social importance of such a right is reflected in the fact that the Right to

Health, though originally mentioned in the Directive Principles of State Policy, on recognition of the significance of a healthy population, was elevated to be incorporated into the Fundamental Rights, with the aim of providing cheap and accessible healthcare to all citizens. However, according to WHO reports, despite an increasing GDP, India still spends only one percent of its income on healthcare.

However, Right to Health can be read as a broad term granting a wide ranging array of rights. But this is not the case. To decipher the meaning of this right, international statutes, treaties and covenants can be looked at.

RIGHT TO HEALTH IN INDIA: CONCEPT AND EXTENT

MEANING OF RIGHT TO HEALTH

This terminology may be interpreted in several ways. 'Right to Health' may be read as the right to remain healthy. However, this seems impractical as the state cannot be expected to ensure the good health of a citizen. Proposed alternatives to this term include 'Right to Healthcare', which may be a more specific right but might not be suitable for addressing the real problem in healthcare due to its specific nature.[1] But this phrase also encourages equal treatment for all, thereby promoting equality and justice. Hence 'Right to Health' encompasses multiple aspects; it can be interpreted as a broad right under which several benefits can be claimed. This can have both pros and cons. It may be beneficial for citizens who can see it as an expansion of their rights. However, such a broad right may expand the scope to an extent which may prove to be detrimental for the economy, state liability and burden on the judiciary.

RIGHT TO HEALTH IN THE CONTEXT OF INTERNATIONAL LAW

WHO defines 'health' by encapsulating 'state of complete physical, psychological and social well-being'. [2] The meaning of this right can be deciphered using other international sources as well. The African Charter on Human and People's Rights [3] aim for people to "enjoy the best attainable state of physical health". Convention on the Rights of the Child acknowledges "the right of the child to the enjoyment of the highest attainable standard of health".

Human Rights law under the United Nations obtains its source from two major treaties, namely the International Covenant on Civil and Political Rights (ICCPR) and the International Covenant on Economic, Social and Cultural Rights (ICESCR). [4]

Article 12 of the ICESCR entails that governments recognize "the right of everyone to the highest attainable standard of physical and mental health." It is a broad

right since 'health' includes several components like surgeries, treatments, medicines, doctor consultations etc. to ensure against both physical and mental ailments, as well as other determinants to which are essential to sustain good health, like clean water, housing, pollution-free environment etc[5]. It is therefore necessary to highlight the elements that are guaranteed under Right to Health in order to make them specifically enforceable while claiming a remedy under this right. Therefore, "highest attainable standard" indicates the duty of the state to provide this right to the maximum extent as a reasonable right rather an absolute right.

"Scholars have developed a sophisticated understanding of civil and political rights but have failed systematically to examine the meaning and enforcement of social and economic rights." [6] This may be due to the paucity of economic and human resources or the willingness of the state to emphasize on civil and political rights over socio-economic rights. However, recognizing health as a right allows it to be seen as a social necessity rather than a mere economic or legal issue.

"Highest attainable standard" gives scope for multiple aspects to be covered under it, and can allow citizens to demand for rights which they require to live a healthy and dignified life. A particular health service may have wider implications. For instance, the non-availability of blood to a cancer or thalassaemic patient can be life threatening. Hence the state must be duty bound to protect the lives of its citizens by providing safe blood to them.

RIGHT TO HEALTH IN THE INDIAN JUDICIAL SCENARIO

Prima facie, Right to Health may seem like an absolute right which compels the state to provide medical services at free or low cost as part of its duty since it is a Fundamental Right. Article 47 of the Directive Principles of State Policy enshrines that it is the "duty of the State to raise the level of nutrition and the standard of living and to improve public health." Several cases have decided that Right to Health is an inseparable part of Fundamental Rights.[7] The legitimacy of such a right can be derived from other such rights such as 'Right to live with Dignity' which is guaranteed under Article 21.[8] However, it has also been adjudged in other cases like Pt. Parmanand Katara vs Union of India & Ors [9], that Right to Health only has certain aspects which are undeniable, for instance, the right to emergency treatment. The state has a duty to provide treatment to patients in case of accidents and protect their Right to Health. However, it is not practical for the state to provide free or cheap medical aid for all types of procedures in the name of health, for instance, Botox or implants. It is realistic to consider the economic potential of the government and its ability to grant such rights. It may be concluded that social rights often prove to be

non-justiciable, despite their being recognized as part of the state's obligation under Directive Principles of State Policy, and certain aspects under Fundamental Rights.

SOCIAL RIGHTS AND STATE CAPACITY

Many social rights are enforced by countries like the South African constitution. It says that civil and political rights are provided completely where money does not have to be spent. But a 'margin of appreciation' is given to state in case of giving socio-cultural rights which require more resources. This situation can be compared to that of the United States ratifying ICCPR but not ICESCR. Hence these social rights are still enforceable but will not always provide remedy. A South African case[10] regarding AIDS patients asking for anti-retroviral therapy discussed the state's argument that due to limited economic resources and the expensive therapy, it is an enforceable right but will not always provide a remedy based on the capacity of the state. The economic state of the country will only allow the therapy to be administered to a few, which would deny others the Right to Equality. The court, conceding to the state, adjudged that this exclusion is unfair and the margin of appreciation should be applied in such situations.

Therefore, it is clear that socio-economic rights are often enforced by the state according to its economic capacity. This might be a flawed argument on behalf of the state, but financial resources do play an essential part in providing such rights which have an enormous monetary impact on the economy. It is observed that states provide civil and political rights more readily than socio-economic rights[11]. For instance, in India, the Right to Freedom of Speech and Expression under Article 19 was one of the first rights recognized as a Fundamental Right under the Constitution, whereas the Right to Education which used to be a Directive Principle of State Policy was incorporated as a Fundamental Right due to improving economic conditions of the country and well as the realization of its importance, as late as in 2010. The state, in providing cheap and accessible healthcare facilities to those who are sick, might violate the rights of many others who are healthy and require governmental assistance in something else, thereby denying the Right to Equality and the Right to Life to many citizens.

However, healthcare facilities and economic power are not necessarily inter-dependent[12]. For example, Sri Lanka and China have achieved the life expectancy of sixty-nine to seventy years, which is at par with that of higher-income countries.

EXTENSION OF RIGHT TO HEALTH WITH RESPECT TO AVAILABILITY OF BLOOD

"Highest attainable standard of health", as enshrined in multiple international treaties giving wider scope of

claims to people must also cover those which directly affect a patient's life. The General Comment under ICESCR imposes three main state obligations in terms of health, which are to respect, protect and fulfill human rights[13]. This read with the recommendations of the National Health Policy 2002[14] to increase the "affordability, availability and accessibility" of health facilities in India, call for providing important health related components in a manner which fulfill these criteria. Hence blood, being a direct determinant of the life of a cancer or thalassaemic patient, attracts state obligation to provide safe, affordable blood in a timely manner.

Common Cause v. Union of India[15], which upheld that the Right to Health is an integral part of Right to Life under Article 21, specifies the observations of the commission in terms of blood banks. They have suggested for uniform guidelines regarding establishment and functioning of blood banks. This implies the emphasis placed by the judiciary on the state obligation to provide safe blood to patients.

THE AVAILABILITY OF BLOOD TO PATIENTS THE BLOOD MARKET AND ITS LIMITATIONS

The Supreme Court has played a pivotal role in ensuring blood safety and curbing and unchecked blood market through proactive measures. In the landmark case of Common Cause vs. Union of India in January, 1992 the SC issued directive to make licensing of blood banks mandatory.[16] On January 1, 1998, the SC banned paid donation. However, the problem still persists.[17] There exists a huge "blood market" in India. According to AIDS Actionis a global, multi-million dollar industry exists in India. India, with its population of 1.2 billion people, needs 12 million units of blood annually but collects only 9 million.[18] This deficit provides professional donors and other middlemen with a conducive opportunity.[19] Investigative journalists have published accounts of illegal blood trade racket amongst major hospitals in the national capital.[20] Tehalka, did an investigative piece on this particular phenomena and published an article named "Blood thirsty".[21] They discovered the existence of "blood farms" in Gorakhpur, Bihar,[22] where sixteen people were locked up in the farm and forced to give blood every three day.[23] The Red Cross prescribes that donors should give blood only once every eight to twelve weeks.[24] Many licensed banks in India still accept professional donors. In 2013, the Indian Journal of Medical Ethics reported the existence of an unlicensed blood bank that transfused patients without testing.[25] Consequently, two children died and several others had contracted HIV.[26] The prevalence of professional blood donors is unfortunate. These people mainly belong to the lower strata of society and take it up as a profession. They do so by flouting standards and

regulations such as maintaining a certain interval between consecutive blood donations.

Organizations open blood banks with the primary objective of collecting and dispensing blood and not for storage purposes which is the need of the hour. Moreover, other institutions create blood banks as a foundation for commercial ventures like plasma fractionation.[27] Hospitals open blood banks because insurance providers allow them to charge higher for their services with a blood bank.[28] It is not surprising that they often compromise on the requirement for modern and specialized infrastructure, basic testing and etc.

DRUGS & COSMETICS ACT, 1945

The Drugs and Cosmetics Act, 1940 and Drugs and Cosmetics Rules, 1945 (D and C Act) form the skeletal legal framework for imperative regulations of blood banks in India[29]. The National Blood Policy (NBP) was adopted by the government in 2002 to develop a system for adequate and safe blood supply. In order to monitor quality and operations of the blood banks, the government established the Drugs Controller General of India (DCGI) at the center and Drug Controllers in the states[30].

Under Section 2(b) of Drugs and Cosmetics Act human blood is treated as a 'drug'. Whole human blood is included in the Indian Pharmacopoeia under Schedule C of the Act and the standards to be met by blood banks are given under schedule 'F' of the said rule[31].

With the classification of blood as a drug, the drugs controller became the regulatory authority[32]. Licensing is an elemental part for ensuring quality. The licensing procedure of blood banks is mentioned in the D and C Act 1940 and D and C Rules, 1945. But unfortunately, over the past decades, basic licensing standards for blood banks have remained unchanged apart from minor changes such as rising the age of donation from 60 to 65 years and recognition of transfusion medicine as a specialty[33]. Perhaps the only major amendment has been the guidelines for setting up blood storage centers. Dual licensing system by state and center has been acting as a deterrent, as the licensing procedure takes profuse amount of time[34].

Due to advances in transfusion science, it is apparent that this act needs revision. There is a need for clarity on the functionality of the blood banks. Moreover, this act only licenses procedures instead of products, such as single donor (apheresis) platelets (SDP), plasma and leukocytes and modified whole blood[35]. Licensing products would make the process of blood transfusion much efficient and safe as the blood banks would not need to seek special permissions for Apheresis and broaden the

umbrella of transfusion procedures[36] [37]. In addition to that, the D & C act allows only government blood banks, licensed blood bank run by voluntary or charitable organizations etc. to hold blood donation camps [38]. Limiting the type of institution that can hold blood donation camps can prove to be a counterproductive move when the state is aiming for higher voluntary blood donation.

BLOOD TRANSFUSION

Advancement in blood transfusion technology is not accompanied by similar advancement in transfusion law. This creates a vacuum between the legal and medical world affecting the patients and the quality of treatment, thus at large forming an issue under health rights.

Despite the availability of a number of consensus guidelines, inappropriate blood transfusion continues. At least 34% of blood banks are unlicensed. Nearly 50% of collection is estimated to be from paid blood sellers. Only 5% of voluntary donors are repeat donors.

In the absence of a legal authority empowered by the national blood law for enforcements of GMP and GLP in optimal quality of Blood Transfusion Services (BTS) will remain a mirage for us.[39] Moreover, transfusion transmitted infections (TTIs) is unsatisfactory and poorly regulated in India. We propose that a national blood law has to be passed in India that will address all these issues. It is imperative that blood is tested for TTIs in the donated blood.[40] The world has moved on from testing technologies to processing technologies but processing technologies, whereas even the basic TTI test does not mention in the D and C Act. Thus, as we have no standards whatsoever with regards to testing and processing technologies. Further, there are no audits by a competent technical body to ensure compliance with existing standards.[41]

Furthermore, the (D and C Act) does not mention patient informed consent, patient identification, and administration of blood or haemovigilance.[42] The requirement of informed consent for the process of blood transfusions is established as a legal directive by the National Consumer Redressal Forum in the case of M. Chinnaiyan vs Sri Gokulam which the "consent of the patient is required for transfusion of blood".[43] A documented method/protocol for positive patient identification is essential.[44] Absence of this may lead to wrong transfusions and may be construed as negligence on the part of the doctors.[45]

REGULATORY AUTHORITY

Today as it stands there are two separate bodies; the Drugs Controller and the National Blood Transfusion Council (NBTC) which play regulatory and advisory role respectively. The Drugs Controller, which is the

regulatory authority, oversees the Food and Drugs Administration. The NBTC, which is an offshoot of the National Aids Control Organization (NACO) was constituted in accordance with the Supreme Court directive in 1996. A blood bank technically comes under the purview of the regulatory authority overseeing Food and Drug Administration by the virtue of blood being a drug.[46] However, the infrastructural, instruments, spacing and workforce are monitored by the drugs controller effectively, the medical and quality aspects of transfusion medicine are neglected.[47] Moreover, the drug controller is already overburdened with drugs, devices and clinical licensing. Blood transfusion which is emerging as a field of its own should be regulated by a special agency well verse with the scientific knowledge of transfusion medicine such as the NBTC.[48] NBTC has played a proactive role in improving blood safety by infrastructure development, setting up component separation units, promoting voluntary blood donation, training staff and has also laid down standards for blood banks in India. Thus, the role of NBTC should not be limited to an advisory and policy making body[49].

IMPLICATIONS OF TECHNOLOGY

The business of blood banking has become an intricate balance of safety and efficiency. As they strive to perform safe blood transfusions laboratories are under constant pressure to optimize their operations[50]. In order to do so they need new generation technological solutions, that are intuitive, flexible and designed to be an extension of the laboratory's team. This reduces the potential for instrument downtime and prevents workflow interruptions. Ultimately, this paves the way for automated testing which can increase the capacity of the laboratory and operate more efficiently.

Furthermore, for a secure and effective clinical use of blood, well-equipped blood centres with adequate infrastructure and trained manpower is an essential requirement. The blood bank or BTS should have its own constitution, with explicated responsibilities and management authority[51].

The D and C Act does not allude to any of the upcoming testing technologies such as CLIA/NAT/ELFA, which have already been incorporated developed countries since half a decade[52]. The Indian BTS also lacks something as elementary as a centralized TTI testing system, a threshold recommended by the WHO, is not difficult to achieve but is imperative for improving blood safety[53]. Adding into that bargain, the processing technologies too have been precluded from the D and C Act.

For compliance and quality assurance we require ordered law for infrastructure and storage[54]. These are absent in many countries with the barriers to the implementation

of safe transfusion practices. Quality assurance is a legal obligation in mandating good practices in blood banks. Efficacy is intended by perpetuating guidelines that are needed to sustain licensing and accreditation standards[55]. Much amelioration seen in our country over the last decade and a half has been the consequence of licensing which laid down minimum requirements in terms of space, staff and equipment and also NACO's support for blood safety[56].

PROBABLE SOLUTIONS AND CONCLUSION

Considering the delicate balance between a healthy workforce and the growth of a nation, one of the most obvious solutions to better healthcare facilities in India is greater resource allocation, not only in terms of financing, but also infrastructure and planning. To ensure that this right reaches all in uniformity, meaningful decentralization is required. The Indian economy faces a paradox; despite being called the Pharmacy of the World, a majority of the healthcare expense of an Indian patient constitutes of medicines[57]. Hence to improve access, the government should distribute them to the public at low prices or free of cost. Public-private partnership in the healthcare sector might also prove to be beneficial[58].

Segregation of access to health services according to the nature of healthcare, gender and area is essential[59]. For instance, drawing out statistics determining preventive measures for HIV affected children in certain rural districts of a state is tedious but useful in deciding the distribution of resources. It is also essential to see the extent to which judgments by the judiciary with regard to Indian healthcare are followed and implemented in order to assess the accountability of the government.[60] Most importantly, implementing framework legislation, standard health guidelines adopting appropriate health indicators and resource allocations, establishing a uniform legal structure identifying issues of health and its position in India, and meting out remedies and accountability of judiciary in matters of healthcare is necessary. Health care can be made lucrative by taking measures which are preventive and not curative. This would involve raising awareness about health concerns, making research and policies more interactive and relevant to healthcare etc[61].

Blood transfusion is a bounteous act of ethical responsibility. One of the crucial and effective ways of resolving the blood scarcity issue and inhibit paid blood donations is through, the government encouraging voluntary donor by incentivising donation. The public must be made aware of the perks and exigency of donating blood. Incentives such as remuneration payable by the health insurance or tax-reliefs for regular donors can be offered.

One of the other ways, which many blood banking officials feel should be adopted to make the blood banking system efficient, is to centralise the whole system. A body such as central blood collection agency can be established. The objective should be to implement uniform standards of testing and different pricing structure. Accreditation, a peer review process could be an effective alternative wherever licensing is deficient but national guidelines are available.

The public-private partnership should be encouraged to ensure quality in testing and bring down cost and for future advancement in design. Gujarat is the best example for BTS in this direction.

There is a need for inspection and audits at frequent intervals.

Most cardinal of all, an apprised legal system would precisely ensure safety and benefits of both the donor and the recipient. The D and C Act should be reviewed at frequent intervals to keep up with the change in blood transfusion technology. A national blood law such as the NBT Act 2007 should be legislated which should prescribe specific punishment for blood transfusion related offence. Dual licensing should be abolished and the procedure for grant or renewal of license should be reappraised so as to finish off within three months. The blood law should corroborate provisions for better facilities in the BTS. Despite an abundance of measures there continue to be fatalities due to blood transfusion. A dedicated blood law might be a leap forward in this scenario

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