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Imperative Need of Conscripting a Legal Regime on Blood Transfusion

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Abstract

Hospitals, clinics and health care establishment while treating patients are at times required to suggest blood transfusion for various ailments, surgery and cases of accidents. Patients, relatives and attendants are required to fend for themselves due to absence of any comprehensive law and regulation mandating supply of blood through such establishments. The 2800 odd licensed blood banks do not have adequate stock as voluntary blood donations are yet to pick up in the country. Licensing too cane to be introduced after banning of the operation of unlicensed blood banks by the Supreme Court. Hence most of the blood comes either from friends and relatives of patients or commercial donors which may not be of high quality.

The endeavour of the author has been to address the issue of absence of a comprehensive legal regime to ensure hygienic collection, safe storage and supply of whole blood and blood components. The resolutions, guidelines and guidance documents of the World Health Organisation as well the National Blood Policy has been analysed in relation to the implementation agencies. The provisions of the Drugs and Cosmetics Act and the Clinical Establishments Act in relation to blood banks safe transfusion reveal the shortcomings and highlight the necessity of a specific law on this score.

Analysis of judgments of the Supreme Court and recommendations of the Consumer Forums reveal and reflect the current state of affairs in the shape of much avoidable harm suffered by patients either on account of transfusion of contaminated blood or negligence on the part of health care professions involved in the process. Such a measure can lead to promotion of safe and healthy blood transfusion by encouraging donors targeting at cent percent voluntary bold donation. It can also lead to measures at accountability.

Key Words*: Blood Transfusion, Contamination, Blood Policy, Legislation, Haemovigilanc.*

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I. Introduction

Medical science is an arena of fast paced developments across the global. During the past decade or so, path breaking developments have been witnessed in the field of medical research Yet, its outreach has not been uniform despite various efforts and initiatives. Emerging challenges have to be met with much alacrity in adherence to the regulatory bodies, be it at the domestic, regional and international level. At the tertiary level the World Health Organisation has been engaged with providing direction through guidelines and various instruments. However, initiatives at the domestic level matter the most.

The role of the WHO through policy initiatives and regulatory measures under the World Health Assembly are looked upon by member countries and the scientific community for guidance, technical support and cooperation. In the specific area of blood transmission or transfusion the WHO has been actively engaged towards providing an effective policy with a call to back up through effective legislative measures by all countries. This has been emphasised upon primarily attributed to the realisation that contaminated or unsafe blood is attended with the propensity of causing immense harm that may at times result in morbidity or mortality besides other forms of prolonged sufferings and surmounting medical bills. On the other hand, blood transfusion saves millions of lives besides improving the quality of life of many patients.

There is a propensity or possibility of atleast 50 percent morbidity or mortality in the event of failure to provide for blood transfusion[2]. Therefore, it is of significance to note that blood transfusion is generally resorted to in many instances as a life saving intervention, either to replenish blood loss arising out of surgery or accident. Besides, situations may arise necessitating blood transfusion due to other factors.[3] Transfusion besides saving lives can help

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**The present article is primarily based on the ongoing research work on " Facilitating the Right to Health Through Patient Safety" and the author has liberally taken recourse to her work.

[2] Nabajyoti Choudhury, *Transfusion transmitted infections: How many more*? Asian Journal of Transfusion Science, Asian / transfusion Sci. 2010 Jul; 4(2):71-72. doi: 10.4103/0973-6247 67017
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2937299 accessed on 30.4.2021 at 9.13 pm.

[3] Anemia, bleeding disorder, sickle cell disease.

restore functioning of vital parameters leading to recuperation of a patient. Therefore, transfusion in adequate measure has to be resorted to for achieving optimum results. It has been observed that at times it is taken recourse to in order to boost deficit blood components.

Before venturing into such policy framework, it is considered pertinent to delve into the ground reality in the context of India, since the article intends to revolve around the domestic developments, including law, guidelines and policy parameters. It is expected that this would throw light on ground reality relative on the extent of safe blood transfusion, it being an important parameter of patient safety. The need for safe blood transfusion stands unquestioned and assumes paramount importance. Despite such realisation the situation depicts a different picture, hence the present endeavour.

II. The Situation of Scarcity and Market Factors at Play

It is very much common for attendants of patients and relatives to encounter situations in health care establishments to meet urgent requirements of adequate blood supplies or components thereof when called upon by such establishments to do so. They often need to fend for themselves, at times very desperately at extremely short notice to provide for such matching whole blood supply or components like plasma, red blood cells and platelets when called upon to do so to save the lives of their near and dear ones or to be prepared at times for surgeries or other medical interventions. At times attendants are called upon to replenish blood provided by hospitals, because whenever provided by such medical establishments and clinics they do so on the undertaking that the emergency supplies are replenished, purportedly on the ground that such establishments are woefully short of requisite blood groups in their blood banks.

The plight of patients and attendants get all the more accentuated as many among them are unable to provide the same also on account of lack of equitable access. The Covid situation is a case in point where attendants in many cases after frantically searching and managing the requirement for plasma therapy realised that their efforts came to naught for want of matching supplies. Though the precarious situation more or less came to be witnessed across jurisdictions, the state of affairs under normal circumstances too reflect the sorry state of affairs in many jurisdictions including India. The helpless and shocking state of affairs are not far to seek. These are attributable in the main to the woefully

short supply of whole blood and blood components compared to the high demand. Against rising demand there is a shortfall in supply attributed to lack in knowledge of the benefits of voluntary blood donation and the immense benefit that accrues to suffering humanity. Though accurate estimates are difficult to be had, the scarcity, more particularly among the countries of the South are very much well known. According to WHO of the 118.5 million blood donations globally, the high income countries that account for 16 percent of the total population contributes upto 40 percent .[4]Against the ideally desirable 3 percent donors in the underdeveloped countries, hardly . 5 percent of the population happen to be donors, that too accounted for by family members of replacement donors.[5] Shortage of available blood is due to lack of adequate number of donors as well as want adequate safety measures .This is accentuated by the short shelf life of blood that ranges between 35 to 42 days.

Such a state of affairs places attendants in a very delicate situation at the mercy of private players and touts who very often fleece their customers. Many a time they fall prey to professional donors, most of whom fail to provide healthy blood. The situation has been aggravated primarily on account of two factors; namely want of an effective law and policy and presence of touts and unscrupulous persons linked with the illegal trade. The latter, partly attributed to the lack of awareness about the need for blood donation as donors are far fewer in the country compared to the first world.

While foraying into the pertinent issues, the present endeavour has been to address the issue of blood transfusion in a holistic manner so that the primary concern of patients of receiving proper treatment are met through zero harm. This in the process of blood transfusion so that it does not imperil the lives and livelihood of patients and their dependants. In this regard, apart from addressing the concerns, emphasis is being laid on ensuring the guidelines of the Supreme

[4] Factsheet, WHO Blood safety and availability, dated 10 June, 2020.
http://www.who.int/newsroom/factsheets/detail/blood-safety-and-availability
accessed on 31.5.2021 at 9.26 pm.

[5] Risks and complications, American red Cross, One in two
, https://www.redcrossblood.org/donate-
blood/blood donation process/what happens to donated-blood/blood-transfusions/risks-complications.html
accessed on 3.5.2021 at 5.15 pm.

Court[6] focusing on strict compliance of procedure towards ensuring safe and healthy blood of high quality and the need to robe in blood transfusion either through a comprehensive law on patient safety or an exclusive enactment as called for by the WHO.

III. Implications of Blood Transfusion

It is evident from the above that blood transfusion involve the infusion of either whole blood or components thereof to a needy patient's bloodstream. At times instead of drawing blood from another person it may be drawn from the patient, prior in point of time, which is known in medical parlance as autologous transmission. Here it involves subsequent reinfusion. Such blood administered through a patient's vein takes time depending on the component administered.[7] Whether it be whole blood or components thereof as mentioned above, extreme care and precaution is required to be taken in the process of transfusion taking into consideration any possibility of mismatch of the RH factor[8] which is required to be avoided. Hence it is of utmost importance to ensure that facilities of blood transfusion are made available, ensuring easy accessibility of safe blood in highly hygienic conditions. Blood transfusion is normally regarded as safe, and as such the procedural formalities are required to be adhered to. However, as briefly mentioned above, contaminated whole blood or components thereof may lead to severe problems which may result in avoidable harm. All measures at ensuring safe transfusion to patients assume utmost significance as severe consequences may visit a patient in case of any lapses on account of safety measures. Hence administration of safe blood of high quality in compliance with the procedural requirements[9] has to be taken up with right

[6] Common Cause v UOI and Ors, AIR 1996 SC 929.

[7] An unit of plasma may take between half an hour to one hour for administration whereas the time required for transfusion of an unit of red blood cells roughly takes double the time https://www.who.int/bloodsafety/transfusion_services/ClinicalTransfusionPracticeGuidelinesforMedicalInternsBangladesh.pdf ACCESSED ON 3rd.July.2021 at 7 25 pm.

[8] An Rh factor is a protein found on some red blood cells (RBCs). Not everyone carries this protein, though most do. They are **Rh-positive**. People who don't carry the protein are **Rh-negative**. https://kidshealth.org/LAWW/en/parents/rh.html accessed on 3rd. July.2021 at 8 pm.

[9] All possible care and precaution has to be adopted to do away with any mismatch to avoid any sort of antibody resistance.

earnest to avoid any possibility of infection that may lead to transmission of virus, bacteria and parasitic infections agents[10] as well as sepsis. At times minor complications may occur for which the administering professional and para-medics are required to adopt corrective measures which may include stopping further transfusion . These may be occasioned by allergies, acute haemolytic reaction or fever, mycrocardial infection and renal failure.[11]

Such infection may be occasioned either through administration of contaminated blood or at times due to lack of resistance of one's body. Blood banks are required to filter such blood before being certified prior to transfusion to patients. In fact the magnitude of the problem can be gauged from the fact that upto 2 recipients per thousand get infected on an average.[12] Hence thorough examination of blood and blood products through strict procedural formalities as mandate is considered essential. The problem stands compounded and actuated accounted for by asymptomatic carriers in the shape of window period infection donors[13] which are said to occur either during or within 24 hours of transfusion or even thereafter. It has been recorded that " despite advanced technology use, particularly since the 1940s, the risks of infection cannot be undermined, as seen from several cases of pyrogenic reaction , HIV,[14] Hepatitis B[15] and C[16] and Cytomegalovirus (CMV) infected persons in different parts of the world, particularly transfusion associated Leishmaniasis[17]. Chinkungunya and West Nile virus into the immune compromised recipients leading to protective antibodies.[18]The issue of infection again came to the fore in case of SARS 2 and COVID 19.The present endeavour has been to address the legal

[10] Supra n 1.
[11] Sriparna Rakhowa, Facilitating the Right to Health Through Patient Safety (unpublished Ph.D thesis), 102.
[12] Supra n 1.
[13] Fever allergic reactins, pruritus, or auticaria or shortness of breath and red urine.
[14] Risks and complications, American red Cross, One in two .
, https://www.redcrossblood.org/donate-blood/blood donation process/what happens to donated-blood/blood-transfusions/risks-complications.html
accessed on 3rd Feb.2021 at 5.15 pm referred to in Supra n 9, p 102.
[15] Ibid, One in 3,00,000.
[16] ibid, One in 1.5 million.
[17] Prevalent in South Asia.
[18] Supra n 8.

issues and the prevailing state of affairs to ensure an adequate legal regime pertaining to safe blood transfusion. Yet it may be mentioned by way of passing reference that much depends on the progress achieved by the scientific community. Advances in science have undoubtedly been achieved but there remain certain identified issues that are yet to yield results like those of "alloimmunization to various blood components, those related to cold chain maintenance, platelet refractoriness, transfusion (iron) overload, transfusion associated graft versus host diseases (GvHD), immunomodulatory effects, etc."[19]

Towards this end implementation of certain criteria by way of creation of a database of reporting by donors as well as identification of recipients as adopted by the WHO would go a long way in providing for an effective mechanism.[20]

IV. Efforts of WHO in Promoting Safe Blood Transfusion

Before addressing the country situation it is considered apposite to briefly look at the efforts undertaken by WHO in promoting safe blood transfusion. Two important parameters related to blood donation as identified by WHO.These happen to be blood screening and blood processing., but the capacity of low income countries to process blood is much lower compared to high income countries. When it comes to separation into different components they account for only 37 percent as against 97 percent in high income countries.[21] It has been revealed that 54 percent of countries lack in an effective surveillance system.[22]Towards an effective policy it has called upon to adopt sustainable blood and plasma programmes and development of hospital transfusion committees in order to improve the safe transmission through universal access to safe blood and blood products. Towards this end it has encouraged effective

[19] Ibid.
[20] Department of Blood Safety and Clinical Technology of World Health Organization.
[21] www.int/ news-room/ factsheet /bloodsafety and availability. 10.6.2020 accessed on 22nd April.2021.
[22] Id.

cooperation, adoption of ethical policies besides legislation and regulation.[23]The key areas identified[24] include:

- appropriately structured, well-coordinated and sustainably resourced national blood systems;
- regulatory capacity to ensure the quality and safety of blood;
- functioning and efficiently managed blood services;
- effective implementation of patient blood management to optimize transfusion practices;
- effective surveillance, haemovigilance and pharmacovigilance, supported by comprehensive and accurate data collection systems;
- partnerships, collaboration and information exchange to achieve key priorities and jointly address challenges and emerging threats at global, regional and national levels.

Measures at ensuring supply of safe and compatible blood transfusion through adequate precautions and measures by the WHO have met positive dividends. Towards this end, it has impressed upon the member countries to facilitate effective collecting, testing and processing and distribution.[25] Pursuant thereto it has called for adoption of national bood policy and legislative measures. It has received encouraging response[26] from different countries as can be gauged from the fact that two thirds of the responding countries have indicated of the presence of such a blood policy with 64 percent putting in place legislative measures. Aspects of transfusion practices and blood services form part of on an ongoing (2020-2023) action framework which *inter alia* provides for access to safe blood banks.[27]

The ongoing process of WHO has been developed through identification of blood safety as one of the key priority issues. The theme 'Blood Saves Life:

[23] Id

[24] *https://www.who.int/news/item/26-02-2020-who-steps-up-action-to-improve-access-to-safe-blood accessed on 2th.April.2021* at 6 pm.

[25] Supra n 14.

[26] World Health Assembly resolution WHA63.12.

[27] WHO Action framework to advance universal access to safe, effective and quality assured blood products 2020-2023, https://www.who.int/news/item/19-02-2020-who-action-framework-to-advance-universal-access-to-safe-effective-and-quality-assured-blood-products-2020-2023accessed on 3st Mar..2021 at 10.38pm.

Safe Blood Starts with Me.' It was adopted two decades back, on the occasion of world health day precisely in the year 2000.

V. The Situation in India

India, a country with her teeming millions requires a robust health care system to be put in place. However, the allocation of resources leaves much to be desired. With her public health system much in need of improved infrastructure, many patients have to fall back upon the private sector that comprises about 70 percent of the health care establishments. In such a scenario it becomes all the more imperative to ensure good practices, particularly with regard to uncontaminated blood transfusion. This is all the more essential as till date no form of substitute or alternative exist with regard to blood transfusion. Blood transfusion provides life support, hence it should be made available and accessible

As stated before, such supplies being grossly inadequate in view of the very high demand, the need for a comprehensive policy backed up by an effective legal regime is all the more necessary. Without a vibrant system, that includes adequate number of licensed blood banks having adequate infrastructure with proper procedures in place, the possibility of illegal and unfair practices exist. People desperately in need of urgent supplies either of whole blood or components thereof can often be at the mercy of dubious laboratories, their personnel and touts who are on the lookout for exploiting helpless patients and their attendants and relatives. Strict adherence to procedures becomes all the more necessary since any form of negligence or lapse may result in innumerable sufferings, prolonged treatment resulting in avoidable escalated costs besides the possibility of morbidity even leading to mortality. Hence ensuring an effective system in place is regarded as absolutely vital, rather indispensible.

Besides existence of physical infrastructure the personnel involved and engaged in the blood transfusion process requires to be infused with proper knowledge and training. They should be able to handle cases of unexpected reactions as well. Besides ensuring proper patient identification, emphasis should be laid on safe transfusion therapy through integration and coordination of multiple

hospital services that requires setting up of hospital transfusion committee tasked with oversight of transfusion safety.[28]

VI. Patient Consent prior to Blood Transfusion

The prime requirement of any health care professional is to inform the patient on the need for transfusion. This is necessary to obtain his consent based on his understanding of the benefits and attendant risks. Religious belief and practices too have to be taken into account. Here the issue of patient autonomy comes to the fore as it is for the patient to decide whether to opt from blood transfusion if such a patient is in a position to provide such consent. It becomes the duty to provide the reasons in detail and obtain a written consent if possible in the presence of witnesses. However while treating a patient for oesophageal variances, the physician has to arrange for blood in advance. Such blood has to be requested from recognised blood banks. In respect of transfusion in congestive cardiac failure resort has to be to transfuse packed blood cells.

A case in point that some people strongly invoke relates to the Jeovah's faith.[29] Though it does not pose much of an issue in India, in the United States it has very major ramification when the need for blood transfusion arises.

VII. Law and Policy

Till date the country lacks in a specific law on blood transfusion though the Drugs and Cosmetics Act deal with it in a certain measure. Hence in the said context the scenario in the country is being addressed in the following paragraphs.

As stated hereto fore, there was much slackness on the part of the government till such time the apex court issued a set of guidelines pertaining to blood banks in terms of its judgment in the Common Cause case. The judgment set in motion certain measures that have witnessed regulation of licensed blood banks[30]

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[28] Walter H Dazik et.al. *patient safety and blood transfusion: new solutions.* Transfusion Medicine Reviews, Vol 17 ,. 169-18 https://www.sciencedirect.com/science/article/abs/pii/S0887796303000178?via%3Dihub accessed on 3Rd April,.2021 at 6.22pm.

[29] Such people hold the belief that blood transmission is proscribed due to their interpretation of the Bible. They believe that injecting blood is prohibited by religion.

[30] On an average each of the blood banks caret to about three per 10 lakh population.

which have to operate under challenging circumstance of high demand on account of shortage of safe and quality blood to the extent of 1.95 million units.[31] This brings to the fore the scenario of patients inability to obtain safe blood for transfusion even when it happens to be the only source of their survival. The situation of distress is compounded by the fact that unlike many other jurisdictions, where hospital authorities are tasked and mandated to manage blood transfusion in case of need, the situation is not so in India. Therefore it becomes the responsibility of patients , attendants and individuals to scout for the same. Even when they find sources the quality cannot be guaranteed as many a times these are from professional donors. Here, for want of voluntary blood donors not only the supplies are very much inadequate but the quality of available supplies remain much to be desired. Matters stand compounded due to transfusion transmitted infections despite the functioning of the centralized Hemovigilance Programe[32] under the National Institute of Biologicals.[33]

A. National Blood Policy

Due to the directions of the apex court as well as the policy guidelines of WHO, the National Blood Policy was adopted in the year 2002.However, public health being a state subject the existence of dualism has at times put on checks to the detriment in the uniform advancement of the policy. Another draw back has been the lack of enforcement and compliance due to the voluntary nature of the policy , hence proper supply and utilisation of human blood and blood products' besides availability, safety and quality that remain the prime mandate of the WHO cannot be vigorously pursued. To that extent enforcement needs to be geared up followed by adoption of effective legislative measures.

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[31] ET HeathWorld, Oct 14,2020,20:29IST. https://health.economictimes.indiatimes.com/news/industry/towards-achieving-safe-blood-transfusion-for-all-prof-bejon-misra/78664621 Accessed on 31 Jan.2020 at 10.58 pm.

[32] Its very aim of is to improve transfusion safety.

[33]chemiluminescence (CLIA) enzyme-linked florescence assay(ELFA) are increasingly being used by blood banks cited in Alvarez M. Chueca N, Guillot V,Bernal, MdelC, Garcia, F. Improving clinical laboratory efficiency: Introduction of Systems for the Diagnosis and Monitoring of HIV infection, Open Virol J.2012:6:135-43,[PMC free article] [PubMed] [Google Scholar] accessed on 3.Feb.2021 at 7.56 pm.

The policy is considered to be of much significance in the health delivery system since it addresses the issue of Blood Transfusion Service aimed at eliminating transfusion transmitted infections. It aims at effective clinical use of blood through trained personnel. Towards this end, good manufacturing practices and quality management have been stressed upon identified through the set of the following eight objectives.[34]

1. To reiterate firmly the Govt. commitment to provide safe and adequate quantity of blood, blood components and blood products.
2. To make available adequate resources to develop and reorganise the blood transfusion services in the entire country.
3. To make latest technology available for operating the blood transfusion services and ensure its functioning in an updated manner.
4. To launch extensive awareness programmes for donor information, education, motivation, recruitment and retention in order to ensure adequate availability of safe blood.
5. To encourage appropriate clinical use of blood and blood products.
6. To strengthen the manpower through human resource development.
7. To encourage Research & Development in the field of Transfusion Medicine and related technology
8. To take adequate regulatory and legislative steps for monitoring and evaluation of blood transfusion services and to take steps to eliminate profiteering in blood banks.

These are to be strategized through National Blood Transfusion Council, National AIDS Control Organisation besides providing for licensing it prohibited trade in blood with the ultimate aim of voluntary non remunerated donors. Maintenance of minimum standards through strategized quality schemes have been introduced. It has further been promoting transfusion medicine including research and development through related technology. Although in terms of the policy, regulatory measures have been adopted, legislative measures are yet to be on the envil.

The country has at present about 2800 licensed blood banks most of which are small in size, hence of limited capability. Further the need of trained manpower very much remain.

[34] Objectives of Quality Management .

The judiciary has form time to time through various judgments shed light on the level of adequacy of blood transfusion services. Though pursuant to some landmark judgments, the National Blood Policy has been adopted the country is yet to come up with a comprehensive law on the issue.

VIII. Judicial Gloss

The judgment of the Supreme Court in the Common cause[35] case can be regarded as a landmark decision delivered by the apex court. The issue of contaminated blood transfusion was taken up by HD Shourie through a writ petition wherein the court issued a set of 18 guidelines *inter alia* directing the State to set up a National Blood Transfusion Council to be registered as a Society along with State Councils. The intention behind was to promote voluntary blood donation so as to achieve the twin objectives of ensuring adequate supply of healthy blood and facilitating transfusion of safe blood. Towards regulating the growth of unlicensed blood banks it issued a direction to the government to close down all unlicensed blood banks within a period of two years. This has been done to obviate the malpractices and other deficiencies in the operation of blood banks.

The National Consumer Disputes Redressal Commission in *Mrs 'S' v. Dr Mohan Gerra*[36] disposing of an appeal against an order of the Maharastra State Commission, held the doctor responsible for providing blood transfusion without informed consent, resulting in her being infected with HIV. The Forum found the action of the doctor to amount to deficiency in service. The facts of the case are that the appellant following labour was provided with four units of blood transfusion which on ELISA test was found to be HIV I and II positive, though she was tested negative prior to delivery. She breasts fed the infant who too turned out to be positive.

Earlier, the Supreme Court in "*PGIMER v. Jaspal Singh and Ors*,[37] in disposing a Special Leave petition by PGIMER, Chandigarh against a decision of the National Consumer Disputes Redressal Commission concurred with the commission affirming their order relating to payment of compensation. The case arose out of an accidental burn injury suffered by Smt Harjit Kaur, wife of

[35] Supra,n. 6
[36] Supra n11, 111, FA No. 138 of 2008.
[37] (2008) 7 SCC 330.

Jaspal Singh. The lady having A positive blood group was administered B positive while under the supervision of Dr. Kulshastra, Senior Resident Doctor, after being initially transfused the right blood group. This led to severe complications, including a fall in her haemoglobin and rise in urea level, besides causing damage to her kidneys and liver that ultimately resulted in her death. The defendant doctor while admitting of blood mismatch denied negligence on his part in administering mismatched blood transfusion, contending that the patient suffered from septicaemia which resulted in her death. The court considered it to be a case of medical negligence resulting in administration of transfusion infection and dismissed the Special Leave Application."[38]

IX. Legislative Framework

"A legal regime pertaining to patient safety bears immense significance as it extends to providing a framework in the arena of blood transfusion services. Such a measure can ensure an effective and enforceable transfusion mechanism It has to be kept in mind that resolutions and guidelines of WHO, as well as the National Blood Policy have envisaged and voluntary blood donation targeted more specifically in promoting an infection free blood bank service. Such a measure can promote and standardize an effective blood bank system, among other things through grant and renewal of license for operationalisation and regulation of such services following set international standards. The present blood bank policy does not permit blood banks operating in the hospitals to conduct camps for collecting blood from voluntary donors. Consequently, they mostly rely on replacement donations from relatives and family members of recipients. Moreover, these banks still await permission to open storage centres, these being the preserve of Regional Blood Transfusion Centres. In fact, many of the hospital based blood banks have been set up to meet requirements of insurance companies and for meeting reimbursements eligibility requirements of international insurance claims. Therefore a comprehensive and effective legal system requires to be put in place for ensuring an efficacious mechanism, that can lead to quality, exhibiting high standards."[39]

In India in the absence of an exclusive law on blood transfusion the establishment of blood banks are being facilitated through Rules adopted in

[38] Ibid.
[39] Ibid.

1945 under the Drugs and Cosmetics Act, 1940 (as amended), a pre-independence law where blood has been classified as a drug under the law.

The relevant provision, namely Section 2 (d) of the Drugs and Cosmetic Act, 1940 and section 18 thereof provides for issuance of license along with provisions for penalty under Section 27 (b) (ii). Section 33 enables the framing of Rules under the Act. "The Drugs and Cosmetic Rules initially framed in 1945 has been extensively amended from time to time, particularly with regard to provisions relating to safe blood collection and storage in 1996, and 2001 providing for the functioning and operation of blood banks. Yet, shortcomings have been noticed like lack of punitive action for professional blood sellers till introduction of such measure, providing for penal action under the national blood policy. Supplies reagents are provided for under the Rules,[40] besides ensuring good manufacturing practices.[41]However, a conjoint reading of the Act and the Rules are a reflection that accommodation of the recent technological developments have not been brought within the ambit of the law. For instance, chemiluminescence or nucleic acid testing (NAT)[42] find no mention in the Act.[43] So too, 'products like pooled platelet concentrates or modified whole blood, therapeutic procedures like erythropheresis plasma exchange, stem cell collection and processing technologies like leukoreduction and irradiation are not a part of the Act[44]."

"Blood transfusion calls for a highly safe clinical and regulatory mechanism to be put in place, with adequate infrastructure, qualified and trained manpower to deal with manufacture, processing and scientific storage. An analysis of the said legislation reveals the lack of any effective mechanism towards safe transfusion.

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[40] Drugs and Cosmetics Rules 1945, Schedule F, Part XII-B --- Clause I make mandatory to maintain all records to facilitate their checking and functioning of the blood banks.

[41] ibid, Schedule F, Part XII-B-KG).

[42] is mandatory and regularly used in many countries like New Zealand Australia, Egypt, Israel, Japan, South Korea, Singapore, Hong Kong, Thailand, Malaysia, Indonesia, South Africa, France, Denmark, Greece, Italy etc Supra,n.29.

[43] S.Chandrashekar & A. Kantharaj , Legal and ethical issues in safe blood transfusion, *Indian Journal ofAnesthesia,*Volume 58(5): Sep Oct2014, https://www.ncbi.nlm.nih.gov/pmc/issues/246312/ accessed on 3.2.2021 at 7.29 pm.

[44] Supra n 11, 112-13.

Of course, the national blood policy adopted in the year 2002, following the WHO recommendations and WHA resolutions, has laid down provisions for protective measures through 'informed consent, patient identification and administration of blood or haemovigilance."[45] This has been done through facilitative terms towards improving blood transmission services and transmission medicine. In this regard the role of the National AIDS Control Organisation is considered important. It has laid down certain safety measures in respect of safe blood donors apart from safe blood issues, but is yet to be permitted to address safe transfusion.[46] Yet, along with the National Blood Transfusion Council and Blood Safety Technical Resource Group, it has formulated guidelines facilitating blood safety infrastructure and transfusion medicine including supervision during transmission."

Similarly, "the Clinical Establishment (Registration and Regulation) Act 2010 that has been applicable to all recognized systems of medicine is a step in the positive direction. Adopted in the year 2010 it came to be notified on the 28th February, 2012. Presently the Act has been adopted by 11 states and six union territories. Some states have passed their own health laws similar to the Act. It aims at setting up of minimum standards of treatment protocols[47] towards achieving quality health and bring diagnostic centres and investigative services within its ambit. Enabling provision for adoption of Rules is provided for under section 52 and 53. Recently, Rules have been framed to specify minimum standards for human resources in respect of diagnostic laboratories.[48] The earlier

[45] PS Dhot, Amendments to Indian drugs and cosmetics act and rules pertaining to blood banks in armed forces. *Med J Armed Forces India*. 2005;61:264-66. [PMC free article] [PubMedGoogle Scholar].

[46] Supra n 11, p 113 Access to Safe blood, NACO, http://naco.gov.in/access-safe-blood accessed on 2.Feb.2021 at 9 am.

[47] OPERATIONAL GUIDELINES FOR CLINICAL ESTABLISHMENTS ACT. http://clinicalestablishments.gov.in/WriteReadData/2591.pdf accessed on 6.feb.2021 at 1.39pm.

[48] Supra n 11, p 113 Clinical Establishments (Central Government Amendment Rules, 2020 (Amendment in part III a) in respect of human resource minimum standards for Medical Diagnostic Laboratories (or Pathological Laboratories)].

Rules had been amended in 2018 providing for aspects of biochemistry and Haematology amongst others.[49]

X. **Conclusion**

The brief analysis undertaken so far highlight the need for enactment of legislative measures incorporating certain aspects mentioned above. In fact they can be considered a dire necessity to replace the adhocism resorted to. Enactment of a law can certainly facilitate a holistic approach leading to regulation of centralized testing to protect Transfusion Transmitted Infections besides giving a fillup to the process of monitoring transmissions as per guidelines followed globally.[50] Furthermore, it would be ideal for any such legislation to consider the situation in respect of Jehovah's Witnesses as they refuse transfusion of whole blood as well as the components.[51] The existing legislations in other countries can certainly provide a leeway and basis for formulation of an enabling legal regime in the country.

The author is of the view that such an Act and Rules there under can provide for a legal regime through an established framework. It can also hedge in provision for safe processing and storage of whole blood and segregated products leading to safe blood in the hands of the administering professionals.[52] Yet it has to be acknowledged that the process of transfusion presents possibilities of infection. Hence such process has to be handled with utmost care in highly sanitized hospital settings, with all necessary precautions being religiously followed by the administering professionals, including nurses and other health care workers, leading to lower incidence of transfusion transmitted infections. Such a law should also contain provisions relating to elective transfusion in case of minors. Furthermore it should facilitate monitoring as per established international standards, procedures and mechanisms leading to meticulous adherence ,

[49] Gazette of India, Notification No. G.S.R. 468(E) dated 18 May, 2018.
[50] A M.Hurris, CLI Atterbury ,B. Chaffe .C Elliott , T Hawkins SJ. Hennem , et al. Guideline on the Administration of Blood Components. British Committee for Standards in Hematology. 2009. Available from http://www.bcshguidelines.com/documents/Admin_blood_components_bcsh_05012010.pdf. accessed on 3.2.2021.
[51] P.Frati M..Arcangeli ,.*Faculty of Care and Self-Determination of Patient*, Torino: Medical Minerva: 2002 ISBN-13 978-88-7711-412-9.
[52] Supra n 11, 115.

facilitating prompt action by adequately trained, qualified and competent personal in the event of any adverse reaction.[53] Enactment of a dedicated law would go a long way in the promotion of safe blood transfusion services though quality management laboratory practices, leading to quality assurance in the country. A more ambitious but effective way out would be to include various aspects of patient safety into a comprehensive law rather than treating different aspects as silos.

It has to be acknowledged that a law in itself may not prove to be a panacea removing all shortcomings. The law apart, advances in technology including artificial intelligence has to be incorporated to put to effective use. Clear communication with adequate monitoring and reporting has to be facilitated and developed, as many a case of adverse reaction through transfusion results from miscommunication. Resort to healthy laboratory practices can also reduce possibility of infection.[54]

In the ultimate analysis, in order to promote safe and healthy blood transfusion, total voluntary blood donation should be the objective. This would ensure regular database of donors who can be fallen back upon in case of emergencies besides ensuring increase in stock of whole blood. Presently there is a demand for permitting unbanked direct blood transfusion as provided for in some countries. The matter is pending before the apex court, that should result in effective directions for implementation. Nevertheless, adequate safeguards are required to be put in place else it may run counter in reducing transfusion related infections. The flaws in the prevailing system calls for identification and elimination to remove blood transfusion impaired issues related to blood banks besides factoring other issues of contamination and other impaired issues aimed at promoting patient safety.[55]

[53] Ibid n 11, 115.
[54] Ibid.
[55] id