The quest for an Indian blood law as of blood transfusion services regulatory framework

Ranabir Pal, Sumit Kar, Forhad Akhtar Zaman, Shrayan Pal

Abstract:
Background: Blood transfusion services are a vital part of the national health delivery system. The responsibility for ensuring a continuous supply of blood rests with health administrators, who need to galvanize entire communities towards regular and non-remunerated blood donation. Objective: The present study aimed to examine the prevailing global regulations and practices related to blood transfusion and press the case for a dedicated blood law in India. Materials and Methods: We attempted a comprehensive, annotated assembly of published studies on blood transfusion services in India. Data Abstraction and Synthesis: Laws related to blood transfusion services exist in India as a part of the Drugs and Cosmetics Law. In the developed world, most blood donors are unpaid volunteers who give blood for a community supply. In order to augment safe blood transfusion services in India, we have to develop operational legal guidelines on recruitment and retention of voluntary blood donors to direct related organizations for this imperative activity. Conclusion: Several factors, such as political will and a professional and ethical approach can help in formulating a common vision, building trust, by providing optimum information towards a social movement for the rational blood transfusion services. We have to come together for a dedicated blood law in order to improve the quality of blood transfusion services in India.

Key words: Blood law, India, Drugs and Cosmetics Act India

Introduction

The World Health Organization (WHO) has identified blood safety as one of seven priority areas. The theme of the World Health Day for 2000 was ‘Blood Saves Life: Safe Blood Starts with Me.’ The member countries of the South-East Asia Region (SEAR) recognized blood safety as an important issue. It is one of the 13 chosen areas where WHO has requested to accelerate technical cooperation.

Concerted efforts have been initiated by WHO to assure blood safety, especially in developing countries, to improve the availability and quality of blood. It has been observed that health professionals in the SEAR countries were not well versed with the principles and practice of quality blood transfusion services (BTS). Accordingly, Quality Management Project (QMP) is being implemented from 2001 in all the regions of WHO to introduce/strengthen quality in all aspects of BTS, with the broad objective of improving the safety, adequacy, and quality of blood. One of the important components of QMP is capacity building in quality management training to improve the skills of BTS professionals in assuring the quality of its services and products. WHO has developed a generic curriculum for this training, which was modified to suit the needs of the member countries of SEAR and field tested in a regional workshop held at Bangkok, Thailand, from 26 March to 13 April, 2001. A national Quality Management Training (QMT) course was conducted in India in October 2001. A meeting of state program officers for blood safety was organized to sensitize them about the QMP and the utility of QMT in assuring quality, safety, and adequacy of blood.[1]

Laws related to BTS in India are a part of the Drugs and Cosmetics Law. From the age of 18 years onwards, i.e., upon reaching the age of majority, any donor is eligible to sign the donor registration card in India and donate blood. In developing countries, where stored blood in blood banks is limited, people usually donate blood when a family member or a friend needs a transfusion. Potential donors are evaluated for any condition that might make their blood unsafe for use. How often a donor may donate blood varies from days to months, depending upon what they donate and the laws of the concerned country.

In the WHO report for South-East Asia it was revealed that the BTS in the member countries of SEAR are in varying stages of development. Against an estimated annual requirement of 15 million units of blood only around 9.3 million units are collected. Voluntary non-remunerated donations constitute 40%-93% of the total donations, the proportion varying from country to country. Paid donors continue to be a major source in Bangladesh.[2]
In the developed world there are laws to regulate blood transfusion and continuous scientific research is ensured for quality and safety of blood products and the transfusion services. Blood transfusion is an important mode of transmission of infections and the risk can be immensely reduced by pre-donation counseling.

Against this backdrop, we designed this study to examine the prevailing global regulations and practices related to BTS and argue for the implementation of a dedicated national blood law in India to regulate BTS at the grassroot level.

**Materials and Methods**

**Study period**
July 2008 to June 2010.

**Data collection**
We attempted the comprehensive, annotated assembly of survey results from different sources: Published surveys and field studies which examined BTS in India, presentations at various meetings, and personal communications about recent surveys that had not been published as yet. Through an extensive search in indexed literature and website-based reports, we identified 250 potentially relevant articles related to the BTS in India. All articles published between 1960 and 2007 in indexed journals available from institutional library and web sites on BTS in India were included in this study. Studies were identified by searching PubMed and abstracts of scientific meetings (1985–2007). Citations and reference lists were reviewed to identify additional eligible studies. The search terms included ‘blood transfusion service’ and ‘blood law’. Where possible, the sources were contacted for further information on survey data that was not available in the public domain. Manual searches were conducted to identify relevant review articles and previous meta-analyses. When necessary, we contacted the authors for additional information or for translations from languages other than English.

**Selection criteria**
In the absence of universally accepted criteria for reporting of BTS in India, we included all reports for our study.

**Data abstraction and synthesis**
BTS is a vital part of the health care service. Advances in the field of transfusion medicine and technology have made it necessary to enforce measures to ensure quality of blood and blood products. Blood transfusion services made major move ahead in donor management, storage, testing for transmissible diseases, and rational use of blood. Voluntary blood donation remains the foundation for a safe and good-quality BTS as non-remunerated blood donors are considered to be safer. New principles of safe handling, cost and administration of blood components have impact on blood safety with the growing concern for apt utilization of blood products. Despite availability of a number of consensus guidelines, inappropriate blood transfusion continues. The BTS does not exist in isolation. It is an integral and indispensable part of the National Health Service. Without blood transfusion, effective management of severe trauma, major elective surgery, and serious obstetric complications is not possible, as it is an essential part of the infrastructure.

Before donation the prospective donors are screened with the medical history and a short physical examination to make sure donation is not hazardous to donor’s own health and testing for transfusion transmitted infections (TTI) in the donated blood. The principles of good manufacturing practices (GMP), developed for the guidance of the pharmaceutical industry, are ever more tailored for the production of labile blood components and plasma fractionation. The Commission of the European Communities introduced nine basic requirements and principles for blood transfusion services.

In order to improve the standards of blood banks and the BTS in our country, the National AIDS Control Organization (NACO), through the Technical Resource Group on Blood Safety, has formulated comprehensive standards to ensure better quality control in the collection, storage, testing, and distribution of blood and its components. For quality, safety, and efficacy of blood and blood products, well-equipped blood centers with adequate infrastructure and trained manpower is an essential requirement. For effective clinical use of blood, it is necessary to train clinical staff. To attain maximum safety, requirements of good laboratory practices (GLP) and GMP to attain a total quality management is vital for organization and management of the BTS. The blood bank or BTS should have its own constitution, defining the responsibilities and authority of the management.

We require ordered law for infrastructure and storage for compliance and quality assurance. These are absent in many countries with the barriers to the implementation of safe transfusion practices. Screening and safe storing blood requires trained and motivated personnel with classy tools and consumables. Quality is intended by safe blood and its components, reagents, and services provided with simple practical guidance and standards that are needed to sustain licensing and accreditation standards. Quality assurance is a legal obligation in mandating good practices in blood banks. Updating the rules maintain a uniform approach for the self-sufficient supply, product quality, transfusion safety.

AIDS pandemic has helped us realize the value of safe transfusion service that is an expensive endeavor and colossal challenge for developing countries with limited resources. The honorable Supreme Court of India has taken up the issue of blood safety by banning paid donations in 1997 and has ordered the establishment of an autonomous National Blood Transfusion Council and State Transfusion Councils.

In India, an improved transfusion service is required 10 percent of the collected blood is available for component separation, and all donated blood units are not screened for TTI. Testing for TTIs is unsatisfactory and poorly regulated in India. Reporting of adverse events after transfusion is poor and no stringent donor deferral system exists. The acute medical services could not exist without blood transfusions as it is life-saving treatment in many situations. But transfusions can also be a quick and easy route for the transmission of infectious agents such as HIV, HBV, HCV, and malaria. A review of the current scenario in transfusion medicine (TM) in India indicates an urgent need for restructuring the BTS that is hospital based, with extreme variations in management and technology. Compliance with quality assurance and GMP is not ensured. In spite of legislation, 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. Under the Blood Component Separation Unit (BCSU) scheme NACO has modernized 130 component separation units. NACO also
supports 10 model blood banks. Besides, there are the corporate sector blood banks, which have high-tech equipment. WHO has set up a blood safety policy that encourages member countries to establish their own national blood transfusion policies supported through its Global Program on AIDS and the Global Blood Safety Initiative. However, any blood safety program can only succeed with political commitment.[13]

A major problem plaguing blood banks is poor monitoring and control because of the multiplicity of agencies involved. Blood and blood products are under the regulatory control of the Drug Controller (General) of India, the central licensing authority, which is assisted by the State Drug Controllers. What we need is a truly autonomous agency manned by competent people from the blood transfusion sector. This agency should have branches in all the States. The Supreme Court in its 1996 judgment had asked the government to consider the advisability of enacting legislation to regulate the collection, processing, storage, distribution of blood, and the operation of blood banks. This is yet to happen, though, as directed by the Court, the government has set up a National Blood Transfusion Council as the apex policy-making body for BTS. Subsequently, State Blood Transfusion Councils were also set up. But these bodies have an advisory role only and exercise no control over the blood banks. These various bodies are in addition to the Drug Controller General of India. This multiplicity of authority has resulted in poor monitoring of blood banks. But more than any legal or bureaucratic measure, what is really necessary is achieving 100% voluntary donation - a goal highlighted by the government’s plan of action in pursuance of the national policy on blood transfusion to improve the blood safety in clinical practice.

In India, human blood is covered under the definition of ‘drugs’ under Section 2(b) of Drugs and Cosmetics Act and the blood banks are imperatively regulated under this Act. The license for operating a blood bank be granted by the state and central licensing approving authorities.

Whole human blood is included in the Indian Pharmacopoeia under Schedule ‘C’ of the Drugs and Cosmetics Rules. The standards that have to be met by blood banks is given under schedule ‘F’ of the said rule. These are also indicated in British Pharmacopoeia (BP), United States Pharmacopoeia (USP) and Food and Drug Administration of the United States of America (US-FDA). So a license is vital for blood transfusion under Section 18 (c) of the said Act. Any person who collects blood meant for transfusion without license is liable for penalty under Section 27(b)(ii) of the said Act.[14]

The Drugs and Cosmetics Act, 1940 and the Rules thereof provide the legal framework for regulating the functioning of blood banks. The government adopted the National Blood Policy (NBP) in April 2002, to develop a system to ensure an adequate and safe blood supply. The establishment of the Drugs Controller General of India (DCGI) at the center and Drug Controllers in the states is to ensure quality and to monitor the functioning of blood banks. The NBP envisages technical training in transfusion medicine and encourages the use of current technology for BTS; it even provides for a corpus of fund to be used for research and development in the field of transfusion medicine and related technology.

The NBP aims to ensure an easily accessible and adequate supply of safe and quality blood and blood components collected/procured from voluntary non-remunerated regular blood donors in well-equipped premises; the blood should be free from TTIs, be stored and transported under optimum conditions. Transfusion under supervision of trained personnel for all who need it, irrespective of their economic or social status, through a comprehensive, efficient, and total quality management (TQM) approach will be ensured under the policy.[15] Recruitment of safe donors is a challenging task. It is necessary that people realize that blood donation is their duty to society. No blood bank, hospital, or government can sustain health care without adequate blood from such donors. Blood donor organizations play a crucial role in this endeavor. In order to improve voluntary blood collection through a comprehensive program, an operational guideline was released by NACO. To operationalize the NBP, NACO had formulated an action plan which calls for a multi-agency response involving government, private sector, universities, the Indian Council of Medical Research, the Medical Council of India, NGOs, the Indian Red Cross Society, and others. Unfortunately, against a blood collection target (annual) for National AIDS Control Programme Phase – III [2006-2011] (NACP-III) of 10000000 units, only 4532395 units were collected in 2007.[16]

Legislation in blood transfusion services in developed countries

In France there are rules and regulations for blood product transfusion. The clinician will ensure informed consent from the recipients, immune hemato logical tests, and prescribe with precision the quantity and quality of products and record preserved for 30 years to guarantee the transfusion security.[17]

The US FDA finally amended the biologics regulations in the Federal Register in 2007(72 FR 45883), by updating specific regulations applicable to blood products to be more consistent with current practices in the blood industry.[18]

The law of the European Community (EC) applies to medicinal products, medical devices, blood, and tissue preparations. In Germany, the requirements were set forth in the EC Tissues and Cells Directive was implemented within the national legal framework incorporating the sanction of Medicinal Products Act, Transplantation Act, and Transfusion Act.[19] We have to go for in-depth analyses of these rules and regulations for blood product transfusion that can be put into operation in our country. Further, the concept of the Public Private partnership (PPP) has gained inroads in the primary health care delivery in India. In order to gain insight for future advancement in design, implementation, and management of quality BTS we hope PPP model will serve to help us reach grass root levels of health care system in India.[20] Gujarat is the best example for BTS in this direction.

In India there is a national blood policy and the NACO is working hard to improve BTS in India, but there is still no national blood law. In the absence of a legal authority empowered by the national blood law for enforcements of GMP and GLP in optimal quality of BTS will remain a mirage for us. We propose that a national blood law has to be passed in India that will address all these issues.

The strength of this study was that we have touched over a sensitive as well as neglected issue that has long been not addressed well. We have discussed prevailing laws, regulations, and grass-root level practices of BTS and blood donation practices, with special
reference to the scenario in India and analyzed the current scenario in the BTS in the absence of a dedicated blood law in India.

Limitations of the study
Of the 1800 blood banks in India, 60% are run by private parties and NGOs. This hampered our data collection. First, we are not confident that we have collected the entire available data for compilation. However, we feel that, given the resource constraints, the approach used in this study is a cost-effective means of acquiring information and our data should be substantially more representative of the ground situation than that provided by the either general impressions of individual workers in the field or in-depth studies of individual blood banks. Another limitation was that, despite our best efforts, we could not retrieve the blood laws and state of affairs of BTS in the neighboring SEAR countries.

Future directions
A few questions need to be answered. How much blood is transfused? Who are the beneficiaries? Why do health care personnel prescribe blood products? Substantial data exists in answer to the first question, and some data exists regarding the second. The answer to the third question is the real key to the control of blood utilization. We have sincerely shared our views on the prevailing legal aspects that regulate the BTS in India and hopefully go on with our work till our mission will be achieved regarding dedicated blood law in India.

Conclusion
Blood transfusion is an altruistic medical act of ethical responsibility. The blood law would ensure that health care personnel provide both donor and recipient all necessary and updated information on BTS at all times. An updated legal system will precisely encourage more people to become regular donors.

The information, education, and communication (IEC) system must be strengthened. Advertisements to motivate the personnel provide both donor and recipient all necessary and updated information on BTS at all times. An updated legal system will precisely encourage more people to become regular donors. The information, education, and communication (IEC) system must be strengthened. Advertisements to motivate the public must be informed of the importance of saving life on clearing the myths and misconceptions about blood donations. The public must be informed of the importance of saving life through blood donation. A blood insurance scheme may be started. Non-monetary incentives, such as issuance of certificates of recognition, can be used as a motivating factor to improve voluntary blood donation. The law will have to ensure provision of better facilities in the BTS. Increasing awareness about the advantages of blood donation, not only for the recipient but also for the donor himself, could possibly encourage voluntary donation.

We have to unite and raise our voice in the demand for a dedicated blood law to improve the quality of BTS.

References
1. Quality Management Training in Blood Transfusion Services in India. Report of a National Meeting of State Program Officers of

Pal, et al.: Indian blood law

Indian on Blood Safety Shimala, HP, India, 19- 20 July 2001/ WHO Project: ICP BCT 001. Retrieved from http://www.searo.who.int/en/Section10/Section17/Section58/Section330_961.htm. [cited in 2010].
2. Blood Safety and Clinical Technology. Available from: http://www. searo.who.int/en/Section10/Section17/Section1976.htm#blood. [retrieved on 2011 Feb 26].
3. Kim DU, The quest for quality blood banking program in the new millennium the American way. Int J Hematol 2002;76:258-62.
4. Mathai J, Sulochana PV, Satyabhanam S, Nair PK, Sivakumar S. Profile of transfusion transmissible infections and associated risk factors among blood donors of Kerala. Indian J Pathol Microbiol 2002; 45:319-22.
5. Joshi GP, Landers DF. Audit in transfusion practice. J Eval Clin Pract 1998; 4:141-6.
6. Britten AB, Fereydoun, FH, El-Nageh MM. Blood transfusion a basic text; World Health Organization, Regional Office for the Eastern Mediterranean Alexandria, Egypt: 1994. p. 6-9, 63.
7. Wagstaff W. GMP in blood collection and processing. Vox Sang 1998;74(Suppl2):513-21.
8. Standards For Blood Banks and Blood Transfusion Services. National AIDS Control Organisation. Ministry of Health and Family Welfare. Government of India, New Delhi: 2007.
9. Slopecki A, Smith K, Moore S. The value of Good Manufacturing Practice to a Blood Service in managing the delivery of quality. Vox Sang 2007;92:187-96.
10. Chevrrole F. Quality assurance in blood transfusion [Article in French]. Ann Pharm Fr. 2002;60:318-25.
11. Ray VL, Chaudhary RK, Choudhury N. Transfusion safety in developing countries and the Indian scenario. Dev Biol (Basel) 2000;102:195-203.
12. Kapoor D, Saxena R, Sood B, Sarin SK. Blood transfusion practices in India: Results of a national survey. Indian J Gastroenterol 2000;19:647. Comment in: Ibid 2000;19:51-2.
13. Koistinen J. Safe blood: The WHO sets out its principles. AIDS Anal Afr 1992;2:4,6.
14. The Gazette of India: Extraordinary, Ministry of Health and Family Welfare, notification GSR 28(E), 22 Jan 1993.
15. National Blood Policy (India). Available from: http://www.naco. nic.in. [cited on 2010 May 31].
16. Voluntary Blood Donation Programme: An Operational Guideline. National AIDS Control Organisation Ministry of Health and Family Welfare. Government of India, New Delhi: 2007.
17. Péli ssier E, Bierling P. What are the rules and regulations for blood product transfusion in France? [Article in French]. Rev Prat 2009;59:90-2.
18. Revisions to the requirements applicable to blood, blood components and source plasma; Confirmation of effective date and technical amendment. Direct final rule; Confirmation of effective date and technical amendment. Food Drug Administration, HHS. Fed Reg 2008; 73:7463-4.
19. von Auer F. The implementation of European directives into national law, demonstrated by the example of the EC Tissues and Cells Directive 2004/23/EC [Article in German], Bundesgesundheitsblatt Gesundheitsforschung Gesundheitsschutz 2008;51:757-63.
20. Pal R, Pal S. Primary health care and public-private partnership: Indian perspective. Ann Trop Med Public Hlth 2009;246-52.