

LEGAL AND ETHICAL ISSUES CENTRAL TO THE TRANSFUSION MEDICINE: AN INDIAN SCENARIO

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In modern era Blood Transfusion has become a massive need both for the health care services and for the population also. But in developing countries like India the practical scenario of the society, proved Blood Transfusion services as unavoidably unsafe and inherently dangerous activity. This study attempts to draw a picture describing various risk or challenges involved in the procedure of blood transfusion. Along with the risks of affecting bodily safety of the patient, some legal and ethical challenges also exists on the part of the doctors, technicians and health service providers while using this health care technology, for example, a competent adult patient might refuse blood transfusion due to reasons such as religious belief, fear of adverse reaction or cost. What would be responsibilities of the health care providers in such situations? He should obey the legal rights of the patient or should follow the medical ethics etc. The purpose of this vignette is to analyze the legal and ethical challenges associated with transfusion medicine as well as to evaluate the suggestions given by many in order to make transfusion medicine an effective health care service in India.

Keywords: Blood Transfusion, risks, law, ethics, informed consent

INTRODUCTION

Among the eight vital life-saving mediations in health care services, blood transfusion service is also considered as one of them (Mishra, Sachdev et.al., 2016: 19). It is a technological invention in medical science where blood is transfused to a patient through an intravenous (IV) line in one of his blood vessels. The medical practitioners used to apply this technology to replace blood lost due to any serious bodily injury or during surgery or if the body becomes unable to make blood properly due to an illness (National Institute of Health, 2017). The trend of the modern era of blood transfusion coincided with Second World War and subsequently it becomes the massive needs among the populations (Alter and Klein, 2008: 2617). American Medical Association recognized overworked five medical treatments such as ear tubes, cardiac stents, and induction of birth in pregnant women antibiotics along with blood transfusion. But at the same time it also tinted about needless transfusion. US Blood Shield Laws considered blood transfusion as “unavoidably unsafe and inherently dangerous” (Goodnough, 2013: 1791).

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Although blood transfusion safety has been increased in European Countries, (Farrel, 2006: 155) USA etc. but in India the scenario is different. Even today also it seems that there are so many risk associated with blood transfusion services in India and as because of implementation of expensive blood tests, tolerance of blood transfusion risk seems to be very low among the patients (Kramer *et al.*, 2017: 32).

RISK ASSOCIATED WITH BLOOD TRANSFUSION

With the developments in component separation, cellular techniques and integration of molecular methods, blood transfusion services in India has accomplished a newer elevation (Pahuja *et al.*, 2017:6). But, increased frequency of blood transfusion has at the same time enhanced the risk in recipient's life, for example, errors in blood transfusion, such as ABO incompatibility which can cause serious harm to patient including death or major morbidity (Watt *et al.*, 2016), a developmental mismatch in hemostasis by transfusion of adult donor plasma should be considered a risk factor for pulmonary hemorrhage (PH) patient (Usemann *et al.*, 2017:1619) etc. To lessen the risk of transfusion reaction, ABO and RhD group of the donor's red cells including Anti-A and Anti-B antibody titers from blood group O are directed to be tested before transfusing it to recipients (Paul *et al.*, 2016:66). Other transfusion menaces endure, including human error resulting in the inadvertent transfusion of incompatible blood, acute and late transfusion reactions, transfusion-related acute lung injury (TRALI), transfusion-coupled graft-versus-host disease (TA-GVHD), and transfusion-induced immunomodulation (Alter *et al.*, 2008:2617). Specific donor screening valuates and other interventions have minimized, but not eliminated, infectious disease transmission. Along with various risks associated with the process of blood transfusion, HIV transmission through blood transfusion, specifically among the first-timer donor rather than the regular and lapsed donor, in hospitals in India is becoming one of the most precarious issues now-a-days (Maryam *et al.*, 2017:135). In developing countries like India, up to 10% of HIV infections results from transfusion of blood or blood products which is extremely high in comparison to the developed countries where viral transmission from contaminated blood or blood products is extremely rare. Donations in developing countries causes thousands of infections as up to 45% of donations are not screened for HIV, HCV, and Hepatitis B etc. (Weinberg *et al.*, 2002: 312).

Among 2574 AIDS cases in India reported by 1996, almost 232 cases were infected only because of HIV –infected blood transfusion. While there is zero incidence of risk of HIV contamination through blood transfusion in countries like US, UK, Canada and Australia, in India 2,234 people were contaminated in HIV through blood transfusion in between October 2014 and March 2016 and in last seven years 14,474 people infected HIV through blood transfusion only in India.

As per India HIV Estimation Report 2015, after Nigeria (34 lakhs) and South Africa (68 lakhs), India has occupied third position having number of people living with HIV (21.17 lakhs) and among them, about 2, 11700 people are infected with HIV due to blood, blood products, surgical instruments and needles. In response to the Right to Information (RTI) petition filed by Chetan Kothari, an activist, National AIDS Control Organization (NACO) reveals the total number of cases filed by patients infected with HIV through blood transfusion in such States, such as in UP-361, Gujarat-292, Maharashtra-276, Capital Delhi- 264 cases (Foreign Policy News, 2016). In 2013-14, 2014-15 and 2015-16, a total of 85 people in Mumbai had reported contracting the HIV infection through blood transfusions (The Hindu, 2016). During 2011-2012 total numbers of 136 patients infected with HIV through blood transfusion in the State of Karnataka. Hence, it was estimated that 95% of the blood supply here was not safe. Many blood banks in India are closed for supplying HIV infected blood to the hospitals (Weinberg *et. al.*, 2002: 312).

With the introduction of new blood product screening in the mid-1980s, HIV transmission through blood transfusions became rare in the developed world. To maintain and manage an effective transfusion service an expensive endeavor is compulsory which is not a big issue for the developed countries, but at the same time it is a challenge for the developing countries with limited resources and other priorities (Ray *et. al.*, 2000: 195). Hence, contaminated blood is still a significant source of infection in the developing world. A survey conducted by the WHO indicates that the percentage of safe blood donor uppermost in a system where number of voluntary and non-remunerated donors are exists, and it was estimated that in developed countries 85% donors are voluntary and non-remunerated, but in developing countries only 15% donors are voluntary and in less developed countries it is only 7% (Gibbs and Corcoran, 1994: 377). To meet the targets of voluntary blood donation in developing countries, it is necessary to provide donor information, motivate and extent education among the public specifically the high school children ((Mishra, Sachdev *et. al.*, 2016: 19).

The primary reasons for inadequate blood testing are the cost of test kits and reagents and the unreliability of supplies. Blood safety would be improved by more appropriate use of transfusions and the provision of alternatives such as saline and colloids. In India, there are 576 laboratories accredited in accordance with the Standard ISO 15189: 2012 and 2545 licensed blood centers to certify blood and blood components. In terms of the Standards for Blood Banks & Blood Transfusion Services prepared by NACO, various tests such as Viral Hepatitis A, Hepatitis B (HBs Ag), Hepatitis C (anti-HCV) are carried out on every unit of donated blood and classified according to its ABO Blood group and Rh (D) type to detect blood-borne infectious disease including HIV before transfusion to the patient. But in actual practice, these standards are not followed by the blood banks, clinicians or

medical practitioners carefully. Sadly, the Drugs and Cosmetics Act, 1940 is also silent about advance processing technology such as NAT, CLIA, ELISA etc. (Chandrashekar and Kantharaj, 2014: 558) even a few centers in India issued NAT screened blood (Marwaha, 2010:68). The National Thalassemia Welfare Society reported that around 6-8% of Thalassemia patient are infected with HIV through blood transfusion because those patients are found to be transfused blood without any testing. The situation in rural areas in comparison to urban areas is much more depressing where patients are transfused blood without any testing even directly from the donor. Several authors point out both the technology and technologist inadequacies as a reason behind the failure of blood transfusion services (Naidu *et. al.*, 2016).

Other problems include insufficient blood supply (e.g., none of the less developed and only 9% of developing countries collect 30 units or more per 1000 population per year) and inadequate quality assurance in all aspects of preparatory testing (Times of India, 2016). In order to meet the growing population, there is an urgent need for the developing countries to upsurge blood availability also (Williamson and Devine, 2013: 1866). The Supreme Court of India in 1996 banned paid blood donation and allowed for the implementation of a system of “replacement donors” to promote altruistic donation. But practically, when a patient needs multiple units of blood and they are unable to arrange multiple donors, then the situation push them to turn to touts and force them to take help from ‘professional donor’ in the name of ‘replacement donor’ (BBC News, 2015). According to a report prepared by World Health Organization (2012), while the need is for 12 million units in India for the population of 1.2 billion, only 9.3 million unit of blood has been collected annually, so that India faces shortage of three millions of blood units. Women with pregnancy complications, children with severe anemia and trauma victims in India are adversely affected by this shortage of blood supply. Due to post-partum haemorrhages about 25000 women are dying every year (Ramani *et. al.*, 2007). Recommendations are given by many to transfuse blood in limited situations only e.g., risk of dying if blood transfusion denied (Adejuyigbe *et. al.*, 2003: 329).

Another risk associated with blood transfusion is wrong blood transfusion due to the negligence of the medical professionals. As per the standards prescribed by the NACO, it is the responsibility of a specially organized blood transfusion service for selecting and testing donors and then makes preparation, quality control and stores the blood products. Transfusion laboratories in local hospitals will match the product with the patient before transfusing it to the patient and clinician exerts little control over the laboratories.

(Case study: The concerned Doctor of SBD Hospital in U.P. negligently sent wrong report of patient blood group to the hospital’s blood bank. The blood bank without performing the proper compatibility testing of the blood such as grouping and cross-matching, issued as prescribed by the concerned doctor. B (+ve) blood

was transfused to the patient Neelam Gupta whose blood group was actually B(- ve) as a result her every pregnancy from 1988-1994 was resulted into fetal loss i.e. death) (Dr. Anil Kumar Mittal vs. Smt. Neelam Gupta and Ors.)

The Supreme Court of India stated that wrong blood transfusion is that error which no doctor/hospitals would have made while exercising ordinary care. Such an error cannot be considered as error in professional judgment, because it is a sure instance of medical negligence (P.G. Institute of Medical Education and Others vs. Jaspal Singh and Others). Life of a person is precious and if it is lost because of the negligence and carelessness of the health practitioners (either government or private) it is a very serious matter.

LEGAL AND ETHICAL ISSUE IN TRANSFUSION MEDICINE

Doctors, technicians and health service providers face several legal challenges while discharging their professional responsibilities towards the patients. Sometimes, ethical and psycho-social issues baffle both doctors and patients.

Informed consent is a process indicating provision of necessary information about the expected benefits and prospective risk of accepting or rejecting hemotherapy to the patient or to the care-taker (Kajja *et. al.*, 2011: 33). The principles of Nuremberg Code (1947), the Declaration of Helsinki (1964) and the Belmont Report (1979) encompass the concept of informed consent in it. (Nijhawan *et. al.*, 2013:134). Respect for human rights and self-sufficiency of patient require obtaining informed consent before any medical intervention otherwise liability would be arise on the part of the medical practitioner even if there is no deficiency has been occurred on his part. (Malette vs. Shulman, Goodnough and Shuck, 1990: 602).

[Case study: After completion of a hysterectomy operation in Gokulam Hospital, Madras, a lady was transfused two units of blood without taking any informed consent neither from the patient nor from her relatives. After 4 years of the transfusion, the lady developed recurrent loose-motions, respiratory infection, weight loss and difficulty in swelling etc. On being tested she was found to be HIV positive and a symptom of AIDS was detected. One year later she developed left-sided hemiparesis, oral candidiasis and TB. She was diagnosed with glioma of the brain and finally died.] (M. Chinnaiyan vs. Sri Gokulam Hospital And Anr)

The National Commission of Chennai while dealing with this case held that it is the duty of the concerned doctor to inform the patient or his relatives/friends about the benefits, risks associated with blood transfusion or alternatives if any before transfusing. Here, deficiency in service on the part of the doctor arises as without taking any informed consent, blood was transfused to the patient negligently by the concerned doctor. The United States Courts of Appeal also affirmed that before initiating an operation or other course of treatment the doctors must pursue for his patient's informed consent (Canterbury vs. Spence). The general rule is that, a medically competent and conscious patient has right to decline life -saving

treatment by refusing the urgent need of blood transfusion advised by doctors even in emergency situation. It has been adjudicated that a competent adult patient has the right to refuse blood transfusion irrespective of whether his refusal arises from religious belief, fear of adverse reaction or cost. (Ram Gopal Varshnev vs. Lasor Sight India Private Limited & others).

[*Case study: An operation was needed to stop upper gastrointestinal bleeding of the patient. The patient gave assent for surgery, but denied for blood transfusions. The hospital authority solicited the Court for an authorizing order for blood transfusion by stating that to undergo the necessary operation without a blood transfusion was equivalent to suicide and accordingly a violation of penal law. The Court denied the hospital's petition by stating that the patient was competent and capable to give informed consent and he has right to decide whether to go through the specific medical treatment or not.*] (Erickson vs. Dilgard).

But if the patient refuses to take blood transfusion, it might create ethical hardship between patient's autonomy to reject transfusion even in crucial situation also and a physician's duty to provide optimum treatment (KiranChand *et. al.*, 2014). For example, if an unconscious patient in a potentially life-threatening condition is urgently in need of blood transfusion, but he or she is carrying a card opposing blood transfusion in any circumstances because of religious belief, a doctor would be liable for administering blood to the patient on ground of battery even though the treatment was executed with a high degree of skill and for the well-being of the patient (St. Mary's Hosp. vs. Ramsey). While treating an unconscious patient in emergency situation, medical practitioner faced greater complication while the treatment required blood transfusion. This situation is particularly onerous in cases in which the family members of unconscious patient's reveal that for religious belief the patient is opposed to blood transfusion and the family will also not give the necessary consent. In this situation majority of courts have appraised the clinical standard (Chandrashekar and Kantharaj, 2014: 558) under which the transfusion is permitted if it is clear that the patient is not competent to make healthy decisions and if there is a danger of being die without the blood transfusion. Jehovah's witnesses believing on their religious persuasion choose standard medical care but by refusing blood transfusion. Even in Japan, a court case upheld 'the patient's right to take decision' as patient's personal right. The advancement in health care services, transfusion alternative treatments made it stress-free to adopt bloodless surgery and medicine (Ariga and Hayasaki, 2003:72) e.g. ruptured chronic type B aortic dissection can be safely repaired on bypass through a left thoracotomy with no blood transfusion if the preoperative Hb value is >10.0 g/dL (Yamamoto *et. al.*, 2012:11). Again another alternative namely homologous blood transfusion, although can reduce the legal, ethical and moral dilemmas, still it is associated with risks like bacterial contamination chances, hemolysis, misidentification etc. (Deb, 2001: 268).

There are various ethical issues and challenges inherent on the part of the health worker in the implementation of the blood transfusion system, such as at the time of scheming and operating the transfusion procedure, it might be unethical not to consider either amplification of efficiency or cost saving and thus they are sometimes failed to provide 'personal care' to the patient. Sometimes conflict arises between law and ethics even, for example if the medical practitioner is in legal obligation to disclose the confirmed HIV positive test to the relevant public health authority, at the same time it might be unethical for them to disclose the information according to medical ethics (Somerville, 1998: 162).

Again, another important issue which causes medico-legal problems is inappropriate maintenance of medical records for which both the medical practitioner and patient had to suffer. Patient and their relatives are unprepared to face the adverse reactions specifically death due to blood transfusion, and if this happens the doctors used to face cry against him. Sometimes due to lack of evidence a patient or his relatives failed to prove negligence on the part of the doctor. In order to solve these types of crisis all the fact and informed consent of the blood transfusion should be recorded by the hospital authorities for a reasonable period of time as per the laws of the land, e.g. in France these types of records are kept for 30 years (Herbich, 1976:437). Some authors feel it safer to have a neutral witness in case of high risk transfusion case such as autoimmune haemolytic anemia (Chandrashekar and Kantharaj, 2014: 558).

Blood Transfusion is always a matter of risk even though it is advised by the medical practitioner and all the prescribed standards are adopted in the process of transfusion by them, still there might be a possibility of infection. So that many scientific societies such as the Society of Clinical Care Medicine, the American Society of Anesthesiologists, the American College of Physician, the American Association of Blood Banks and the British Committee for Standards in Hematology etc. published momentous guidelines for the use of blood transfusion (Yaddanapudi and Yaddanapudi, 2014: 538).

Blood transfusion services in India are a part of the Drugs and Cosmetics Act, 1940 and the Drugs and Cosmetics Rule, 1945. Section 2(b) of the said Act defines blood under the definition of 'drugs' and the blood banks are also compulsorily administered under this Act. This Act mentioned about indispensability of a license for a blood bank, penalty for blood collection for transfusion without having a license and the standards that have to be followed by the licensed blood bank etc (Pal *et. al.*, 2011: 171). National AIDS Control Organization (NACO), and National and State Blood Transfusion Councils were established for ensuring safe and adequate blood transfusion services in India. The Government of India adopted the National Blood Policy in 2002 which aims at ensuring easy accessibility and adequate supply of safe and quality blood and blood components collected from Voluntary and non-remunerated blood donors (Nair and Mammen, 2015: 749).

But in absence of strict applicability of these policies, still there are numerous mushrooming unlicensed blood banks exist in India. A study reveals that in India 60% of blood transfusion take place due to anemia, 42% is due to surgery, and 26% for acute hemorrhage and 16% is for pregnancy. 74% of adult blood transfusions are going on inappropriately without following the government transfusion guidelines and the possible nearby reason for these inappropriate transfusions are due to unnecessary transfusion for volume replacement and for iron-deficiency anemia cases (Bray *et. al.*, 2003: 17).

Safe blood supply is dependent on government funding blood banking services, blood volunteers and experts who supervise the whole blood transfusion procedure such as blood collection, testing, storage and supply. Along with it there is an urgent need for adequate observation of commercial blood supplies (Mortimer, 1991: 1). As 'Blood money' has been a controversial topic specially, in Third World and developing nations (Poza and Del, 1994: 31). Although measures have been adopted to abolish trade in human blood in various countries, still blemishes do exists. Blood banks are secretly functioning in some parts by selling and buying blood while in other parts continue to make profit by imposing huge sums of money in the name of "testing fees" (Ashok Naik vs. Union of India through Secretary)/The Supreme Court of India in 1996 banned paid donation and make it's mandatory to have a legal license to run a blood bank. In India, total 2760 numbers of licensed blood bank providing services to the patient, but unfortunately the Government has no statistical data about the mushrooming growth of unlicensed blood banks existing in India.

CONCLUSION

To reduce the risk in blood supply specifically in developing countries the WHO has expanded a global approach which includes regimented and nationally co-ordinated transfusion services with quality system, blood collected from voluntary and non-remunerated donors only and worldwide collaboration for blood safety measures (Dhingra and Hafner, 2006: 200). Some changes are required in this provision in India for the protection of the blood recipients, such as the hospital who prescribe the patient for blood transfusion shall take the responsibility of obtaining or collecting blood for their patients through their confederation with licensed blood banks. However, the State is hopeful that through conviction, dedication, enthusiasm, perseverance among the donor motivators and organizers within the transfusion service or from outside can eliminate the commercialization in blood banking, of course, with adequate support from the Government. Government should take appropriate steps to bring better technology to reduce the risk of blood transfusion and to make it affordable to common people as soon as possible as it becomes a hardship for some patient with poor financial capacity to go to private hospital blood bank to get Nucleic Acid Amplification Test which detect anti-bodies such as HIV etc. even in 'window period' also.

As blood transfusion services rendering an essential service to the society, they should not be burdened with excessive legal liability. But for the better protection of public health and for public interest they should perpetuate safe and adequate blood supply because the very reason of existence of blood transfusion services is to save lives through supply of safe blood. Along with it in order to minimize the risk of transmission of HIV or other infectious diseases associated with blood transfusion, Government has to place appropriate policies and procedures. It is the prime responsibility of the State to assist the blood transfusion services in reaching their goals in order to protect the blood recipients from unnecessary risks.

References

- Adejuyigbe, EA., Durosinmi, MA., Onyia, FN., Adeodu, OO. (2003). Blood transfusion related paediatric HIV/ AIDS in Ile-Ife, Nigeria. *Aids Care*, 15(3): 329-335.
- Alter, HJ., Klein, HG. (2008). The hazards of blood transfusion in historical perspective. *Blood*, 112:2617-2626.
- Ariga, T., Hayasaki, S. (2003). Medical, legal and ethical considerations concerning the choice of bloodless medicine by Jehovah's Witnesses. *Legal Medicine*, 5: (72-75).
- Ashok Naik vs. Union of India through Secretary [Writ Petition (PIL) No. 159 of 2011.*
- BBC News. Blood for sale: India's illegal red market. <http://www.bbc.com/news/business-30273994> [accessed on 01.04.2017].
- Bray, TJ., Salil, P., Weiss, HA., Porter, JDS. (2003). Transfusion medicine in India: A survey of current practice. *Transfusion Medicine*, 13: 17-23.
- Canterbury vs. Spence (464) F.2d (772) 1972*
- Chandrashekar, S., Kantharaj, A. (2014). Legal and Ethical Issues in Safe Blood Transfusion. *Indian Journal of Anaesthesia*, 58 (5):558-564
- Deb, P. (2001). Homologous Blood Transfusion: Do We Have Any Alternative?. *Med J Armed Forces India*, 57(3): 268.
- Dhingra, N., Hafner, V. (2006). Safety of blood transfusion at the international level. The role of WHO. *TransfusClin Biol.*, 13(3): 200-2.
- Dr. Anil Kumar Mittal vs. Smt. Neelam Gupta and Ors. [(R.P.No.3145/2008)].*
- Farrel, AM. (2006). Is the gift still good? Examining the politics and regulation of blood safety in the European Union. *Medical Law Review*, 14:155-179.
- Foreign Policy News. (2016). <http://foreignpolicynews.org/2016/06/10/blood-transfusion-indian-hospitals-causing-hiv/> [accessed on 12.02.2017].
- Gibbs, WN., Corcoran, P. (1994). Blood safety in developing countries. *Vox Sang*, 67(4):377-81
- Goodnough, LT. (2013). Blood management: transfusion medicine comes of age. *Lancet*, May 25; 381 (9880): 1791-2.
- Goodnough, LT., Shuck, JM. (1990). Risks, options, and informed consent for blood transfusion in elective surgery. *Am J Surg*, 159: 602-609.
- Herbich, J. (1976). Blood transfusion: medicolegal aspects. *Wien KlinWochenschr*, 88(14): 437-43.

In Erickson vs. Dilgard [44 Misc.2d 27, 252 N.Y.S.2d 705 (1962)]

Kajja, I., Bimenya, GS., Smit Sibinga, C. (2011). Informed consent in blood transfusion: Knowledge and administrative issues in Uganda hospitals. *Transfusion and Apheresis Science*, 44 : 33–39.

Kiran Chand, N., Bala Subramanya, H., Venkateswara Rao, G. (2014). Management of patients who refuse blood transfusion. *Indian Journal of Anaesthesia*, 58(5).

Kramer, K., Zaaijer, HL., Verweij, MF. (2017). The Precautionary Principle and the Tolerability of Blood Transfusion Risks. *The American Journal of Bioethics*, 17(3): 32-43.

M. Chinnaiyan vs. Sri Gokulam Hospital And Anr [III (2007) CPJ 228 NC].

Malettevs. Shulman [72 OR (2d) 417].

Marwaha, N. (2010). Whole blood and component use in resource poor settings. *Biologicals*, 38(1): 68-71.

Maryam, Z., Pourfathollah, AA., Mahboube, R., Gharib, K. (2017). Trends in Sero-Epidemiology of Human Immunodeficiency Virus in Voluntary Blood Donations in Iran, 2008-2013. *Archives of Iranian Medicine (AIM)*, 20(3):135-140.

Mishra, SK., Sachdev, S., Marwaha, N., Avasthi, A. (2016). Study of knowledge and attitude among college-going students toward voluntary blood donation from north India. *J Blood Med*, 7: 19–26.

Mortimer, PP. (1991). Transfusion in crisis: HIV in the developing world. *Transfus Med*, 1(1):1-3.

Naidu, NK., Bharucha, ZS., Sonawane, V., Ahmed, I. (2016). Nucleic acid testing: Is it the only answer for safe Blood in India?. *Asian J Transfus Sci*, 10(1).

Nair, SC., Mammen, JJ. (2015). Repeat voluntary non-remunerated blood donor is the best quality indicator for blood safety. *Indian J Med Res*, 141: 749-752.

National Institute of Health. What is a blood Transfusion? <https://www.nhlbi.nih.gov/health/health-topics/topics/bt/> [accessed on 05.01.2017].

Nijhawan, LP., Janodia, MD., Muddukrishna, BS., Bhat, KM., Bairy, KL., Udupa, N., Musmade, PB. (2013). Informed Consent: Issues and Challenges. *J Adv Pharm Technol Res*, 4:134-140.

P.G. Institute of Medical Education and Others vs. Jaspal Singh and Others [(2009) 7SCC 330].

Pahuja, S., Puri, V., Mahajan, G., Gupta, P., Jain, M. (2017). Reporting adverse transfusion reactions: A retrospective study from tertiary care hospital from New Delhi, India. *Asian J Transfus Sci*, 11(1): 6–12.

Pal, R., Kar, S., Zaman, FA. (2011). The quest for an Indian blood law as of blood transfusion services regulatory framework. *Asian Journal of Transfusion Council*, 5: 171-174.

Paul, B., Nesbitt, Ian D. (2016). Anaemia and blood transfusion. *Surgery (Oxford)*, 34(2): 66–73.

Pozo, P., Del, R. (1994). Paying donors and the ethics of blood supply. *Journal of Medical Ethics*, 20: 31-35.

Ram Gopal Varshnevs. Lasor Sight India Private Limited & others [(2008) 4 C.P.R. 227].

Ramani, K V., Malavankar, D., Govil, D. (2007). Management of Blood Transfusion Services in India: An illustrative study of Maharashtra and Gujarat States. India. *IIMA*, http://www.iimahd.ernet.in/publications/data/2007-03-09_kvramani.pdf [accessed on 05.04.2017]

- Ray, VL., Chaudhary, RK., Choudhury, N. (2000). Transfusion safety in developing countries and the Indian scenario. *DevBiol (Basel)*,102:195-203.
- Somerville, MA. (1998). Ethical Issues and Challenges in Implementing a New Blood System. *Transfusion Medicine Reviews*,12(3): 162-174.
- St. Mary's Hosp. vs. Ramsey [465 So.2d 666 (1985)]*
- The Hindu. (2016). Tracking HIV caused by blood transfusions in Mumbai. <http://www.thehindu.com/news/national/Tracking-HIV-caused-by-blood-transfusions-in-Mumbai/article16075545.ece> [accessed on 25.03.2017].
- Times of India. (2016). Unsafe blood transfusion infects around 30k annually: Dr Harish Warbhe. <http://timesofindia.indiatimes.com/city/nagpur/Unsafe-blood-transfusion-infects-around-30k-annually-Dr-Harish-Warbhe/articleshow/55233542.cms> [accessed on 27.03.2017].
- Usemann, J., Garten, L., Bühner, C., Dam,e C., Cremer, M. (2017). Fresh frozen plasma transfusion – a risk factor for pulmonary hemorrhage in extremely low birth weight infants?.*Journal of Perinatal Medicine*, 45(5):1619-3997
- Watt, Alison, J., Gyuchan, TW., Patrick. (2016). Noticing errors in blood transfusion prevents harm to patients. <https://dspace.lboro.ac.uk/dspace-jspui/handle/2134/23551> [accessed on 17.01.2017].
- Weinberg, PD., Hounshell, J., Sherman, LA., Godwin, J., Ali, S., Tomori, C., Bennett, CL. (2002).Legal, Financial, and Public Health Consequences of HIV Contamination of Blood and Blood Products in the 1980s and 1990s. *Ann Intern Med*, 136:312-319.
- Williamson, LM., Devine, DV. (2013). Challenges in the management of the blood supply. *Lancet*, 381: 1866–75.
- Yaddanapudi, S., Yaddanapudi, LN. (2014). Indications for blood and blood products transfusion. *Indian J Anaesth*: 58: 538-542.
- Yamamoto, H., Yamamoto, F., Yamaura, G., Motokawa, M., Tanaka, F., Sato, H., Ishibashi, K., Shirotto, K. (2012). Rupture of Chronic Type B Aortic Dissection in a Jehovah's Witness: Successful Surgical Repair without Blood Transfusion. *Ann VascSurg*, 26: 11-16.