

The Medico-legal Aspects of Blood Transfusion

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Abstract

Blood transfusion is considered as an essential part of the health care system. Timely transfusion, on one hand, saves lives and on the other hand, unsafe blood transfusion can lead to critical problems which may even result in death of the patient. Such death creates mayhem and panic. Resultantly the attending doctor faces medico-legal exertion. Proper knowledge of the fact, timely medical intervention, and appropriate legal precaution can minimize the occurrence of a medico-legal crisis. India has a National Blood Policy 2002. Though the policy came into existence in 2002 India still does not have any dedicated blood legislation and solely works through licencing. The review paper deals with the medico-legal snags of blood transfusion. It also explains how medical practitioners can provide timely medical support to the patient and at the same time overcome legal hurdles so as not to lose precious time, so crucial on certain occasions. The paper considers the data collected from two tertiary level hospitals of North-East India to draw its conclusion(s) on blood deficit.

Keywords: Blood transfusion, drugs, deficit, medico-legal, North-East India

INTRODUCTION

Blood is defined as body fluid that carries vital substances like oxygen and other necessary nutrients to the body cells and carries out metabolic waste products from the cells. Blood transfusion is a mechanism of transferring blood from a healthy person to a needy. It is a two-step process. In the first step, blood is collected from a healthy donor, and in the second step, it is administered to the recipient. In India, the Drugs and Cosmetics Act of 1940 deals with the legal framework for blood transfusion. Section 3(b) of the act defines drugs. The drug also includes blood [1]. The other laws applicable are Article 21 of the Indian Constitution, ensuring the right to life, Section 269 and 270 of the Indian Penal Code, and the Consumer Protection Act.

Constitution under Article 21 declares “right to life” as a fundamental right. Life here does not merely mean “physical act of breathing” or sheer animal existence. It also comprises the “right to a healthy life” [2], right to have a healthy life so as to “enjoy all faculties of the human body” to its optimum [3]. Therefore, even if blood transfusion does not lead to death or partial bodily damage it can still amount to an abuse of the fundamental rights as enshrined under Article 21 if it causes harm to a person’s health in any manner. Rendering immediate medical support to the injured person is an obligation for the state through its hospitals and doctors [4]. The immediate medical aid also includes safe medical aid. State-aided hospitals and medical officers are articulated to give medical support for saving human life. It is of utmost importance [5]. It is pertinent to mention here that generally fundamental rights plead can be filed only against a public body or corporation. Thus, the usual view is fundamental right plead cannot stand against private hospitals or doctors. However, with the widest interpretation of Article 21, a petition can be filed against a private hospital or doctor as well [6].

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The other civil and criminal remedies available to the patient against the hospitals and practitioners are under Section 269 and 270 of IPC (Indian Penal Code), under the Consumer Protection Act, and under Indian Medical Council Act 1956. Indian Medical Council Act cannot provide any compensation to the aggrieved party and is only empowered to cancel the licence of the practitioner. Sections 269 and 270 of IPC provide a criminal remedy to the aggrieved party. Section 269 states the punishment for acts those are unlawful or done negligently. Punishment can be imprisonment for up to six months along with fine or only fine or imprisonment. And Section 270 deals with the malignant act. Punishment for a malignant act can be imprisonment for up to two years along with fine or only fine or imprisonment. Under Section 2 (d) (ii) of the Consumer Protection Act of 1986, a patient who takes doctors and hospital services qualify to be a consumer and is eligible for remedies under the act. Medical services provided are treated as services under Section 2(1) (o) of the 1986 act [7]. Even under the new Consumer Protection Act, 2019, medical services plunge into the scope of services. Section 2 (42) of the current act deals with the definition of services which also includes medical services [8]. The act creates civil liability and empowers the court to compensate the aggrieved party. “Medical negligence” by a doctor or a hospital is considered as a “deficiency in service” under Section 42 (11) of the new Consumer Protection Act, 2019. A person aggrieved with the service(s) can claim “damages for medical negligence” against the doctor as well as the hospital. A complaint of medical negligence must be filed within two years of the injury [9]. In order to avoid all these legal complications, it is always advisable for medical practitioners and hospitals to take some precautionary legal measures which will be discussed herein below.

METHODOLOGY

Data on demand and supply of blood from 2020 to mid-2021 is collected from the two tertiary level hospitals of North-East India. One hospital is in Guwahati, Assam and the other is in Shillong, Meghalaya. The authors’ conclusions were based on these data. The authors also referred to the existing scholarly literature on the subject and the guidelines of the Ministry of Health and Family Welfare before drawing their conclusions.

DISCUSSION

Purposes of Blood Transfusion

Blood transfusion serves various purposes. It is done to restore blood volume lost due to haemorrhage; to raise Hb level in cases of severe anaemia, to treat deficiencies of blood proteins; to provide immunity to persons having lower immunity; to replace haemolytic agents; in the case of agranulocytosis, it improves leukocyte count; and to combat infection in case of leukopenia. Statistics show that approx. 1.2 billion people in India need nearly 15 million units of blood. However, the total collection is only 9 million, which means a deficit of nearly 40% (Figure 1).

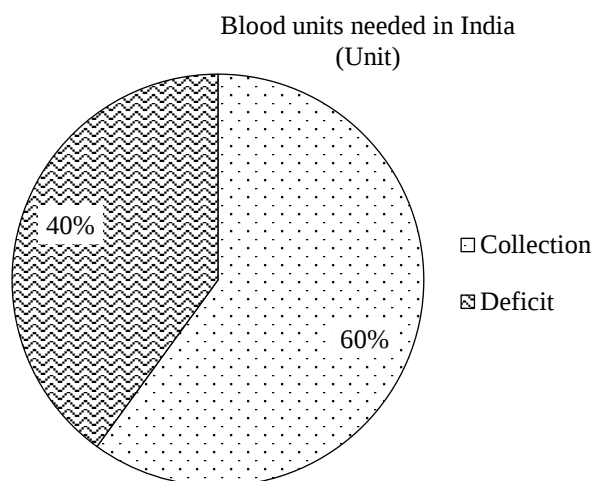


Figure 1. Blood unit collection and deficit in India.

Blood Utilization

A study has been done on the amount of blood utilized in two major hospitals in north-eastern India in 2020 and the first half of 2021. Data collected is approximate and is the evidence of alarming need of blood in the country.

Figure 2 shows that in hospital A the consumption of blood was approximately 6500 units, and in hospital B, it was more than 34000 units in 2020. By mid-2021 approximately 3000 units were consumed in hospital A and 18000 units in hospital B.

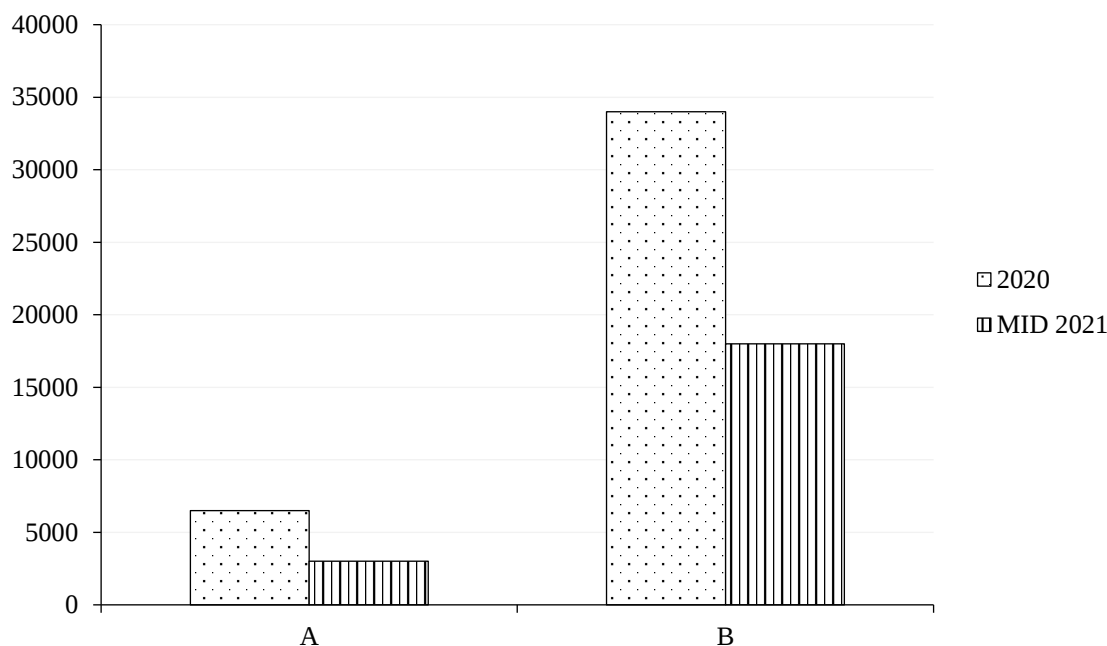


Figure 2. Blood demand and supply in hospital A and B in 2020 and till mid-2021.

Complications of Blood Transfusion

The complications that arise due to blood transfusion may be divided into the following categories.

Reason Behind TTI (Transfusion Transmission Infection)

The International Society of Blood Transfusion in 1980 for the first time came up with the code on ethics of blood transfusion. This code was adopted by World Health Organization and was subsequently tailored in 2000. This code states only volunteered donations should be accepted and used. National Blood Transfusion Act 2007 prohibits the practice of professional blood donation. The act came up as per the guidelines of the Supreme Court [10]. In spite of the various steps taken to minimize TTI, professional donors are a great hazard to the transfusion world and they are the root cause of TTI have italicized it here only for the sake of clarity as shown in Table 1.

However, this ban has created a huge gap between demand and supply. The illegal red market in India to a large extent fills this gap. Studies show that there is a deficit of 25% to 50% of blood supply in India [11]. The reasons are many. To cite a few-religious beliefs, social beliefs, lack of women donors despite the fact that their need for blood transfusion is more often higher than that of men. Lack of proper government run blood banks, especially in the interiors, lack of sufficient tertiary centres, etc. also adds to the contributory factor. Trafficked human to a large extent fills the gap that exists between the demand and supply of blood. In one such trafficking case, an artisan and his friend were rescued from a blood farm in Gorakhpur at the India-Nepal border where they were held captive and forced to donate blood at the rate of 7 US dollars per unit [12].

Table 1. Types of blood transfusion complications.

<i>Immune mediated reactions</i>	• Acute haemolytic transfusion reaction. • Delayed haemolytic and serologic reaction. • Febrile nonhemolytic transfusion reaction. • Allergic reaction. • Anaphylactic reaction. • Graft versus host disease. • Transfusion related acute lung injury. • Posttransfusion purpura. • Alloimmunization.
<i>Nonimmunologic reactions</i>	• Hypothermia. • Electrolyte toxicity. • Iron overload. • Hypotensive reactions. • Immunomodulation.
<i>Infectious complications</i>	Hep B, Hep C, HIV virus, Malarial parasite, Syphilis, Cytomegalovirus, Parvovirus.
<i>Bacterial contamination</i>	Fever, Chill, Septic shock, DIC allosensitization.
<i>Other complication</i>	RBC allosensitization, and HLA.

In order to avoid all legal complications, a medical professional should take all due care in all cases of transfusion. This will defend him against the charges of negligence. While deciding whether a medical professional is guilty of medical negligence or not certain guidelines are kept in mind. Culpable or gross negligence that a reasonable man will not do should be established in every case of negligence. A mere error of judgment is not considered as negligence. A medical professional is expected to be reasonably skillful and will be held for misconduct only if he falls below that reasonable level. Any differences of opinion between two doctors or choosing one option over the other that might not give the desired result are not considered as negligence. The principle emphasized on protecting medical professionals as long as they perform their duty in the interest of the patient and imposed obligations on society that they are not unnecessarily harassed or disgraced [13].

Posttransfusion Complications

Out of the total wrong blood transfusions, 2%-5% result in fatalities. Here are a few examples of posttransfusion complications:

- 2016 Bhubaneswar TTI case of two elderly patients: They were transfused with HIV and hepatitis infected blood in Burla [14].
- In 2013 four persons in Mangaldai town of Assam were detected with HIV after blood transfusion [15].
- In 2016 Jaiprakash, 11yr old from New Delhi reported a case of transfusion transmitted HIV after blood transfusion [16].
- In 2000 a 39-week male child developed CMV after a blood transfusion in Delhi (case report from Teg Bahadur Hospital, Delhi) [17].
- In 2009 two children died at Bhubaneswar Municipal Corporation hospital while a six-year-old died in Choudwar area in 2013 after a blood transfusion.
- Similarly, a seven-year-old died in Jaipur.
- All the above-mentioned deaths happened after administering blood transfusion [18].

RESULTS

Medico-legal Aspect

One can escape from these medico-legal complications by adopting some precautionary measures as listed below.

- Reasonable sound mind adults have right over their bodies and are free to decide how it should be treated. Therefore, before blood transfusion, written consent must be taken in the presence of

a witness. Blood transfusion carried out without consent, may result in an adverse action against the doctor and hospital.

- Immune haematological results and specific prescriptions about the quantity and quality of blood products before transfusion are necessary. If necessary, the blood which is being transfused should be rechecked to find that all the required tests have been done.
- All the alternative modes of treatment adopted during an emergency must be well recorded and documented. The urgent need for blood transfusion must be recorded without fail.
- All blood transfusion cases must be documented appropriately in the hospital file. The records should be safely kept for a specific period, as prescribed by the law. In India, it is two years for outdoor patients and three years for indoor patients [19]. However, the Consumer Protection Act, 2019, allows condoning of delay in certain cases. Thus, a record may be required even after a period of three years.
- Certain religious beliefs restrict blood transfusion. For example, members of the sect Jehovah's believe in not using blood even for therapeutic purposes. In such cases, blood transfusion should be done only after obtaining consent from the patient or his representative.
- In case of transfusion reactions, transfusion should be immediately stopped and supportive treatment should be started. The concerned blood bank should be immediately informed and the remaining blood should be returned for re-examination. This entire process should be properly recorded and documented.

Investigation of Transfusion Reaction

All adverse reaction cases should be immediately investigated and recorded. It should be recorded that no clerical mistake has been made in collecting blood and that the blood has not been transfused to the wrong person. In order to avoid any error, blood regrouping should be performed from the blood bag and form pre-transfusion and posttransfusion samples. To rule out bacterial contamination of blood, culture of donor should be done. Urine collected should be free Hb (Hemoglobin), urobilin, and indicators of intravascular haemolysis. A thorough examination of the donor should be done. This is to ensure that supportive treatment is given for renal failure, hypotension, hyperkaliaemia, DIC (Disseminated intravascular coagulation), and bacterial contamination. Intravascular haemolysis in the transfusion kidney is characterized by haemoglobinuric nephrosis, acute tubular necrosis, and cast of Hb in tubules.

Legislations Guiding Blood Transfusion

Only a registered medical practitioner can prescribe for blood distribution or its components. Blood is covered under the definition of 'drugs' in India [20]. Licence for distribution of blood is granted only by the state or central licencing authority as per the Drugs and Cosmetics Act. The act structures the legalities for regulating blood banks in India. The quality of the blood bank at the centre is ensured by the Drug Controller General of India and at the state level, it is monitored by the Drug Controller. Schedule C of the Drugs Rule talks about human blood and Schedule F mentions the standards to be met by all the blood banks. All the policies related to the BTS (Blood Transfusion Services) are made by the National Blood Transfusion Council (NBTC), a body under the Ministry of Health and Family Welfare. The State Blood Transfusion Council assists NBTC at the state level. The commitment of the government to provide safe and adequate blood supply throughout India is adhered by NBTC. The council launched an extensive awareness program encouraging blood donation and providing latest technology for BTS. The council is also responsible for monitoring and evaluating BTS and take legal action against exploitative blood banks. However, it is to be noted that these body function only as advisory. Thus, in April 2002 NBP (National Blood Policy) was adopted by the government of India for developing a system that ensures a sufficient safe supply of blood. The NBP is responsible for designing technical training in the field of transfusion medicine and encourages the use of the latest technology for BTS.

Obtaining a licence from the appropriate authority is mandatory for BTS [21] and for running a blood bank [22]. Collection of blood for transfusion without a license is a punishable offense under

Section 27(b) (ii) of the Drugs & Cosmetic Act. In spite of all the legislation in place, 34% of blood banks in India are unlicensed. Nearly 50% of the donors are paid donors and only 5% of voluntary donors are repeated donors [23]. The NACO (National Aids Control Organization) designed a comprehensive standard for collecting, storing, testing, and distributing blood or its components. This ensures better and improved BTS in India.

NACO Guidelines for BTS

NACO advocates acceptance of blood only from voluntary donors. Proper medical screening of all the donors should be done and blood should be collected only from safe and healthy donors. Paid donors should be phased out. Efforts should be made towards retaining an adequate number of healthy repeated donors. Every donor should be recognised and shown gratitude for their timely contribution and aid.

NBTC Guidelines for BTS

1. Informed consent: Patient and his or her family should be informed of the need for transfusion and the risk associated with or without transfusion, preferably in a language that the patient can understand. In the case of a minor or an unconscious person, consent from near relatives can be taken.
2. Verification of details: Patient identity, blood unit, blood group, and cross-match report should be re-verified before transfusion. The credentials attached to the blood containers should remain intact until the transfusion is over. The patient file must possess the blood compatibility report.
3. Supervision: Blood transfusion should be prescribed and administered by a qualified medical practitioner. Transfusion should be under constant observation of the doctor and any unseemly reaction should be treated immediately. A hospital transfusion committee should formulate to ensure good quality service.
4. Administration of blood: Blood and blood components should be maintained at the optimum temperature before transfusion. Sterile, pyrogen-free, and disposable transfusion set along with filter must be used for administration of transfusion. Blood temperature must align with the body temperature in case of swift or massive transfusion. Temperature must also match while administering transfusion in infants and patients with cold agglutinins. Blood should not be warmer than 37-degree Celsius and medication should never be added to whole blood or components.

NBTC COVID-19 Guidelines for BTS

Blood can be collected from a COVID recovered patients only after 28 days of discharge from the hospital or after 28 days of home isolation with negative RT-PCR (Real-Time Reverse Transcription Polymerase Chain Reaction). A gap of 28 days should also be observed for vaccinated individuals. A healthy person can donate blood after 28 days of taking the second dose of vaccination.

CONCLUSION

The deficit in blood supply is the root cause of illegal blood collection practices persisting in the blood market. The demand for blood far outnumbers the supply. This gap between demand and supply provides scope for the illegal blood market to thrive. Blood transfusion is a selfless medical act of ethical responsibility. The invention of blood transfusion in the field of medicine was a great boon to the field of medicine. But its involvement with profit and business turned it into a life-threatening curse. It is an ethical duty of every medical professional to maintain complete transparency and disclose the blood source while administering the transfusions. All the recommendations and guidelines by various authorities or regulatory bodies should be diligently followed and any form of monetary transaction related to transfusion should be strongly discouraged. These will not only ensure the safety of the patient but also that of the doctors and the hospitals against any medico-legal complications. This resultantly will increase the goodwill of the doctor and the hospital, which in turn will generate more business and profit in the long run.

Rather than procuring blood from illegal blood banks and markets, voluntary blood donation should be encouraged. Hospitals and blood banks along with non-profit organizations should organize more awareness camps promoting and encouraging blood donation. This will not only facilitate the bridging of the gap between demand and supply but will also ensure the collection of healthy blood and minimize the possibility of TTIs.

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N/A

Conflicts of Interest

No conflict of interest.

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