

Indian blood transfusion services – legal framework and challenges

Sana Zia, Student of MBA(HM), College of Hospital Administration, TMU, Moradabad

Email:-sanaziarizvi300@gmail.com

Add : Moh.Gudia, near khatri dharmsala, Moradabad (UP)

Abstract

Blood and blood components are categorised as a “drug” under section 3(b) of Drugs and Cosmetic Act, 1940 because of their internal administration. Legal Issues play a vital role in providing a framework for the Indian blood transfusion service. Deaths are not common but they do occur rarely during blood transfusion. Most of the Medico-legal problems faced by the doctors are due to the reason that medical records are not properly maintained and there is lack of informed written consent. Blood and its components were given to the above organizations, following the National Blood Policy made by the Government of India.

Introduction

Blood transfusion is a safe common procedure in which blood is going through an intravenous line (IV) in one of blood vessels.

Blood transfusions are done to replace blood lost during surgery or due to serious injuries. Transfusion may also be done if a person's body can't make blood properly because of an illness.

During a blood transfusion, a small needle is used to insert an IV line into one of your blood vessels. Through this line the body receive healthy blood the procedure usually takes 1 -4 hours, depending on how much blood needed for body.

Blood transfusion are very common each year almost, 8 million Indian need a blood transfusion.

Most blood transfusions go well. Mild complications can occur, very rarely serious problem develop.

Legal issues play a vital role in the structure of blood transfusion services in the country and ethical issues. The supreme Court directive in 1993, making licence of blood bank in the country mandatory, all blood banks are licensed today. Licencing is only the first step towards quality.

Blood has been treated as a 'drug' under the drugs and cosmetic Act (Drug and Cosmetic), 1940 and Drugs and Cosmetics.

Elements of blood safety-

Safe donor- Donating blood is a safe and easy process which gives us the chance to change lives. It is not possible to get AIDS or other infectious disease by giving blood. A brand new, sterile, disposable needle is used for each blood donation. Once used, the needle is discarded.

An increase of 10.7 million blood donations from voluntary unpaid donors has been reported from 2008 -2013. In total, 74 countries collect over 90% of their blood supply from voluntary unpaid blood donors; however, 72 countries collect more than 50% of their blood supply from family/replacement or paid donors.

Types of blood donors

There are 3 types of donors:

1-voluntary unpaid

2-family /replacement

3-paid

A voluntary donor is one who donates blood at least once a year and is considered safer than occasional voluntary donors, as the blood bank is aware of his previous test results also. Friends and relatives of patients called 'replacement donors'. Professional /paid donors may sometimes be passed off as replacement donors too.

Safe blood-

Transfusion medicine packed RBCS and blood products from persons with no known risks for exposure to transfusion – transmissible microorganisms (TTM; e.g., malaria, HIV), which have been fully tested and are negative for TTM by a direct assay of viral product.

The anticoagulant preservative solutions used in blood collection have been developed to prevent coagulation and to permit storage of red cells without loss of metabolic integrity. All of these solutions contain sodium citrate, citric acid and glucose, and some of them also contain adenine, guanosine and phosphate.

Safe Transfusion –

Blood transfusion is generally the process of receiving blood or blood products into one's circulation intravenously. Transfusions are used for various medical conditions to replace lost components of the blood. Early transfusions used whole blood, but modern medical practice commonly uses only components of the blood, such as red blood cells, white blood cells, Plasma, clotting factor, and platelets.

Objectives

- To understand the legal framework on Indian Blood transfusion services
- To identify the challenges faced by the Indian blood transfusion services

Methodology

The information is gathered through variety of secondary sources, viz., Blood transfusion services guidelines released by National Blood Transfusion Council (NBTC), National Aids Control Organisation, relevant research papers and books. The information thus gathered is analysed to identify the challenges faced by the Indian blood transfusion services.

Discussion and findings

Framework of Indian blood transfusion services

National Blood Transfusion Council (NBTC) and Blood Policy

WHO recommends that National Blood system should be governed by National Blood policy and legislative framework to promote uniform implementation of standards and consistency in the quality and safety of blood and blood products.

In accordance with the directive of the Supreme Court, in 1996, National Blood Transfusion Council was constituted with the objective to promote voluntary blood donation, ensure safe blood transfusion, provide infrastructure to blood centres, develop human resource and formulate and implement the blood policy. NBTC is the apex body for all matters pertaining to the organization, standards, operations and training of a sustainable and safe blood transfusion services for the country.

Role of National Aids Control Organization(NACO)

NACO has been primarily responsible for ensuring provision of safe blood for the country since 1992. NACO supports a network of 1131 blood banks across the country in over 600 districts and strives to achieve accessibility to adequate quantity of safe, quality and affordable blood components to the needy. NACO has taken number of steps towards the modernization of blood banks in the country by providing the critical inputs for ensuring provision of safe blood for the country. With the efforts of NACO, HIV sero-reactivity among blood donors also declined to 0.14% in NACO supported Blood Banks. Availability of Blood Banks has increased to 10.8 million blood units in 2015 -2016.

Licensing of blood banks by drugs controller

The procedure for licensing of blood banks is written in the Drug and Cosmetic Act 1940 and Drugs and Cosmetics Rules, 1945. Basic licensing standards for blood banks have remained unchanged over the past decades. The Drug and Cosmetic act has only seen minor changes such as rising the age 60 to 65 years and recognition of transfusion medicine as a specialty. Perhaps the only major amendment has been the guidelines for setting up blood storage centres.

Who can operate a blood bank

Any individual or institution can apply for opening of a blood bank. Following an application to the drugs controller, a joint inspection is conducted by drug control authorities from state and centre which make a recommendation to the Central Licensing Approving Authority (CLAA). Which is the ultimate authority for grant of license. This drug controller inspection is preceded by an inspection by the SBTC, the advisory body, which gives its consent to the drugs controller.

Space Requirements

Blood transfusion service is a vital part of the National Health Service and there is no substitute for Human Blood and its components. The area required for setting up the facility is only 10 square metres, well clean and preferably air conditioned and near to the emergency department.

Staff Requirements

The medical officer may be a person with MD in transfusion medicine or pathology, Diploma in pathology with 6 months experience or MBBS qualified with 1 year experience in blood banking. Technician with BSc (MLT) or (DMLT) and staff nurses are additional requirements.

Who can regulate

Successful blood services depend on legally empowered regulatory services. Blood transfusion services are important constituents of national health services. Blood transfusion services in India are regulated by the drugs and cosmetics Act, 1940 and its subsequent amendments. Regulatory affairs in the Indian blood banking system are controlled by central and provincial drug control authority under Drug controller organization (NACO) act as a facilitator to Indian blood transfusion services on behalf of the ministry of Health and Family Welfare Government of India.

Problems faced by the Indian Blood transfusion Services

-Fragmented blood transfusion services

Blood banks are opened in India for various reasons. Some hospitals open blood banks as they are denied permission to open storage centres. Only Regional Blood Transfusion Centre are permitted to open storage centres and very few blood banks are Regional Blood Bank Transfusion Service. Some hospitals open blood banks because insurance providers allow them to charge higher for their services with a blood bank.

-Absence of standards for safe transfusion

National Aids Control Organization standards address only safe donor and safe blood issues and do not cover safe transfusion, the third element of blood safety. Transfusion triggers are at best limited to individual institutions. Further, there are no audits by a competent technical body to ensure compliance with standards.

-Positive patient identification

A documented protocol for positive patient identification is essential. Absence of this may lead to wrong transfusions and may be construed as negligence on the part of the doctors. Use of wrist bands is one-way achieving this.

-Deficiencies in documentation and monitoring of beside transfusions

Blood request form

As per the Drug and Cosmetic Act “the blood and its components shall be distributed on the prescription of a Registered Medical Practitioner.” However, owing to practical difficulties, this rule is seldom followed. The Drug and Cosmetic Act must be revamped to replace manual signatures with electronic signatures of doctors.

Conclusion

The Drug and Cosmetic Act needs to be reviewed every 2 years, to keep in tune with the changing types and needs to be modified to state that in the event of any components or procedure not include in the Drug and Cosmetic Act, the same may be performed by the blood bank as per standards laid down by NACO/NABH. NBTC should engage in the licencing process more actively. Suitable amendments to the act are necessary to facilitate this. Emphasis of inspection, audit should be to enhance the quality by adherence to standards and protocols and must facilitate smooth functioning of blood banks. Licensing should not become a hindrance to the adoption of safe transfusion practices.

References

- Indian Journal of Anaesthesia.
- Drugs and Cosmetic rules ,1945
- IyerR.The law of torts .8th edition. Tripathi publications.p561
- Book by J.C Joshi Hospital Administration
- International Society of Blood Transfusion(homepage on the internet. A code of ethics for blood donation and blood transfusion.)(Cited2009 june18)Available from:http://www.isbt-web.org/files/documentation/code_of_ethics.pdf