

Review Article

Safe Transfusion Practices: Challenges and Opportunities

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ABSTRACT

The aim of quality in blood transfusion services (BTS) is to ensure the provision of safe transfusion of blood and its components. Blood bank is the only laboratory directly responsible for the patients with no intervening physician (doctor) interpretation, so any mistake in blood transfusion service (blood banks) can be disastrous. In order to prevent mistakes in blood transfusion services it is essential to have adequate quality assurance in blood transfusion services. There are many terms used in relation to quality i.e. quality control, quality assurance and quality audit.

Blood transfusion service (BTS) is a vital part of the National Health Service and there is as yet no substitute for human blood or its components. Increasing awareness of blood transmissible disease has necessitated enforcement of stricter control over the quality of blood and its products. In most of the developed countries the blood transfusion services has advanced in all facets of donor management, storage of blood, grouping and cross matching, testing of blood transmissible diseases and the rational use of blood and its products.

However, in our rural and resource constrained set up blood banks operate in total isolation; their standards vary from states to states, cities to cities, and from one centre to another centre in the same city. The hospital based decentralized blood banking system has led to a skewed distribution of resources and makes difficult any implementation of a stringent quality control program.

Key words: blood transfusion services, blood bank, blood donors.

INTRODUCTION

Blood is the elixir of life. It is essential for human life and has no substitutes. No wonder blood is mentioned in the Bible. On March 15, 1937, the world's first blood bank was established

at Chicago's Cook Country Hospital by Dr. Bernard Fantus. In India, the first blood bank was set up at Kolkata.^[1]

The history of Blood transfusion dates back to around 200 years. The credit of first successful human to human blood transfusion goes to Dr James Blundell, an obstetrician, who successfully transfused around 227ml (8 oz) of blood to a patient having postpartum hemorrhage in the year 1818.^[1,2]

Current blood transfusion practices began around hundred years back, with the discovery of the ABO blood group antigens and antibodies by a Nobel Laureate, Karl Landsteiner, in the

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year 1901 and the Rh blood group antigens by Lanesteiner and Wiener in the year 1940.^[3,4] Blood collection and storage became possible with the introduction of anticoagulants/preservatives of blood. The widely used blood anticoagulants/preservatives, acid citrate dextrose (ACD), was introduced in the year 1943. Previously blood was collected in glass bottles which were unhygienic and had high risk of contamination because of improper sterilization. However, at present blood is collected in sterile plastic bags containing a measured amount of anticoagulants. Introduction of plastic bags and tubing have revolutionized modern day transfusion practices by facilitating the incorporation of satellite bags which enabled us to segregate each donation into several blood components-the red cells, platelets, fresh plasma and cryoprecipitate there by ensuring the most appropriate use of the precious donations.^[5]

Transfusion Medicine in its current form is a new discipline of medicine quite different from blood banking. Transfusion Medicine today is a blend of laboratory medicine, clinical activities and managerial functions. Today, blood banks are not content with playing the supportive role of physicians and surgeons.^[6] Globally, blood banks are evolving being mere storage centers and are entering into the area of the therapeutics. Aphaeresis have enabled blood bank to delve into therapeutics. Whether it is therapeutic plasma exchange (TPE) for myasthenia, erythropheresis for sickle cell anemia or hematopoietic stem cell transplantation, the transfusion physicians have an active role to play.^[1] The goal of any transfusion service is to provide

blood components that are safe for transfusion and pose minimal risk of transfusion-transmissible infections. To achieve maximum safety at an acceptable cost requires multi-layered risk reduction strategies involving safe blood donors, safe blood components and safe transfusion practices.^[6] Obtaining safe blood donors who have a low risk of carrying transfusion transmissible infections (TTI) requires effective donor selection and screening strategies. Safe blood depends also on laboratory testing with stringent quality controls and processing. Safe transfusion practices are essential so that the correct blood is given to the correct patient and given only when it is truly needed.^[7]

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.^[1]

Recent concept of blood transfusion emphasizes on the transfusion of component therapies instead of transfusion of whole blood.^[1] Throughout the world blood services aim to provide a lifesaving service by ensuring an adequate supply of safe blood. The approach towards blood transfusion practices should be based on “Four Principles” of autonomy, beneficence, non-maleficence, and justice which offers a common, basic moral analytical framework and a common, basic moral language to think about ethical issues in any field of health care services.^[7]

The key elements of this strategy address the issues of nationally coordinated blood

transfusion services, collection of blood only from voluntary blood donors, quality testing of blood to ensure its freedom from infectious markers and rational use of blood in clinical settings.^[8] Lack of knowledge amongst clinicians and non-availability of sufficient quantity of components have become part of a vicious circle. Though some orientation programmes have been conducted to upgrade the knowledge of clinicians, however, several such courses are needed to generate demand for use of blood components.^[9]

The WHO Global Database on Blood Safety (GDBS) 2000-2001, based on data from 178 countries, shows that about 81 million units of whole blood and 20 million litres of plasma are collected annually.^[1] While the Indian health sector has made some noteworthy achievements over the last 65 years, it has not responded satisfactorily to meet the national goals on blood transfusion services. As a result, there is fragmented mix of competing independent and hospital based blood banks of different levels of sophistication, serving different types of hospitals and patients. In addition, there are large numbers of trusts, independent commercial and private blood banks with the Indian Red Cross Society holding a primary position.^[7] The piecemeal evolution of blood banking has thrown several challenges.

The risk of disease transmission increases many fold if blood donors selection are inappropriate and mandatory serological testing are inadequate. For many years WHO has been working to help nations to make the transfusion safe with the following guidelines : establishment of a nationally coordinated blood

transfusion services, collection of blood only from voluntary donors, testing of all blood for compatibility and TTIs and reduction of unnecessary transfusions.

The hazards of blood transfusion, specially the risk of transmission of disease through transfusion, can never be totally eliminated. Transfusion of blood and blood components should thus be considered in terms of risk versus benefit. Transfusion should be planned judiciously and, side by side, efforts should be made to minimize the risk of disease transmission through adopting the guidelines of WHO for safe blood transfusion.^[10]

In spite of considerable awareness, blood transfusion services suffer from inadequate political commitment, lack of priority, fragmentation and insufficient resources. Myths and lack of information amongst communities prevent a large number of people to donate blood.^[1] Human resource managing blood transfusion services are inadequate in number and lack training on recent concepts of blood safety. Several CMEs have been conducted to upgrade the knowledge of clinicians, however several such courses are needed to create awareness for use of blood components.^[2]

If 2% population of any country can be motivated to donate blood regularly, blood needs can easily be met by voluntary blood donors. To motivate people to donate blood voluntarily is a fundamental task for any transfusion services. Awareness has to be generated for regular voluntary blood donation in the communities.^[1] Misconceptions, fear complex and prejudices have to be removed scientifically by rationally emphasizing that blood donation is harmless to

the donors.^[3]

Human blood is categorized as a “drug” under Section 3 (b) of the Drugs and Cosmetics Act, 1940.^[1] This Act and the Rules therefore provide the legal framework for regulating the functioning of blood banks, which in turn directly impacts and determine blood transfusion service delivery in the country. Since initial formulation of the Drugs and Cosmetics Act, 1940 has been expanded, and the rules accordingly frequently amended to incorporate ongoing and current concerns.^[1]

India still lags behind the goal of 100% voluntary blood programmes. Against an annual requirement of 10 million units, India now collects 5.5 million units per annum from voluntary blood donors.^[1] However, our National blood collection scenario is variable. Maharashtra, Gujarat, West Bengal, Tripura, Tamil Nadu and Chandigarh are considered to be “high performance” i.e. collection from voluntary blood donors is more than 80% of total collection^[1] while Bihar, Delhi, Haryana, U.P., Punjab are “low performance” states with only 40% of their total collection coming from voluntary blood donors. All other states and Union Territories are in between.^[1]

For quality, well trained, motivated and dedicated, human resources are the important requirements along with quality kits, equipment's, facilities and efficient supervision.^[3] The ultimate objective is to highlight that blood donor motivation, recruitment and retention is a specialized art based on scientology. As only the voluntary blood donors can ensure safe blood transfusion, they are considered to be the backbone of blood

safety.^[4]

Along with donor recruitment, donor loyalties should also be emphasized. Donor loyalties are more complex to measure than biological parameters. However, certain criteria's have been developed to access donor loyalties which include donor retention rates (i.e. the percentage of donors who return to donate within the next 12 months), donor satisfaction with the donation procedure, the increase in frequency of donations after recruitment appeals, and the grievance monitoring mechanism.^[11]

The most important positive effects on donor loyalties are considered to be the performance of the staffs of the blood transfusion services. The donors must feel appreciated and get the impression that the staffs are skilled professionals.^[3] The positive social aspects of being a blood donor also needs to be highlighted and appreciated.^[4]

Barriers to donation are varied. The most important of which is the failure to motivate a potential donor to give blood. Along with the changing times the various approaches for donor motivation and donor loyalties should be changed.^[1]

Discomfort and outright fear of the needles required for phlebotomy, and adverse reactions to donation remain important disincentives to donation.^[12] Remediation of this is primarily a responsibility of staff training and experience, along with improved technologies. The more prosaic barriers to donation, like inconvenient timing of camps, poor customer services by blood collection staffs are repeatedly cited in the various donor motivation services.

These problems are managed by making the blood donation procedure more “donor friendly”, arranging for a clean, hygienic and comfortable places and by selection, training and retention of staffs who adopt a mission of social services along with donor enlightenment.^[13]

Given the current donor selection criteria testing and process controls, it is likely that some incentives, like distribution of T- shirts, donors felicitation programmes organizing of socio-cultural events such as streets plays with the theme of voluntary blood donation and organizing academic activities like posters, essays and debate competition with the theme of voluntary blood donation.^[14] Will promote blood donation.

In 1980, the International Society of Blood Transfusion (ISBT) endorsed its first formal code of ethics, which was adopted by the WHO and the League of Red Cross and Red Crescent Societies.^[1] A revised code of ethics for donation and transfusion was endorsed in 2000.^[1] The first and foremost principle is that when transfusions are required, the patients should be advised of the current risks of receiving blood components, based on the type of components and its attendant risks.^[1] Both the noninfectious and infections risks should be correctly and completely discussed with patients before administration of a blood transfusion. Ethical principles of autonomy, beneficence, non-maleficence and justice provide a rational basis for decision-making when a new blood management programme is instituted. By proactively considering the ethical dilemmas posed by the juxtaposition of patient needs with clinical judgment at the outset, institutions may devise workable programmes that improve

patient safety and quality outcome.^[7]

Donor deferral might appearing as discrimination and a violation of a human right, but the patient's right to safer blood is more important here, as blood centers are made to help the patients and not the donors.^[15] Donor consent and confidentiality are important issues. Personal information disclosed by the blood donor during the course of a pre-donation interview and information obtained from the various tests performed on the donated component, are expected to be held in confidence by the blood bank authority. Blood safety depends partly on the information provided by the donor and it is also the donor's moral duty to provide truthful information. It is unethical for a donor to willfully conceal information about his/her high-risk behavior or medical history. Consent for transfusion has to be informed consent. The patient should be informed of the known risks and benefits of transfusion, and alternative therapies such as autologous transfusion or erythropoietin. Only then should the consent be documented. If the patient is unable to give prior informed consent, the basis of treatment by transfusion should be in the best interest of the patient. The patient's right to refuse blood transfusion should be respected. Some religious sects such as Jehovah's Witnesses do not accept blood transfusion.^[16] If the patient has been transfused blood and components that were not intended for him /her, whether there was any harm or not, he/she has the right to be informed. Similarly a patient who has inadvertently received blood positive for a transfusion transmissible marker has a right to be informed and give due compensation. There are also some ethical principles for blood

establishments such as profit motive should not be the basis of establishing and running blood transfusion services. Wastage should be avoided to safeguard the interest of all potential donors and recipients.

Of late blood transfusion services in our rural set up has undergone a paradigm shift beginning with procurement of slippers for routine usage to the installation of software for blood management system along with dissemination of information for promotion of voluntary blood donation in camps coupled with serious, sustained efforts to convert the family donors into a regular voluntary donors. Our usage of whole blood has gradually decreased over the years with increasing emphasis on blood component therapy with 100% blood components separation, collection and storage. In the year 2008 the number of voluntary donors were 4915 units which more than doubled to 9880 units by the year 2012. Similarly, components separation increased from 408 in the year 2008 to more than 9672 units by the year 2012. Awareness for usage of leuco-depleted blood have also been initiated.

The practice of transfusion medicine involves a number of ethical issues because blood comes from human beings and is a precious resource with a limited shelf life.^[1] It involves a moral responsibility of the physicians and blood banks towards both the donors and the patients. Decisions must be based on four principles as mentioned earlier and of course, the Hippocrates' principles of "Primum non nocere" (i.e first do no harm).^[3]

Today's transfusion medicine is sophisticated and complex involving an understanding of a variety of scientific

disciplines in addition to the medical management of patients.^[1] Transfusion medicine seems to be on the threshold of several major changes which will add to the complexities of transfusion medicine and would continue to provide exciting opportunities for transfusion medicine physicians, scientists, and technologists in the future.^[4]

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