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Reviewed Study on Blood Bank Standard Operating Procedure

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Abstract – The SOPs must be validated prior to their use to prove their effectiveness in the environment of the respective blood bank. Realizing that the capacity to develop their own SOPs is currently limited in the countries of the South-East Asia Region, we have developed 'model' SOPs for some of the essential procedures that are followed in blood banks. They are meant to serve as a reference and assist in writing and validating their own SOPs for all blood banks. We hope that these will not only serve as models for SOP growth, but will also enable blood transfusion services to use SOPs for different procedures and improve their quality systems.

Keywords – Blood Bank, Sop

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INTRODUCTION

The donor cell selection criteria rely on the absence of antigens on donor cells for antibodies found in the serum of the patient that require transfusion during the detection and identification of antibodies. Effective detection and recognition of antibodies in the serum of the recipient relies on the use of suitable and systematic screening and red cell panelling. Information of phenotype frequencies helps to devise in-house red cells for antibody detection and recognition of major blood group systems. Since India is a large country with different population groups throughout the country, there is a strong need to evaluate phenotype frequencies in different parts of India. For the identification of blood group antigens on red blood cells, many techniques such as Tube technique, Micro column, Flow Cytometry & Molecular methods can be used.

Tube technique is historically and regularly used for blood grouping out of these methods in the blood banks. In this work, we plan to see the viability of the micro column technique as an alternative to the conventional approach of the Tube technique for donor red blood cell antigen typing. Through this work, we plan to provide an estimate of phenotypes of major blood group systems prevalent in South Gujarat, India blood donors and to formulate red cells in house screening and panels to detect and identify antibodies in recipients requiring blood & blood products transfusion, respectively. A thorough evaluation of the situation has recently been carried out in blood transfusion centres, including the private sector, under the WHO blood safety initiative. The evaluation was carried out by a group of specialists in transfusion medicine and the DGHS management team of the Ministry of Health. The data collected from the centres revealed that very few centres have SOPs developed for certain processes that are not regularly conducted in other centers for blood transfusion centres, nor have SOPs developed.

INSTRUCTIONS FOR USE OF MODEL SOP

The standard operating procedures (SOP) are vital documents which are essential components of quality system in any organization. These are used to ensure consistency in performing an activity. Their use is mandatory by all the staff members of the blood bank every time they perform an activity. The accreditation and licensing procedures also demand compulsory use of SOP. Every SOP has two components: one gives information about the location, subject, functions, distribution and genesis of SOP and the other provides instructions for carrying out the specific activity. Since equipment, reagents, methodology and kits used may vary in different blood banks, it is important for every blood bank to have its own SOP. To assist blood banks in this endeavour, WHO has developed SOP for most of their activities. These can be used as guide to develop blood bank specific SOP.

The information part of SOP shall have following components:

- Name of the blood bank

- Subject of SOP
- Location of SOP
- Function of SOP
- Distribution of SOP
- Unique Number of SOP
- Version and revision
- Date from which SOP shall be effective and the period after which it has to be reviewed
- Number of pages and No of copies (Quality Manager or designated official shall keep a record of those whom SOP has been distributed)
- Name and signature of the author
- Name and signature of the person who has been authorized to approve SOP
- Name and signature of the person who is to authorize the use of SOP from effective date (He must belong to the top management and is usually the Chief Executive Officer of the blood bank)

LITERATURE REVIEW

Blood and Blood Groups

Blood is a biologically active substance. It is the red body fl uid that flows through all the vessels except the lymph vessels. Blood is a viscous fluid. It is thicker than water. Blood constitutes about 8 percent of the total body weight. The blood volume of an average sized male is 5 to 6 litres. The average sized female has 4 to 5 litres. Blood is composed of two portions: formed elements(cells and cell like structures) and plasma (liquid containing dissolved substances). The formed elements compose about 45 percent of the volume of blood; plasma constitutes about 55 percent. Formed elements of the blood are of the following types: Erythrocytes(red blood cells); Leucocytes (white blood cells); Granular leucocytes (neutrophils / eosinophils I basophils); Agranular leucocytes (lymphocytes /monocytes); Thrombocytes (platelets). (Tortora and **Anagnostakos, 1990).**

Human red blood cell membranes contain over 300 different antigenic determinants, the molecular structures of which is dictated by genes at an unknown number of chromosomal loci. The term blood group is appl ied to any well defined system of red blood cell antigens controlled by a locus having a variable number of allelic genes, such as A, B, and O in the ABO system. The term blood type refers to the antigen phenotype, which is the serologic expression of the inherited blood group genes. Nearly all individuals produce "natural occurring" antibodies against the A or B antigens not present on their own red blood cells. In routine practice, the ABO type is determined by testing the red blood cells with anti-A and anti-B and by testing the serum against A, B and O red blood cells.(Giblett, 1991).

Levine and Stetson (1939) made the discovery of a new factor, when they observed that after a mother gave birth to a still born child and subsequently transfused with her husband's blood she suffered a severe reaction in blood. Both the mother and the husband were group 0, but they did not have any name to this new factor. The name was given by **Lansteiner and Wiener (1940),** after its discovery. They conducted a study in which they injected blood from monkey-Rhesus Monkey into rabbits and guinea pigs, collected the blood, took the serum, which contain the anti-Rh factor, was mixed with the blood cells from a number of samples from individuals of a population of Newyork city. Red blood cells of 85% of this population agglutinated with this serum. This population was called rhcsuspositive(Rh-positive). The remaining 15% that did not have any agglutination were rhesus negative (Rh-negative). At least 30 commonly occurring antigens and hundreds of other rare antigens, each of which can at times cause antigen-antibody reactions, have been found in human blood cells, especially on the surfaces of the cell membranes. Most of them are weak and therefore of importance principally for studying the inheritance of genes to establish percentage. The particular groups of antigens are more likely than the others to cause blood transfusion reactions. They are the O-A-B systems of antigens and Rh-systems. **(Guyton 2000).**

Blood Donation and Donors One of the keys to a good Blood transfusion is starting with good Blood. The most common eligibility guidelines of blood donor in the United States are outlined below.

- Be in generally good health and feeling well.
- Be at least 17 years of age; upper age 60 years.
- Weigh at least l l O pounds (45 kg).
- Pulse: 80 to 100 beats/min and regular.
- Temperature: Should not exceed 99.5 °F.
- Blood Pressure: acceptable range is 160/90 to 110/60.
- Skin: the venipuncture site should be free of any lesion or scar of needle pricks

indicative of addiction to narcotics or frequent Blood donation (as in the case of professional Blood donors).

Arankalle (2000) reported that various organizations such as world health assembly, world health organization, international society of blood transfusion, international federation of blood donor organization and several national organizations have pleaded for voluntary blood donation as the universal standard. The data provided by Kapoor et al(2000) are alarming, as only 39% of blood donation in India seems to be voluntary. Thus the primary aim should be adequate donor motivation programmes. Potential donor populations need to be educated about the role of voluntary blood donations from individual without high risk behaviour.

Despite the fact that only 3 .1 % of blood donors in India are paid donors, the participation of so called "replacement donors" (58%) remains disturbing. The possibility of a significant proportion of these being paid donors can not be ruled out. If blood collected from such replacement donors is not tested or tested using inadequately sensitive serological assays, the possibility of infectious units being transfused is high. Blood products intended for transfusion are routinely collected as whole blood (450_ ml) in various anti-coagulants. Most donated blood is processed into components: Packed red blood cells (PRBC), Platelets and fresh frozen plasma (FFP) or cryoprecipitates. Whole blood provides both oxygen carrying capacity and volume expansion. It is the ideal component for the patients who have sustained acute hemorrhage of 25% or greater total blood volume loss. Whole blood is not readily available because of the need to process blood into components that can be used for different recipients, thus a continuous requirement for blood donation is needed. Donor blood is transfused to the recipient, but sometimes transfusion leads to several complications.Transfusion reactions are classified as immune or nonimmune. The immunologically mediated reactions may be directed against red blood cells or white blood cells, platelets or atleast one of the immunoglobulin's, IgA. Other less well defined hypersensitivity reactions also occur. The major no immune reactions are due to circulatory overload, massive transfusion or transmission of an infectious agent.

Jeffery and Kenneth (1998) reported that infectious complications of transfusion have become less frequent, although fear of these complications remains the primary concern of both patients and clinicians. The incidence of transfusion related infections has been reduced substantially due to improved donor screening and testing of collected blood. Infections, like any adverse transfusion reaction, must be brought to the attention of the blood bank for appropriate" look back" studies. Infectious complications include: viral infections (hepatitis C virus, hepatitis B virus, human immunodeficiency virus, cytomegalovirus, human T lymphotropic virus type I, parvovirus B 19), Bacterial contamination, parasitic infections (malaria, babesiosis, chagas disease).

Choudhury and Phadkc (2001) reported that transfusion transmitted disease (TTD) is a major challenge to the transfusion services all over the world. The problem of TTD is directly proportionate to the prevalence of the infection in the blood donor community. In India, hepatitis B/C, HIV, malaria, syphilis, cytomegalovirus, parvo-virus B-19 and bacterial infections are important cause of concern. Hepatitis B and C infections are prevalent in India and carrier rate is about 1-5% and 1 % respectively. Post transfusion hepatitis B/C is a major problem in India (about 10%) because of low viraemia and mutant strain undetectable by routine ELISA.

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