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An Overview on Blood Bank Standard Operating Procedure

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Abstract – There has been growing awareness about quality in blood transfusion services with the objective of releasing only those blood products and blood which fulfill the desired standards in terms of safety and efficacy. Consistency is the hallmark of quality and can be achieved only through the use of standard operating procedures (SOP) by all staff engaged in blood centres at all times. Use of SOPs has also become essential for licensing and accreditation. Each blood bank has to develop its own set of SOPs matching their requirement and resources. SOP need to be developed for all critical procedures. There is now an international unanimity on the framework of SOPs. Each SOP must have the following components: Each SOP must be given a unique identity number along with the revision number, if any. Information about the procedure, location where the SOPs will be used, its function and distribution list; date from which it will be effective and signatures of the author(s) and the person from top management who can authorize the use of SOP from the effective date must precede the technical details.

Keywords – Standard, Operating, Procedure

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INTRODUCTION

The ultimate goal of transfusing blood and blood products to any patient is that the transfusion remains beneficial and safe for the patient. In Red Blood Cell (RBC) transfusions, transfused RBCs should have an acceptable survival rate, and there should not be significant destruction of the recipient's own RBCs.1,2 As per the Standards for blood banks & transfusion services, by American Association of Blood Banks3 , Working party of the British Committee for standards in Hematology Blood Transfusion Task Force4 and Pre-transfusion Compatibility testing for red blood cell administration by Shulman IA et al5 , every attempt must be made by the Blood Transfusion services to make sure that the transfused RBCs have optimal survival and functioning in the recipient.

When transfused RBCs have shortened survival, there is an increase in the number of units transfused with all its associated risks and problems. This issue is very important in cases of patients requiring multiple transfusions like that of Thalassemia, Sickle Cell Disease, Myelodysplastic Syndrome, Chronic Renal Failure, Leukemias, etc. After ABO and Rh blood group testing on recipient blood sample, the most important component of pre-transfusion compatibility testing for red blood cell administration is screening for unexpected alloantibodies and alloantibody identification in recipient using screening and panel red cells. Red cell alloantibody other than naturally occurring anti-A or anti-B are called unexpected red cell alloantibodies. Antibody detection & Identification in the proposed recipient of transfusion is the approach accepted and practiced worldwide for compatibility testing. Depending upon the selected group of patients or donors studied and the sensitivity of the test methods used, alloantibodies can be found in 0.3% to 38% of the population. Majority of the Blood Transfusion services in India do not perform screening for unexpected alloantibodies & alloantibody identification in recipient using screening and panel cells and are resorting to the old time crossmatch using recipient's serum and donor red blood cells. This is due to lack of database of antigen frequency in the local donor population, issues related to the availability, shelf life and cost of screening and panel red cell and scarcity of technical expertise.

OBJECTIVES OF THE STUDY

- To identify and select donors for preparing screening cells and panel cells for antibody detection and identification respectively.
- To compare the Conventional tube technique Vs Column agglutination

technique for extended antigen typing of red blood cells.

Blood group

Taken literally any variation or polymorphism detected in the blood could be considered a blood group. However, the term blood group is usually restricted to blood cell surface antigens and generally to red cell surface antigens.

A blood group could be defined as 'An inherited character of the red cell surface, detected by a specific alloantibody'.

Inherited variations in human red cell membrane proteins, glycoprotein and glycolipids, are detected by alloantibody. Alloantibody is an antibody produced in one individual against the red blood cell antigens of another individual of the some species. These alloantibodies occur either 'naturally' as a result of immunization by ubiquitous antigens present in the environment or as a result of all immunization by human red cells, usually introduced by blood transfusion or pregnancy. Although it is possible to defect polymorphism in red cell surface proteins by other methods such as DNA sequence analysis, such variations cannot be called blood groups unless they are defined by an antibody.

The science of blood group serology materialized in 1900 with the discovery of the ABO blood groups by Landsteiner. Together with the development of anticoagulants, it was this discovery that made the practice of blood transfusion possible. Landsteiner mixed serum and red cells from different individuals and found that in some tests the cells were agglutinated (clumped) and in others they were not, demonstrating individual variation. The mixing of serum, or at least antibodies with red cells followed by observation of the presence of absence of agglutination is the basis for most methods for determining blood group phonotype in use today. By 1910, the ABO blood groups had been shown to be inherited characters, in the 1950s they were shown to represent oligosaccharide chains on glycoproteins and glycolipids and in 1990 the gene encoding the enzymes responsible for synthesis of the ABO antigens was cloned. ABO is considered a blood group system because it was discovered on red cells and its antigens are readily detected by haemagglutination techniques, on red cell. However, they are also present in many different tissues and organs and in soluble form in secretions and so are often referred to as his to-blood group antigens. Because they are widely expressed, ABO antigens are a major consideration in solid organ and bone marrow transplantation.

Features of an SOP

An SOP is a written document of instruction to perform various operations in a testing site. It provides step-by-step instructions to ensure consistency, accuracy, quality of a laboratory process. An essential sub-element of a quality system required to ensure quality. Any written instruction is safe guard for those who uses it and it is a legal document. It is the pillar of all quality works. Without SOPs there is risk of error that endangers human life. SOP ensures reduction of variation, ensure consistency in procedure, ensure quality i.e. doing right thing every time to get right results. SOP is required for

- Quality System
- ISO
- Accreditation
- Audit
- Regulatory requirements

It gives confidence of reliability of report and confidence to the customer. Each of the process must have SOPs. Generally each SOP has six core processes which includes

- Scope & application
- Responsibility
- Reference
- Material Required
- Procedure
- Documentation

Each SOP document has two sections: one gives information about the location, subject, functions, distribution and genesis of SOP and the other is the technical section contained instructions for carrying out the specific activity.

The instruction part of SOP shall have following components:

- Name of the blood transfusion centre
- Subject 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.

CONCLUSION

At present the only means of preventing new cases of hepatitis C are to screen the blood supply, encourage health professionals to take precautions when handling blood and body fluids and inform people about high risk behaviours. Vaccines and immunoglobulin products do not exist for hepatitis C and development seems unlikely in the near future because these products would require antibodies to all the genotypes and variants of hepatitis C. Nevertheless advances in immunization make it likely that some form of vaccine for hepatitis C will eventually be developed. The high rates of progression to chronic infection and the lack of effective means of prevention require that HBV and HCV infection be differentiated from other causes of viral hepatitis. Despite recent progress, efforts to develop more effective therapies must remain a high priority. Worldwide, the best hope for a solution to the epidemic of HCV infection is the development of an effective vaccine. For those who are already infected with HCV, new therapeutic approaches can be expected in the future. The study shows that despite all the efforts made to reduce the risk of transfusion transmitted hepatitis, there is still need to strengthen the immunization programs. Blood banks should also inform the donors, tested positive for HBV and HCV and should encourage and guide them for proper treatment. Also blood banks should permanently defer the infected individuals for blood donation. Education of such subjects may limit further spread and in case of hepatitis B, lead to vaccination of susceptible contacts.

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