

GUIDELINES FOR COMPETENCY BASED POSTGRADUATE TRAINING PROGRAMME FOR DIPLOMA IN IMMUNOHEMATOLOGY AND BLOOD TRANSFUSION (DIHBT)

Preamble

The purpose of PG education is to create specialists who would provide high quality health care and advance the cause of science through research & training.

Transfusion medicine is a unique multi-dimensional speciality that incorporates elements of blood banking, immunohematology, coagulation, and hematology. A transfusion medicine specialist requires knowledge in haematology, immunology, stem cell and organ transplantation, histocompatibility and immunogenetics, microbiology, public health medicine, medical law and molecular biology, all integrated into a unique discipline. Hence, training programmes in transfusion medicine must include appropriate knowledge and skills in these subjects and need special training. Transfusion medicine specialist must (a) monitor the transfusion practices of fellow clinicians and advise them on the management of patients needing sophisticated transfusion services, (b) be well versed with Regulatory requirements, (c) be competent to establish transfusion services commensurate with international standards, (d) be equipped to manage an adequate and safe blood atorage and supply and (e) interact closely with clinicians in the hospital to ensure optimal and appropriate use of blood and blood components as well as availability of transfusion alternatives.

The overall goal of these Guidelines is to enable the post graduate student to acquire the skills and knowledge to become a competent transfusion medicine specialist. This document will provide teachers and learners illustrative guidelines to achieve defined outcomes through learning and assessment. This document was prepared by various subject-content specialists. The Reconciliation Board of the Academic Committee has attempted to render uniformity without compromising the purpose and content of the document. Compromise in purity of syntax has been made in order to preserve the purpose and content. This has necessitated retention of “domains of learning” under the heading “competencies”.

SUBJECT SPECIFIC OBJECTIVES

On completion of the Diploma programme, the post graduate student would have acquired the following competencies and be able to:

1. Organize blood bank including blood donations, component separation and storage, appropriate use of blood and blood components,
2. Understand the importance of blood and blood components as a precious, life saving resource and be competent in the judicious use of this resource,
3. Understand the need for transfusion safety and its importance in all aspects of medical care,
4. Act as the medical expert in providing advice and clinical decision making with regard to the need for blood transfusion and work with clinical colleagues in formulating evidence-based guidelines,
5. Function as a member of the health care team and coordinate with the team in critical situations, like working with surgeons and colleagues in anaesthesia to ensure that optimal care is given to all patients, especially with the support of blood and its products in resuscitation and haemostasis,
6. Understand the national and public health importance of safe blood components including a sound knowledge in the area of transfusion transmitted Diseases (TTDs) and their testing methods
7. Possess up to date knowledge of immunohematology and its application to ensure safe transfusion practices,
8. Have a sound knowledge in laboratory haematology, automation and quality control and should be able to interpret hematological tests in the clinical context and provide consultative services to clinicians for effective patient care,
9. Able to offer expert advice in histocompatibility and immunogenetics for stem cell and organ transplantation and to provide laboratory support to transplant team,
10. Incorporate comprehensive and evidence-based medicine into all areas of its discipline,
11. Apply knowledge of molecular biology in transfusion medicine,
12. Apply knowledge of transfusion haematology to patient management,

13. Contribute to the education of students, physicians, other health care professionals, patients and their families and communicate effectively, especially with the public and media in matters of the national blood supply and safety,
14. Effectively use information technology for the smooth functioning of blood banks,
15. Undertake accurate self-appraisal, develop a personal continuing education strategy and pursue lifelong mastery of transfusion medicine,
16. Learn the diagnostic techniques required in the practice of transfusion and haematology,
17. Appreciate the value of research, audit and team working, which underpin haematology and transfusion practice, and
18. Understand the need for research and development in transfusion alternatives, molecular immunology and cellular therapy.

During the course of the training programme, the post graduate student must undertake a broad range of practical, clinical, laboratory and management experiences including on call for transfusion medicine and haematology consults. The training, especially in the laboratory will also be “hands on” bench work. She/he will attend a programme of formal education activities and have exposure to and involvement with current research activities.

SUBJECT SPECIFIC COMPETENCIES

1. Identify the need for appropriate blood and blood components for transfusion.
2. Perform all necessary laboratory investigations before transfusion of blood or its components for safety.
3. Diagnose a case of mismatched blood transfusion.
4. Manage a case of mismatched blood transfusion.
5. Knowledge of immunogenetics and its applications in Transfusion Medicine
6. Conduct blood donation camps.
7. Show professionalism by maintaining patient autonomy and confidentiality
8. Demonstrate knowledge and skills regarding safety of patients and laboratory personnel.
9. Demonstrate knowledge and skills required to carry out research
10. Investigate for hematological conditions like anaemia, hemophilia, Idiopathic thrombocytopenic purpura (ITP) etc.

11. Demonstrate knowledge and skills for maintain quality control in Blood bank as per the Standard guidelines.
12. Function as a member of a health care team to support Clinical Transfusion services.

These Competencies can be attained by meeting the following objectives of different domains, as follows.

At the end of the course, the student should have acquired knowledge in the following:

A. Cognitive Domain

I. Basic Sciences (Immunology, Medical Genetics, Hemostasis & Physiology of Formed Elements of blood)

- Demonstrate familiarity with the current concepts of structure and function of the immune system, its aberrations and mechanisms thereof. The student should be able to demonstrate understanding of the basic principles of immunoglobulins, antigen, antibody and complement system, antibody development after immunization and infection.
- Understand the basic concepts and their clinical relevance of the following:
 - Mechanisms of acute inflammation
 - Healing and repair
 - Physiology of immune system
 - Hypersensitivity reactions
 - Autoimmunity
 - Transplantation Immunology
- Demonstrate familiarity with the scope, principles, limitations and interpretations of the results of important procedures employed in clinical and experimental studies relating to immunology – this is inclusive of but not limited to:
 - ELISA techniques
 - Radioimmunoassay
 - HLA typing
 - Hybridoma technology

- Isolation of T & B lymphocytes
- CD4 / CD8 count
- Micro lymphocytotoxicity test
- Cellular assays
- Electrophoresis and Immunofluorescence
- Understand the principles of genetics with regard to Mendelian Laws of Inheritance, phenotype / genotype and population genetics.
- Know the nomenclature, organization and polymorphism of the human major histocompatibility complex, including HLA class I, II, and III genes. Understand the role of HLA typing in organ and bone marrow/stem cell transplantation and association with disease.
- Understand the basic concept of hematopoiesis and bone marrow kinetics.
- Understand the physiology and biochemistry of red cells, platelets and leukocytes in terms of their kinetics, function, life span and antigenic systems. Know the membrane structure and function of red cells, platelets and leukocytes and be able to apply their implication in transfusion medicine.
- Understand hemoglobin structure, synthesis, function, its aberrations and degradation including iron and bilirubin metabolism, laboratory diagnosis of anemia and management.
- To learn the disorders of white blood cells, their laboratory diagnosis and management and the role of transfusion medicine in the management of these disorders.
- Understand the composition and function of plasma constituents.
- Know the pathophysiology and laboratory features of intravascular and extravascular hemolysis.
- Understand the physiology of hemostasis with regard to role of platelets, coagulation pathway and fibrinolysis, its aberrations and mechanisms thereof such as coagulopathy of liver disease, vitamin K deficiency, disseminated intravascular coagulation & hemophilias (A, B, and C) etc.
- Understand hemodynamics of blood flow and shock; estimation of blood volume and be able to interpret the application of radionuclides tagging for blood volume estimation.

- Understand the principles of Molecular Biology especially related to the understanding of disease processes and its use in various diagnostic tests.

II. Blood Collection/Blood Center/Component Processing

The student should be able to demonstrate understanding of the processes associated with Blood Donor motivation (motivation strategies), recruitment, selection and proper donor care in blood center as well as in outdoor blood donation camps and be able to understand the importance of cold chain maintenance.

- Be able to understand donor counseling and notification (Pre- and Post-donation).
- The student should be familiar with various categories of blood donors including autologous and directed donors and be able to know their clinical relevance.
- Understand the process of apheresis and demonstrate proficiency in selection of apheresis machine, apheresis donor and be able to obtain apheresis product meeting quality standards.
- Understand the mechanisms of adverse effects of blood / apheresis donation, its clinical features, management and prevention.
- Demonstrate understanding of various anticoagulants / preservatives used for collection and storage of blood and components.
- The student should be familiar with various “storage lesions” in blood components, factors affecting the storage lesions and its prevention.
- The student should be able to demonstrate understanding of various plasticizers used in blood banking and their clinical relevance.
- Understand the principles of component preparation by various methods. The student should be familiar with preparation of modified components such as leukofiltered, irradiated or saline washed, pooled or volume reduced components following aseptic conditions.
- The student should be able to demonstrate understanding of the basic principles of preparation and composition of recombinant products such as Factor VII, Factor VIII, Factor IX, concentrate and hematopoietic growth factors.

- Understand the factors influencing quality of blood and blood components including quality of blood bag / apheresis.
- Be able to understand maintenance of quality of blood components as per recommended standards by various agencies (DGHS, DCGI, NABH, NACO, AABB, EC).
- Should be able to identify problems in the blood / apheresis collection and component preparation area and offer viable solutions.

III. Transfusion transmitted infection

- The student should be able to demonstrate understanding of various strategies for improving blood safety in general and TTI testing in particular pertaining to Indian conditions.
- The student should be able to understand the typical time course of appearance and disappearance of serum antigens and antibodies used in screening of major transfusion transmitted infection, including: HIV, hepatitis B, hepatitis C, syphilis, malaria and others.
- The student should be able to demonstrate understanding of the principles of blood safety including testing for various transfusion transmitted infection (TTI), proper disposal of infectious waste, laboratory safety, personnel safety.
- Demonstrate understanding of newer technologies that are being introduced in the field of TTI testing. Understand the feasibility of NAT in Indian blood transfusion services.
- Demonstrate understanding of new emerging threats (including Prions, vCJD, Lyme Disease, West Nile Virus, Dengue, Chikungunya etc.) to blood supply in the country including bacterial contamination, their detection and prevention.

IV. Immunohematology / Blood Group Serology / Compatibility testing

The student should be able to:

- Demonstrate understanding of the knowledge of various major and minor blood group systems including their biosynthesis, antigen/antibodies, phenotype/genotype frequency, clinical significance.
- demonstrate understanding of the various immunohematological laboratory tests including its quality essentials.

- Demonstrate knowledge of principle of pretransfusion testing, including ABO/Rh testing, RBC antibody screen, and antibody identification. The student should also demonstrate understanding of resolution of discrepant results in ABO/Rh grouping and pre-transfusion testing and be able to provide solutions for the management of such cases.
- demonstrate the understanding of use of various potentiators and their applications in solving immunohematological problems such as polyagglutination, subgroups of ABO system, red cell antibody detection
 - Enzymes
 - Lectins
 - LISS / Albumin
 - others
- have knowledge of various advances in this field including automation and computerization.
- demonstrate understanding of the pathophysiology, clinical features, lab diagnosis & management of various clinical conditions requiring immunohematological and transfusion support including,
 - Multi-transfused patients such as thalassemia, sickle cell disease etc
 - Alloimmunized antenatal cases (HDN)
 - Transfusion reactions
 - Immune hemolytic anemias
 - ABO mismatched transplants (BMT / Solid organ)
- demonstrate understanding of the pathophysiology, clinical features, lab diagnosis & management of Rh, ABO and other blood group incompatibility in antenatal patients including exchange transfusion / intra-uterine transfusion.
- demonstrate the knowledge regarding “rare blood group donor” including identification, cryo-preservation of rare blood and making their registry.

V. Clinical Transfusion Service

The student should be able to:

- Demonstrate knowledge of the principles of patient/ unit identification and its importance in blood safety.

- Understand the principles of blood inventory management.
- The student should be able to demonstrate understanding of the rational use of blood and components in various clinical conditions including monitoring of transfused patients.
- Recognize the symptoms and signs of hemolytic and non-hemolytic transfusion reactions and demonstrate knowledge of the pathophysiology, treatment, and prevention of these complications
- Demonstrate understanding of the major non-infectious complications of blood transfusions, including red cell alloimmunization, transfusion-related acute lung injury, transfusion associated graft versus host disease, volume overload, post transfusion purpura, iron overload etc. and the risk of these complications, and strategies to prevent them. Student should have knowledge of pathophysiology, clinical features, diagnosis and management of these conditions.
- Demonstrate knowledge of pathophysiology, diagnosis & management of anemia
 - Iron deficiency anemia
 - Megaloblastic anemia
 - Aplastic anemia
 - Anemia of chronic diseases
 - Neonatal anemia
- Demonstrate understanding of pathophysiology, clinical / laboratory diagnosis and treatment of patients with bleeding disorders such as Hemophilia, von Willebrand's disease, thrombophilia, acquired coagulation disorders including DIC, liver disease etc.
- The student should demonstrate understanding of the pathophysiology, clinical features, lab diagnosis and platelet support in thrombocytopenic conditions such as aplastic anemia, ITP, NAIT, hematological malignancies etc. The student should also demonstrate understanding of complications of platelet transfusion including refractoriness to platelets, its diagnosis and management.
- The student should demonstrate understanding of the basic principles of neonatal transfusions including serological testing, type of transfusion support, exchange transfusion, intra uterine transfusion and monitoring.

- The student should demonstrate knowledge of the pathophysiology, diagnosis and transfusion support in acute blood loss including massive transfusion protocols, complications of massive transfusion and their prevention.
- Demonstrate understanding of the knowledge of various methods of blood conservation, including pre- and peri-operative autologous blood collection, and approaches to “bloodless” surgery.
- Demonstrate knowledge of the use of various point-of-care tests (TEG, ROTEM) for hemostasis & recommend component therapy depending on the results.
- The student should demonstrate knowledge of principles of transfusion support in general surgery and special procedures such as cardiac surgery or oncological surgery.
- Demonstrate knowledge of the principles of hematopoietic stem cell transplantation, including collection, processing, and storage of these stem cell products, and the indications for use (e.g., bone marrow, peripheral blood, and cord blood).
- The student should demonstrate understanding of regulatory guidelines for stem cell research (ICMR, DBT).

VI. Therapeutic Apheresis, Therapeutic Plasma Exchange and Cytapheresis

The student should:

- Understand the principles of apheresis technology, including centrifugation, filtration, and immunoadsorption.
- Demonstrate knowledge of the indications for therapeutic apheresis including cytapheresis and of the appropriate replacement fluids to be used in various situations.

VII. Regulatory Skills / Quality Assurance/ Quality Control in blood transfusion

The student should be able to:

- Demonstrate knowledge concerning the requirements and applications of all applicable regulatory and accrediting agencies. [e.g., DCGI, NABH, AABB].
- Become familiar with the patient / blood donor privacy and data security requirements, including the use of institutional review board (IRB) protocols for conducting clinical

research, for conducting stem cell research- ICSCRT (Institutional Committee for Stem Cell Research and Treatment).

- Understand training, certification, licensing, and competency assessment standards for transfusion laboratory professionals, including medical laboratory technicians.
- Understand the importance of a comprehensive transfusion laboratory safety policy and programme.
- Understand how SOPs are used, developed, authored, and reviewed and their importance in mandatory laboratory inspection by various accrediting agencies.
- Understand development of quality manual.
- Understand the role of quality assurance, quality management, and process improvement principles in laboratory operation and planning.
- Understand the role of risk management in the transfusion laboratory and become familiar with the nature of patient safety initiatives, and forensic testing such as paternity testing.
- Demonstrate understanding of the elements of current good manufacturing practices as they apply to the collection, processing, and storage of all blood components / products.
- Understand the principles & objectives of total quality management in transfusion service including premises, personnel, instruments / reagents, biosafety and external / internal quality control.
 - Operational aspects: Understand the importance of EQAS in blood transfusion services.
 - Understand the principles and objectives of equipment management including specification, equipment selection, installation, calibration/standardization/validation, and preventive maintenance.
- Know the fundamental concepts of medical statistics. Demonstrate familiarity with importance of statistical methods in assessing data from patient material and experimental studies e.g., correlation coefficients, expected versus observed, etc. and their interpretation.
- Understand principles of specimen collection (e.g., phlebotomy technique, safety, and specimen tubes) and specimen processing and traceability
- Demonstrate understanding of knowledge of error management in blood bank including root cause analysis and CAPA.

- Demonstrate knowledge of various records and their maintenance as per regulatory requirements.

B. Affective Domain

I. Basic Sciences (Immunology, Medical Genetics, Hemostasis & Physiology of Formed Elements of blood)

The student should:

- Demonstrate honesty and integrity in all interactions.
- Demonstrate responsibility and trustworthiness in the execution of all duties.
- Demonstrate the ability to accept criticism and to understand the limitations of one's own knowledge and skills.
- Demonstrate a commitment to excellence and ongoing professional development
- The student should demonstrate professionalism in taking a bleeding history from a patient.

II. Blood Collection/Blood Center/Component Processing

- The student should be able to function as a part of a team that is essential for the selection and management of a blood donor. She/he should therefore develop an attitude of cooperation with colleagues so necessary for this purpose. It is implied that she/he will, whenever necessary, interact with the blood donor, patient, clinician and other colleagues to provide the best possible blood transfusion support, diagnosis or opinion.
- Demonstrate compassion and sensitivity in the care of patients and respect for their privacy and dignity.
- Respect for donor / patient autonomy.
- The student should demonstrate professionalism during blood donor selection, counseling and notification. Always adopt ethical principles and maintain proper etiquette in her/his dealings with blood donors, outdoor camp organizers and other health personnel.
- Be able to obtain informed consent from donor.

- Respect the rights of the blood donor including the right to information and maintaining confidentiality.
- Develop communication skills not only to word reports and professional opinions but also to interact with blood donors, outdoor camp organizers, peers and paramedical staff.
- Always adopt principles of laboratory / personnel safety and respect documentation required as per law.

III. Transfusion transmitted infection

The student should:

- Respect the rights of the sero-positive blood donor including confidentiality, right to information.
- Adopt ethical principles and maintain proper documentation while interacting with other inter related labs such as ICTCs, counselor, state AIDS Control Societies etc.
- The student should follow all safety policies and adhere to the department's laboratory safety plan and personal hygiene plan.

IV. Immunoematology / Blood Group Serology / Compatibility testing

The student should:

- Should be able to interact with clinical colleagues in professional manner to provide best possible transfusion support and opinion in immunoematological problems.
- Demonstrate improvement in the affective traits of organizational skills, work habits, attitude, interpersonal skills, and problem-solving ability.
- The student should maintain a clean and orderly work area.

V. Clinical Transfusion Service

The student:

- Should be able to function as a part of a team that is essential for the diagnosis and management of a patient. She/he should therefore develop an attitude of cooperation with colleagues so necessary for this purpose.

- Should be able to interact with clinical colleagues in professional manner to provide best possible transfusion support and opinion.
- Demonstrate improvement in the affective traits of organizational skills, work habits, attitude, interpersonal skills, and problem-solving ability.
- should maintain a clean and orderly work area.
- should accept constructive criticism as a learning process. Utilize constructive criticism to correct deficiencies and improve performance.
- The student should demonstrate inquisitiveness by asking necessary questions concerning practical performance or theoretical application of laboratory procedures.

VI. Therapeutic Apheresis, Therapeutic Plasma Exchange and Cytapheresis

The student should be able to:

- Communicate effectively with clinicians and patients regarding emergent or scheduled therapeutic apheresis procedures through conversations and writing of consult notes.

C. Psychomotor Domain

At the end of the course, the student should acquire the following skills:

- Demonstrate competency in performing & interpretation of various methods of hemoglobin estimation and complete hemogram.
- The student should be able to demonstrate competency in preparation and interpretation of peripheral blood smear in health and disease conditions – inclusive of but not limited to:
 - Nutritional (Iron deficiency/Vit B12 and Folic acid deficiency) anemia
 - Hemolytic anemia (Immune, Sickle Cell, Thalassemia, Microangiopathic)
 - Thrombocytopenia
 - Acute leukemia
 - Chronic leukemia
 - Hemoparasites
 - Myelodysplastic syndromes

- Myeloproliferative disorders
- Demonstrate competency in performing and interpretation of laboratory tests in coagulation and thrombosis such as prothrombin time, activated partial thromboplastin time (APTT), fibrinogen, thrombin time, platelet function testing, mixing tests, factor assays, investigations in DIC etc.
- Demonstrate competency in interpretation of Hb electrophoresis/HPLC
- Should be conversant in performing and interpreting various laboratory immunological tests pertaining to transfusion science such as:
 - isolation of T & B lymphocytes
 - immunoelectrophoresis
 - flow cytometry
 - CD4 / CD8 counts
- Should be conversant in HLA typing techniques, including serological methods, micro-cytotoxicity assays, nucleic acid assays and lymphocyte culture.
- Should be conversant with the steps of a Polymerase Chain Reaction (PCR) and should demonstrate competence in the steps and interpretation of Western Blot and Hybridization procedures.

Blood Collection/Blood Center/Component Processing

- Compare and contrast the eligibility requirements for allogeneic, autologous & apheresis blood donations.
- Demonstrate proficiency in selection of whole blood donors (minimum 300) and apheresis donors (minimum 15).
- Demonstrate competency in various types of autologous blood collection and their application in clinical transfusion service.
- Demonstrate proficiency in collection of whole blood with regard to preparation of phlebotomy site, proper volume and sample collection in minimum 300 donors.
- Demonstrate proficiency in evaluating and managing minimum 15 adverse reactions associated with blood donation/phlebotomy (whole blood and apheresis donations).

- Demonstrate the proficiency in organization of at least 05 outdoor blood donation camps and demonstrate skills to motivate blood donors / organizers.
- Demonstrate knowledge of the indications for therapeutic phlebotomy and demonstrate proficiency in at least 5 cases.
- Demonstrate proficiency in preparation of following components 200 each as per department SOP
 - Packed red blood cells
 - Fresh Frozen Plasma
 - Platelet concentrate
 - Cryoprecipitate (Minimum 25)
- Understand the significance of storage of blood components at appropriate temperature and demonstrate proficiency in compatibility, labeling requirements of various components.
- Proficient in donor notification and counseling (Pre- and Post- donation) and the donor look-back process.
- Demonstrate proficiency in various modifications of blood components such as irradiation, cell washing, volume depletion and leuko depletion.
- Demonstrate proficiency in performing leuko-filtration in at least 5 blood components.
- Demonstrate proficiency in selection of apheresis machine, blood donor and be able to obtain apheresis product meeting quality standards in at least 10 procedures.
- Demonstrate proficiency in performing quality control tests on at least 15 each blood components such as PRBC, FFP, Platelets, cryoprecipitate.

Transfusion transmitted infection

The student should be able to:

- Compare & contrast various methodologies such as ELISA, rapid & chemiluminescence used in screening of transfusion transmitted infections.
- Demonstrate proficiency in performing, interpretation, documentation of at least 200 blood donor screening tests for TTIs as per departmental SOP.

- Demonstrate proficiency in preparation and interpretation of LJ Chart (5 nos.) and root cause analysis (RCA) and Corrective and Preventive action (CAPA) as and when required.
- Perform and be able to interpret non-treponemal and treponemal antibody tests used to diagnose syphilis.
- Demonstrate proficiency in proper handling and disposal of biohazardous material as per regulatory requirements.
- Demonstrate proficiency in the preparation and use of in-house external controls in transfusion transmitted infection screening.
- Demonstrate proficiency in Gram staining in at least 10 samples of biological fluids.

Immunohematology / Blood Group Serology / Compatibility testing

The student should be able to:

- Demonstrate proficiency in preparation of cell suspensions of appropriate concentration following cell washing techniques correctly & grade and interpret antibody-antigen reactions according to the established criteria.
- Demonstrate proficiency in performing ABO/Rh grouping in at least 200 donor / patient samples using department SOP.
- Demonstrate proficiency in performing, interpretation and resolving discrepant results in pre-transfusion testing, ABO/Rh grouping, red cell antibody screen, and antibody identification.
- Compare and contrast conventional cross matching versus type and screen using various advanced technologies. Demonstrate proficiency in performing at least 25 cross matches as per department SOP.
- to differentiate between the direct and indirect antiglobulin tests and identify appropriate uses for each. The student should be able to perform direct and indirect antiglobulin test on appropriate specimens, grading and recording the results appropriately with the use of "check cells".
- to identify sources of error in antiglobulin testing.

- Using a cell panel, perform antibody identification procedures and correctly interpret the results. Identify clinically significant RBC antibodies from an antibody panel including multiple alloantibodies and mixtures of alloantibodies and autoantibodies; determine how difficult it will be to obtain blood for this patient, and effectively communicate these results to clinicians.
- Demonstrate proficiency in performing & interpretation of various immunohematological tests
 - Direct Antiglobulin test (30 tests)
 - Indirect Antiglobulin test (30 tests)
 - Red cell antibody detection and identification (15 tests)
 - Titration of Anti D and Anti A and Anti B (15 tests)
 - Elution (05 tests)
 - Adsorption
 - Minor blood group typing
 - Saliva Inhibition Test
 - Resolution of ABO discrepancy
- Demonstrate proficiency in selection of blood unit for a patient with auto immune hemolytic anemia in at least 5 cases.
- Demonstrate proficiency in cryo-preservation of reagent red cells in minimum 5 cases.

Clinical Transfusion Service

The student should be able to:

- Demonstrate proficiency in evaluating and recommending treatment plans for minimum of 10 transfusion reactions.
- Be able to identify irregular antibodies in pregnant patients that are clinically significant and make appropriate recommendations for blood products. Demonstrate proficiency in preparation and transfusion of blood for intra uterine transfusion / exchange transfusion.
- Choose appropriate blood components and derivatives based on a thorough knowledge of the indications for transfusion.

- Demonstrate proficiency in the evaluation and appropriate transfusion therapy of thrombocytopenic patients (both adult and pediatric) including neonatal alloimmune thrombocytopenia.
- Demonstrate proficiency in provision of transfusion support in special patient populations (e.g., hematology/ oncology, pediatrics, thalassemia, hemophilia, transplantation, cardiac surgery and burn/trauma).
- Demonstrate proficiency in the appropriate use of blood components in several clinical conditions such as (inclusive of but not limited to) hemoglobinopathies, hemophilia, autoimmune hemolytic anemia, massive transfusion, obstetric conditions etc.
- Demonstrate familiarity with the appropriate use of highly specialized blood products (e.g., granulocytes, donor lymphocyte infusions, HLA-matched platelets, and coagulation factor concentrates).
- Demonstrate competence in the management of blood inventory and the ability to communicate effectively the hospital's needs to the blood donor recruiters, Triage and screen requests for blood components appropriately during inventory shortages.
- Demonstrate proficiency in evaluating effectiveness of platelet transfusion including patient's with refractoriness to platelet transfusions. Outline the principles of histocompatibility testing and platelet cross-matching and apply this knowledge in selecting appropriate platelet products when indicated.
- Demonstrate competency in providing transfusion and immunohematological support to patients with bone marrow / stem cell transplantation including cryo-preservation of stem cell, quality control and infusion.

Therapeutic Apheresis, Therapeutic Plasma Exchange and Cytapheresis

The student should be able to:

- Demonstrate proficiency in evaluating and preparing patients for therapeutic apheresis, including discussion with the patient of the risks and benefits associated with apheresis procedures and obtaining informed consent.
- perform plasma exchange including calculation & type of replacement fluid to be used and monitoring patient for complications and efficacy of the procedure.

- Demonstrate proficiency in evaluating and treating adverse reactions associated with therapeutic apheresis.
- Demonstrate proficiency in the treatment of patients using specialized methods (e.g., photopheresis and immunoadsorption columns).

Regulatory Skills / Quality Assurance/ Quality Control in blood transfusion

The student should be able to:

- Demonstrate proficiency in preparing at least 5 SOP for the department.
- understand proper use of instrumentation and computerization in a transfusion laboratory.
- Compare and contrast the various means of performing blood utilization reviews.
- Explain the logistics required in determining appropriate blood inventory for a geographic region and the process of meeting daily, weekly and monthly collection goals.
- Recognize sources of pre-analytical variation and the role of biological variability in laboratory assessment.
- calculate means, standard deviation and standard error from the given experimental data
- Demonstrate the proficiency in preparedness for getting accreditation.
- Ability to generate various reports required for the various regulatory authorities.
- Be able to perform root cause analysis in at least 5 cases.

Syllabus

Course contents:

I. Blood donation

- Motivating factors for donation
- Whole blood donation vs apheresis donation
- Types: allogeneic, autologous, directed
- Donor questionnaire and interview: Eligibility and deferral criteria
- Donor reactions and their management

II. Blood component preparation, composition & storage

- Basic steps in component preparation and labeling
- Composition: volume, cellular, plasma and clotting factor content

- Storage conditions for components
- “Storage lesions”
- Quality control standards
- Specialized blood components - irradiated, volume reduced, CMV free, HLA matched

III. Plasma derivatives

- Basic principles of preparation & composition
- Recombinant clotting and hematopoietic growth factors
- Clinical indications and dosage

IV. Blood groups

- Biochemical structure of major blood group antigens
- Clinically significant blood group antibodies
- Properties and significance of naturally occurring vs unexpected antibodies

V. Pretransfusion testing

- Patient specimen labeling requirements
- Patient /component identification requirements
- ABO/Rh, Red cell antibody screen, Cross match
- Abbreviation of compatibility testing in emergency

VI. Transfusion indications

- Red blood cells, Platelets, Plasma/cryoprecipitate, Granulocytes
- Massive transfusion
- Metabolic complications
- Dilutional coagulopathy
- Switching ABO /Rh types

VII. Transfusion reactions

- Diagnosis, Pathophysiology, Treatment, Prevention

VIII. Infectious complications

- Bacterial, parasitic, viral, prions
- Current risk & Prevention strategies

IX. Transfusion therapy in special patients

- Hematology/Oncology
- Pediatric/neonatal

- Obstetric including intra uterine
- Cardiac surgery with CPB
- Burn patients and Trauma patients
- Transplantation: Stem cell / Bone marrow, Liver, Kidney

X. Hemolytic disease of new born

- Pathophysiology
- Causative blood group antibodies
- Treatment and Prophylaxis

XI. Hemoglobinopathy

- Classification, Pathophysiology, Diagnosis and Transfusion therapy

XII. Immune hemolytic anemia

- Warm, Cold, Drug induced hemolytic anemia
- Compatibility testing issues
- Special transfusion needs

XIII. Thrombocytopenia

- Immune thrombocytopenic purpura
- Thrombotic thrombocytopenic purpura
- Post transfusion purpura
- Fetal and neonatal thrombocytopenia

XIV. Neutropenia

- Classification, etiology and treatment
- Granulocyte transfusion

XV. Clotting factor disorders

- Principle of hemostasis and coagulation
- Laboratory tests of coagulation status
- Selection and dosage of factor preparations
- Management of patients with inhibitors

XVI. Platelet refractoriness

- Recognition and evaluation
- Calculation of CCI and platelet recovery
- Principles of HLA typing and platelet cross match

- Selection of appropriate platelet product

XVII. Transfusion alternatives

- Synthetic and natural volume expanders
- Hemoglobin solution, Perfluorochemicals, Fibrin glue, Hemostatic agent

XVIII. Autologous blood

- Preoperative autologous deposit
- Perioperative blood salvage
- Acute normovolemi chemo dilution

XIX. Laboratory management

- Quality assurance and quality control
- Equipment procurement
- Writing policies and procedures
- Blood inventory management
- Look back
- Maximal surgical blood order schedule
- Hospital Transfusion Committee

XX. Therapeutic apheresis

- Principles of apheresis technology
- Indications, risk and benefits
- Replacement fluids
- Monitoring of patient and central venous canula

XXI. Stem cell collection and processing

- Donor preparative regimen
- Collection technique and complications
- Cell count targets and engraftment monitoring
- Processing and storage

XXII. Regulatory / accreditation agencies

- Drugs and cosmetics act of India
- Licensing requirements
- National blood policy, ISO / NABH, GM
- Inventory management
- Donor notification and counseling

TEACHING AND LEARNING METHODS

Teaching methodology

Teaching methodology includes:

1. Didactic lectures
2. **Seminar/journal club presentation (once a fortnight).**

Evaluation sheets may be incorporated for the purpose of assessment of presentations. The following points may be considered in the scheme for evaluation of presentations.

- Topic selection
- Completeness of presentation
- Clarity of presentation
- Understanding of the subject and ability to convey the same
- Whether relevant references have been consulted
- Ability to convey points in favor and against the subject under discussion
- Proper use of audio-visual aids
- Ability to answer questions

3. **Case presentation, case work up, case handling/management (once a week)**

Each post graduate student in transfusion medicine presents an interesting case in clinical transfusion practice or in laboratory exercise of choice.

4. **Attending clinical grand rounds / clinic-pathological conference**

The post graduate students are encouraged to attend lectures and grand rounds of other clinical and basic science departments of the hospital.

5. **Attendance at Scientific meetings, CME programmes**

The post graduate students are expected to attend meetings related to transfusion medicine, present papers/posters in these meetings.

6. **Quality performance meetings:**

The post graduate students should attend meetings of hospital transfusion/blood usage committee, meetings to review transfusion service errors, variances, and incidents, mortality meetings, audit related meetings.

7. **Paper/poster presentation:**

A post graduate student of a post graduate degree course in broad specialities/super specialities would be required to present one poster presentation, to read one paper at a national/state conference and to present one research paper which should be published/accepted for publication/sent for publication during the period of his postgraduate studies so as to make him eligible to appear at the postgraduate degree examination.

8. Teaching skills:

The post graduate students shall be required to participate in the teaching and training programme of undergraduate students and interns.

9. A **logbook** should be maintained recording the duration of posting, the period of absence, if any, skills performed, and remarks if any by the teacher/faculty member. The logbook should also record journal clubs, seminars attended and partaken as well as undergraduate teaching activities the post graduate student has participated and should be signed by the faculty in charge.

11. Department should encourage e-learning activities

Rotation:

✓ **Departmental rotation of students**

Title	Content of training activities	Learning objective
Orientation [1 month]	Brief orientation to computer system, blood bank activities, teaching program	Be conversant with computer system & operation of blood bank activities
Blood donation [3 months]	Donor recruitment & motivation, Donor selection Phlebotomy, Post donation care of donor, outdoor blood donation	Should be able to select the donor, perform phlebotomy with aseptic precautions, and manage donor reactions
Apheresis - donor and therapeutic [2 months]	Access evaluation, donor suitability, selection of machine, product manipulation, QC of product, donor observation for adverse effects and its management Indications, contra indications,	Should be able to perform the procedure independently, obtain quality product and manage any adverse effects

	replacement fluids, frequency, monitoring of TPE	Should be able to select proper patient, machine, plan TPE, select replacement fluids and monitor the patient
Component preparation & QC [3 months]	Preparation of blood components. Product manipulation such as Leucocyte removal or Irradiation. Storage & quality control	Should be able to understand factors affecting quality of components,
Immunoematology [3 months]	Diagnosis & transfusion support in AIHA, PNH Evaluation of transfusion reaction. Investigations in antenatal serology. ABO-Rh typing, antibody screening, identification, evaluation of positive DAT	Should be able to interpret immune hematological tests. Should be able to provide consultation to physicians regarding transfusion management
Pretransfusion testing & cross match [3 months]	Investigation of difficult cross match, formal consultation on transfusion support in complex cases, checking indications & dosage for blood components, emergent issue of blood, transfusion in special cases such as massive transfusion, organ transplantation, platelet refractoriness.	Should be able to provide consultation on transfusion therapy. Should be able to resolve difficult & complex cross matching problems. Ensure appropriate and judicious use of blood and components
Transfusion Transmitted infection screening [3 months]	Screening for various markers such as HIV, HCV, HBs Ag, Syphilis. Methodology such as Elisa, spot, rapid, automated analyzer NAT techniques such as PCR, TMA. Laboratory safety	Should be able to understand blood screening principles and disposal of reactive units. Should be able to validate ELISA, maintain QC
Quality control/ records [1 months]	Quality control of components, equipment, reagents. Quality assurance. Development of documents, SOPs, Regulatory compliance	Should be able to understand QC principles, Recognize common management & regulatory issues, identify management strategies
PBSCT [1 month]	Processing, storage, thawing, infusion of PBSC. Immunoematological monitoring of ABO mismatch transplants, Transfusion support – irradiation, CMV issues	Describe common procedures and basic concepts behind PBSC processing and cellular product therapies.

✓ **Training in allied departments:**

Students should be sent for training for 3 months in allied laboratories and clinical departments.

Subjects for training in laboratories:

Complete hemogram
Work up of hemolytic anemias
Reading peripheral smear
Bone marrow aspiration
Coagulation work up
HLA typing
Isolation of lymphocytes
CD4/ CD8 / CD 34 counts using flow cytometry
Immunofluorescence
Bacterial culture, Grams staining
Special molecular techniques

Subjects for training in Clinical Departments:

Transfusion support for thalassaemia, hemophilia, leukemia, solid organ transplantation
Platelet transfusion therapy and its monitoring
Neonatal exchange transfusion
Bed side management of transfusion reactions
Intra-operative hemodilution, use of Cell saver, intra-operative blood salvage

During the training programme, patient safety is of paramount importance, therefore, skills are to be learnt initially on the models, later to be performed under supervision followed by performing independently; for this purpose, provision of skills laboratories in medical colleges is mandatory.

ASSESSMENT

A standardized scheme of evaluation is necessary to train post graduate students in any teaching program. Both formative and summative evaluations are therefore mandatory.

Formative Assessment

Formative assessment should be continual and should assess medical knowledge, patient care, procedural & academic skills, interpersonal skills, professionalism, self-directed learning and ability to practice in the system.

FORMATIVE ASSESSMENT, i.e., during the training

Quarterly assessment during the Diploma course training should be based on:

1. Journal based / recent advances learning
2. Patient based /Laboratory or Skill based learning
3. Self-directed learning and teaching
4. Departmental and interdepartmental learning activity
5. External and Outreach Activities / CMEs

The student to be assessed periodically as per categories listed in postgraduate student appraisal form (Annexure I).

SUMMATIVE ASSESSMENT, i.e., at the end of training

The summative examination would be carried out as per the Rules given in POSTGRADUATE MEDICAL EDUCATION REGULATIONS, 2000.

The examination shall be in two parts:

1. Theory Examination:

There shall be three papers each of three hours duration. These are:

- Paper I: Basic applied aspects related to Transfusion Medicine (including Hematology and Immunology)
- Paper II Blood donor organization, Technology of components, clinical hemotherapy.

- Paper III Recent advances in transfusion Medicine

Pattern of question paper

Option I:

Each question paper will have following pattern

- One Structured Essay Question
- Six short answer questions
- Two Problem Based Analysis /Interpretation

Option II:

Each question paper will have following pattern

- Ten short answer questions of which four questions will be Problem Based Analysis /Interpretation

2. Clinical/Practical and oral examination:

Clinical/Practical examination shall be carried out for two days:

Laboratory and clinical skills:

Minimum of 6 exercises (*stations*) covering all aspects of Transfusion Medicine (inclusive of but not limited to).

- blood donor / apheresis donor selection
- component processing
- immunohematology
- antenatal serology
- transfusion reaction management
- quality control of reagents, equipment, components
- coagulation testing,
- basic hematology tests
- transfusion transmitted infection screening
- stem cell transplantation
- Interpretation of Flow cytometry/HPLC/TEG

- Clinical hemotherapy

Minimum of 6 exercises shall be given to each post graduate student. The duration of each exercise shall vary from 30 minutes to 90 minutes. Each exercise or *Station* shall be followed by Viva on the particular exercise. Laboratory performance of the student is evaluated using the following criteria:

- Familiarity with the procedure.
- Setting up and performing the procedure (organizational skills).
- Appropriate specimens and reagents are obtained and utilized.
- Proper use of equipment, reagents, supplies and specimens.
- Proper labelling, handling and disposal of specimens, tubes, etc.
- Organization and performance of individual tasks.
- Completion of tests within a reasonable amount of time.
- Clean up of work area.
- Correct interpretation of results with recognition of discrepancies or abnormal results.
- Results are recorded and reported in proper format.
- Ability to correlate clinically

Clinical case discussion (6 per post graduate student)

There shall be minimum 06 Hemotherapy exercises and administrative issues for each candidate. The candidate is required to make his own assessment of the problem and come out with solutions.

Communication / presentation skills

The candidate will be required to present a topic of his/her dissertation/thesis in Power Point format for 10 minutes. The candidate will be examined on the presentation style, communication skill, slide design and content.

Spots (10 per candidate)

05 clinical/ laboratory situations and 05 OSPE per candidate. The candidate will be required to answer on each situation. For example, candidate may be shown picture of chest X-ray with pulmonary edema developing after FFP infusion. The candidate will be asked to give different possibilities and their investigations.

Log book discussion

Oral/Viva Voce examination

Oral examination shall be comprehensive enough to test the post graduate student's overall knowledge of the subject.

Recommended reading:

Books (latest edition)

1. Technical Manual, Mark E Brecher, AABB Bethesda, Maryland.
2. Transfusion Medicine Technical manual, R. K. Saran, Directorate General of Health Services, Ministry of Health and Family Welfare, Govt. of India, New Delhi.
3. Mollison's Blood Transfusion in Clinical Medicine. Harvey G. Klein. David J. Anstee, Blackwell publishing, Oxford.
4. Rossi's Principles of Transfusion Medicine, T.L.Simon, W.H. Dzik, E.L.Snyder, C.P.Stowell, R.G. Strauss, Lipincott Williams and Wilkins.
5. Modern Blood Banking & Transfusion Practices, Denise M Harmening, FA Davis Company, Philadelphia.
6. Blood Transfusion Therapy, Gotschall J. L. AABB press, Maryland.
7. Donor recruitment: Tips, Techniques and Tales, Perkins S, AABB Press, Maryland.
8. Transfusion therapy: Clinical Principles and Practice, Mintz P.D. AABB Press, Maryland.
9. Blood Banking and Transfusion Medicine: Basic Principles and Practices, C.D. Hillver. L.L. Silberstejn. P.M.Ness, K.C.Anderson, Churchill Livingstone.
10. Practical Transfusion Medicine, M.F.Murphy. D.H.Pamphilton, Blackwell Science.
11. Human Blood Groups, Geoff Daniels, Blackwell Science.
12. Dacie and Lewis's Practical Hematology, S.M. Levis. BJ. Bain. I. Bales, Churchill Livingstone.
13. Apheresis: Principles and Practices, B.C. McLeod. R. Weinstein, AABB Press Bethesda, Maryland.
14. Transfusion Medicine, Jeffrey McCullough, Churchill Livingstone.

15. Applied Blood Group Serology, P.D. Issit, Anstee, D.J. Winters, Montgomery Scientific Publication.

16. Immunohematology: Principles and Practices, Eva D. Quinley, Lippincott Williams and Wilkins.

Journals

Three International and 02 national journals (all indexed).

Standards and Regulatory documents

- DGHS Standards
- Drugs and Cosmetic Act 1940, Amended Drug Rules 1945
- NACO Standards for Blood Banks
- NABH Standards for Blood Banks
- NABH Standards for Storage Centres
- AABB Standards
- NACO Training Modules



Postgraduate Students Appraisal Form

Clinical Disciplines

Name of the Department/Unit :

Name of the PG Student :

Period of Training : FROM.....TO.....

Sr. No.	PARTICULARS	Not Satisfactory			Satisfactory			More Than Satisfactory			Remarks
		1	2	3	4	5	6	7	8	9	
1.	Journal based / recent advances learning										
2.	Patient based /Laboratory or Skill based learning										
3.	Self directed learning and teaching										
4.	Departmental and interdepartmental learning activity										
5.	External and Outreach Activities / CMEs										
6.	Research work										
7.	Log Book Maintenance										

Publications

Yes/ No

Remarks*

*REMARKS: Any significant positive or negative attributes of a postgraduate student to be mentioned. For score less than 4 in any category, remediation must be suggested. Individual feedback to postgraduate student is strongly recommended.

SIGNATURE OF ASSESSEE

SIGNATURE OF CONSULTANT

SIGNATURE OF HOD