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Annexure-III

GUIDELINES FOR COMPETENCY BASED POST DOCTORAL CERTIFICATE COURSE (PDCC) IN APHERESIS TECHNOLOGY AND BLOOD COMPONENT THERAPY

The PDCC course [Apheresis and Blood Component Technology] in Sanjay Gandhi Postgraduate Institute of Medical Sciences (SGPGIMS) is a 1-year Senior Residency program which is conducted primarily for those who have already earned MD (IHBT/TM) or MD (Pathology) and are further interested in obtaining intensive training in Transfusion Medicine with special emphasis on Apheresis Technology and Blood Component therapy

Main objectives of this course are as under.

1. To impart composite training in fundamental and applied aspects of Apheresis and Blood Component Technology.

   a) To understand the basic principles and concepts presented in Apheresis Technology and Blood Component therapy and develop a fund of basic knowledge in the field

   b) To recognize problems in clinical medicine those are related to transfusion and apply concepts and principles in the core curriculum to clinical situations especially with regard to local, regional and national scenario

   c) To provide appropriate therapeutic solutions to transfusion medicine problems pertinent to clinical conditions prevalent al local, regional and national level.

2. To recognize significance of important research in the advancement of transfusion medicine and to impart training and stimulate interest in research in the field of Transfusion Medicine to keep abreast with the situation internationally.

3. To recognize motivational, organizational and managerial skills for efficient operation of blood centre being established at local and National level, with emphasis on Apheresis (Donor and Therapeutic)

After completion of the 1-year period, the student is expected to have an in-depth, comprehensive knowledge of all facets of Apheresis Technology and Blood Component therapy, have skills to effectively deliver high quality blood services and healthcare delivery, have attitudes and behaviour consistent with highest professional global standards, teaching, leadership and research in the field.

The candidate is expected to learn to develop an attitude of committed learning, teaching, and research for the welfare of the society at all levels local, regional and National.

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Competence expected at end of Training Period

It is expected that at the end of the course, the PDCC student will be specifically equipped for the following tasks.

- Sound knowledge about starting a blood centre including the licensing procedure pertinent to the National rules and regulations, especially Component and Apheresis centre.
- Provide direction to blood centre with regard to organization of the collection, preparation, storage, distribution and clinical use of blood and components in diseases prevalent locally, at regional level or throughout the country.
- Promote optimal use of blood products and develop a system for clinical control of their use
- Organization of Quality Management programme in blood transfusion services in line with the national standards.
- Develop skills needed for effective communication with the various stakeholders, blood donors, organizers, patients, colleagues, and ability to involve in the coordinated teamwork.
- Participate in research in blood transfusion medicine and upgrade the scientific knowledge by continuing medical education applicable to Indian scenario.
- Organize training program for manpower development in the field
- Develop essential skills in teaching, leadership, conducting medical research, and to get them presented in scientific forums and published in peer-reviewed National and International journals of high repute.

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Subject Specific Competencies

A postgraduate appearing for the Post Doctoral Certificate Course [Apheresis Technology and Blood Component therapy is supposed to have acquired not only professional competence expected of a well-trained specialist but also academic maturity, a capacity to reason and critically analyze a set of scientific data. He is supposed to keep himself abreast with the latest developments in the field of Apheresis (Donor/ Patient) and Blood component therapy. The student is expected to understand the variations in blood transfusion practices at national and international level. A brief outline of what is expected to have learnt during each of the postings in the different sections/laboratories during the PDCC Course is given under each head.

Course 1: Basic Sciences such as immunology, genetics pertinent to blood components & Apheresis, Instrumentation, Automation, Computerization and Records, Legal, ethical & Administrative aspects of Blood Transfusion Services

A Cognitive Domain (Knowledge)

A.1 Basic Sciences such as immunology, genetics pertinent to blood components & Apheresis.

- 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 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 the following procedures employed in clinical and experimental studies relating to immunology.
    - ELISA techniques, Chemiluminescence assay, HLA typing,
    - Rapid diagnostic test and their application in resource limited settings as primary health centers, community health centers, health camps and remote areas.
- Understand the principles of basic genetics with regard to Mendelian law 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 polymorphism in organ and bone marrow/stem cell transplantation and association with disease prevalent at National and international level.

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- Understand the basic physiology, biochemistry and immunohematological aspects 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
- Should have understanding of variability of blood group distribution and its clinical significance at local, national and international level.
- Understand hemoglobin structure, synthesis, function, its aberrations. and degradation including iron and bilirubin metabolism
- 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.
- Should be able to understand application of various methods of pre-transfusion testing according to the local needs and its comparison with international practices.
- The student should be able to demonstrate understanding of the pathophysiology, clinical features, lab diagnosis & management of various clinical conditions requiring immunhematological and transfusion support including
    - Multi-transfused patients such as thalassemia, sickle cell disease etc
    - Alloimmunized antenatal cases,(HDN)
    - Transfusion reactions
    - Immune hemolytic anemias
- 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.
- 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 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 and pathogen inactivation in Indian blood transfusion services
- Climate change and impact on health
    - Understand the current changes in climate on a global scale
    - Understand the effects on epidemiology of infectious diseases and its impact on donor selection and deferral

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- Understand the effects on the ecosystem and zoonotic diseases
- Understand the possible changes in transfusion requirements in developed and developing countries
- Understand the potential of extreme weather disturbances disrupting power and supplies, frequent disaster like situations

- Air pollution and impact on health
  - Understand the types of air pollutants and their sources
  - Understand the effects on lungs, heart and brain
  - Understand the possible consequences on blood donation and clinical transfusion
- Heat wave and its impact on human health
  - Understand the increased physiological stress and increased mortality due to heat waves
  - Understand the impact of power shortages on health services and specifically blood transfusion services.

A.2 Instrumentation, Automation, Computerization and Records

- The student should have understanding of various automated platforms used in blood transfusion services along advantages and disadvantages of individual platforms.
- Student should understand the principles of equipment management including Design qualification (DQ), Installation qualification (IQ), Operational Qualification (OQ) and Performance Qualification (PQ). Annual maintenance contract with / without spares, comprehensive maintenance contract.
- Student should have knowledge of Calibration, validation and standardization of equipment / instruments.
- Understand how SOPs are used, developed, authored, and reviewed and their importance in mandatory laboratory inspection by various accrediting agencies.
- The student should have basic knowledge of computers, software and data security requirements to maintain confidentiality.

A.3 Legal, ethical & Administrative aspects of Blood Transfusion Services

- Demonstrate knowledge concerning the requirements and applications of all applicable National [e.g., DCGI, NABH, NIB, AERB] and international [e.g AABB, JCA etc] regulatory / accrediting agencies.
- Become familiar with the patient / blood donor privacy including the use of institutional review board (IRB) protocols for conducting stem cell research as per National (ICMR) and international guidelines.

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- Understand training, certification, licensing, and competency assessment standards for transfusion laboratory professionals, including medical laboratory technicians.
- Understand the role of quality assurance, quality management, and process improvement principles in laboratory operation and planning.
- The student should understand basic process of procurement of consumables and supplies.
- Should be able to identify the differences in quality standards for blood and blood components at National and international level.
- Understand the principles & objectives of total quality management in transfusion service including premises, personnel, instruments / reagents, biosafety and external / internal quality control. Operational aspects.

B Psychomotor Domain (Skills)

- Demonstrate competency in performing & interpretation of various methods of hemoglobin estimation and complete hemogram. Be able to identify variations in the methodology at national and international level
- The student should be able to demonstrate competency in preparation and interpretation of peripheral blood smear in health and disease conditions.
- Demonstrate proficiency in selection of apheresis machine
- Demonstrate competency in performing and interpretation of coagulation tests
- Demonstrate understanding of histocompatibility testing and platelet cross-matching and apply this knowledge in clinical practice.
- Demonstrate proficiency in performing and interpreting various laboratory immunological tests pertaining to transfusion science
- Demonstrate proficiency in preparing SOP for the department.
- Be able to 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 preanalytical variation and the role of biological variability in laboratory assessment.
- Be able to 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.

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C **Affective Domain (Behaviour)**

- 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.

Course II: Application of Blood components in the clinical Practice, Donor Apheresis & Therapeutic Plasma Exchange, Fractionation, good manufacturing practice (GMP) including good laboratory practice (GLP); Transfusion medicine related to organ transplantation, Recent Advances.

A **Cognitive Domain (Knowledge)**

A.1 **Application of Blood components in the clinical Practice, Fractionation, good manufacturing practice (GMP) including good laboratory practice (GLP)**

- 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.
- The student should be able to identify the barriers for voluntary blood donation in India vis a vis International scenario.
- Should be able to understand importance of cold chain maintenance and its implementation specially in extremes of weather prevalent nationally.
- Be able to understand donor counselling and notification (Pre and Post-donation) and its implications in developing country like ours versus developed countries.
- 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 National quality standards
- Understand the mechanisms of adverse effects of blood / apheresis donation, its clinical features, management and prevention.
- Demonstrate understanding of various anticoagulant / preservatives used for collection and storage of blood and components.

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- The student should be familiar with various "storage lesions" in blood components, factors affecting the storage lesions and its prevention. 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 and their variations at local , national and international level transfusion services. 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 National agencies (DGHS, DCGI, NABH, NACO, NIB, AERB) and international agencies (e.g -AABB, EC)
- Should be able to identify problems in the blood / apheresis collection and component preparation area and offer viable solutions.
- Should have knowledge of preparation, indications and transfusion of newer blood components including pooled platelet concentrates.
- Should have understanding of newer red cell and platelet preservatives such as Platelet additive solutions and their practical applications
- Should be aware of various technologies for irradiation of blood components and should be able to compare and contrast Co based vs Ce based Vs X-ray based irradiators and variation in irradiation practices at international level.
- 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 nonhemolytic transfusion reactions and demonstrate knowledge of the pathophysiology, treatment, and prevention of these complications
- Demonstrate understanding of the major noninfectious 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.

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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. Student should also demonstrate understanding of complications of platelet transfusion including refractoriness to platelets, its diagnosis and management.
- 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 perioperative autologous blood collection, and approaches to "bloodless" surgery.
- Student should demonstrate knowledge of principles of transfusion support in general surgery and special procedures such as cardiac surgery or oncological surgery.
- Should be aware of the concept of patient blood management and its clinical application.
- Understand the life-threatening complication of blood transfusion including TA-GvHD and their prevention.
- The student should understand the concept of Hemovigilance. Its implementation at local level and the reporting of adverse events at National level.

A.2 Donor Apheresis & Therapeutic Plasma Exchange, Transfusion medicine related to organ transplantation, Recent Advances.

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

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- Should be able to identify the disease conditions prevalent locally / nationally where therapeutic apheresis / cytapheresis may be useful as a therapeutic option.
- 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). Student should demonstrate understanding of National regulatory guidelines for stem cell research. (ICMR, DBT).
- Demonstrate knowledge of the use of various point-of-care tests (TEG, ROTEM) for hemostasis & recommend component therapy depending on the results.
- Should demonstrate the knowledge and understanding of various immunotherapies including Car-T cell therapy, Dendritic cell therapy, etc.
- Should have knowledge of upcoming cellular therapies including platelet rich plasma therapy and mesenchymal cell therapy etc.

B Psychomotor Domain (Skills)

- Compare and contrast the eligibility requirements for allogeneic, autologous & apheresis blood donations.
- Demonstrate proficiency in selection of whole blood donors (minimum 100) and apheresis donors (minimum 15)
- Demonstrate proficiency in evaluating and managing minimum 25 adverse reactions associated with blood donation/phlebotomy (whole blood and apheresis donations).
- Demonstrate the proficiency in organization of outdoor blood donation camps and demonstrate skills to motivate blood donors / organizers.
- Demonstrate proficiency in preparation of following components 100 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-filtration

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- Demonstrate proficiency in performing quality control tests on at least 15 each blood components such as PRBC, FFP, Platelets, Cryoprecipitate
- Demonstrate proficiency in evaluating and recommending treatment plans for minimum of 05 transfusion reactions.
- 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 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.
- 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.
- Should be able to perform plasma exchange (minimum 05 procedures) 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).

2.1.3 Affective Domain (Behaviour)

- Demonstrate compassion and sensitivity in the care of patients and respect for their privacy and dignity.
- Respect for donor / patient autonomy and confidentiality.
- The student should demonstrate professionalism during blood donor selection, counseling and notification. Always adopt ethical principles and maintain proper etiquette in his/her dealings with blood donors, outdoor camp organizers and other health personnel.

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- 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 documentation required as per law.
- Should be able to function as a part of a team that is essential for the diagnosis and management of a patient. He/she should therefore develop an attitude of cooperation with his/her 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.
- The student should accept constructive criticism as a learning process. Utilize constructive criticism to correct deficiencies and improve performance.
- Communicate effectively with clinicians and patients regarding emergent or scheduled therapeutic apheresis procedures through conversations and writing of consult notes
- Understand principles of specimen collection (e.g., phlebotomy technique, safety, and specimen tubes) and specimen processing and traceability
- Demonstrate the understanding of knowledge of error management in blood bank including root cause analysis and CAPA.

General competencies & recent advances specific to transfusion medicine common to all courses

1 **Ethical Issues**

- Demonstrate the knowledge of ethical issues related to patient management, donor care and clinical research.

2 **Patient Care**

- Be able to apply recent developments in the field from research to clinical practice such as:
    - Blood and platelet substitutes
    - Biomaterials e.g., fibrin glue, platelet gel
    - Growth factors
    - Cryopreservation techniques
    - Gene therapy / Proteomic / Microarray

- Demonstrate understanding of principles of Disaster Management including transfusion support

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3 **Practice-Based Learning and Improvement**

- Demonstrate the ability to develop new policies and procedures or change existing policies and procedures based on a review of the literature or issuance of new guidelines by regulatory agencies.

4 **Interpersonal and Communication Skills**

- Demonstrate the ability to discuss the process of therapeutic apheresis with patients, and/or family members where appropriate; answer their questions; and obtain informed consent.

5 **Research methodologies and Biostatistics**

- Demonstrate the knowledge of various research methodologies and their applications of bio statistics in analyzing the research data.

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SYLLABUS:

I- SCIENFIFIC BASIS OF TRANSFUSION:

A- Biochemistry & physiology of elements of blood

1.0 Process of cell production and life span
- 1.1 Red Cells
- 1.2 White blood Cells
- 1.3 Platelets

2.0 Red Cells
- 2.1 Haemoglobin structure & function
- 2.2 Metabolic pathways
- 2.3 Membrane structure & function

3.0 White Cells
- 3.1 Structure, function & Kinetics

4.0 Platelets
- 4.1 Structure & function

5.0 Physiology of haemostasis
- 5.1 Role of platelets
- 5.2 Coagulation pathways
- 5.3 Fibrinolysis

6.0 Haemodynamics of blood flow & volume (Haemorrheology)

B- Immunology

7.0 Principles of basic immunology
- 7.1 Antigen / Antibody reaction
- 7.2 Lymphocytes in humoral & cellular Immunity
- 7.3 Immune response, hypersentivity, auto-immunity

8.0 Immunobiology of transplantation

9.0 HLA & genetic control of immune response

C- Genetics

10.0 Principles of basic genetics

11.0 Genetics of blood groups

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11.1 Phenotypes & genotypes
11.2 Principles of blood group inheritance
11.3 Population genetics of blood groups

II- BLOOD GROUP SYSTEMS

12.0 Red Cells
13.0 White cells
14.0 Platelets

III- BLOOD COLLECTION PROCESSING, COMPONENT PREPARATION

A- Management of blood donation

15.0 Donor recruitment
- 15.1 Voluntary blood donation system
- 15.2 Categories of blood donor
- 15.3 Education & awareness of prospective donor

16.0 Acceptability criteria of blood donor

17.0 Care of blood donors
- 17.1 Pre-donation
- 17.2 Mid-donation
- 17.3 Post-donation
- 17.4 Prevention & management of complication of blood donation.

18.0 Blood Collection
- 18.1 Anticoagulants & preservatives
- 18.2 Procedure
- 18.3 Transportation
- 18.4 Blood donation camps

B- Blood Components

19.0 Components
- 19.1 Types
- 19.2 Methods of preparation
- 19.3 Indications, dosage & administration
  - 19.3.1 Haemoglobinopathies
  - 19.3.2 Methods of preparation
  - 19.3.3 Anaemia
  - 19.3.4 Transplantation patients

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19.4 Leuco-depletion

20.0 Storage of blood & components

- 20.1 Whole Blood
- 20.2 Red Cell concentrate
- 20.3 Granulocyte
- 20.4 Cryoprecipitate

21.0 Plasma fractionation

IV. PRE- TRANSFUSION TESTING:

22.0 Compatibility testing

- 22.1 ABO grouping & Rh typing
- 22.2 Antibody screening
- 22.3 Method of cross matching

23.0 Screening for transfusion transmitted diseases

V. ADVERSE EFFECTES OF BLOOD TRANSFUSUION:

24.0 Clinical presentation, investigations management

- 24.1 Haemolytic transfusion reaction
- 24.2 Non haemolytic transfusion reaction
- 24.3 Transfusion transmitted diseases

VI. APHERESIS:

25.0 Haemapheresis (Platelats, Granulocytes, Stem cells, plasma)

- 25.1 Donor selection
- 25.2 Procedure
- 25.3Complications

26.0 Therapeutic apheresis

- 26.1 Indications, procedure & complications
- 26.2 Plasmapheresis & plasma exchange
- 26.3 Erthtrocytapheresis & red cell exchange
- 26.4 Granulocytapheresis

VII. AUTOLOGOUS TRANSFSUION

27.0 Basic principal, indications, Contra0-indications

27.1 Pre-deposit

- 27.2 Haemodilution
- 27.3 Intra-operative blood salvage

VIII.IMMUNOHEAMATOLOGY

28.0 Classification, diagnosis, management

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28.1 Immune-haemolytic anaemia

28.2 Immune-thrombocytopenia

28.3 Immune-neutropenia

IX. TRANSPLATION

29.0 Transfusion support to transplant patients

30.0 Irradiation of blood product

X. BLOOD SUBSTITUTES, HAEMOPOIETIC AGENST & PHARMACOLOGIOCAL AGENTS

31.0 Crystalloid, colloids and Albumin

32.0 Oxygen carrying compounds

33.0 Recombinant coagulation factors

34.0 Haemopoloietic growth factors

35.0 Pharmacological agents

35.1 NADDP, protamine sulphate, Vit K

XI. TOTAL QUALITY MANAGEMENT

35.0 Development of standard operating procedures (SOP) manual

36.0 Quality Control

36.1 Reagents

36.2 Instruments

36.3 Personnel

36.4 Blood & components

37.0 Quality assurance

37.1 Internal quality control

37.2 External quality assessment

38.0 Hospital Transfusion Committee

39.0 Medical Audits

40.0 Good Manufacturing Practice (GMP)

41.0 Good Laboratory Practice (GLP)

42.0 Turnaround Time

XII. ORAGANISATION & MANAGEMENT OF TRANSFUSION SERVICES

43.0 Organization and function of blood services and hospital transfusion practice

43.1 Donor recruitment & motivation

43.2 Development of transfusion services

43.3 Inventory control

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43.4 Development of forms, label, records etc

43.5 Drugs & cosmetics Act

43.6 Bioethics & Confidentiality

43.7 Medicolegal aspects

XIII. BLOOD SAFETY

44.0 Sterilization

45.0 Disposal of boi-hazardous material

46.0 Safe laboratory practice

XIV. APPROPRIATE USES OF BLOOD

47.0 Whole Blood

48.0 Blood components

49.0 Fresh blood

50.0 Massive transfusion

Teaching And Learning Methods

General principles

The basic aim of postgraduate medical training and education is to produce specialists who understand the needs of community health of the state and country and enhance the quality of health care as well as provide an impetus to research, education, and training of the medical community. The postgraduate doctor after completion of the skill based competency training programme should be able to successfully address the medical requirements of the community. Learning during the programme is not only goal-oriented and didactic but also essentially self-directed and emanates from clinical and academic work. The designated academic sessions are meant to supplement the student's core efforts.

Teaching Methodology

Teaching sessions shall be an overall judicious amalgamation of case presentations, journal clubs, seminars, group discussion related to Quality Control lab data, Internal Audit meetings, focused brief topic presentations as allotted from time to time, case-based learning, integrated and interdepartmental meetings including any other collaborative activity with allied departments, as deemed necessary. Suggested modalities of teaching-learning methods are summarized below but shall not be limited to these.

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Formal teaching sessions

These include regular didactic lectures, journal clubs, seminars, discussions related to quality control lab data, internal audit meetings, case-based learning, interdepartmental meetings and collaborative meetings with allied departments.

This will comprise of the following:

Minimum Sessions

- Journal club - Once a week
- Seminar - Twice in a week
- Internal Audit meeting - Once a month
- Mortality meeting - Once a month
- Combined Grand rounds/ - Once a week

Log Book: During the training period, the student shall maintain a detailed and comprehensive Log Book indicating the duration of the postings and work done in various labs. Data should include the procedures assisted and performed, and teaching sessions attended. The purpose of the Log Book is to:

- Maintain a record of the work profile during training,
- Enable Consultants to access information about the work of the student
- Keep an eye on the progress and intervene if and when necessary
- As a means to assess from time to time, the experience gained and quality of work performed by the trainee.

The Log Book shall also serve as a source to help in the internal evaluation of the trainee. The Log book shall be cross-checked and assessed periodically by the faculty members who are involved in imparting the training. It shall be signed by the Head of the Department and a proficiency certificate from the Head of Department regarding the student's clinical competence, overall skillful performance of procedures and general approach towards patients will be necessary before the student is allowed to appear in the final examination.

- Departmental postings

The training program may be arranged in the form of postings to different areas, based on the curriculum, for specified periods as outlined below. The period of such assignments/postings is recommended for 11 months. Posting schedules may be modified depending on needs, feasibility and exigencies. It is appreciated that individual institutions may find it convenient to follow a different pattern of posting.

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Title	Content of training activities	Learning objective
Blood donation	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, manage donor reactions and maintain records
Apheresis – donor and therapeutic	Access evaluation, donor suitability, selection of machine, product manipulation, QC of product, donor observation for adverse effects and its management Indications, contra indications, replacement fluids, frequency, monitoring of TPE	Should be able to perform the procedure independently, obtain quality product and manage any adverse effects Should be able to select proper apheresis equipment, plan TPE, select replacement fluids & monitor the patient
Component preparation & QC	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,
Immuno-haematology	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 immuno- hematological tests. Should be able to provide consultation to physicians regarding transfusion management
Pretransfusion testing & cross match	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	Screening for various markers such as HIV, HCV, HBsAg, Syphilis.	Should be able to understand blood screening principles and disposal

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Title	Content of training activities	Learning objective
infection screening	Methodology such as Elisa, spot, rapid, automated analyzer NAT techniques such as PCR, TMA. Laboratory safety	of reactive units. Should be able to validate ELISA, maintain QC
Quality control/ records	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	Processing, storage, thawing, infusion of PBSC. Immunohematological monitoring of ABO mismatch transplants, Transfusion support – irradiation, CMV issues	Describe common procedures and basic concepts behind PBSC processing and cellular product therapies.

- Postings in the allied departments

For allied laboratory and clinical department posting the rotation shall be a for 1 month, based on the facilities and super-specialties available in the institution/centre.

Laboratory area subjects:

- Complete hemogram
- Work up of hemolytic anemias
- Reading peripheral smear
- Bone marrow aspiration
- Coagulation work-up

Allied Clinical Department subjects:

- Transfusion support for thalassemia, hemophilia, leukemia, solid organ transplantation
- Platelet transfusion therapy and its monitoring
- Intrauterine and Neonatal exchange transfusion
- Bed side management of transfusion reactions
- Intraoperative hemodilution, Use of Cell saver, Intraoperative Blood salvage

Recommended Readings

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SN	Title	Editors	Authors	Year	Publisher
1	Transfusion Medicine Technical Manual	R K Saran	R K Saran	1991	Directorate General Of Health Services
2	Plasmapheresis: Therapeutic Applications and New Techniques	Helen E Kambic	Helen E Kambic	1983	International Center For Artificial Organs
3	Rossi's Principles of Transfusion Medicine	Toby L Simon	Toby L Simon		Lippincott Williams And Wilkins
4	Blood Banking and Transfusion Medicine: Basic Principles And Practice	Christopher D. Hillyer	Christopher D. Hillyer , John D. Roback, Kenneth C Anderson, Leslie E Silberstein Paul M. Ness	2006	Churchill Livingstone
5	Paediatric Transfusion Therapy	Catherine S Manno	M.D. Herman, Jay H	2003	AABB
6	Mollison's Blood Transfusion in Clinical Medicine	Harvey J Klein David J Anstee	Harvey J Klein David J Anstee	2005	Wiley Blackwell
7	Transfusion Medicine	Jeffery Mccullough	Jeffery Mccullough	2004	Churchill Livingstone
8	Text Book Of Blood Banking and Transfusion Medicine	Sally V Rudmann	Sally V Rudmann	2005	Saunders
9	Modern Blood Banking and Transfusion Practices	Denise M Harmening	Denise M Harmening	1999	F.A.Davis Company

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SN	Title	Editors	Authors	Year	Publisher
10	Apheresis: Principles and Practice.	Mcleod, Bruce C	Mcleod, Bruce C., Thomas H. Price, Robert A. Weinstein	2003	AABB

- **List of Journals**

1. British Journal Of Hematology / wiley https://onlinelibrary.wiley.com/journal/13652141
2. Transfusion / Wiley
   https://onlinelibrary.wiley.com/journal/15372995
3. Transfusion And Apheresis Science / Elsevier
   https://www.sciencedirect.com/journal/transfusion-and-apheresis-science
4. Transfusion Medicine Reviews / Elsevier
   https://www.sciencedirect.com/journal/transfusion-medicine-reviews
5. Vox Sanguinis / Wiley
   https://onlinelibrary.wiley.com/journal/14230410
6. Seminars In Hematology / Elsevier
   https://www.sciencedirect.com/journal/seminars-in-hematology
7. Transfusion Medicine / Wiley
   https://onlinelibrary.wiley.com/journal/13653148
8. American Journal Of Hematology / Wiley
   https://onlinelibrary.wiley.com/journal/10968652
9. Annals Of Hematology / Springer
   https://www.springer.com/journal/277
10. Blood Coagulation And Fibrinolysis / Lippincott Williams And Wilkins
    https://journals.lww.com/bloodcoagulation/pages/default.aspx
11. Indian Journal Of Hematology And Blood Transfusion / Indian Society Of Hematology And Blood Transfusion.
    https://www.springer.com/journal/12288
12. Asian Journal of Transfusion Sciences (AJTS)
    https://www.ajts.org

E-learning resources

- https://www.isbtweb.org/resource/transfusion-reactions-e-learning-module.html

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[International Society of Blood Transfusion resource on Transfusion Reactions]

- https://bloodsafelearning.org.au/
  [Comprehensive online modules for transfusion practices and PBM]
- https://www.learnbloodtransfusion.org.uk/
  [Comprehensive modules for Transfusion practice, PBM, good manufacturing practice Legal issues related to transfusion Blood collection]
- https://www.nybc.org/about-us/professional-education/education-resources/elearning-transfusion-medicine/
  [Comprehensive module for Acute & delayed Transfusion Reactions, Blood groups, Basics of PBM]
- https://www.aabb.org/education/access-my-learning-programs
  [Webinars on Blood Banking, Transfusion Medicine and PBM]
- https://professionaleducation.blood.ca/en/transfusion/courses/learntransfusion-series
  [Weekly Webinars on various scientific, technical and clinical aspects of TM]

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Method for computing program outcome

The summative assessment examination shall include two heads:

A. Theory examination.

B. Practical examination and Viva-voce.

Theory examination and Practical/ Viva-voce shall be separate heads of passing.

Theory examination:It shall comprise of two papers, each representing two courses. Passing percentage shall be cumulatively 50% with minimum of 40% marks in each theory paper (or as per institute norms in this regard).

Practical examination: Practical examination shall include various major components of the syllabus focusing mainly on the psychomotor domain. The duration of each exercise shall vary from 30 minutes to 1 hour. Each exercise or station shall be followed by Viva on the exercise.

1. Laboratory and clinical skill: Minimum of 3 exercises *(stations)* covering all aspects of Transfusion Medicine. Some examples are as under.
   - blood donor / apheresis donor selection, blood processing, component preparation,
   - immunohematology, antenatal serology, transfusion reaction management
   - quality control of reagents, equipment, components
   - coagulation testing, basic hematology tests, transfusion transmitted infection testing
   - stem cell transplantation

2. Laboratory performance of the student: 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 appropriate format.

2. Clinical case discussion (minimum 02)

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There shall be minimum 02 Hemotherapy exercise and administrative issues for each candidate. The candidate is required to make his own assessment of the problem and come out with solutions.

3. *Spots/ images (minimum 10)*
4. *Log book discussion*
5. *Grand Viva Voce*

In addition to the above-mentioned formal examination, each student will also be evaluated on day-to-day basis based on the following activities

- Case presentation, Seminars, Journal Club, Laboratory performance
- Empathy shown by the student towards blood donors / patients
- Willingness to accept the responsibility by a student
- Level of confidence while performing a procedure such as phlebotomy, therapeutic plasma exchange
- Ownership for the procedure related complications
- Willingness to learn new skill and acquire new knowledge
- Self-motivated reading and learning
- Punctuality to work and patient care
- Willingness to teach and train
- Skill to teach and train others
- Interpersonal relationship

Slow learners will be identified based on their performance as following:

- Comprehension Difficulty-
  - no active interaction during presentations, inability in answering and asking simple subject related questions.
  - Quality of seminars with regard to content of slides and timeliness.
- Difficulty in expression: Poor communication with stakeholders including blood / apheresis donors/ patients, clinical colleagues, peers etc.
- Poor memory- Delay in performance of routing tasks, difficulty in interpretation, delay in documentation and reporting
- Weakness in rational thinking
- Lack of attention
- Below average performance in the internal assessment

Strategies for improving performance of slow learners

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Needs: Local : Pink, National : Orange, Regional: light blue, International : green

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- Emphasis on topic to improve basic understanding of the subject during departmental teachings.
- Involvement in group activities to boost interactive learning and confidence among them
- Conduct remedial classes for the slow learners so that their problems can be addressed in a separate class at their own pace
- different learning exercises to help students understand the topics that are hard for them to comprehend and allow them the space to go through the concepts, starting from the basics.
- Assigning mentor from their peer group (hand-holding.

The Objectives of the PDCC is to **train the medical postgraduate as a best skilled "Transfusion Medicine Consultant"** in different aspects of theoretical, clinical and practical spheres of Immunohematology and Blood Transfusion and enable them to offer skill-based diagnostic, consultative and transfusion support with the highest professional standards. This training will help to accomplish the local, regional and national health care needs for quality care commensurate with international standards

Local level	**Following issues are of importance for efficient management of blood transfusion services at local level** 5. **Voluntary Blood donation-** compared to national statistics the rate of voluntary blood donation is lower. Through this program should be able to develop efficient voluntary blood donation program by identifying the gaps specific to the local needs. 6. **Rational use of blood components-** use of blood components is still not so popular owing to lack of awareness among the clinical colleagues along with limited availability of components at blood transfusion services. The student will be able to raise awareness among the clinical colleagues and will ensure availability of components at respective blood centers. 7. **Immuno-hematological support-** Specialized transfusion support for various category of patients such as Rh-immunized ante-natal women, multi-transfused patients such as thalassemia/ sickle cell anemia/ leukemia is lacking. After completion of the program, student is expected to provide diagnostic support and specialized transfusion to these patients (antigen -negative blood, Intra-uterine transfusion etc) 8. **Blood Safety-** currently, there exist variation in testing methodology for transfusion transmitted infections and its interpretation. Student is expected to bring uniformity through implementation of standard practices.

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Regional level (State level)	**In addition to the challenges at local level, following additional issues will be address by implementation of MD (IHBT / TM) program** 6. **Voluntary Blood donation** 7. **Rational use of blood components** 8. **Immuno-hematological support** 9. **Blood Safety** 10. **Development of regional standards, SOPs and documents-** after completing this program the student will provide advocacy and guidance to state authorities / agencies for development of these documents.
National level	**In addition to the challenges at local and regional level, following additional national issues will be address by implementation of MD (IHBT / TM) program** 5. **Human resource-** Though Government of India has taken initiative such as short-term training of various cadre of staff posted in blood centers, it may not be sufficient. This program (MD IHBT/TM) will help in filling the gap by creation of specialized consultants needed to improve blood transfusion services in the country. 6. **Rare donor registry-** required for transfusion management of patients with rare blood group such as **Bombay phenotype**. Currently there is no registry at National level. After completing this program the student will provide advocacy and guidance to National authorities / agencies for development of rare donor registry and its linkage with international registries. 7. **Apheresis donor registry-** required for transfusion management of patients who need long term platelet transfusion support such as **Aplastic anemia, Stem cell transplant recipients,** leukemia etc. Development of apheresis donor registry will ease the burden of arranging apheresis donor specially for patients with platelet transfusion refractoriness. After completing this program the student will provide advocacy and guidance to National authorities / agencies for development of HLA / HPA typed apheresis donor registry and its linkage with international registries. 8. **Advancement of transfusion facilities** and implementation of improved technology such as tissue banking, organ transplantation, regenerative medicine, immunotherapies (Dendritic cell and CarT cell therapy)
Global level	All the issues covered in the courses of the MD Program (IHBT/TM) are contextual and pertinent to global health issues. Moreover India being home to appx 17% of the global population, health care decisions and policies based on Indian data are likely to create a global impact

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