

Guidelines
for
Competency Based Training Programme
in
**DNB- IMMUNO HEMATOLOGY AND TRANSFUSION
MEDICINE**



NATIONAL BOARD OF EXAMINATIONS

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INTRODUCTION

- Transfusion medicine (Blood Transfusion and Immunohematology) is a diverse and multifaceted discipline.
- The responsibilities of transfusion medicine physicians in hospital blood transfusion service are more varied than those of most other medical specialties. It includes direct patient care and clinical consultation, medical direction of clinical testing laboratories, supervision of blood component manufacture and storage, inventory management and distribution, and regulatory compliance.
- The transfusion medicine physician, therefore, must be adept at balancing patient care issues, regulatory standards, manufacturing principles, and resource limitations in meeting patient needs.
- In the last 20 years, clinical transfusion therapy has evolved from whole blood transfusion to blood components and derivatives. In addition, sophisticated technology now makes it possible to selectively remove blood components from donors or patients by a process called apheresis.
- While, many choices of blood products have complicated the physician's decision making process, it has also made hemotherapy more specific and effective. It becomes important that DNB students are trained in this specialty so that they are properly equipped to render special consultative service.
- The purpose of the course is to provide didactic education and practical training in all aspects of blood transfusion technology, to develop the knowledge required to analyze immunohematology problems, to provide expertise in blood center administrative policies such as donor recruitment, collection, storage, preservation, administration of blood and components and to develop those qualities needed for component supervisory and academic responsibilities.

Programme Objectives

It is expected that at the end of the course, the blood transfusion specialist will be specifically equipped for the following tasks.

- Provide direction to academic blood center with regard to organization of the collection, preparation, storage, distribution and clinical use of blood and components.
- Promote optimal use of blood products and develop a system for clinical control of their use.
- Participate in research in blood transfusion medicine and upgrade the scientific knowledge by continuing medical education.
- Organize training program for manpower development in the field.

Programme Goals

1. To impart composite training in fundamental and applied aspects of Transfusion Medicine at postgraduate level leading to degree of DNB in Transfusion Medicine [Immunohematology and blood transfusion].
 - a) To understand the basic principles and concepts presented in the transfusion medicine core curriculum 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.
 - c) To provide appropriate therapeutic solutions to transfusion medicine problems.
2. To provide consultants and teachers in Transfusion Medicine in various medical colleges and institutions for operating a well organized & efficient transfusion services.
3. 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.
4. To recognize motivational, organizational and managerial skills for efficient operation of blood center.

ELIGIBILITY CRITERIA FOR ADMISSIONS TO THE PROGRAMME

(A) DNB Immuno Hematology and Transfusion Medicine Course:

1. Any medical graduate with **MBBS** qualification, who has qualified the **Entrance Examination** conducted by NBE and fulfill the eligibility criteria for admission to DNB **Broad Specialty** courses at various NBE accredited Medical Colleges/ institutions/Hospitals in India is eligible to participate in the Centralized counseling for allocation of DNB Immuno hematology and transfusion medicine seats purely on merit cum choice basis.
2. Admission to 3 years post MBBS DNB Immuno hematology and transfusion medicine course is only through **Entrance Examination** conducted by NBE and Centralized Merit Based Counseling conducted by National Board of Examination as per prescribed guidelines.

Duration of Course :

3 Years

Every candidate admitted to the training programme shall pursue a regular course of study (on whole time basis) in the concerned recognized institution under the guidance of recognized post graduate teacher for assigned period of the course.

TEACHING AND TRAINING ACTIVITIES

The fundamental components of the teaching programme should include:

1. Case presentations & discussion- once a week
2. Seminar – Once a week
3. Journal club- Once a week
4. Grand round presentation (by rotation departments and subspecialties)- once a week
5. Faculty lecture teaching- once a month
6. Clinical Audit-Once a Month
7. A poster and have one oral presentation at least once during their training period in a recognized conference.

The rounds should include bedside sessions, file rounds & documentation of case history and examination, progress notes, round discussions, investigations and management plan) interesting and difficult case unit discussions.

The training program would focus on knowledge, skills and attitudes (behavior), all essential components of education. It is being divided into theoretical, clinical and practical in all aspects of the delivery of the rehabilitative care, including methodology of research and teaching.

Theoretical: The theoretical knowledge would be imparted to the candidates through discussions, journal clubs, symposia and seminars. The students are exposed to recent advances through discussions in journal clubs. These are considered necessary in view of an inadequate exposure to the subject in the undergraduate curriculum.

Symposia: Trainees would be required to present a minimum of 20 topics based on the curriculum in a period of three years to the combined class of teachers and students. A free discussion would be encouraged in these symposia. The topics of the symposia would be given to the trainees with the dates for presentation.

Clinical: The trainee would be attached to a faculty member to be able to pick up methods of history taking, examination, prescription writing and management in rehabilitation practice.

Bedside: The trainee would work up cases, learn management of cases by discussion with faculty of the department.

Journal Clubs: This would be a weekly academic exercise. A list of suggested Journals is given towards the end of this document. The candidate would summarize and discuss the scientific article critically. A faculty member will suggest the article and moderate the discussion, with participation by other faculty members and resident doctors. The contributions made by the article in furtherance of the scientific knowledge and limitations, if any, will be highlighted.

Research: The student would carry out the research project and write a thesis/ dissertation in accordance with NBE guidelines. He/ she would also be given exposure to partake in the research projects going on in the departments to learn their planning, methodology and execution so as to learn various aspects of research.

SYLLABUS

A. Immunology and Immunogenetics

Level I

- Understand the basic principles of immunoglobulins, antigen, antibody and complements.
- Understand complement activation pathways and their role in transfusion medicine
- Understand the antibody development after immunization and infection.
- Understand the principles of antigen antibody reaction and factors affecting these reactions.
- Understand the antigen systems of formed elements of blood such as red cells, platelets and leukocytes and be able to know their implications in transfusion medicine.
- Understand the principles of structural and functional evaluation of B cells, T cells, NK cells.
- Understand the principles of classification of primary immune deficiency diseases, including defects in humoral immunity, cellular immunity.

- 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.

Level II

- Know the Hybridoma technology and be able to understand its role in Immunoematology
- Understand the role of HLA typing in organ and bone marrow/stem cell transplantation and how HLA antigen mismatching results in allogeneic reactions in recipients.
- Know HLA typing techniques, including serological methods, microcytotoxicity assays, nucleic acid assays and lymphocyte culture techniques.
- Understand the HLA association with disease

B. Physiology of the formed elements of blood and hemostasis

Level I

- Understand the basic physiology and biochemistry of red cells, platelets and leukocytes in terms of their kinetics, function and life span
- Understand hemoglobin structure, synthesis, function and degradation.
- Know the membrane structure and function of red cells, platelets and leukocytes and be

able to apply their implication in transfusion medicine

- Understand the principles of hemoglobin screening
- Describe iron and bilirubin metabolism
- Understand the physiology of hemostasis with regard role of platelets, coagulation pathway and fibrinolysis
- Understand the pathophysiology of thrombocytopenia and thrombocytosis
- Know the pathophysiology and laboratory features of intravascular and extravascular hemolysis.
- Develop basic understanding of hemostatic and thrombotic disorders:
- Understand the coagulopathy of liver disease;
- Understand the pathophysiology of vitamin K deficiency and antagonism;
- Understand the laboratory evaluation of disseminated intravascular coagulation;
- Understand the pathophysiology of the hemophilias (A, B, and C)

Level II

- Understand hemodynamic of blood flow, estimation of blood volume and be able to interpret the application of radionuclides tagging for blood volume estimation
- Understand the pathophysiology of immune thrombocytopenia and thrombotic thrombocytopenic purpura.
- Demonstrate competency in taking a bleeding history.
- Understand the general principles & clinical utility of platelet function testing.
- Understand the clinical utility of coagulation and thrombosis testing.
- Understand the general principles of screening coagulation tests (e.g., prothrombin time, activated partial thromboplastin time, fibrinogen, and thrombin time).
- Understand the International Normalized Ratio derivation and its clinical significance.

C. Blood Collection/Blood Center/Component Processing

Level I

- Describe the factors that influence the motivation of volunteers to donate blood
- Demonstrate professionalism in interactions with prospective donors.
- Be able to know the clinical relevance of directed donation
- Compare and contrast the eligibility requirements for allogeneic, autologous & apheresis blood donations.
- Understand 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
- Demonstrate proficiency in evaluating and treating adverse reactions associated with blood donation/phlebotomy (whole blood and apheresis donations).
- Understand the factors influencing quality of blood bag for whole blood collection
- Demonstrate the proficiency in organization of out door blood donation camp and be able to understand importance of cold chain maintenance.
- Demonstrate knowledge of the indications for therapeutic phlebotomy.
- Outline the assay principles of required donor blood tests such as donor Hb for whole blood donation and platelet count for plateletpheresis and the associated confirmatory testing and describe donor re-entry algorithms.
- Understand the process of platelepheresis
- Summarize the steps in blood component preparation by different methods
- Know various factors affecting the quality of blood components
- Understand the significance of storage of blood components at appropriate temperature and demonstrate proficiency in compatibility, labeling requirements of various components.

Level II

- Outline the necessary steps in donor notification and counseling associated with positive infectious disease testing results, and the donor look-back process.
- Understand various modifications of blood components such as irradiation, cell washing, volume depletion and leuko depletion.
- Demonstrate proficiency in selection of apheresis machine, blood donor and be able to obtain apheresis product meeting quality standards.
- Demonstrate proficiency in maintaining quality of blood components as per recommended standards by various agencies (AABB, EC, DCI).
- Understand process of plasma fractionation and summarize critical steps in preparation such as pooling, viral inactivation.

D. Therapeutic Apheresis

Level I

- Summarize the principles of apheresis technology, including centrifugation, filtration, and

immunoabsorption.

- Demonstrate knowledge of the indications for therapeutic apheresis and of the appropriate replacement fluids to be used in various situations.
- Demonstrate proficiency in evaluating and preparing patients for therapeutic apheresis, including discussion with the patient of the risks and benefits associated with apheresis procedures.
- Communicate effectively with clinicians regarding emergent or scheduled therapeutic apheresis procedures through conversations and writing of consult notes.

Level II

- 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 immunoabsorption columns).

E. Transfusion transmitted infection serology

Level I

- 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, cytomegalovirus, bacterial / fungal / protozoal infections and syphilis,
- Understand and be able to interpret nontreponemal and treponemal antibody tests used to diagnose syphilis.
- Compare & contrast various methodologies such as ELISA, rapid & chemiluminescence used in screening of transfusion transmitted infections
- Demonstrate proficiency in proper disposal of bio hazardous material as per recommended standards.

Level II

- Understand the feasibility of NAT in Indian blood transfusion services
- Demonstrate proficiency in the preparation and use of internal control in transfusion transmitted infection screening.

F. Clinical Transfusion Service

Level I

- Demonstrate knowledge of the principles of patient/ unit identification and pretransfusion testing, including ABO/Rh testing, RBC antibody screen, and antibody identification.
- Compare and contrast conventional cross matching versus type and screen using various advanced technologies such as gel, solid phase, and column agglutination.
- Recognize the symptoms and signs of hemolytic and nonhemolytic transfusion reactions and demonstrate knowledge of the pathophysiology, treatment, and prevention of these complications.
- Identify 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.
- Choose appropriate blood components and derivatives based on a thorough knowledge of the indications for transfusion.
- Demonstrate knowledge of the pathophysiology, prevention, and treatment of hemolytic disease of the newborn. Recognize those 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.
- Demonstrate knowledge of the pathophysiology and treatment of neonatal alloimmune thrombocytopenia.
- Demonstrate proficiency in the evaluation and appropriate transfusion therapy of thrombocytopenic patients (both adult and pediatric).
- Apply the principles of a massive transfusion protocol.
- Demonstrate a working knowledge of the principles of hemostasis and coagulation and proficiency in the initial treatment of patients with bleeding disorders.
- Demonstrate knowledge of the transfusion requirements of special patient populations (e.g., hematology/ oncology, pediatrics, thalassemia, transplantation, cardiac surgery and burn/trauma).

Level II

- 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 evaluating and recommending treatment plans for complex transfusion reactions.
- 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 familiarity with the requirements of all applicable regulatory and accrediting agencies [e.g., DCI, NABH].
- Demonstrate competence in the management of blood inventory and the ability to communicate effectively the hospital's needs to the blood supplier.
- Demonstrate knowledge of various methods of blood conservation, including pre- and perioperative autologous blood collection, and approaches to "bloodless" surgery.
- Demonstrate proficiency in evaluating patient's refractory 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 proficiency in the evaluation of patients with immune-mediated and non-immune-mediated hemolytic anemia and in the appropriate transfusion management of these patients.
- 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).
- Develop an understanding of emerging areas of cellular therapy, including hematopoietic graft engineering and cellular immunotherapeutics.
- Develop and understanding of blood substitutes and hematopoietic agents.

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

Level I

- Demonstrate knowledge concerning the requirements of all applicable regulatory and accrediting agencies. [e.g., DCI, 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.
- 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 program.
- Understand how SOPs are used, developed, authored, and reviewed and their importance in mandatory laboratory inspection by various accrediting agencies.
- Understand the role of quality assurance, quality management, and process improvement principles in laboratory operation and planning.
- Be able to understand proper use of instrumentation and computerization in a transfusion laboratory.

Level II

- 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.
- 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.
- 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.
- Know fundamental concepts of medical statistics.
- Understand principles of specimen collection (e.g., phlebotomy technique, safety, and specimen tubes) and specimen processing.
- Recognize sources of preanalytical variation and the role of biological variability in

laboratory assessment.

H. ADDITIONAL COMPETENCIES SPECIFIC TO TRANSFUSION MEDICINE

Patient Care

- Correctly classify transfusion reactions and give appropriate treatment recommendations.
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- Choose appropriate cross-matching methods for various patients (e.g., electronic, immediate spin, and antiglobulin).
- Recognize and appropriately refer serological evaluations that are beyond the scope of a hospital-based transfusion service/blood bank.
- Correctly choose (or recommend) the appropriate blood product for patients with special needs.
- Triage and screen requests for blood components appropriately during inventory shortages.
- Demonstrate the ability to perform blood utilization reviews.
- Perform a donor interview and exam.
- Evaluate and perform initial management of whole blood and apheresis donor reactions.
- Write physician orders for peripheral blood hematopoietic stem cell collections and therapeutic apheresis procedures.
- Appropriately manage reactions that occur during peripheral blood hematopoietic stem cell collections or therapeutic apheresis procedures.
- Be able to apply recent developments in the field from research to clinical practice such as gene therapy, proteomics, microarray etc.

Medical Knowledge

- Demonstrate understanding of and ability to interpret major regulations and guidelines that are applicable to collection, processing, storage, and release of blood and other cellular therapeutic products.

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.

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.

Note:

Skill I = corresponds roughly to the types of activities and responsibilities that a first- and/or second-year DNB student would be engaged in, that is, the level of achievement to be attained during the student's first exposure to the discipline as a postgraduate

Skill II = corresponds to the achievements expected of a third year DNB student that is, the higher level of responsibility and expertise that one would acquire and consolidate during repeat exposure to the discipline.

Theoretical training

Didactic lectures

Typical examples of transfusion medicine didactic lectures

Lecture topic	Content
Blood component therapy	Various kinds of blood components, methods of preparation, composition of components, storage and cross matching requirements, component modification, special components
Adverse effects of transfusion (Immune)	Recognition, testing, treatment, prevention strategies for hemolytic transfusion reaction, allergic anaphylactoid reaction
Adverse effects of transfusion	Recognition, testing, treatment, prevention of septic reactions, TRALI, TAGvHD, PTP, iron overload
Transfusion transmitted infection	Risk, clinical significance, testing, prevention strategies, for viruses, parasites, prions
Apheresis	Principles, techniques, instrumentation for donor and therapeutic apheresis, indications and treatment plan for therapeutic apheresis,
Red cell antibody detection	Perform and how to interpret antibody panels with single / multiple antibodies, evaluation of auto antibodies

Training Programme

The candidates will be rotated through various sections of the Department as under :

- | | | |
|-----------|---|----------|
| A. | Blood donor management
Donor recruitment & motivation
Donor selection
Phlebotomy
Post donation care of donor
Apheresis
Donor apheresis
Therapeutic plasma exchange
Outdoor blood donation camps | 5 months |
| B. | Component preparation & quality control
Preparation of various components
PRBC, FFP, PC, Cryo, Leuco poor
Irradiation of blood components
Storage & quality control | 5 months |
| C. | Transfusion Transmitted infection screening
Screening for various markers
HIV, HCV, HBsAg, Syphilis
Methodology
Elisa, spot, rapid, automated analyzer
Molecular techniques | 5 months |
| D. | Immuno-haematology
Diagnosis & transfusion support in
AIHA
PNH
Transfusion reaction
Antenatal serology
Multi transfused patients
Secretor status
Minor red cell antigen typing | 5 months |
| E. | Pretransfusion testing & cross match
ABO group & Rh type
Du testing, genotype
Irregular antibody screening
Cross match | 5 months |

F. Quality control/ computers/ records 2 months

Total 27 months

Training in allied departments:

Students should be sent for training for 6 months in allied laboratory and clinical departments.

Laboratory areas subjects:

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

Clinical Department subjects:

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

Topics to be included in all subjects:

- **Biostatistics, Research Methodology and Clinical Epidemiology**
- **Ethics**
- **Medico legal aspects relevant to the discipline**
- **Health Policy issues as may be applicable to the discipline**

Competencies

Subject	Course content
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
Blood component preparation Composition & storage	Basic steps in component preparation & 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
Plasma derivatives	Basic principles of preparation & composition Recombinant clotting & hematopoietic growth factors Clinical indications and dosage
Blood groups	Biochemical structure of major blood group antigens Clinically significant blood group antibodies Properties & significance of naturally occurring Vs unexpected
Pretransfusion testing	Antibodies Patient specimen labeling requirements Patient / component identification requirements ABO / Rh, Red cell antibody screen, Cross match Abbreviation of compatibility testing in emergency
Transfusion indications	Red blood cells, Platelets, Plasma / cryoprecipitate, Granulocytes
Massive transfusion	Metabolic complications Dilutional coagulopathy Switching ABO / Rh types
Transfusion reactions	Diagnosis, Pathophysiology, Treatment, Prevention

Infectious complications	Bacterial, parasitic, viral, prions Current risk & Prevention strategies
Transfusion therapy in special patients	Hematology / Oncology Pediatric / neonatal Obstetric including intra uterine Cardiac surgery with CPB Burn patients & Trauma patients Transplantation: Stem cell / Bone marrow, Liver, Kidney
Hemolytic disease of new born	Pathophysiology Causative blood group antibodies Treatment & Prophylaxis
Hemoglobinopathy	Classification, Pathophysiology, Diagnosis & Transfusion therapy
Immune hemolytic anemia	Warm, Cold, Drug induced hemolytic anemia Compatibility testing issues Special transfusion needs
Thrombocytopenia	Immune thrombocytopenic purpura Thrombotic thrombocytopenic purpura Post transfusion purpura Fetal and neonatal thrombocytopenia
Neutropenia	Classification, etiology and treatment Granulocyte transfusion
Clotting factor disorders	Principle of hemostasis & coagulation Lab tests of coagulation status Selection and dosage of factor preparations Management of patients with inhibitors
Platelet refractoriness	Recognition and evaluation Calculation of CCI and platelet recovery Principles of HLA typing and platelet cross match Selection of appropriate platelet product
Transfusion alternatives	Synthetic and natural volume expanders Hemoglobin solution, Perfluorochemicals, Fibrin glue, Hemostatic agent
Autologous blood	Preoperative autologous deposit Perioperative blood salvage Acute normovolemic hemodilution

Laboratory management	<ul style="list-style-type: none"> Quality assurance and quality control Equipment procurement Writing policies and procedures Blood inventory management Look back Maximal surgical blood order schedule Hospital transfusion committee
Therapeutic apheresis	<ul style="list-style-type: none"> Principles of apheresis technology Indications, risk and benefits Replacement fluids Monitoring of patient and central venous canula
Stem cell collection & processing	<ul style="list-style-type: none"> Donor preparative regimen Collection technique and complications Cell count targets and engraftment monitoring Processing and storage
Regulatory / accreditation agencies	<ul style="list-style-type: none"> Drugs and cosmetics act of India Licensing requirements National blood policy, ISO / NABH, GMP Inventory management Donor notification and counseling

THESIS PROTOCOL & THESIS

The candidates are required to submit a thesis at the end of three years of training as per the rules and regulations of NBE.

Guidelines for Submission of Thesis Protocol & Thesis by candidates

Research shall form an integral part of the education programme of all candidates registered for DNB degrees of NBE. The Basic aim of requiring the candidates to write a thesis protocol & thesis/dissertation is to familiarize him/her with research methodology. The members of the faculty guiding the thesis/dissertation work for the candidate shall ensure that the subject matter selected for the thesis/dissertation is **feasible, economical** and **original**.

Guidelines for Thesis Protocol

The protocol for a research proposal (including thesis) is a study plan, designed to describe the background, research question, aim and objectives, and detailed methodology of the study. In other words, the protocol is the 'operating manual' to refer to while conducting a particular study.

The candidate should refer to the NBE Guidelines for preparation and submission of Thesis Protocol before the writing phase commences. The minimum writing requirements are that the language should be clear, concise, precise and consistent without excessive adjectives or adverbs and long sentences. There should not be any redundancy in the presentation.

The development or preparation of the Thesis Protocol by the candidate will help her/him in understanding the ongoing activities in the proposed area of research. Further it helps in creating practical exposure to research and hence it bridges the connectivity between clinical practice and biomedical research. Such research exposure will be helpful in improving problem solving capacity, getting updated with ongoing research and implementing these findings in clinical practice.

Research Ethics: Ethical conduct during the conduct and publication of research is an essential requirement for all candidates and guides, with the primary responsibility of ensuring such conduct being on the thesis guide. Issues like Plagiarism, not maintaining the confidentiality of data, or any other distortion of the research process will be viewed seriously. The readers may refer to standard documents for the purpose.

The NBE reserves the right to check the submitted protocol for plagiarism, and will reject those having substantial duplication with published literature.

PROTOCOL REQUIREMENTS

1. All of the following will have to be entered in the online template. The thesis protocol should be restricted to the following word limits.
 - Title : 120 characters (with spacing) page
 - Synopsis [structured] : 250-300
 - Introduction : 300-500
 - Review of literature : 800-1000
 - Aim and Objectives : Up to 200

- Material and Methods : 1200-1600
 - 10-25 References [ICMJE style]
2. It is mandatory to have ethics committee approval before initiation of the research work. The researcher should submit an appropriate application to the ethics committee in the prescribed format of the ethics committee concerned.

Guidelines for Thesis

1. The proposed study must be approved by the institutional ethics committee and the protocol of thesis should have been approved by NBE.
2. The thesis should be restricted to the size of 80 pages (maximum). This includes the text, figures, references, annexures, and certificates etc. It should be printed on both sides of the paper; and every page has to be numbered. Do not leave any page blank. To achieve this, following points may be kept in view:
 - a. The thesis should be typed in 1.5 space using Times New Roman/Arial/Garamond size 12 font, 1" margins should be left on all four sides. Major sections viz., Introduction, Review of Literature, Aim & Objectives, Material and Methods, Results, Discussion, References, and Appendices should start from a new page. Study proforma (Case record form), informed consent form, and patient information sheet may be printed in single space.
 - b. Only contemporary and relevant literature may be reviewed. Restrict the introduction to 2 pages, Review of literature to 10-12 pages, and Discussion to 8-10 pages.
 - c. The techniques may not be described in detail unless any modification/innovations of the standard techniques are used and reference(s) may be given.
 - d. Illustrative material may be restricted. It should be printed on paper only. There is no need to paste photographs separately.
3. Since most of the difficulties faced by the residents relate to the work in clinical subject or clinically-oriented laboratory subjects, the following steps are suggested:
 - a. The number of cases should be such that adequate material, judged from the hospital attendance/records, will be available and the candidate will be able to collect case material within the period of data collection, i.e., around 6-12 months so that he/she is in a position to complete the work within the stipulated time.
 - b. The aim and objectives of the study should be well defined.
 - c. As far as possible, only clinical/laboratory data of investigations of patients or such other material easily accessible in the existing facilities should be used for the study.
 - d. Technical assistance, wherever necessary, may be provided by the department concerned. The resident of one specialty taking up some problem related to some other specialty should have some basic knowledge about the subject and he/she should be able to perform the investigations independently, wherever some specialized laboratory investigations are required a co-guide may be co-opted from the concerned investigative department, the quantum of laboratory work to be carried out by the candidate should be decided by the guide & co-guide by mutual consultation.

4. The clinical residents are not ordinarily expected to undertake experimental work or clinical work involving new techniques, not hitherto perfected OR the use of chemicals or radioisotopes not readily available. They should; however, be free to enlarge the scope of their studies or undertake experimental work on their own initiative but all such studies should be feasible within the existing facilities.
5. The DNB residents should be able to freely use the surgical pathology/autopsy data if it is restricted to diagnosis only, if however, detailed historic data are required the resident will have to study the cases himself with the help of the guide/co-guide. The same will apply in case of clinical data.
6. Statistical methods used for analysis should be described specifically for each objective, and name of the statistical program used mentioned.

General Layout of a DNB Thesis:

- **Title-** A good title should be brief, clear, and focus on the central theme of the topic; it should avoid abbreviations. The Title should effectively summarize the proposed research and should contain the PICO elements.
- **Introduction-** It should be focused on the research question and should be directly relevant to the objectives of your study.
- **Review of Literature -** The Review should include a description of the most relevant and recent studies published on the subject.
- **Aim and Objectives -** The 'Aim' refers to what would be broadly achieved by this study or how this study would address a bigger question / issue. The 'Objectives' of the research stem from the research question formulated and should at least include participants, intervention, evaluation, design.
- **Material and Methods-** This section should include the following 10 elements: Study setting (area), Study duration; Study design (descriptive, case-control, cohort, diagnostic accuracy, experimental (randomized/non-randomized)); Study sample (inclusion/exclusion criteria, method of selection), Intervention, if any, Data collection, Outcome measures (primary and secondary), Sample size, Data management and Statistical analysis, and Ethical issues (Ethical clearance, Informed consent, trial registration).
- **Results-** Results should be organized in readily identifiable sections having correct analysis of data and presented in appropriate charts, tables, graphs and diagram etc.
- **Discussion—**It should start by summarizing the results for primary and secondary objectives in text form (without giving data). This should be followed by a comparison of your results on the outcome variables (both primary and secondary) with those of earlier research studies.
- **Summary and Conclusion-** This should be a précis of the findings of the thesis, arranged in four paragraphs: (a) background and objectives; (b) methods; (c) results; and (d) conclusions. The conclusions should strictly pertain to the findings of the thesis and not outside its domain.

- **References-** Relevant References should be cited in the text of the protocol (in superscripts).
- **Appendices** -The tools used for data collection such as questionnaire, interview schedules, observation checklists, informed consent form (ICF), and participant information sheet (PIS) should be attached as appendices. Do not attach the master chart.

Thesis Protocol Submission to NBE

1. DNB candidates are required to submit their thesis protocol within 90 days of their joining DNB training.
2. Enclosures to be submitted along with protocol submission form:
 - a) Form for Thesis Protocol Submission properly filled.
 - b) Thesis Protocol duly signed.
 - c) Approval letter of institutional Ethical committee. (*Mandatory, non receivable of any one is liable for rejection*)

Thesis Submission to NBE

1. As per NBE norms, writing a thesis is essential for all DNB candidates towards partial fulfillment of eligibility for award of DNB degree.
2. DNB candidates are required to submit the thesis before the cut-off date which shall be 30th June of the same year for candidates appearing for their scheduled December final theory examination. Similarly, candidates who are appearing in their scheduled June DNB final examination shall be required to submit their thesis by 31st December of preceding year.
3. Candidates who fail to submit their thesis by the prescribed cutoff date shall NOT be allowed to appear in DNB final examination.
4. Fee to be submitted for assessment (In INR): 3500/-
5. Fee can be deposited ONLY through pay-in-slip/challan at any of the Indian bank branch across India. The challan can be downloaded from NBE website www.natboard.edu.in
6. Thesis should be bound and the front cover page should be printed in the standard format. A bound thesis should be accompanied with:
 - a. A Synopsis of thesis.
 - b. Form for submission of thesis, duly completed
 - c. NBE copy of challan (in original) towards payment of fee as may be applicable.
 - d. Soft copy of thesis in a CD duly labeled.
 - e. Copy of letter of registration with NBE.
7. A declaration of thesis work being bonafide in nature and done by the candidate himself/herself at the institute of DNB training need to be submitted bound with thesis. It must be signed by the candidate himself/herself, the thesis guide and head of the institution, failing which thesis shall not be considered.

The detailed guidelines and forms for submission of Thesis Protocol & Thesis are available at www.natboard.edu.in.thesis.php.

LOG BOOK

A candidate shall maintain a log book of operations (assisted / performed) during the training period, certified by the concerned post graduate teacher / Head of the department / senior consultant.

This log book shall be made available to the board of examiners for their perusal at the time of the final examination.

The log book should show evidence that the before mentioned subjects were covered (with dates and the name of teacher(s) The candidate will maintain the record of all academic activities undertaken by him/her in log book .

1. Personal profile of the candidate
2. Educational qualification/Professional data
3. Record of case histories
4. Procedures learnt
5. Record of case Demonstration/Presentations
6. Every candidate, at the time of practical examination, will be required to produce performance record (log book) containing details of the work done by him/her during the entire period of training as per requirements of the log book. It should be duly certified by the supervisor as work done by the candidate and countersigned by the administrative Head of the Institution.
7. In the absence of production of log book, the result will not be declared.

Leave Rules

1. DNB/FNB Trainees are entitled to avail leave during the course of DNB/FNB training as per the Leave Rules prescribed by NBE.
2. A DNB/FNB Trainees can avail a maximum of 30 days of leave in a year excluding regular duty off/ Gazetted holidays as per hospital/institute calendar/policy. This leave shall be processed at the institutional level.
3. Any kind of study leave is not permissible to DNB/FNB Trainees.
4. Under normal circumstances leave of one year should not be carried forward to the next year. However, in exceptional cases such as prolonged illness, the leave across the DNB/FNB training program may be clubbed together with prior approval of NBE.
5. Unauthorized absence from DNB/FNB training for more than 7 days may lead to cancellation of registration and discontinuation of the DNB/FNB training and rejoining shall not be permitted.
6. Any Leave availed by the candidate other than the eligible leave (30 days per year) shall lead to extension of DNB /FNB training. The training institute has to forward such requests to NBE along with the leave records of the candidate since his/her joining and supporting documents (if any) through the Head of the Institute with their recommendation/comments. NBE shall consider such requests on merit provided the seat is not carried over and compromise with training of existing trainees in the Department.
7. Any extension of DNB/FNB training beyond the scheduled completion date of training is permissible only under extra-ordinary circumstances with prior approval of NBE. Such extension is neither automatic nor shall be granted as a matter of routine.
8. DNB/FNB trainees are required to complete their training by a prescribed cutoff date (as per information bulletin of Exit exam) for being eligible to DNB/FNB Exit examination.
9. The eligibility for DNB/FNB Final Examination shall be determined strictly in accordance with the criteria prescribed in the respective information bulletin.
10. Candidates join on or after 2018 can avail Maternity / Paternity leave, as per the Central or State Government policies, whichever is applicable to DNB/FNB training institute.
11. DNB/FNB trainees are eligible for stipend either during the leave period or extension of training period as per the policies of DNB/FNB training institute and prevailing rules.

EXAMINATION

FORMATIVE ASSESSMENT

Formative assessment includes various formal and informal assessment procedures by which evaluation of student's learning, comprehension, and academic progress is done by the teachers/ faculty to improve student attainment. Formative assessment test (FAT) is called as "Formative" as it informs the in process teaching and learning modifications. FAT is an integral part of the effective teaching. The goal of the FAT is to collect information which can be used to improve the student learning process.

Formative assessment is essentially positive in intent, directed towards promoting learning; it is therefore part of teaching. Validity and usefulness are paramount in formative assessment and should take precedence over concerns for reliability. The assessment scheme consists of Three Parts which has to be essentially completed by the candidates.

The scheme includes:-

Part I:- Conduction of theory examination

Part-II :- Feedback session on the theory performance

Part-III :- Work place based clinical assessment

Scheme of Formative assessment

PART – I	CONDUCT OF THEORY EXAMINATION	Candidate has to appear for Theory Exam and it will be held for One day.
PART – II	FEEDBACK SESSION ON THE THEORY PERFORMANCE	Candidate has to appear for his/her Theory Exam Assessment Workshop.
PART – III	WORK PLACE BASED CLINICAL ASSESSMENT	After Theory Examination, Candidate has to appear for Clinical Assessment.

The performance of the resident during the training period should be monitored throughout the course and duly recorded in the log books as evidence of the ability and daily work of the student

1. Personal attributes:

- **Behavior and Emotional Stability:** Dependable, disciplined, dedicated, stable in emergency situations, shows positive approach.
- **Motivation and Initiative:** Takes on responsibility, innovative, enterprising, does not shirk duties or leave any work pending.
- **Honesty and Integrity:** Truthful, admits mistakes, does not cook up information, has ethical conduct, exhibits good moral values, loyal to the institution.
- **Interpersonal Skills and Leadership Quality:** Has compassionate attitude towards patients and attendants, gets on well with colleagues and paramedical staff, is respectful to seniors, has good communication skills.

2. Clinical Work:

- **Availability:** Punctual, available continuously on duty, responds promptly on calls and takes proper permission for leave.
- **Diligence:** Dedicated, hardworking, does not shirk duties, leaves no work pending, does not sit idle, competent in clinical case work up and management.
- **Academic ability:** Intelligent, shows sound knowledge and skills, participates adequately in academic activities, and performs well in oral presentation and departmental tests.
- **Clinical Performance:** Proficient in clinical presentations and case discussion during rounds and OPD work up. Preparing Documents of the case history/examination and progress notes in the file (daily notes, round discussion, investigations and management) Skill of performing bed side procedures and handling emergencies.

3. Academic Activity: Performance during presentation at Journal club/ Seminar/ Case discussion/Stat meeting and other academic sessions. Proficiency in skills as mentioned in job responsibilities.

FINAL EXAMINATION

The summative assessment of competence will be done in the form of DNB Final Examination leading to the award of the degree of Diplomate of National Board in Immuno Hematology and Transfusion Medicine. The DNB final is a two-stage examination comprising the theory and practical part. An eligible candidate who has qualified the theory exam is permitted to appear in the practical examination.

Theory Examination

1. The theory examination comprises of **Four** papers, maximum marks 100 each.
2. There are 10 short notes of 10 marks each, in each of the papers. The number of short notes and their respective marks weightage may vary in some subjects/some papers.
3. Maximum time permitted is 3 hours.
4. Candidate must score at least 50% in the aggregate of **Four** papers to qualify the theory examination.
5. Candidates who have qualified the theory examination are permitted to take up the practical examination.
6. The paper wise distribution of the Theory Examination shall be as follows:

Paper I Basic sciences as applied to the specialty
 Introduction to Immunology and Transfusion Medicine
 Antigen systems in formed elements of Blood
 Research methodology

Paper II Blood collection , processing and component preparation
 Pre transfusion testing
 Adverse effects of Blood transfusion
 Apheresis
 Autologous Transfusion

Paper III Antenatal and neonatal transfusion practice

Immunohaematology
Hemotherapy
Transplantation
Blood substitutes and hemopoietic agents

Paper IV Medico legal considerations
 Total quality management
 Organization and management of transfusion services
 Biosafety
 Automation and computerization
 Recent advances and Investigations

a) Practical Examination:

1. Maximum Marks: 300.
2. Comprises of Clinical Examination and Viva.
3. Candidate must obtain a minimum of 50% marks in the Clinical Examination (including Viva) to qualify for the Practical Examination.
4. There are a maximum of three attempts that can be availed by a candidate for Practical Examination.
5. First attempt is the practical examination following immediately after the declaration of theory results.
6. Second and Third attempt in practical examination shall be permitted out of the next three sessions of practical examinations placed alongwith the next three successive theory examination sessions; after payment of full examination fees as may be prescribed by NBE.
7. Absentation from Practical Examination is counted as an attempt.
8. Appearance in first practical examination is compulsory;
9. Requests for Change in center of examination are not entertained, as the same is not permissible.
10. Candidates are required not to canvass with NBE for above.

Declaration of DNB Final Results

1. DNB final is a qualifying examination.
2. Results of DNB final examinations (theory & practical) are declared as PASS/FAIL.
3. DNB degree is awarded to a DNB trainee in the convocation of NBE.

RECOMMENDED TEXT BOOKS AND JOURNALS

A. BOOKS

1. Blood transfusion in clinical medicine, Ed. PI mollison, Blackwell Sci. Pub. Oxford.
2. Transfusion Medicine, Ed. WH churchill, SR Kurtz, Blackwell Sci, Pub, Oxford.
3. Clinical Practice of Transfusion Medicine, Ed. L Petz, Swisher, Churchill Livingstone, New York.
4. Blood transfusion therapy: A problem oriented approach, Ed. JAF napier, John Willey & sons, Chichester.
5. Principles of transfusion medicine, Ed. EC Rossi, TL simon, GS Moss, William & Wilkins, Tokyo.
6. Modern blood banking & transfusion practices., Ed. Denise M Harmenninge, FA Davis, PA.
7. Applied blood group serology, Ed. PD Issit, Montogmerry Sci. Pub Florida.
8. Clinical Blood Transfusion, Ed LA Kay, ER Huehns, Churchill Livingstone, London.
9. The Human blood groups, Ed PH Anderson, CC Thomas, Springfield, USA
10. Fundamentals of immunohematology: Theory & techniques, Ed. ML Turgeon, Lea & Febiger.
11. Scientific basis of transfusion medicine: Implications for clinical practice, Ed Anderson, PM Ness, Saunders.
12. Progress in Transfusion medicine Vol. No. I,II,III,IV, J.D.Cash Churchill Livingstone.
13. Blood Component therapy in clinical practice R.W Bcal & J.P Isbister, Black Well scientific Publications: Oxford.
14. Blood group Serology K.E Boorman, B.E Dodd Churchill Livingstone, London.
15. Blood groups in Man, R.R Race & R sanger, Black Well scientific publication, Oxford.
16. The Districution of Human Blood Groups, A.E Mourant, Black Well Scientific Publication, Oxford.
17. Future development in Blood Banking, C T S Sibinga, P.C Das & Greenwalt Martinus Nijhoff Publishers, Boston.
18. Serological & Immunological methods of the Canandian Red Cross Blood Transfusion Service, B P L Moe, Canadian Red Cross Society, 95, Wellesley, Street past: Toronto: Ontario M4 YI H6.

19. Collection, Fractionation, Quality Control and uses of blood & blood products.
World Health Organisation expert committee, Geneva.
20. Australian Red Cross Society, Blood Transfusion services- Sydney, A Guide to
Blood Transfusion Ed. R.J. Walsh: H.K Ward: G.T Archer
21. Technical Manual : American Association of Blood Banks, Ed. F.K Widmann.,
S.Karger.
22. Transfusion Immunology & Medicine, Ed. Carel J van Oss, Marcel Dekker, New
York.
23. Blood separation & plasma fractionation, Ed. J Robinson, Harris, Willey Liss,
New York.
24. Practical blood transfusion, Ed. DW Huestis, JR Bove, J Case, Little Brown &
com, Boston.
25. Transfusion Medicine: Recent technological advances Ed K Murawski, F
Poetooni, Blackwell Sci Pub, Oxford.
26. Blood transfusion (Methods in Hematology, Vol 17) Ed TJ Greenwalt, Churchill
Livingstone, London.
27. Blood transfusion: A conceptual approach, Ed. JG Kelton, N Heddle, M
Blajchman, churchill Livingstone.
28. Plasma fractionation & Blood transfusion, Ed CTS Sibinga, PC Das, S Seidl,
Martinus Nijhoff Pub, Boston.
29. Transplantation & blood transfusion, Ed CTS Sibinga, PC Das, G Opel, Martinus
Nijhoff Pub, Boston.
30. Quality assurance in blood banking & its impact, Ed. CTS Sibinga, PC Das, HF
Tassel, Martinus Nijhoff Pub Boston.
31. Microbiology in blood transfusion, Ed JJ Barbara, PSG Wright, Bristol.
32. The text book of blood sciences, Ed. CM Zmijewaski, WE Haesler, Appleton
Century Crofts, New York.
33. Transfusion therapy: Principles & procedures, Ed. RC Rutman, WV Miller, Aspen
Publication Rockville.
34. Fundamentals of immunohematology: Theory & techniques Ed. ML Turgeon, Lea
& Febiger, PA.
35. Bone marrow & stem cell processing : A manual of current techniques Ed. EM
Areman, HJ Deeg, RA Sacher, FA Davis PA.

B. LIST OF JOURNALS

1. Vox Sanguinis : International Journal of blood transfusion & Immunohaematology, S.Karger medical and scientific Publishers, 1986.
2. Transfusion: American Association of Blood Banks, J.B Lippincott Company, Philadelphia.
3. Transfusion medicine review
4. Transfusion Medicine
5. Transfusion Science
6. Journal of clinical apheresis
7. Lancet
8. Nature
9. British Medical Journal
10. British Journal of Hematology
11. Journal of clinical pathology
12. American journal of clinical pathology
13. Annals of Hematology
14. European journal of hematology