



# Body of Knowledge

## Doctor of Clinical Laboratory Science

### CONTENT OUTLINE

This document belongs to all practicing medical laboratory professionals. It is our right to define its contents, our responsibility to monitor and update it, and our privilege to use it to promote our personal growth and to enhance our professional stature.

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# INTRODUCTION

A Body of Knowledge (BOK) encompasses the essential knowledge base for what is recognized and practiced in a profession.

## I. Purpose

The purpose of the Body of Knowledge is to:

- A. Specify the knowledge unique to the profession thus defining the relationship of the Doctor of Clinical Laboratory Science (DCLS) to other health professionals, administrators, patients, and the public.
- B. Serve as a basis for differentiating various levels of practice in clinical laboratory science, developing or revising curricula and educational resources, developing assessment and certification examinations, interfacing with the accrediting agencies in defining education standards, and designing job descriptions.
- C. Serve as a basis for defining professional advancement and the requisite knowledge to achieve and sustain higher levels of practice.
- D. Serve as a source document that, through periodic revisions, will reflect practice, scientific, and technical advances in the profession.

## II. Content and Use

### A. Description of the Content Outline

1. The document follows an outline format with behavioral objectives. There are two major sections: Professional Practice and Foundational Knowledge. The latter section contains the knowledge required for professional practice.
2. The Professional Practice section consists of the five core competencies defined by the Institute of Medicine, now the National Academy of Medicine, for all health professionals (*Health Professions Education: A Bridge to Quality*, 2003): Patient-centered Care, Interprofessional Teams, Evidence-based Practice, Quality Improvement, Informatics, plus additional subsections on Professionalism and Ethics, Education, Health Care Policy, and Laboratory Services Management, Delivery, and Access.
3. The Foundational Knowledge section is divided into two major subsections: Scientific/Medical including Research, Epidemiology, Clinical Pharmacology, Pathophysiology, and Health Assessment; and Advanced Clinical Laboratory Science including advanced concepts in all the major divisions of clinical laboratory science: Clinical Chemistry, Hematopathology/ Hemostasis, Clinical Immunology, Microbiology and Infectious Disease, Molecular Diagnostics and Medical Genetics, and Transfusion Services.
4. The ASCLS *Body of Knowledge* at the Medical Laboratory Scientist level is the required foundation upon which the *Body of Knowledge* of the Doctor of Clinical

- Laboratory Science was developed. The ability to achieve Doctor of Clinical Laboratory Science competencies subsumes achievement of the competencies specified at the Medical Laboratory Science level.
5. The Doctor of Clinical Laboratory Science objectives were not categorized as recall, interpretation, and problem-solving as in the undergraduate level document because most of the objectives require the highest cognitive level reflecting the doctoral degree.

B. Use of the Content Outline

1. The content outline may be used by educators to help define and design curricula. It can also be used to identify the depth/breadth of what is to be taught at the doctoral level.
2. For administrators, it is useful in writing job descriptions. The outline identifies various skills and functions that reflect job roles for the Doctor of Clinical Laboratory Science.
3. For laboratory practitioners, it may be used as a guide in determining continuing educational needs.

III. Development Process

- A. Contributors to the Body of Knowledge consisted of current and past members and participants of the ASCLS DCLS Oversight Committee who were selected based on their expertise as educators, managers, and practitioners, including DCLS educators and practitioners. This was designed to ensure results that were consistent with DCLS responsibilities as well as being academically appropriate.
- B. Approach. The DCLS Oversight Committee began working on the Body of Knowledge document in Fall 2014. A BOK subcommittee formed in January 2015 and began compiling relevant documents and resources. These included:
  1. *Doctorate in Clinical Laboratory Science Competencies/Model Course Descriptions/ Objectives*, approved by the ASCLS Professional Doctorate Task Force on February 9, 2006 and accepted by the Graduate Task Force of the National Accrediting Agency for Clinical Laboratory Sciences in 2006, and updated on April 11, 2012. The areas of competencies included 1) Patient Care; 2) Interpersonal and Communication Skills; 3) Professionalism; 4) Outreach; and 5) Continuous Practice Improvement. It also included course related competencies in the areas of Scientific and Medical Knowledge and course descriptions and behavioral/learning objectives for courses in Biochemistry and Cell Biology, Clinical Immunology, Microbiology and Infectious Disease, Biostatistics, Hematopathology, Immunohematology and Transfusion Services, Health Informatics and Epidemiology, Evidence Based Practice, Issues in Clinical Laboratory Science, Education Principles in Health Care, Health Assessment, Pathophysiology for Clinical Decision Making, Medical Genetics and Molecular Diagnostics, Issues in Public Health, Patient Interactions and Health Care Communications, Pharmacology, Clinical Patient Management, Research Design, Evaluation of Laboratory Technology, and Clinical Project.

2. *NAACLS Guide to Accreditation for Doctorate Programs in Clinical Laboratory Science* (adopted 10/2011) and *NAACLS Standards for Doctoral Programs* (adopted 2018, revised 9/2018 and 4/2021). These documents included curricular requirements for DCLS programs.
3. *Health Professions Education: A Bridge to Quality*. Institute of Medicine - IOM (now the National Academy of Medicine). Washington, DC: National Academies Press, 2003. This document published the results of a Health Professions Education Summit that proposed five core competencies for all health practitioners to promote patient safety: provide patient-centered care; work in interdisciplinary teams; employ evidence-based practice; apply quality improvement; and utilize informatics.
4. ASCLS Position Paper: *Advanced Practice: Doctorate in Clinical Laboratory Science* (approved August 2013, and revised August 2016). This document contains a description of DCLS professional responsibilities.
5. ASCLS Position Paper: *Practice Levels and Educational Needs for Clinical Laboratory Personnel* (approved July 25, 2009).
6. ASCLS Position Paper: *Scope of Practice* (approved 2012).
7. ASCLS Position Paper: *Patient Safety and Clinical Laboratory Science* (approved July 2015).
8. Course syllabi from DCLS Programs (Rutgers, The State University of New Jersey, University of Texas Medical Branch Galveston, and University of Kansas Medical Center)
9. ASCLS *Body of Knowledge* for the Medical Laboratory Science level (updated in 2014 and published in 2015). This provided the foundation upon which the DCLS competencies were built.

The committee compiled content and objectives from the source documents listed above into Professional Practice, Medical/Scientific, and Advanced Clinical Laboratory Science sections. They chose a framework for the Professional Practice section that included the five IOM competencies for health care practitioners to emphasize the importance of patient safety in DCLS practice. In addition, the framework provides the profession, other health care practitioners, patients, governmental and regulatory agencies, and the public a description of the role and contribution of the DCLS within the five competencies and how they interrelate with other health professionals. The Body of Knowledge at the Medical Laboratory Science (MLS) level was used to summarize the MLS competencies for each major section so the undergraduate competencies would not need to be repeated in the DCLS document. This established a baseline for the DCLS competencies. After multiple iterations, the final organizational structure was divided into two major sections: Professional Practice and Foundational Knowledge, the latter including the Medical/Scientific and Advanced Clinical Laboratory Science subsections.

In July 2018 the BOK subcommittee presented a working draft to the entire DCLS Oversight Committee. Members of the Committee continued to meet from 2019 to 2021 to carefully review and edit the content and level of the objectives in each major section line by line. After that task was completed, the sections were combined into one

document in January 2022 and subsequently reviewed and edited again to reorganize sections, delete redundancies, and clarify language.

A completed draft was presented to the ASCLS Board of Directors and Education Scientific Assembly in March 2022 and posted for comments from the general membership in various online communities on the ASCLS website.

#### IV. Future Directions

- A. This is the first edition of the *Body of Knowledge* for the Doctor of Clinical Laboratory Science. At the time this document was completed, there were three DCLS Programs in the country and less than fifty DCLS graduates in practice. It is anticipated that as more DCLS graduates mature into their professional practice, revisions and refinements will be needed.
- B. This document will be updated again under the guidance of the ASCLS Board of Directors.
- C. This document belongs to all practicing medical laboratory professionals. It is our right to define its content, our responsibility to monitor and update it, and our privilege to use it to promote our personal growth and to enhance our professional stature.

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## PROFESSIONAL DESCRIPTION

The Doctor of Clinical Laboratory Science increases diagnostic efficiency, facilitates patient management outcomes, and improves timely access to accurate and appropriate laboratory information by participating directly in patient care decisions, monitoring laboratory utilization, and conducting research on the diagnostic process.

Specifically the DCLS:

- Provides patient-centered, customized consultation services on appropriate test selection and interpretation for the purpose of clinical decision making among the interprofessional health care team and for the patient.
- Monitors laboratory data, test utilization, and diagnostic testing processes in individual patients and populations using informatics and analytics to reduce diagnostic errors, improve efficiency, and reduce costs.
- Conducts research and applies evidence to demonstrate clinical utility of laboratory tests and algorithms and to improve the quality, efficiency, and safety of the overall diagnostic testing process including tests used for screening, diagnosis, prognosis, and monitoring disease states.
- Educates health care providers, patients, their families, and the general public about the indications, best evidence, patient preparation, and interpretation of clinical laboratory testing, including home self-testing.
- Directs laboratory operations to comply with all state and federal laws and regulations, as well as guidelines determined by professional boards of licensure, and certification/accreditation agencies.
- Participates in public and private health policy decision making at all organization and government levels using best evidence.

Excerpted from: American Society for Clinical Laboratory Science Position Paper *Advanced Practice: Doctorate in Clinical Laboratory Science* (approved by the ASCLS House of Delegates, August 2016).

## CONTENT OUTLINE

*The Body of Knowledge (BOK) of the Medical Laboratory Scientist (MLS) is the required foundation upon which the BOK of the Doctor in Clinical Laboratory Science (DCLS) is developed. Ability to develop competence in the DCLS BOK subsumes competency in the MLS BOK. The Scientific/Medical and Advanced Clinical Laboratory Science sections contain the Foundational Knowledge to be applied in the Professional Practice Section.*

## PROFESSIONAL PRACTICE

### I. Patient-centered Care

#### A. Customizing Patient Laboratory Testing Needs

1. Review patients' medical records/charts and extract pertinent information about their history and physical exam.
2. Develop a problem list and potential differential diagnoses using appropriate medical terminology, standard format, and sound organization of both subjective and objective data.
3. Recommend laboratory tests to be performed, or evaluate the appropriateness of laboratory tests ordered, based on analysis of patient information.
4. Evaluate patient laboratory data to develop individualized diagnostic algorithms
  - a. Develop patient-specific laboratory test interpretations considering the patient's health status, possible pathophysiologic conditions, and/or possible test interferences.
  - b. Recommend appropriate follow-up tests to confirm a diagnosis, prognosis, and/or monitor the patient's condition.
  - c. Discuss therapeutic options (when applicable) and the laboratory tests needed to monitor therapy.
5. Cite the applicable guidelines and evidence in the literature for recommendations regarding laboratory screening, diagnosis, prognosis, treatment, and monitoring of disorders.
6. Manage transitions of care effectively and provide for continuity of care in laboratory services.
  - a. Participate in thorough laboratory testing reconciliation, when necessary.
  - b. Follow up on all identified diagnostic testing process problems.
  - c. Participate effectively in laboratory and diagnostic testing process education.
  - d. Provide accurate and timely follow-up information when patients transfer to another facility, or level of care, or provider, as appropriate, including shift changes.
  - e. Follow up with patient and provide additional monitoring and education, as appropriate.
  - f. Take appropriate and effective steps to help avoid unnecessary hospital admissions and/or readmissions.

7. Educate patients, their families, and the general public about the indications, best evidence, patient preparation, and interpretation of clinical laboratory testing, including home self-testing.
- B. Patient Interactions (Cultural Competence, Communication, Patient Education, Ethical Practice)
1. Discuss cultural, ethnic, religious, and social beliefs and how they impact healthcare beliefs and practices.
  2. Explain the impact of the patient's cultural beliefs and value systems on the ability to effectively communicate aspects of clinical laboratory testing.
  3. Integrate knowledge of various cultures to communicate with and educate patients, families, and advocates on the aspects of the total testing process.
  4. Respect patients' autonomy, privacy, beliefs, values, cultural differences, and individual preferences in all interactions and communications.
  5. Abide by ethical principles pertaining to provision or withholding of clinical care, confidentiality of patient information, informed consent, and business practices.
  6. Promote shared decision-making and management among patients and the health care team and empower patients to take responsibility for their health.
    - a. Encourage patients and their advocates to ask questions or voice concerns about their laboratory testing.
    - b. Answer questions from patients and their advocates about their laboratory tests.
    - c. Provide patients and their advocates with resources such as brochures or reliable websites where they can find more information about their tests.
    - d. Communicate with patients about how they can obtain a copy of their laboratory test results.
    - e. Discuss the advantages, opportunities, and pitfalls of direct access testing.
    - f. Consult with consumers on direct-to-consumer lab ordering, testing, and interpretation and refer as appropriate.
  7. Communicate effectively with patients, their family, and advocates.
    - a. Demonstrate empathy and advocacy for patients.
    - b. Demonstrate cultural competence.
    - c. Appropriately adapt communication style and messages to the context of the individual patient interaction.
    - d. Use effective listening, nonverbal, explanatory, questioning, and writing skills to elicit and provide information.
    - e. Demonstrate caring and respectful behaviors when interacting with patients, their families and advocates.
  8. Demonstrate responsibility to patients.
    - a. Give priority to patient care activities.
    - b. Routinely complete and assume responsibility for all steps of the diagnostic testing management process.
    - c. Actively work to identify the potential for significant testing related problems.
    - d. Help patients learn to navigate the healthcare system, as appropriate.

- e. Inform patients how to interpret their test results and recommended follow-up testing.
- f. Determine barriers to patient compliance and make appropriate adjustments.
- g. Maintain accuracy and confidentiality of patients' protected health information.

### C. Disease Prevention and Wellness Promotion

1. Discuss laboratory perspectives on wellness, impairment, disease, disability, and health risks related to age, gender, culture, and lifestyle with other healthcare perspectives.
2. Provide clinical laboratory services and education aimed at maintaining health and preventing disease.
3. Participate in community education about clinical laboratory testing and screening.

### D. Population Health

1. Obtain and apply information (e.g., surveillance programs such as newborn screening, infectious disease tracing, antibiotic resistance, etc.) about the local/regional population of patients and the larger population from which their patients are drawn.
2. Discuss local, regional, and national health care policies and decisions, and their impact on patients under their care.
3. Analyze data and determine needs for local/regional populations.
4. Discuss strategies to address health disparities and ensure equitable access to testing and screening.

## II. Interprofessional Teams

### A. Consultation

1. Consult with health care providers, in a variety of settings including interprofessional teams and patient rounds, about specific patients or laboratory testing problems, contributing expertise related to:
  - a. Test ordering for appropriate utilization of laboratory services.
    - 1) Test options for a particular medical condition.
    - 2) Lack of indication for test, duplication, and discrepancies between ordered laboratory tests.
    - 3) Medical conditions for which there is no recommended testing.
    - 4) Laboratory testing ordered that has limited clinical utility or is continued inappropriately for a particular medical condition.
  - b. Pre-analytic issues of laboratory testing such as proper patient preparation, patient identification, specimen collection and transport, timing of collection, supplement/drug-laboratory test interaction or the

- potential for such interaction, and patient informed consent for specific testing.
- c. Post-analytic test interpretation, data validity, advantages and limitations of tests, and diagnostic decision support.
  - d. Appropriate follow up laboratory testing.
  - e. Appropriate laboratory testing to determine compatibility of blood products or tissues prior to transfusion or transplantation.
  - f. Monitoring of anticoagulants, antimicrobials, other therapeutic drugs, and blood component therapy.
  - g. Clinically significant pharmacogenomic or genetic testing results.
  - h. Appropriate therapies such as apheresis, photopheresis, phlebotomy, stem cell transplantation, and blood product transfusion.
  - i. Problems arising from the financial impact of laboratory testing on the patient.
  - j. Patient, family, and advocate comprehension of and compliance with test requirements such as appropriate fasting and timing of specimen collection.
2. Provide information, data/statistics, and participate on interprofessional committees such as those for development of order sets, patient blood management, antimicrobial stewardship, pharmacy and therapeutics, genetic counseling, patient safety, hospital risk management, quality improvement, compliance, emergency medicine, and those addressing policies and procedures for mitigating diagnostic error.
  3. Communicate and document preliminary and significant findings from laboratory testing to the appropriate care provider in a timely manner, with verification of understanding using appropriate techniques.
  4. Ensure processes are in place to accurately communicate critical test results within the established time frame.
  5. Communicate delays in testing to care providers when appropriate.
  6. Collaborate and educate nurses and other care providers performing point-of-care testing to address issues such as patient identification and quality control.
  7. Develop consultation opportunities with other health care providers using clinical data sets from electronic health records (EHR) and test utilization reviews.
  8. Document direct patient care activities (e.g., consults, consent) in the medical record (according to institutional protocols) that is timely, appropriate, and effective in the care of the patient for medical, legal, quality, and financial purposes.

## B. Interprofessional Team Interactions

1. Work effectively with all health care professionals as a member or leader of a health care team ensuring interactions are cooperative, collaborative, and respectful.
2. Use effective listening, nonverbal, explanatory, questioning, and writing skills to elicit and provide information.

3. Demonstrate personal, interpersonal, and teamwork skills critical for effective participation and leadership on interprofessional teams, including:
  - a. Knowledge of one's own role and the roles of other health care professionals on the team
  - b. Thorough preparation for activities (e.g., interprofessional rounds, committees, patient consultations)
  - c. Prompt and accurate follow-up on laboratory-related questions
  - d. Effective time management, conflict management, negotiation, and consensus building skills
  - e. Effective communication skills and styles that are respectful and culturally sensitive
  - f. Emotional resilience, flexibility, and tolerance of ambiguity
4. Integrate knowledge of various cultures to communicate with and educate healthcare providers on the aspects of the total testing process.
5. Promote professionalism, open communication, and respect between disciplines and professions.

### **III. Evidence-based Practice**

#### **A. Concepts, Principles, and Processes**

1. Define the concept of evidence-based practice.
2. Describe the purpose and role of evidence-based practice.
3. Describe the steps involved in evidence-based practice (A6 Method).
4. Differentiate between different types and sources of evidence, and between primary and secondary evidence.
5. Describe the hierarchical system of classifying the quality of evidence (levels of evidence) to make recommendations for clinical decisions.
6. Describe how to apply the process of evidence search, selection, analysis, synthesis, and application to clinical situations.

#### **B. Conduct Evidence-based Clinical Research and Health Outcomes Studies**

1. Develop appropriate clinical questions (e.g., Population, Intervention, Comparison, Outcome (PICO); Population, Action, Alt Action, Result, Evidence (PPARE)).
2. Create appropriate conceptual frameworks to address the clinical questions.
3. Conduct a focused review of the relevant literature to identify clinically relevant scientific studies and clinical guidelines.
4. Access and use informatics strategies for searching literature and clinical databases (e.g., electronic health records, laboratory information systems, radiology information systems, electronic data warehouses).
5. Critically appraise relevant studies and evidence by applying knowledge of study designs and statistical methods.
6. Summarize and integrate evidence from relevant published research to address specific clinical questions and support clinical decision-making.



7. Structure a systematic review of the literature using data gathered regarding a specific clinical question.
8. Develop realistic research proposals and designs using appropriate statistical tools of clinical decision-making.
9. Conduct research following institutional and governmental requirements.
  - a. Ensure studies are approved by applicable IRBs.
  - b. Ensure resources are available to conduct research studies.
  - c. Manage research personnel and budgets to ensure compliance with institution and government policies and regulations.
10. Collect data for analysis, use appropriate statistical tools and software, and draw appropriate conclusions based on the evidence.
11. Acknowledge unanticipated limitations/problems encountered in clinical research and address their impact on interpretation of findings.
12. Communicate research findings and their appropriate theoretical and methodological issues effectively and efficiently,
13. Integrate research to promote evidence-based practice within legal, ethical, and regulatory guidelines.
14. Contribute to research that promotes positive outcomes for individual patients during complex acute, critical, and chronic illnesses as well as research that promotes wellness.

### C. Applications of Evidence-based Research

1. Clinical Decision Support including Population-based Diagnostic Algorithms and Care Pathways
  - a. Define diagnostic algorithms and care pathways.
  - b. Design or redesign safe and effective algorithms/care pathways for diagnostic testing processes for:
    - 1) Diseases/conditions in applicable patient populations (e.g. pediatric, adult, geriatric, male/female).
    - 2) Care pathways/diagnostic order sets (e.g., stroke, sepsis, acute myocardial infarction, etc.).
  - c. Evaluate laboratory test ordering protocols associated with:
    - 1) Commonly used preventative assessments (e.g., viral screens, cancer screens, general chemistry profiles, thyroid profiles)
    - 2) High risk, high cost, and high frequency diagnoses and procedures in local and regional populations.
    - 3) Over and underutilization of specific tests (e.g., 5 rights of laboratory testing, Choosing Wisely)
  - d. Appropriately select and apply principles of clinical research (e.g., statistical measures, measures of predictive and causal relationships, and meta-analysis) in the analysis of patient cases.
  - e. Demonstrate how algorithms, reflex testing, and evidenced-based practice can improve utilization of laboratory services.
  - f. Monitor patients' care pathways and appropriately advise the use of diagnostics services.

- g. Communicate strategies to address socio-economic determinants of health and health disparities to optimize health services delivery and health equity.
2. Patient Management
- a. Create diagnostic algorithms and evidence-based, measurable, and achievable diagnostic process goals personalized for patient/consumer-specific care pathways
    - 1) Consider any pre-analytical, analytical, and post-analytical variables pertinent to the clinical situation.
    - 2) Consider pharmacologic information that may impact testing.
    - 3) Recognize patterns of socioeconomic and racial/ethnic issues and their impact on laboratory selection and testing.
    - 4) Design/redesign diagnostic testing processes that:
      - a) Are appropriate for the patient condition(s).
      - b) Reflect therapeutic goals established for the patient by other interprofessional team members.
      - c) Acknowledge preferences, values, and continuing needs.
      - d) Are in line with best evidence and published guidelines regarding laboratory procedures most appropriate based on clinical and diagnostic findings.
      - e) Consider the limitations of diagnostics.
      - f) Use risk and cost assessment information to determine the protocol of greatest value and ease of compliance for the patient.
    - 5) Effectively evaluate achievement of diagnostic and therapeutic goals considering patient compliance.
    - 6) Ensure adequate, appropriate, and timely follow-up on laboratory testing results.
    - 7) Select the most appropriate methodology for lab testing.
    - 8) Use appropriate reference intervals.
    - 9) Create personalized consultation reports detailing evidence-based protocols for diagnostic management.
3. Analytic Quality and Risk Assessment for New Methods and Analytes
- a. Evaluate the clinical and cost-effectiveness of emerging technology, new analytes, scientific advancements, and laboratory test methods for assimilation and integration into clinical practice.
  - b. Use risk assessment information to determine priority of quality initiatives related to test utilization and health outcomes.
    - 1) Use statistical or qualitative methods to evaluate a needs assessment or pilot study data.
    - 2) Recommend changes to the diagnostics menu based on evidence of clinical and cost effectiveness.
    - 3) Assess laboratory test ordering and report potential areas of over and under-utilized laboratory tests.
  - c. Provide tracking and statistical analysis of procedural and diagnostics-related outcomes to provide evidence-based clinical decision support.

- d. Prepare and review policies and procedures based on standard evidence-based practice for laboratory testing methodologies.
  - 1) Evaluate pre-analytical, analytical, and post-analytical variables.
  - 2) Effectively develop or revise testing algorithms.
  - 3) Demonstrate appropriate assertiveness in presenting laboratory concerns, solutions, and interests to internal and external stakeholders.
- 4. Laboratory Stewardship and Utilization Review
  - a. Manage laboratory stewardship through ordering, interpretation, performance, supervision, risk assessment, and cost-benefit analysis.
  - b. Organize/participate in laboratory utilization evaluations using evidence-based principles.
  - c. Identify laboratory test ordering protocols related to high risk, high cost, and high frequency diagnostic related groups (DRGs) in the local population.
  - d. Effectively synthesize and present laboratory concerns, solutions, and interests to internal and external stakeholders.
  - e. Implement approved changes, as applicable.

#### **IV. Quality Improvement**

##### **A. Laboratory**

1. Collaborate in the development, implementation, and evaluation of both the clinical laboratory and institution quality plans and improvement projects.
  - a. Participate in data collection, analysis, and reporting of measures of risk for patient harm connected to laboratory services.
  - b. Participate in non-conforming event management, investigations, and root cause analyses.
  - c. Participate in the development and use of metrics that are patient-centered to improve laboratory testing processes.
  - d. Participate in risk assessment protocols to identify potential areas with risk for patient harm using established tools.
  - e. Apply results of appropriate research studies for quality improvement.
2. Communicate with the healthcare team regarding the quality and effective operation of the laboratory (risk assessment, performance driven quality control [PDQC], quality management rule selection, etc).
3. During clinical consultations, utilize policies and processes in accordance with established quality systems protocols, and identify and resolve quality non-conformities.
4. Investigate, report, track, and trend adverse laboratory events, errors, and efficacy concerns using accepted institutional resources and programs, including FDA reportable errors.
5. Develop new models and applications for delivery and evaluation of quality and cost-effective laboratory services.

## B. Healthcare Team

1. Participate in quality committees overseeing the utilization and interpretation of diagnostic information and laboratory resources (e.g., antibiotic stewardship, blood management, infectious disease)
2. Perform health outcomes-based improvement activities in concert with other members of the healthcare team.
3. Recognize and appropriately address gender, cultural, cognitive, emotional, and other biases; gaps in medical knowledge; and limitations of the healthcare team or system.
4. Recognize and correct systems-based factors that negatively impact patient care.
5. Partner with providers, health care managers, and other health care providers to assess, coordinate, and improve services delivery and patient outcomes in different practice settings.
6. Promote a safe environment for patients and other health professionals.
7. Partner with case managers when overseeing and directing health care services.
8. Identify changes needed to improve patient care and/or the diagnostic testing process.
9. Participate in development of enterprise-wide protocols to improve patient care and/or the diagnostic testing process.

## V. Informatics

### A. General Concepts

1. Use informatics as a method to communicate laboratory test results to care providers in a manner appropriate for patient diagnosis and treatment decision making.
2. Resolve unexplained discrepancies from the Laboratory Information System (LIS) to identify potentially significant changes or errors in patient test results.
3. Use patient information in LIS and Electronic Health Record (EHR) to provide context for test results.
4. Identify ways to advance the use of LIS, EHR, patient portals, and Computerized Physician Order Entry (CPOE) modules to improve communication and quality of care to prevent errors.
5. Use computerized systems to assist in identification of problems within the laboratory and administrative processes, including billing.

### B. Advanced Applications

1. Use clinical data sets to obtain quality information related to most frequent, highest risk, and highest cost diagnoses utilizing clinical laboratory resources and formulate quality improvement interventions.
2. Use diagnostic (ICD-9/10), LOINC and CPT codes to conduct EHR reviews to improve health outcomes.
3. Use laboratory information data sets to assess disease/condition risk and prevalence in populations of interest.

4. Identify opportunities for improvement of the laboratory information management systems.
5. When needed, make laboratory and diagnostic testing process policy recommendations based on a review of practice standards and other evidence (e.g., National Quality Measures, Joint Commission sentinel alerts, Choosing Wisely recommendations).
6. Collaborate on development, validation, and implementation of new laboratory information system (LIS) testing algorithms/rules and laboratory information management system (LIMS) applications such as laboratory workflow, productivity, and data mining.

## **VI. Professionalism/Clinical and Research Ethics**

### **A. Professionalism**

1. Explain the legal and regulatory requirements, as well as the appropriate role of a Doctor of Clinical Laboratory Science within all healthcare environments.
2. Maintain professional relationships with physicians and other health care providers.
3. Be responsive and accountable to the needs of patients, society, and the profession.
4. Treat patients and co-workers with respect, compassion, and integrity.
5. Demonstrate sensitivity and responsiveness to patients' current medical status, culture, age, gender, and disabilities
6. Engage in self-reflection, critical curiosity, and initiative in improving professional knowledge and abilities.
7. Demonstrate lifelong learning to stay abreast of relevant scientific advances.
8. Provide leadership in development of and advocacy for the Profession to the interprofessional team, the patient, and the public.
9. Apply a process of ongoing self-evaluation and personal performance improvement.
10. Manage one's own practice effectively.

### **B. Clinical Ethics**

1. Adhere to requirements of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) regarding patients' protected health information (PHI).
2. Demonstrate cultural competence by respecting patient's culture, religion, and personal preferences in health decisions.
3. Identify ethical issues in the use of patient information, information technology, and networks.
4. Discuss the ethical and legal issues associated with health care delivery and the relationship/impact on diagnostic testing.

5. Abide by ethical principles pertaining to provision or withholding of clinical care, confidentiality of patient information, informed consent, and business practices.
6. Demonstrate honesty and integrity in all professional interactions with patients, their families, colleagues, and others.
7. Demonstrate a compassionate and dignified treatment of patients.
8. Demonstrate an understanding of basic ethical principles relating to the choices of various pharmacologic, non-pharmacologic and alternative treatments of the major diseases of the various organ systems.
9. Describe the services of an organizational ethics committee and appropriately utilize and participate in these services.

### C. Research Ethics

1. Describe the influential codes of ethics and regulations that guide clinical research.
2. Describe ethical principles and their application in human subject research including respect for persons, beneficence, and justice (e.g., informed consent, privacy, equitable selection).
3. Conduct human subjects research following applicable federal and institutional regulations (e.g., IRB) and policies.

## **VIII. Education**

### A. Education of Diverse Audiences

1. Disseminate and explain laboratory information to patients/consumers and other health care professionals to increase awareness and knowledge of medical laboratory testing performed internal and external to clinical laboratories.
2. Counsel health care professionals and patients/consumers about point of care testing.
3. Inform healthcare professionals about test options resulting from new and emerging technologies.

### B. Design of Effective Educational Materials

1. Define educational needs with regard to target audience and learning level.
2. Write educational objectives and address the audiences' defined learning needs.
3. Use teaching strategies that match learner needs and learning level.
4. Select content that is relevant and evidence-based.
5. Include citations, references, and adhere to applicable copyright laws.

### C. Use of Effective Presentation and Teaching Skills

1. Facilitate audience participation, active learning, and engagement in various settings (e.g., small or large group, distance learning).
2. Use appropriate speaker mechanics to enhance presentations.

3. Summarize important points at appropriate times throughout presentations.
4. Effectively use current technology and written materials to support learning activities.

D. Use effective written communication to disseminate knowledge

1. Write at a level appropriate for the target readership (other health care professionals, patients, the public, etc.)
2. Select content that is relevant and evidence-based including critical evaluation of the literature and knowledge advancements.
3. Develop and employ appropriate tables, graphs, and figures to enhance the reader's understanding of the topic.
4. Include citations, references, and adhere to applicable copyright laws.

## **VIII. Health Care Policy**

A. Current Policies

1. Describe the governance of the healthcare system (national/institutional).
2. Explain the creation of health care policies and the relationship between the various health care related laws, regulations, and agencies (e. g., Departments of Public Health, CMS, etc.)
3. Discuss the current economic, social, regulatory, and professional issues that affect the delivery of quality, cost-effective laboratory services.

B. Policy Development

1. Participate in public and private health policy decision making and implementation at all organizational and government levels.
2. Collaborate with health systems and regulatory agencies in the development of policies and strategies to address health disparities and ensure equitable access to laboratory testing and screening.

## **IX. Laboratory Services Management**

A. Management

1. Explain the elements of the laboratory enterprise and their relationship to the health care system.
2. Participate in laboratory resource management, laboratory services administration, and department management.
3. Design, implement, and evaluate various practices and strategies to effectively manage clinical laboratory services.
4. Participate in implementing changes, using change management and quality improvement best practices and tools, consistent with team, departmental, and organizational goals.
5. Discuss external quality metrics and how they are developed, abstracted, reported, and used.

6. Discuss the components and importance of the department planning process including potential impact factors that influence departmental planning.
  7. Identify appropriate resources to keep updated on trends and changes within laboratory and health care.
  8. Provide oversight of human subjects and other clinical laboratory research.
- B. External Regulation
1. Discuss regulatory issues that impact clinical laboratory services.
  2. Discuss changes in laws and regulations (e.g., value-based purchasing, consumer-driven healthcare, reimbursement models, CLIA, FDA, CMS, AABB, CAP, etc.) related to the laboratory and laboratory testing.
  3. Operationalize regulations in the clinical laboratory services environment.
- C. Financial
1. Employ funding sources and payment systems that provide coverage for patient care.
  2. Design and utilize operations and capital budgets as well as cost/benefit and cost/revenue analysis for optimal efficiency.
  3. Conduct and evaluate informal audits and inspections for laboratory compliance and billing procedures.
- D. Access
1. Implement strategies to ensure equitable access to laboratory testing and screening.
  2. Collaborate with clinical leadership and other stakeholders to ensure appropriate laboratory testing is available (e.g., supply chain issues).



# FOUNDATIONAL KNOWLEDGE

## I. Scientific/Medical

### A. Research

1. Statistical Applications
  - a. Describe the purpose, use, application, and limitations of specific statistical methods used in analysis of data in clinical research.
  - b. Interpret results from diverse statistical methods.
  - c. Communicate statistical methods and results of analysis through a variety of mechanisms.
  - d. Use sound statistical concepts to develop research protocols.
2. Literature Review
  - a. Describe applicable data bases and methods available for conducting a comprehensive literature search to address a clinical question.
  - b. Evaluate/critique current research literature in clinical laboratory science and related health professions.
3. Research Methods
  - a. Describe the difference between translational/applied and outcomes research.
  - b. Discuss research design and data collection strategies.
  - c. Discuss qualitative research related to its use in clinical research.
  - d. Describe concepts and methods of a meta-analysis.
  - e. Describe measurement of variables and concepts of measurement reliability and validity.
  - f. Develop a conceptual framework for a study to investigate a clinical question.
  - g. Determine appropriate outcomes measures (i.e. medical, legal, quality, and financial) for a research study.
4. Management of Research
  - a. Describe the structure of research projects and programs.
  - b. Describe the role of the primary investigator, institutional review board, institutional privacy officer, clinical champion, grant institutions and agencies in local and multi-site research projects.
  - c. Evaluate the use of informed consent and methods of documentation for research projects.
  - d. Apply regulatory requirements to determine differences between clinical, environmental, compounding, and research testing and effects on specimen procurement and tracking, data management, and result reporting.
  - e. Determine laboratory costs for research protocols/projects and provide accounting for financial, workforce, and logistic costs.

### B. Epidemiology

1. Collaborate in outbreak investigations.

2. Identify key sources of laboratory data for epidemiologic research.
3. Collaborate with diagnostic programs and public health screening for effectiveness using sensitivity, specificity, and predictive values.
4. Critically review epidemiologic research.
5. Discuss the general principles of chronic disease epidemiology including trends and risk factors for common chronic diseases, surveillance, and public health interventions to address these conditions and diseases.
6. Describe the incidence and prevalence of common diseases among various U.S. populations and inter-patient variations in laboratory findings.

### C. Clinical Pharmacology

#### 1. Basic Concepts

- a. Explain the mechanisms of action and metabolisms for all drugs that are monitored or cause pre-analytical/analytical variation within the clinical laboratory (anticoagulants, antimicrobials, and chemotherapy agents)
- b. Correlate generic and brand names of drugs that are monitored or cause analytical variation in laboratory testing and the potential impact on test results.
- c. Identify and summarize effects of reversal agents (antidotes, antibody, anti-venom, streptokinase, vitamin K, chelating agents, human recombinant factor Xa, charcoal, etc.) on diagnostic testing.

#### 2. Application

- a. Evaluate pharmaceuticals for analytical interference and discuss/recommend methods used to mitigate those interferences.
- b. Correlate diagnostic test findings with active medications and patient clearance capabilities through the kidney and liver (such as drugs that cause anemia or direct oral anticoagulant effects in renal patients).
- c. Distinguish artifactual laboratory findings due to medication-related interference from expected values in each patient's setting (such as drug metabolite interference with cerebrospinal fluid cell counts).
- d. Discuss best methods to measure/monitor therapeutic drugs.
- e. Correlate pharmacogenetic findings with patient symptoms.
- f. Review formularies to provide laboratory related information regarding selection and adoption of new pharmaceuticals.
- g. See also: Advanced Clinical Laboratory Science sections for discipline specific pharmacology.

### D. Pathophysiology

1. Discuss key diseases of major organ systems including molecular, biochemical, and cellular mechanisms for disease.
2. Differentiate between the normal physiology and pathophysiology of major organ systems using laboratory and other diagnostic data.
3. Discriminate among etiologies, risk factors, and underlying pathologic processes for medical conditions.

4. Correlate clinical signs and symptoms with pathophysiology of diseases in the major organ systems.

#### E. Health Assessment

1. Describe the components of a complete history.
  - a. History of present illness
  - b. Symptoms and chief complaint
  - c. Relevant health data including age, gender, past medical history, family history and ethnicity, health and wellness information, biometric results, physical assessment findings, and social and occupational history
  - d. Medication history including prescription, non-prescription, illicit, recreational, and non-traditional therapies, dietary supplements, immunizations, and allergies
  - e. Current and previous laboratory test results
  - f. Risk factors; lifestyle, diet, and habits; preferences and beliefs; health and functional goals; and socioeconomic factors that affect access to testing, medications, and other aspects of care
2. Describe components of a physical examination and systems review.
3. Explain the features of a symptom including location, radiation, onset, duration, frequency, alleviating and aggravating factors, functional impairment, and patient's interpretation of symptoms.
4. Summarize a patient's history, physical examination, and review of preliminary laboratory and diagnostic information.

## II. Advanced Clinical Laboratory Science

### A. Clinical Chemistry

1. Normal Physiology
  - a. Discuss the normal physiology and interrelationships of carbohydrates, lipids, proteins, enzymes, non-protein nitrogen, electrolytes and trace elements, pH and blood gasses, vitamins, hormones, bilirubin, and porphyrins including terminology, structure, classification, metabolism, and regulation.
2. Therapeutic Drug Monitoring
  - a. Discuss pharmacokinetics, pharmacogenomics, toxicology terminology, mechanisms and factors affecting drug toxicity, drugs of abuse, and specimen requirements and timing.
  - b. Correlate patient results with therapeutic or toxicologic ranges.
  - c. Discuss opportunities for collaboration with pharmacists and other professionals in monitoring therapeutic drugs.
3. Clinical Toxicology
  - a. Describe the fundamentals of toxicology beginning with what constitutes a toxic substance and how it is metabolized by the human body.
  - b. Discuss the advantages and disadvantages of various specimen types and the use of testing to validate the acceptability of the specimen.

4. Disorders (diabetes, cardiovascular, respiratory, renal, hepatobiliary, gastrointestinal and pancreatic, endocrine, reproductive and pregnancy, inborn errors of metabolism, vitamins, trace elements, and nutritional assessment)
  - a. Interpret and analyze pertinent data from the scientific literature.
  - b. Identify and apply published practice guidelines, diagnostic criteria, and other evidence to support recommendations in various disorders.
  - c. Discuss the clinical presentation, etiology (including genetics and risk factors, if applicable), pathophysiology, laboratory diagnosis, clinical management, and treatment options.
  - d. Identify and discuss the sensitivity, specificity, predictive values, interfering substances, advantages, and limitations of laboratory tests considering the application (screening, diagnosis, prognosis, and monitoring of the disorder).
  - e. Identify physiologic, pathophysiologic, or therapeutic conditions that cause interference in testing.
  - f. Correlate laboratory data with various disorders.
  - g. Differentiate between disorders with similar presentations and specify the role of laboratory testing in the diagnosis.
  - h. Evaluate current, new, and emerging tests and strategies for screening, diagnosis, and monitoring of disorders.

## B. Hematopathology/Hemostasis

### 1. Advanced Concepts

- a. Discuss the normal physiology of hematopoiesis, all phases of hemostasis, and interpretation of body fluid analysis including terminology, cellular structure and function, and regulation.

### 2. Disorders (anemia, polycythemia, non-neoplastic leukocyte disorders, neoplastic blood cell disorders, platelet disorders, coagulopathies, thrombophilia)

- a. Interpret and analyze pertinent data from the scientific literature.
- b. Identify and apply published practice guidelines, diagnostic criteria, and other evidence to support recommendations in various disorders.
- c. Discuss the clinical presentation, etiology (including genetics and risk factors, if applicable), pathophysiology, laboratory diagnosis, clinical management, and treatment options.
- d. Identify and discuss the sensitivity, specificity, predictive values, interfering substances, advantages, and limitations of laboratory tests considering the application (screening, diagnosis, prognosis, and monitoring of the disorder).
- e. Identify physiologic, pathophysiologic, or therapeutic conditions that cause interference in testing (such as impact of chemotherapy on laboratory testing and cellular morphology).
- f. Correlate laboratory data with various disorders.
- g. Differentiate between disorders with similar presentations and specify the role of laboratory testing in the diagnosis.

- h. Evaluate current, new, and emerging tests and strategies for screening, diagnosis, and monitoring of disorders.

## C. Immunology

### 1. Advanced Concepts

- a. Discuss the normal physiology of the immune system including terminology, cellular structure and function, regulation, and interrelationships.
- b. Discuss the cellular and molecular immune system responses needed to maintain health, those that contribute to disease, and those involved in recovery.
- c. Integrate immune concepts and principles of immune function with clinical laboratory applications.
- d. Discuss the molecular and cellular events in the inflammatory response including wound healing.
- e. Discuss the structure and function of the major histocompatibility complex/human leukocyte antigen (HLA) systems and application in transplantation, infectious disease, autoimmunity, and pharmacogenomics /pharmacogenetics /kinetics (such as B7 and HIV therapeutics).
- f. Discuss immunological factors influencing the development of cancer.
- g. Discuss the concept of immunotherapy and its application in oncology, transplantation, autoimmunity, vaccinology, and immunomodulation.
- h. Identify and explain the impact of immunotherapy on laboratory testing.

### 2. Disorders (autoimmune conditions, conditions involving tumor antigens, lymphocyte immunodeficiencies, complement deficiencies, phagocyte deficiencies, acquired immunodeficiency syndrome, viral and bacterial infections, hypersensitivity, systemic inflammatory response syndrome (SIRS)/sepsis)

- a. Interpret and analyze pertinent data from the scientific literature.
- b. Identify and apply published practice guidelines, diagnostic criteria, and other evidence to support recommendations in various disorders.
- c. Discuss the clinical presentation, etiology (including genetics and risk factors, if applicable), pathophysiology, laboratory diagnosis, clinical management, and treatment options.
- d. Identify and discuss the sensitivity, specificity, predictive values, interfering substances, advantages, and limitations of laboratory tests considering the application (screening, diagnosis, prognosis, and monitoring of the disorder).
- e. Identify physiologic, pathophysiologic, or therapeutic conditions that cause interference in testing.

- f. Correlate laboratory data with various disorders.
- g. Differentiate between disorders with similar presentations and specify the role of laboratory testing in the diagnosis.
- h. Evaluate current, new, and emerging tests and strategies for screening, diagnosis, and monitoring of disorders.

#### D. Microbiology and Infectious Disease Syndromes

##### 1. Advanced Concepts

- a. Recommend procedures for collection, processing, storage, and transport of the appropriate clinical specimens for identification of all types of infectious agents in tissues and body fluids.
- b. Discuss the impact of the microbiome in health and disease.
- c. Discuss the aspects of biofilms in relationship to infection and disease.
- d. Discuss the principles of therapy relating to the mechanism of action of antibiotics, and the therapeutic agents used in clinical medicine including their pharmacokinetics, pharmacodynamics, and relative costs.
- e. Compare and contrast methods of determining activity of antimicrobial agents and analytical techniques to determine their concentrations in microbial cultures of blood and other body fluids.
- f. Explain the appropriate use of antimicrobial agents in a variety of clinical settings and their potential adverse reactions.
- g. Discuss the laboratory tests needed to monitor antimicrobial therapy to determine efficacy and optimize patient safety.
- h. Describe the appropriate utilization of antibiotics in antimicrobial stewardship to prevent the over or underutilization of antimicrobial therapy.
- i. Discuss complementary and alternative treatments (such as probiotics, fecal transplant, herbal remedies) and the potential impact on result interpretations and clinical presentation.
- j. Discuss the principles of disease control, prevention of nosocomial infections, and immunization programs.
- k. Explain the impact of epidemiologic forces outside the hospital environment on potential community and patient outcomes.
- l. Compare and contrast the principles and practice of hospital epidemiology and infection control, quality improvement, clinical outcomes analysis, and cost containment in clinical microbiology.

##### 2. Infectious Disease Syndromes Affecting Major Organ Systems

- a. Interpret and analyze pertinent data from the scientific literature.
- b. Identify and apply published practice guidelines, diagnostic criteria, and other evidence to support recommendations in various infectious diseases.
- c. Discuss the clinical presentation, epidemiological aspects, etiology (including genetics and risk factors, if applicable), routes of transmission, pathophysiology, natural history, laboratory diagnosis, clinical management, and treatment options.

- d. Explain the effects of underlying disease states and immunosuppressive therapies on host response to infectious agents.
- e. Identify and discuss the sensitivity, specificity, predictive values, interfering substances, advantages, and limitations of laboratory tests considering the application (screening, diagnosis, prognosis, and monitoring of the disorder.)
- f. Identify physiologic, pathophysiologic, or therapeutic conditions that cause interference in testing.
- g. Correlate laboratory data with various disorders.
- h. Differentiate between disorders with similar presentations and specify the role of laboratory testing in the diagnosis.
- i. Evaluate current, new, and emerging tests and strategies for screening, diagnosis, and monitoring of disorders.

## E. Molecular Diagnostics and Medical Genetics

### 1. Advanced Concepts

- a. Discuss mechanisms and regulation of gene expression and the molecular technologies used to assess them.
- b. Discuss molecular technologies and applications in epigenetics, proteomics, pharmacogenomics, and personalized medicine.
- c. Discuss the principles, applications, advantages, and limitations of molecular tests used for identity testing, parentage determination, transplantation, immunohematology, and forensics.
- d. Describe appropriate laboratory regulations and practices required in a molecular diagnostic laboratory.
- e. Describe key considerations in the set up and operation of a molecular diagnostic laboratory.
- f. Discuss ethical, legal, social, and economic issues related to molecular testing.
- g. Discuss the applications, benefits, and pitfalls of direct-to-consumer genetics testing.
- h. Review, develop, and modify protocols and indications for ordering molecular/genetic testing taking into consideration the results of non-molecular tests, previous molecular testing, in-house or reference laboratory testing, and reimbursement issues.
- i. Discuss implications of molecular genetic testing (such as psychological distress, loss of privacy, genetic discrimination, paternity disclosure, effect on reproduction decisions and future health outcomes, psychosocial consequences with family and community).
- j. Discuss the informed consent processes for medical genetic testing including:
  - 1) Patient rights and autonomy.
  - 2) Storage and archiving of DNA material and testing.
  - 3) Use of deidentified DNA material for quality control.

### 2. Disorders (genetic, hematopathologic, malignant, and infectious disease syndromes)

- a. Interpret and analyze pertinent data from the scientific literature.
- b. Identify and apply published practice guidelines, diagnostic criteria, and other evidence to support recommendations in various disorders.
- c. Discuss the clinical presentation, etiology (including genetics and risk factors, if applicable), molecular pathophysiology, laboratory diagnosis, clinical management, and treatment for disorders.
- d. Discuss the principles, appropriate clinical use, sensitivity, specificity, predictive values, interfering substances, advantages, and limitations of molecular tests considering the treatment path stage (screening, diagnosis, monitoring, prediction, risk-assessment, prognosis, and therapeutic decision-making) for the disorder.
- e. Identify physiologic, pathophysiologic, or therapeutic conditions that cause interference in testing.
- f. Correlate laboratory data with various disorders.
- g. Differentiate between disorders with similar presentations and specify the role of laboratory testing in the diagnosis.
- h. Evaluate current, new, and emerging tests and strategies for screening, diagnosis, and monitoring of disorders.
- i. Ensure laboratory reports comply with local, state, and federal regulations regarding interpretation information.
- j. Describe how care is optimally coordinated with appropriate healthcare team members including genetic counselors.

## F. Transfusion Services

### 1. Advanced Concepts

- a. Discuss pertinent physiological, molecular, biochemical, immune, and cellular mechanisms that are important in maintaining body homeostasis, especially of those systems known to be susceptible to volume or component depletion (TACO, TRALI, Trauma, TRIM, TRAGI, etc).
- b. Evaluate, troubleshoot, and resolve transfusion service, blood management, and transfusion outcomes.
- c. Apply all relevant federal, state, and local regulations as they apply to blood product management and transfusion (including FDA 510K clearance regulations).
- d. Discuss the regulations applicable to the transfusion service/blood bank and the concept of quality assurance (QSM, Change Control, etc.) and management as the core of regulation compliance.
- e. Discuss drug interference, resolution techniques, and transfusion requirements for pre-transfusion testing (e.g., DARA).
- f. Discuss when molecular testing is necessary in transfusion services.
- g. Recommend appropriate blood product utilization in specific clinical situations (irradiation, washed, Psoralen treatment, etc.).
- h. Discuss the clinical relevance and importance of HLA, platelet, and other hematopoietic antigens and receptors for transfusion and transplantation.
- i. Outline the role of transfusion services in tissue and cord blood banking.



- j. Support the development of blood bank systems and other electronic systems utilized within transfusion medicine.
2. Disorders (Hemolytic Disease of Fetus and Newborn, Autoimmune Hemolysis)
    - a. Interpret and analyze pertinent data from the scientific literature.
    - b. Identify and apply published practice guidelines, diagnostic criteria, and other evidence to support recommendations in various disorders.
    - c. Discuss the clinical presentation, etiology (including genetics and risk factors, if applicable), pathophysiology, laboratory diagnosis, clinical management, and treatment options.
    - d. Identify and discuss the sensitivity, specificity, predictive values, interfering substances, advantages, and limitations of laboratory tests considering the application (screening, diagnosis, prognosis, and monitoring of the disorder).
    - e. Identify physiologic, pathophysiologic, or therapeutic conditions that cause interference in testing.
    - f. Correlate laboratory data with various disorders.
    - g. Differentiate between disorders with similar presentations and specify the role of laboratory testing in the diagnosis.
    - h. Evaluate current, new, and emerging tests and strategies for screening, diagnosis, and monitoring of disorders.
  3. Transfusion Support
    - a. Discuss transfusion support requirements for various disorders (anemias, platelet deficiencies, coagulopathies, surgery, oncology, transplantation, massive transfusion, emergency transfusion, neonates, pediatrics, autologous and directed donations, and presence of rare/complex antibodies).
    - b. Discuss procurement of blood products in special situations (e.g., rare donor registry).
    - c. Discuss the pathophysiology and investigation of various types of transfusions reactions including immune and nonimmune, hemolytic and nonhemolytic, immediate and delayed transfusion reactions including the strategies to prevent the future occurrence of each type.
    - d. Discuss contraindications for transfusion (such as patient condition and product).
    - e. Explain the ethical considerations for special transfusion populations (neonates, unable to consent, Jehovah's witness, and advance directives).
    - f. Describe blood utilization and auditing techniques and the function of the Hospital Transfusion Service Committee.