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Ethics in Laboratory Medicine: An Overview of Considerations for Ethical Issues

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Abstract

Several ethical issues exist within the diagnostic medical laboratory. The major ethical challenges such as; consent, confidentiality, codes of conduct, conflict of interest, lab utilisation, proficiency, and direct access testing are some times more prevalent in resource-limited settings. Presently, decisions regarding diagnosis and patient's treatment are commonly taken on the basis of outcomes and interpretations of laboratory test results. Therefore, ethics plays a significant role in laboratory medicine. Apart from the lab results, laboratory staff is another important aspect of the laboratory. Hence, it is highly recommended that knowledge of ethics helps to protect confidence; operational integrity, capability, impartiality, and safety of the staff. Many countries and their professional societies have developed policies and guidance material with regard to ethical issues in the area of laboratory medicine. The organizations specially; International of federation of clinical chemistry (IFCC), American Association of Clinical Chemistry (AACC) and International Organization for Standardization (ISO) have defined ethical recommendations for clinical laboratories. They are, in general, outlined the responsibilities of laboratory professionals towards their profession, the patient, and the society. However, implication of ethical standards and guidelines are vary between different cultures, geographies, and according to available resources. In this chapter, we have mentioned the ethical consideration of IFCC, AACC and ISO 15189:2012 with regard to laboratory medicine and also addressed the various ethical issues that arises day to day in laboratory medicine in the current scenario.

Keywords: laboratory, ethics, issues, principles

1. Introduction

In the current time, ethical concerns exist everywhere whether it is a medical field or life science. Lab Medicine and biomedical research, both fields are interconnected by laboratory testing where new results, remaining patient's blood sample, and genetic testing, etc. are some of the major ethical issues that commonly exist. Ethical issues plays very crucial role in laboratory medicine. Therefore, it is required for laboratories to strictly follow ethical principles.

The field of ethics involves ‘a set of principles of right conduct’ [1] and bio-ethics is well-defined as a branch of applied ethics that studies the philosophical, social and legal issues arising in medicine and life sciences. IFCC-task force has suggested that all the area of medicine to fulfill with ethical standards and guidelines and the field of lab medicine is no exemption. According to the IFCC verdict, prognosis as well as medications associated with certain medical conditions is usually determined by outcome, results and analysis of laboratory tests [2]. When we talk about the laboratory system, staff comes at first as they are directly linked in interaction with patients and their care. Apart from laboratory staff, everyone who is involved on the way is equally responsible for maintaining laboratory ethical values. Henceforth, it is highly obligatory to evade any such activity that would downgrade the expertise, neutrality, outcomes, operational truthfulness or patient’s confidence in laboratory. Laboratory staff’s behavior and etiquettes also comes in this category, thus, their actions should be in a professional way for example, wearing laboratory coat/apron, proper dressed-up, phones should be turned silent/OFF during the time of testing and not discussing any report with clients and others. Hence, various international and national guidelines and declarations have been evolved with time to time and thus critically upgraded the practice of bio-ethics in the field of biomedical research. Compliance with these guidelines confirms the autonomy, dignity and well-being of participants as well as the integrity and credibility of research results [3].

2. Evolution of ethics

Evolution of biologically-centered ethical guidelines in medical or biomedical research has upgraded the understanding of ethics over the years. Various guidelines and declarations evolved over the period, including international and national, are mentioned as below:

2.1 International guidelines

- a. **Nuremberg Code, 1947:** This code was the initiation of modern ethical morals. It introduced the discussion on rationale and explanation of research risks or benefits analysis. Initially there was no ethical conduct for the research involving biological subjects, the time before World War II. Nuremberg, during 1947, was the first to establish ethical principles for such researches which delineates the necessity of competent and trained staff, participant’s consent, and circumstances under which research should be discontinued [4].
- b. **Declaration of Geneva, 1948:** It comes into existence soon after Nuremberg code which emphasized guidelines for ethical issues related to clinical medicine. Soon after Nuremberg code, Declaration of Geneva was conscripted and accepted by World Medical Association (WMA) in 1948. It was actually a physician’s oath that was proposed as an amendment of Hippocratic Oath which was the assertion of physician’s commitment towards his duty for humanity in medicine. Its concept is applicable to clinical medicine unlike Nuremberg code [5].
- c. **Declaration of Helsinki, 1964, Revised 1983, 1989, 1996, 2000, 2008, 2013:** It is obliged to make individual rights as informed decisions, duties of

investigators and research participant's welfare as well. It was developed by World Medical Association (WMA) which includes the set of ethical moralities for conducting research involving humans for medical community. Ten principles of Nuremberg code and Declaration of Geneva were tied in a single document named as 'Declaration of Helsinki' [6].

d. Belmont report, 1978–1979: The Belmont Report was generated by the United States of America (USA) National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research in 1978. It is one of the key work concerning ethics and healthcare research and explains the ethical guidelines for experiments involving human participants. It three basic principles includes the respect for participants, justice and beneficence. In research these basic principles obliged to consider. It also saves the rights of participants in clinical and experimental researches. It also describes the approval of study by the Institutional ethical committee and ensures that participant should at least get nominal care for their medical condition [7].

e. CIOMS guidelines [Council for International organizations of Medical Sciences], 1992–1993, Revised 2002: International ethical guidelines were announced by CIOMS for epidemiological studies in 1991 and for researches involving human participants were announced in 1993. It focusses on the pharmacovigilance, reporting of adverse drug effects along with protection of research participants [8].

2.2 National guidelines

a. National ethical guidelines for Health Research and biomedical sciences involving Human Contributors; ICMR, 2017.

In 2017, Indian Council of Medical Research introduced ethical guidelines for research on Human Participants. In India, it is mandatory for all research organizations to strictly follow these guidelines in letter for all types of biomedical research involving human beings, along with complete documentation to protect safety and wellbeing of all participants [9].

3. Principles of ethics

The important three core ethical principles are discussed in all documents. These are as below (**Figure 1**):

a. **Respect for persons:** We must respect patient and their self-respect. There is freedom of decisions to the each participant of the study. It is an obligation to respect the decisions made by people concerning their own lives. This is respecting human dignity. We must not interfere with the decisions of competent adults, and also actively empower others for whom we are responsible.

b. **Beneficence:** It refers to our duties in the best interests of the patients or research participants. The goal is to maximize benefits and minimize harms, the latter sometimes Latinized as *non-maleficence*. Everyone must be fair and correct in all their actions and must take positive steps to prevent harm.

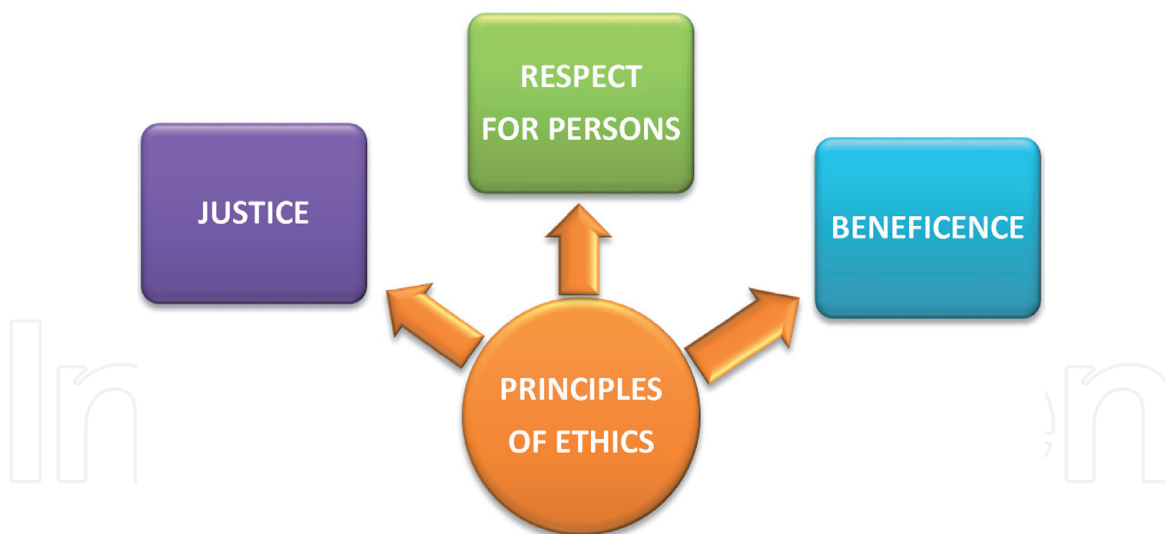


Figure 1.
Core principles of ethics.

- c. **Justice:** It is an obligation to provide all participants with whatever they are deserve. Basically, we have an obligation to treat all people equally, fairly, and impartially. All individuals should have an opportunity to participate in research unless contraindicated and we must not impose unfair burdens. All doubts of research participants should be cleared by concerned staff. We should make available all the safety concerns as demanded by research participants.

4. Various international ethical considerations

Similar to other fields of medicine, laboratory medicine is obliged to adhere to high ethical standards. With the advancement of medical science in the area of laboratory medicine, special ethical considerations should be taken in addition to the general ethical framework followed in biomedical research. Various policies and guidelines related to ethical issues are being developed time to time by several countries or related societies.

4.1 Ethical consideration in ISO 15189

The International Organization for Standardization (ISO) that created ISO 15189:2012 “Medical laboratories-Requirements for quality and competence” in 2012 [10]. Its section 4.1.1.3 elaborated the ethical conduct required in laboratories. ISO 15189 is technically applicable for laboratory equipment, personnel, environmental conditions, consumables, pre- and post-examination processes, reporting and release of laboratory results, and lab information management. As per ISO 15189 standards, the core principles that stated in documents are: (i) there should not be participation in any activities that would diminish confidence in the laboratory’s competence, impartiality, judgment or operational integrity; (ii) management and personnel are free from any undue commercial, financial, or others pressure and influences that may adversely affect the quality of work; (iii) where potential conflicts in competing interests exist, they shall be openly and appropriately declared; (iv) there are appropriate procedures to ensure that staff treat human samples, tissues or remains according to relevant legal requirements; (v) confidentiality of information is maintained.

4.2 Ethical consideration in AACC

The American Association for Clinical Chemistry (AACC) has also recommended fifteen principles of ethical conduct for laboratories. The major highlights are that [11]: (i) to be honest in all professional accomplishments, and retain the high level of personal veracity; (ii) need to avoid any scientific or professional delinquency; (iii) should report any professional that is degrading the standards of laboratory and professionalism that would affect patients care; (iv) to maintain high quality reagents, equipments and consumables. Also, they must confirm the reliability of test reports and quality of confidentiality of reports; (v) respect the privacy and confidentiality of protected health information; (vi) continuously endeavor to augment the professional qualifications, knowledge, and skills, and present them accurately; (vii) encourages the safety of patients, staff and the environment; (viii) must disclose the actual conflicts of interests; (ix) encourage open and honest discussion among physicians, other healthcare providers and/or facility managers; (x) fulfill the appropriate laws and pursue to change whenever they seem contrary to patient's interests.

4.3 Ethical consideration in IFCC

Despite the importance of bio-ethics in lab medicine, still there are lacunae in education training focused on ethics in laboratory. To address this issue, IFCC has recently constituted a task force on ethics (TF-E) to rationalize the documents and spread the education and training on ethics [12]. This task force (TF-E) has created a toolkit which serves as a repository of documents developed worldwide in the kingdom of laboratory ethics [13]. Although the members of the IFCC Task Force on Ethics also contribute to achieve the goal of ethics education in the field of laboratory medicine through the publications on the topic of ethics in collaboration with the electronic journal of International Federation of Clinical Chemistry (eJIFCC).

5. Codes of ethics

Professional personnel of a medical laboratory are bound by the ethical codes of their respective profession. A code of ethics may be described as an expression of basic values –the principles and standards by which we should conduct ourselves. Several laboratory professional societies and organizations have developed codes of ethics, with common principles of conduct which act as guidelines to professional members of those organizations [14]. The International Federation of Biomedical Laboratory Science (IFBLS) suggests to maintain strict confidentiality of patient information and test results; safeguard the dignity and privacy of patients and above all be accountable for the quality and integrity of clinical laboratory services being provided [15]. In same line, the American Society of Clinical Pathologists (ASCP) has also advised laboratory staff to treat patients and colleagues with respect, care and thoughtfulness; perform duties in an accurate, precise, timely and responsible manner; and safeguard patient information as confidential, within the limits of the law.

6. Ethical issues in laboratory

There are several ethical issues in laboratory (**Figure 2**). These issues have divided into three phases according to the laboratory work distribution.

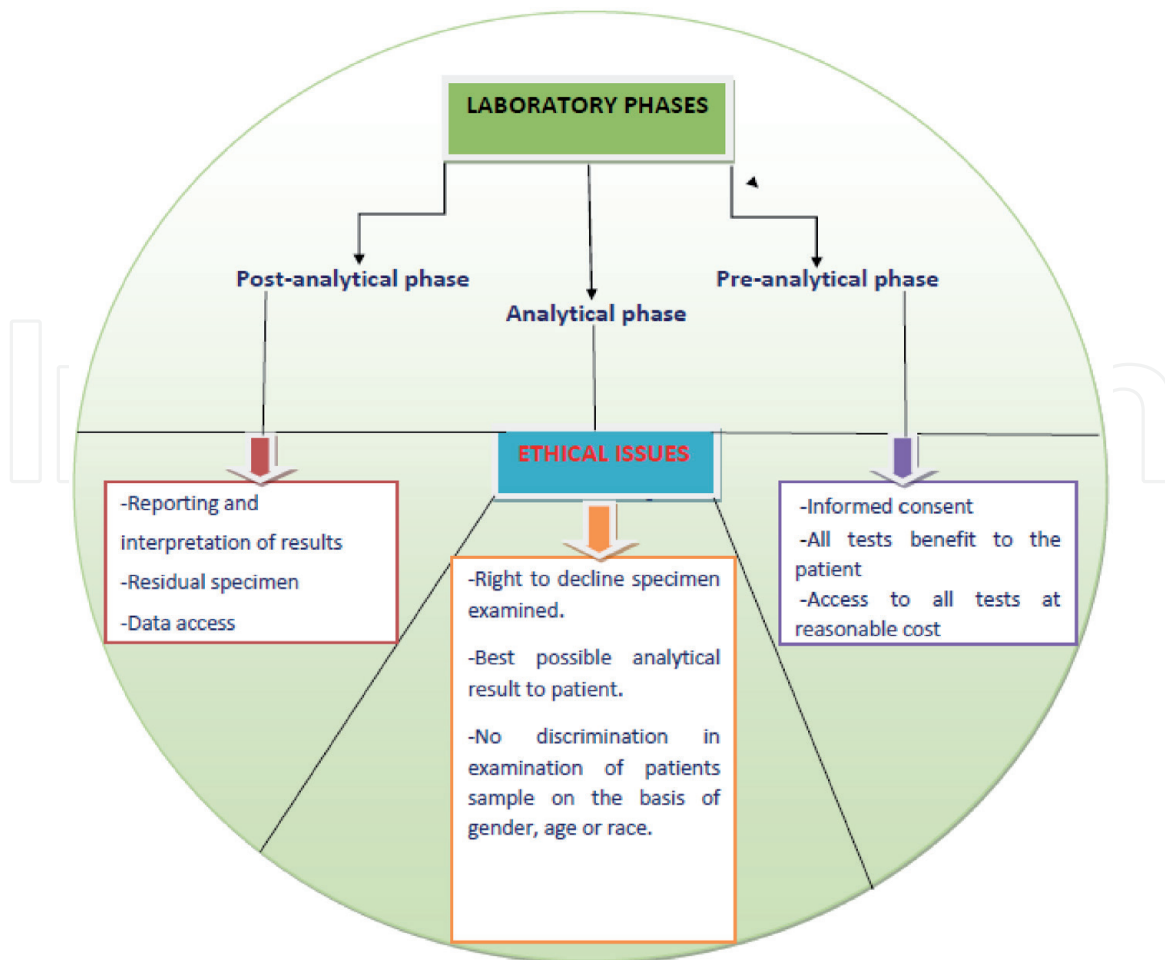


Figure 2.
Ethical issues in laboratory phases.

Pre-analytical phase issues are related to patient's interaction, specimen collection, sample receiving and its transport. Analytical phase issues are usually related to quality control, whereas, post-analytical phase issues are related to reporting of results, keeping and maintaining records [16].

6.1 Pre-analytical phase

Clinicians ordering laboratory tests is also comes under the most important ethical obligations. The laboratory personnel are required to act every time to confirm whether the tests, which are referred by a clinician, are being met with the diseased person requesting the tests or not. However, it is commonly assumed that clinicians are referring laboratory tests so as to benefit the patient without any financial interests. In this phase, there is collective responsibility of many people including nurse, healthcare providers, researcher, or the technical staff collecting the samples. Their role includes:

1. Identification of a patient with respect to the tests ordered.
2. Proper collection, labelling, and handling of samples till the tests are performed.

Three basic ethical principles in pre-analytical phase are:

- a. **Respect for persons:** Consent must be understood by the patient. It may be expressed if a participant is asked for written agreement. It may be implied

when patient is comfortably sits and allows his sample to be taken. Informed consent may lead to an ethical problem if participant is incompetent owing to age, mental status, or critical illness. The patient's right to refuse to get tests done should be appreciated. In special cases, healthcare professionals should be obliged to consult the institutional guidelines. Any information regarding patient's demographics, their visit to the testing laboratory, the tests that were ordered, and the requirement for these tests, should be provided only to suitable personnel. At every step of sample handling, from sample collection to data entry, confidentiality should be maintained.

- b. **Beneficence:** All tests performed/referred must benefit to patient. Any adverse event during or after sample collection have to be managed by trained workers, with the help of standard operating procedures (SOPs). Collection of samples should be done as per universally recommended precautions so as to protect the patient and the healthcare worker. The additional samples should not be drawn from the patient without informing and getting the permission from Institutional ethics committee. The specimens should be well-labeled with minimum two unique identifiers. Transportation of samples should be done to protect the integrity of the sample.
- c. **Justice:** It provides access to several laboratory tests at reasonable cost. The laboratory should evaluate the need to introduce new tests and the opportunities to discontinue older tests when better tests are available. No preference should be given to some patients in order to facilitate or accelerate the collection procedure at the cost of others.

6.2 Analytical phase

In laboratories settings confidentiality, quality and competency are essential. During this, confidentiality is almost a by-product of laboratory automation which uses automated code readers, automated analysis, as well as auto-verification and also names of patients are normally given a unique sequential number for processing. Maintaining confidentiality is more challenging during the analytical phase in small laboratories as compared to larger ones, as smaller laboratories perform manual testing. However, it is most important to maintain ethical standards by each laboratory in conducting patient's testing. The three principles in this phase are as follows:

- a. **Respect for persons:** After collection and processing of samples, patients have the right to refuse to have their specimens examined. In such a case, confidentiality should be appreciated and preserved. Special care must be taken to preserve confidentiality in point-of-care testing as much as possible.
- b. **Beneficence:** The aim of the laboratory is to make available the best possible result to patient. This is accomplished via good laboratory practices (GLP) and maintaining high professional standards. Good laboratory practice should involve the establishment of demanding quality assurance program including quality control analysis, proficiency testing and accreditation of laboratory. In this regard "a wrong result is worse than no result" is a critical guiding principle. Good laboratory practice (GLP) refuses to evaluate or account a result in the presence of poor sample integrity, improper or poor labeling or any other insufficiency that may lead to compromise with the test result. In this regard, Acceptability of "difficult to obtain" (such as cerebrospinal fluid) samples may be taken as special case, and departmental facilities should develop some

suitable policy on examination and records of such specimens where specimen integrity or identification is being compromised. All laboratories should maintain proper authorization as required by their country or region. Only qualified, properly skilled and regularly re-accredited employees should be authorized to execute point-of-care testing (POCT).

- c. **Justice:** There should be no discrimination in the examination of patient's samples on the basis of gender, age or race; otherwise it would be an injustice. All samples should be treated likewise. It is recognized, that laboratories must develop some appropriate provision for STAT or priority testing. Laboratories should also state which tests are included and their expected turnaround times. It is anticipated that all specimens are being analyzed correctly in a timely routine.

6.3 Post analytical phase

This phase includes reporting and interpretation of tests results, storage of residual sample, and access to the data. All laboratories should have a procedure for storage of a specimen that is analyte dependent. An essential part of good laboratory practice is to archive the results either in electronic and/or hard copy format. Documents that can be archived include request forms, raw analytical as well as quality control data, results, and reports. Guidelines on retention or destruction of medical records along with remaining sample retention and its dispose of should be kept in place. Policy manual should also mention the strategies on the identification of authorized personnel such as doctors, patients, and laboratory staff; that would be allowed to access medical records. Besides this, the patient should have the right to give consent to access by others (such as family members), if required. Applying the basic ethical principles in post analytical phase as follows:

- a. **Respect for persons:** Patients reasonably expect that their specimens will not be used beyond the testing prescribed by a clinician and solely used for only prescribed testing for medical purposes. However, in the world substantial differences are there concerning the confidentiality of results. In many areas, the patient and referring clinician are the only authentic recipients of laboratory data. Exceptions are there in case if patients are not able to receive or understand the tests reports. In other areas, the patient's family is also considered to be genuine recipients of a patient's test reports. Laboratories must develop a strategy for results dissemination so as to respect local customs. Reliable communication methods are to be used, and security should be protected in conveying the results regardless of the channel of communications including, hand deliveries by messengers. The local ethics committee or board should also have provision on any further testing in residual specimen (except for the samples used in validation processes), and patient consent may be obligatory.
- b. **Beneficence:** Results misinterpretation may harm the patients and it could be reduced only when a skilled staff would interpret the reports; to minimize this harm. The reporting should be in proper time with correct and all necessary information so that clinician gets the true interpretation. Furthermore, a complete report usually covers the name of the test executed, a suitable reference interval (which might be age or gender specific), units of measurement if needed, and a remarking that the result is within or outside the reference interval. As per laboratory conditions, turnaround time (TAT) should be minimum for any test but it should not compromise the legitimacy of the

results. Timely access to test results is very essential for the welfare of patients, particularly in emergency conditions and delaying the access to results in case of non-payment may harm the patient and ethically also not correct. Hence, delaying in reporting should be avoided. Errors should be notified to clinicians immediately after they came into notice and test results should be rectified or repeat tests should be done, whichever required. Finally, incorrect results should be still accessible but marked as erroneous and corrected result should be mentioned on the report.

c. **Justice:** Although reporting of test results must be consistent for all patients, speedy reporting may possibly be demanded for some results, including “critical” and “significant-risk” results. Instructions for quick reporting must apply irrespective of the source of sample as well as the patient’s financial capability and not disclosing the results just due to payment should also be avoided. Remaining patient’s samples should not be used further without patient’s knowledge which is very common these days. There is much discussion in the literature about who owns patient specimens and whether patients should share in profits if financial gains are derived from leftover samples. However, rules and practices differ among different regions and institutions.

7. Conclusion

Finally, it has been observed that it is necessary to incorporate the core principles and guidelines of bioethics in the areas of laboratory medicine. Any laboratory involving human participants should follow international standards and practices of ethics. Laboratories shall not engage in practices restricted by law and should uphold the reputation of their profession. It is required to develop an ethics policy and add it to the laboratory’s quality assurance manual. Development and implementation of an ethics training program for laboratory staff should be done in such a way that it would promote the development of the professional life of laboratory staff, highlighting human values and responsibility, honesty in their work. This will surely initiate and encourages the change of paradigm with the aim of increasing knowledge keeping in mind ethical principles in daily procedures.

Conflict of interest

The authors declare no conflict of interest.

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