

## Candor in medical laboratory management “Quality is doing the right thing and making things right”

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### Abstract

The practice of medicine in the modern era is exclusively evidence based, focuses on justifiable laboratory reports contributing effective and opportune patient management. For many years, clinical laboratories have picked up astounding significance in medical care services. Laboratory investigations are essential for medical diagnosis in patient care as well as medical research. Reliability of laboratory data/report is therefore of paramount importance. Good Clinical Laboratory Practices (GCLP) is essential to be implemented in the field of medical research and health care services to ensure reliability of laboratory data. Medical Laboratory Professionals endorse the decency, decorum, honour, morality, and self-respect of the profession and maintain a integrity, competence, reputation of honesty, authenticity, and accuracy. All laboratories engaged in testing of biological samples need to establish confidence in the quality and reliability of the results of these tests. In the current time, ethical concerns exist everywhere whether it is a medical field or life science.

Medicine, at the center of which is the sick and dying man, has developed humanism and the morality of pity for the afflicted "Noli noceri", (First do no harm) "Salus aegroti - supreme lex" ( let the welfare of the people be the supreme law ). It coincides with the motto of the World Academy of Medical Sciences mission. "Dedication to duty in a mission for mankind".

**Keywords:** Medical ethics; Misconduct; Justice; Informed consent; Medical research

### 1. Introduction

The significance of laboratory medicine is seen from the fact that 66 % of clinical decisions were based on laboratory tests as shown by a recent study (1).

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Laboratory investigations also form an important component of biomedical research. Though the principles of medical ethics-autonomy, beneficence, non-maleficence and justice, are thought of largely in the context of clinician-patient interaction, they also include the pathologist-patient interaction (2).

Ethical issues related to laboratory medicine are not as commonly addressed as those in other spheres of medicine. This is probably because of the lack of direct contact of pathologists with patients. Issues unique to laboratory medicine include the use of residual samples for research, autopsies and the use of microscopic images (3).

Implied consent is usually considered sufficient for most investigations as the patient presents himself/herself voluntarily to the laboratory. An exception to this is in HIV testing, where, as per WHO guidelines, written consent and counselling is essential prior to testing (4).

If the patient (or the EC) denies permission for the storage of his or her tissue for research purposes, that decision must be respected. It goes without saying that confidentiality must always be maintained. The pathology laboratory thus plays the role of guardian, rather than proprietor, of stored body samples (5,6).

Clinical laboratories should be updated to reflect current rules and regulations (7).

Laboratories should hire personnel who are trained in and display professional ethics, positive patient relations, diligence to the job, and observation of safety protocols (8).

Positive outcomes and patient safety depend strongly on handling specimens in standard ways (9).

Good and effective health services with respect and equal treatment without considering economic, racial, cultural, religious, political, and social reputations is the right to every patient (10).

Laboratory staff should respect their profession and the reliability of their colleagues. They need to enhance their professional qualifications by strengthening their academic background and working collaboratively with other laboratories (11).

General training and discussion about ethical aspects in clinical laboratories should be implemented for the public to increase awareness about human rights and ethics in laboratories (12).

The progress of knowledge and technology in the diagnosis, treatment, and prevention of diseases has significantly changed medicine (13).

All urologists frequently encounter difficulties in making the correct diagnosis of a patient's clinical problem that prompts them to order diagnostic tests.(14).

The presentation of diagnostic exam results is often in 2x2 tables, such as Table 1. The values within this table can help to determine sensitivity, specificity, predictive values, and likelihood ratios. A diagnostic test's validity, or its ability to measure what it is intended to, is determined by sensitivity and specificity (15).

Specificity is the percentage of true negatives out of all subjects who do not have a disease or condition (16).

Sensitivity and specificity are inversely related: as sensitivity increases, specificity *tends to decrease*, and vice versa. Highly sensitive tests will lead to positive findings for patients with a disease, whereas highly specific tests will show patients without a finding having no disease (17).

Sensitivity and specificity should always merit consideration together to provide a holistic picture of a diagnostic test (18).

The Medical Council of India Vision 2015 document, although not specifically mentioning diagnostic errors, does stress on the diagnostic skills as one of the competencies required for the Indian Medical Graduate (19).

Diagnostic errors, defined as a diagnosis that is missed, wrong, or delayed, as detected by some subsequent definitive test or finding, are gradually receiving significant attention from researchers and the authorities (20).

## 2. History

There was no generally accepted coding governing the ethical conduct of human research before World War II.

Ethical principles for human experimentation, was developed in 1947 (21).

The Nuremberg code represents ethical principles for human research, the Declaration of Geneva (22 ) and is a physician's oath intended as meant to be a revision of the Hippocratic Oath. It is a declaration of a physician's dedication to the humanitarian goals of medicine. Currently, most medical schools administer some type of an oath upon graduation, most frequently a version of the Hippocratic Oath or the Declaration of Geneva. In 1964, the World Medical Association tied the 10 principles of the Nuremberg Code and the Declaration of Geneva into a document known as the Declaration of Helsinki (23)

This document is a set of ethical principles for human research developed by and for the medical community. Important concepts of this document include the following: the well-being of the patient prevails over the interests of science and society; written consent; oversight by an independent committee; caution if the participant is in a dependent relationship with the researcher; limited use of placebo; and greater access to the benefits of the research. Although it is not a legal binding legal document, it is accepted as the foundation of human research ethics worldwide (24)

In 1978, the Commission published "Ethical Principles and Guidelines for the Protection of Human Subjects of Research," also known as the Belmont Report (25).

### 2.1. Medical Ethics

The values, conventions, doctrines, etiquette, and customs that regulate human behavior by ethics. Humans' actions can openly affect all mankind. Without any discrimination laboratory should treat all patients fairly. Laboratory medicine ethics starts begins from the collection of information for proper recognition of patients and their specimens. Ethical principles commence at the same time from specimen collection, performing tests, and reporting of the results. Medical Ethics apply values to the practice of clinical and research medicine and in scientific research. Like other areas of medicine, laboratory medicine is also committed to observe complying with high ethical standards.

Patient care now struggles competes with the financial solvency of the health care institutions , and the issue of ethics has become more relevant than ever. Health care services have a special moral quality (26).

The field of medical ethics has long existed, arising from the Hippocrates oath, and tenets of the early religious healing traditions of the West. Several Asian traditions have also had ethical tenets governing the physician patient relationship (27).

The new advancement in medical technology has added new dimensions in diagnostic procedures which beside having high index of accuracy has also raised the cost of medical service. There is often a debate as to what is the reasonable fee for diagnosis to be charged from the patient who wants to undergo a reliable and dependable diagnostic report before undergoing treatment and to monitor the progress of the treatment. (28).

### 2.2. Issues of concern

Addressing human and financial resources, training and supervision, planning and budgeting, quality assurance, logistics and supply, biosafety and equipment management and other relevant laboratory aspects are found to be necessary to optimize laboratory services provided to patients.

In 2018, the World Health Organization developed and released the Essential Diagnostics List (EDL). This list was expected to be used to align the health community in bridging the gap to the accessibility and availability of high-quality testing of clinical laboratories, especially in resource-limited settings (29).

Using the EDL with essential medicines list (EML), authorities can now focus their efforts so that people can receive laboratory services they need the most (30).

Accreditation for clinical laboratories became common recently with the emergence of international laboratory standards. Several guidelines for laboratories have been developed to regulate laboratory test procedures and maintain its quality (31).

An example of laboratory accreditation is the ISO 15189 provided by the International Organization for Standardization (ISO) which focuses on meeting the requirements for quality and competence of medical laboratories (32)

Another example is biosafety guidelines around microbiological agents such as bacteria, viruses, parasites, and other agents and microbiological products

### **2.3. Medical diagnosis: process and pitfalls**

Most patient-physician interactions result in a diagnosis or are a follow-up on decisions made. Diagnostic conclusions are a routine in clinical practice, have major implications for the patient, and will determine subsequent therapy. A doctor is required to make clear decisions based on an unambiguous estimate of the problem. Patients usually seek and physicians often provide a definitive diagnosis and this works well in practice. However, often, the clinical picture is ambiguous, making it difficult for physicians to reach a definitive conclusion. In such situations, the possibility of a mistake is real and is a common professional hazard. Rather than accepting the ambiguity of certain clinical situations and explaining it to patients, doctors are often pressured to make definitive decisions in unclear circumstances (33)

### **2.4. Adherence to medical ethics is of utmost importance**

Expressing concern over medicos resorting to over-enthusiastic laboratory investigations and unethical practice behaviour, Union government's director general of health services Jagdish Prasad says has said that adherence to medical ethics is of utmost importance. During a speech at a recent convention, he stated that the adherence to medical ethics is of utmost importance, particularly in contemporary practice. Your thoughts and actions should be evidence based and conform to best clinical practice guidelines. Resorting to over-enthusiastic laboratory investigations often smack of defensive and at times, unethical practice behaviour. A judicious use of available clinical resources, keeping in mind the socio-economic milieu of the patient and resource limitation of healthcare institutions, can be extremely handy and is desirable," he said.

Noting that the delivery of quality healthcare to the economically deprived sections is the need of the hour, he stated that it is frequently observed that patients from the poorest segments of our society have to spend large sums of money while undergoing treatment in healthcare institutions in the private sector. He also explains that "I in the process they incur tremendous loss of financial resources and landed property. Quite often coming out of vicious cycle of debt and then abject penury becomes virtually impossible," he said, adding that such predicaments are commonplace and extremely unfortunate (34).

### **2.5. Laboratory Ethics**

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.

A professional working in a medical laboratory has several duties, including those towards his colleagues in medicine, institution being served, the society and the profession. But as someone in the noble profession of medicine, their primary duty is towards the patient and stands above all.

- Pledge to keep the patient's welfare above all
- Respect the patient's autonomy and the family's wishes where appropriate
- Care for the patient's confidentiality
- Focus on beneficence and more importantly on non-maleficence
- Practice fair and equitable treatment of patients
- Regard Care for the safety of colleagues working in the laboratory
- Use of available resources in a fair, non-wasteful and responsible way
- Contribution to the progress and growth of the profession and medicine in general
- Working to improve access to healthcare resources

#### **2.5.1. Pre-Analytical Phase**

Ethics in Pre-analytical phase firstly prioritises the need for laboratory tests suggested to the patient by the clinician, it is a genuine necessary necessity and has no without financial interest. Secondly, in holds the it bears collective responsibility starting from the clinician, nurse, healthcare provider, scientists or and researchers and finally as well as the technical staff involved in sample collection. The phase includes patient identification, accurate and perfect sample

collection, its labelling and sample handling till until the tests are performed. There are three main ethical principles in pre-analytical phase which include including respect for the patient (Person), beneficence and 3. J justice.

## 2.6. Respect for the patient

Patient consent is must prior to the sample collection wherein patient or the participant should have the knowledge and the purpose for collecting their sample. Tests should be referred to a certified laboratory. Patient should be informed about the tests to be done, its importance for diagnosis and related risks if any. Informed consent is valid only if the person is adults (above 18), healthy both mentally and physically else otherwise it may raise the ethical and legal issues if the participant or the person is incompetent with respect to their mental status, age, unconsciousness or in critical condition.(35)

As already mentioned, children and adolescents below the age of 18 are generally considered incompetent in making decisions for oneself. In such cases, consent should be obtained from their parents or guardian.(36)

While written informed consent is preferable, P the patient has the right to reject the sample processing. Maintaining patient or participant confidentiality is very important. Any information related to patient like, personal information of the patient or participant, their purpose for the laboratory visits, their demographic details, the details of the tests done, reports, etc; confidentiality should be maintained in all the three phases of laboratory analysis else, may lead to legal consequences. There are some unavoidable situations and certain cases such as prisoners and intravenous drug users wherein the sample collection, processing and reporting is compulsory and could may or may not get the consent from the individual.

## 2.7. Beneficence

Tests referred or performed should benefit the patient. All the phases should have proper standard operating procedures (SOPs). Sample collection should be done very carefully by trained technical members and the staff should possess good knowledge of about the universal recommended precautions. No additional sample should be drawn from the patient or participant with without his/her consent.

## 2.8. Common Errors

- Analytical phase:
- Quality, competency and confidentiality should be maintained in analytical phase too. As mentioned above automation had drastically reduced most of the common and frequent errors occur in analytic phase. Automation includes bar code readers, giving unique identification and sequential number for patient identification before processing the sample, automated analysis and automated verification.(38)

## 2.9. Post-Analytical phase

Reporting results, interpretation, residual sample storage and data access are included in this phase. Results should be archived either in the form of hard copies and/or in electronic format. Proper guidelines and Sstandard SOPs should be practiced to archive the documents or to retain or delete the medical records, disposal or retention of remaining sample. Archived documents generally include request forms, raw analytical data, data related to quality control, final results and reports dispatched.

Laboratory should frame the policy manual emphasizing the strategies and mention the authorized personnel allowed to access the medical records. Laboratory should also have the policy to appreciate patient's right to provide consent to access the reports to his/her family members. The basic ethical principles in post-analytical phase again include the same. Respect for person:; laboratory should ensure that the referred clinician and the patient are the only authentic recipients of the reports or data related to the patient. Even the patient's family members will also be the genuine recipients of the reports or related data in exceptional cases like patient is unavailability, bedridden, unable to understand the reports, old people or children. It is genuine that patient expects that their specimen collected will be used only for testing the prescribed parameter and will not be used for any other purposes or tests that are those not prescribed.

**Table 1** Errors related to the testing phase

	<b>Errors related to the testing phase</b>
Pre-analytical	Missed test Requisition form (TRF) Incorrect sample identification Inappropriate sample tube Collection of sample from IV running area Delayed sample transport Sample insufficiency Mixing up of samples Damaged tubes in centrifuge Inappropriate time for sample/specimen collection Infirm/ invalid sample
Analytical	Icteric and Lipemic sample Hemolysed sample Unstandardized instrument calibration Mixing-up of sample Insufficient/ scanty sample Appearance of interfering substances Wrong/ Inaccurate method of sample analysis No precision
Post-analytical	Wrong patient identification Crabbed report/illegible report Delayed reporting Transcriptional error Lack of specificity in results reported Unavailability of preceding values for comparison.

## 2.10. Specimen collection

Hemolyzed sample cannot be used for processing as it has profound influence on certain parameters such as Acid Phosphatase (ACP), Electrolytes

(Sodium, Potassium and Chloride), Alanine and Aspartate Transaminase (ALT& AST), Lactate Dehydrogenase (LDH), Glucose, Creatinine, Creatine Phosphokinase (CPK), Gamma-Glutamyl transaminase ( $\gamma$ -GT), albumin, etc. few parameters in the above mentioned list are overestimated and few are underestimated when the hemolysed sample is used. The reasons for obtaining the hemolysed samples may be due to syringe draws, alcohol, vigorous sample mixing and plunger to force the blood from syringe into the tube, serum specimen not allowed clotting properly(41)

The reason for insufficient sample may be due to the lack of knowledge about the volume required for the test, if the patient is anaemic, the difficulty to obtain blood sample for infants, debilitating diseases, laboratory personnel not giving proper attention to the details like number of tests mentioned in the requisition form, limited manpower leading to work pressure, the reason for lipemic sample may be due to post-meal collection of sample or if the patient has hyperlipoproteinemias. Usually overnight fasting is suggested to overcome this error. First critical step is patient identification in sample collection. Errors in patient misidentification are the primary and potential errors associated with misdiagnosis; mishandled therapy finally ends up with worst clinical outcomes. Errors in label for instance patient identified is correct but label attached is wrong, this leads to obvious laboratory error.

### 2.10.1. Sample collection

Inpatient samples collection is intended to be collected by qualified and skilled nursing staff wherein, centralized sample collection centre should be the site for collecting sample of outpatients. Transportation of the sample should be assigned

to paramedical staff from various wards and supporting laboratory staff is assigned the job to transfer the sample from OPD to clinical laboratory. Separate sample collection centre is the basic requirement of the independent diagnostic laboratories.

### 2.10.2. Process for Blood sample collection

#### Patient preparation

- Firstly review the patient needs, prepare the patient by providing needs or special instructions in cases where fasting sample is collected. Then can proceed for blood collection. It is recommended for overnight fast for the fasting samples. Certain tests like glucose, lipid profile, lipoproteins require dietary restriction. Consumption of alcohol, smoking, chewing tobacco or consumption of any drug or medicines are not recommended right from a day prior the test.
- Pleasant self-introduction of the phlebotomist to the patient is advised, should be professional, congenial, polite, should clearly explain the details of the procedure to be performed. To make the patient feel comfortable and confident phlebotomist shall show the courtesy to exchange few words in native language. Never try to startle patient, this may influence the outcome or may alter the results.
- Patient identification: establish an absolute patient identification prior to phlebotomy. One should ensure to have at least two types of patient identification strategies before drawing the sample.

#### Inpatient samples

- All inpatients wrist or ankle must be affixed by armband with hospital label with specific details of the patient, ward, department, etc; this is known as patient identification band. First identifier should ask for patient name and if patient is incoherent then the nurse assigned the care of the patient or the guardian/ caretaker should identify the patient. This could reduce or minimize the chances of patient misidentification. Phlebotomist should correctly identify the patient and correlate with labelled wristband before venepuncture.
- Second identifier or second method of patient identification is to verify patient's name and the medical record number on the armband and correlate the same information printed on the requisition form.

#### Outpatients

- First identifier is to ask patient for his/her name.
- Second identifier is patient identification is done by verifying the patient ID, this includes personal ID proofs like driving licence, profession/work ID, etc;
- For minors, their guardian/ parents will be the second identifiers.

#### Inpatient Requisitions/ Demographical review, testing and type of vacutainer for sample collection

- Cross-checking of requisition forms/labels and make certain the appropriateness or selection of correct vacutainers for sample collection.
- Label/ Requisition form should consists of the following details:
  - Patient's full name
  - Hospital ID (Medical records)
  - Location / residential address
  - Gender
  - Age
  - Referred physician's name
  - Collection/reporting priorities: whether routine tests (RT), emergency tests (ASAP), Timed study (ST), etc; should also include date and time of sample collection.
  - Required Testing: this section should include the details of vacutainer type identified by lid colours, required sample size. Phlebotomist is provided with section collection manual that has the detailed description and guidelines for sample collection. Alpha listing manual includes every details required for sample collection like test name, sample size, vacutainer colour, additive and handling of special specimens.
- Additional information: like Date of birth, accession number
- Downtime requisition: this is used when there technical problems like internet problems, computer down-time. In this situation the requisition is manually documented.

Errors accounted for rejection of the sample may be also due to missing samples, inappropriate time of sample collection, sample drawn from.

### 2.11. Specimen handling

- Labelling: proper labelling will ensure to reduce the adverse errors to some extent.

Laboratories should ensure that the specimens collected when transported to the laboratory should have proper labelling.

Specimens labelled should possess the following information: patients name, Medical record number ID, date and time of collection, initials of the staff collecting the samples, source of the specimen collected like spinal fluid, throat swab, bladder, etc; should be mentioned if it is other than blood or urine sample.

Storage: most of the clinical laboratory tests performed in serum, plasma or whole blood. Specimens collected should be refrigerated before and during the sample transport to laboratory. List of tubes used in the laboratory are- Green cap/ top tube: contains lithium heparin (anticoagulant) collects the heparinized serum. Serum- Plain tube (red vacutainer), sodium fluoride/ potassium or sodium oxalate for Glucose estimation (Grey Capped Vacutainer), Glycosylated haemoglobin (HbA1c) EDTA (lavender/pink capped vacutainer), for trace elements heparin (green Cap).

### 2.12. Centrifuge

Samples should be centrifuged only after the sample gets clotted properly. Set it to 3000rpm for 10 mins usually this is the standardized time to obtain good amount of serum/plasma. The lids or caps of the sample tube should always be closed this to avoid exogenous contamination, possible spillage, aerosols, and evaporation, drying-up and to avoid concentration changes.

### 2.13. Specimen transport

- All the specimens collected are transported to the laboratory packed in bio-hazard bag.
- All the specimens, their requisition forms, downtime should be legibly labelled and should contain all the specific details like patients name, collection time, date, origin or source of sample collected if it is other than blood.
- Specimens are transferred to laboratory either through hand delivery or via pneumatic tube system (PTS).
- No contaminated needles or any other sharp objects should ever be sent through PTS.
- Liquid samples should be packed in secondary zip-lock bags to avoid leakage as a precautionary measure in case if the primary container fails.
- Specimens which are difficult to obtain like CSF, amniotic fluid, etc; or Irreplaceable samples should be hand delivered, avoid the transport via PTS,

### 2.14. Sample Rejection

The quality and the integrity of the specimen collected will contribute to the precision and accuracy in laboratory results.

Samples should be rejected if they are not properly labelled. But, for in special cases like precious samples the laboratory should accept and run the sample notifying the healthcare provider prior to the process about the uncertainty with accuracy of the results obtained. Grossly hemolysed sample are also rejected as this may affect the accuracy of some analytes too. Short drawn sample has significant effect on coagulation tests this may be due to sample insufficiency or anticoagulant present. This may provide delayed results.

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## 3. Patient access to medical records

Over the past few decades, there has been growing emphasis on the physician working in conjunction with patients and their loved ones with a common goal. One factor that has been found to help in this approach to healthcare has been the patient's ability to access their own medical records. This helps the patient be more enlightened about their medical condition and helps them as they make crucial healthcare decisions.

As newer technologies get integrated into systems that are in place in healthcare, it gets easier for healthcare providers to help patients access their medical records and also help them better understand how they are being cared for. Especially with the widespread use of Electronic Medical Records (EMRs), it has become easier to allow patients to access their own health records. And it is evident that this helps patients get a better understanding of their medical condition and more importantly of the therapeutic options available to them. Therefore, enabling them to make choices that are better suited to them.



#### 4. Leftover samples in the laboratory

While treating patients, we obtain histories, examine the patient, obtain imaging and also collect specimens in the form of bodily fluids, pieces of organs, organs themselves and sometimes more. This information plays a key role in the evolution of our understanding of medicine.

Most of this information is reviewed, reinterpreted, and published with the goal of learning, teaching, and furthering our understanding of the human body. Most of it, including H&Ps and imaging are used for academic purposes without ethical challenges.

But it is not the same when it comes to samples directly obtained from the human body. The term used for such samples left in the lab after they have served their primary purpose is remnant specimens. It is important that informed consent is obtained from patients before remnant specimens are used for anything other than their direct medical care. The appropriate time to obtain consent varies from case to case, but most institutions go with the approach of obtaining consent at the time of admission.

It is also very important to assure patients that only the amount of sample required for medical care will be obtained and that only the leftover sample will be used for academic purposes. This is very important since the trust between the medical team and the patient is crucial in the treatment process and that should not be hampered for the purpose of academic pursuits.

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#### 5. Conclusion

Quality of test and experiment results, are essential in the healthy management of laboratory. As such, holding to the highest truthfulness accuracy, and reliability, standards safety, security and authenticity are essential. The lab administration encompasses of acquiring grants, personnel, equipment, or the necessary tools, as well as designing the workflow, overseeing the daily operation of the lab, and training new lab personnel.

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#### Compliance with ethical standards

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##### *Disclosure of conflict of interest*

The authors have no conflicts of interest to declare.

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