**Title : Ethical Conundrums in the Clinical Laboratory**

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**Abstract:** Ethics guide in difficult situations to make the distinction between right and wrong. Professional ethics ought to be given priority in laboratory medicine. Laboratory results may deeply impact the decisions of the physician and the well-being of the patient. Hence, the ethical dilemmas in the laboratory have to be addressed to achieve better care for the patient. Ethics encompasses all the three phases – pre analytical , analytical and post analytical of the total testing cycle. Practical implementation of ethical codes is always a challenge. In this paper we aim to decode the various ethical considerations that need to be addressed during the total testing cycle while working in a resource constrained settings and the ethical conundrums during an public health crisis.

**Introduction:** Ethics is the science of discerning good from bad, beneficial from harmful. It is a moral philosophy that contrives, advocates and recommends concepts of right and wrong conduct. Guidelines for ethical standards differ considerably, however, the core ethical values like a) Respect for persons b) Beneficence c) Justice remain constant. (1) With the rise of evidence based medicine laboratories are obliged to adhere to high ethical standards. The International Organization for Standardization (ISO) has created ISO 15189:2012 "Medical laboratories − Requirements for quality and competence". Section 4.1.1.3 of the document summarizes the ethical conduct expected in laboratories. (2) The spectrum of ethical considerations in a clinical laboratory is wide including all the phases of the total testing process, professional conduct, use of biological specimen for research, laboratory response in a public health outbreak.

**Ethical dilemmas in the pre-analytical, analytical and post analytical phase of the testing cycle:**

Patient well‑being is the core value that guides the ethics in laboratory services. Hence, laboratory should treat all patients equally and without any discrimination Laboratories should ensure privacy during reception of test requests and sampling. Appropriate sampling pertaining to the physician request should be ensured. Information relevant to the patient’s investigations is collected after receiving an informed consent and treated with confidentiality. In the event of the specimen arriving at the laboratory in a condition that is unsuitable for the requested examination, it should be discarded appropriately and the referring physician notified immediately . The laboratory should use examination procedures which are user-friendly and fulfil the requisite requirements for the examinations. Standard operating procedures (SOP) should be established by the laboratory for all procedures referring to international or national guidelines, peer-reviewed journals or established textbooks. All procedures suggested by manufacturers or developed in house should be validated and documented. Repeated training of the laboratory staff on the SOP’s and safety protocols will ensure the implementation of ethical practices in the laboratory. Some specific tests like genetic testing, prenatal testing and HIV examinations require special ethical considerations and are often accompanied by pre and post test counselling.

Laboratory professionals are responsible for the accurate reporting of the data generated from the tests performed in the laboratory. Misconstruction of lab data is completely unacceptable in any scenario. All the results generated from laboratory examinations are confidential unless disclosure is authorized. The results ought be reported to the requesting clinician. The results of laboratory may be used for any other purpose only if informed consent is available for the same or required by law. The reporting of results should enable the patient’s clinician to correctly interpret the results. Turnaround time (TAT) specified by the laboratory on their directory of service should be adhered to at all times. (3) Patient feedback and clinician feedback regarding satisfaction toward clinical laboratory services should be encouraged as these feedbacks ensure continual insight on the agility of laboratory services. Unnecessary testing should be avoided and minimum retesting protocol should be followed whenever possible. Laboratories should develop policy for storage of specimen and archiving of results. Laboratories should refrain from entering into financial agreements with referring physicians. Any situation leading to conflict of interest should be avoided.

**Ethical challenges of laboratories in a resource limited setting:**

The dissimilarity in resources between economically developed and developing countries poses ethical concerns in healthcare. In resource-limited settings where scarcity of material and trained manpower is the norm, it is difficult to lead the laboratories ethically. Considering the difficulties of providing basic healthcare services in developing countries, it is an ongoing challenge to meet the basic needs of the laboratory. In resource constrained settings infrastructure and capacity building is essential . Most laboratories in remote areas are not well equipped to handle the sample load , neither do they have resources to conduct special tests. Establishment of regional referral laboratories becomes strategically important in this scenario. Policies and strategic plans that integrate the existing laboratory system and create a well connected national laboratory network, may eventually be beneficial for patient care.

**Ethics considerations in an emergency laboratory during a pandemic:**

Medical laboratory professionals have risen up to public health challenges like H1N1, Influenza, Zika, Ebola, or Nipah virus infections previously. One such challenge which labs are currently facing is the COVID-19 pandemic. Although the risks of acquiring infection is high during an outbreak, it should not deter the laboratory professional to perform their duties. However, it is the responsibility of the laboratory leadership to upscale the safety measures in the laboratory during such crisis. Current bio-safety practice emphasizes Standard Precautions for all patient specimens, but emerging pathogens prod us to re-evaluate the bio-safety protocols customarily. The provision of personal protective equipment, maintaining round the clock staff availability, provision to do the laboratory work while maintaining social distancing and vaccination of laboratory personnel has to be ensured by the administration. A contingency plan should be designed in case of laboratory staff being infected or quarantined. Ethics preparedness refers to the potential of the public health system, to protect and have the ability to swiftly respond to by having in place an ethical framework that would build trust and guide measures to recover from health emergencies. (4) Ensuring ethic preparedness of the laboratories in the midst of a pandemic is of paramount significance.

**Conclusion:** A marginal step towards improving laboratory services is attaining international accreditation standards e.g. College of American Pathology(CAP) , ISO 15189. Accreditation ensures that the laboratory encourages good laboratory practices and also inculcates patient confidence in the laboratory. Ethics in laboratory medicine is an ongoing effort which ameliorates if practised judiciously by all the laboratory staff. A conscientious effort by the laboratory professionals to deliver their duties with diligence and dexterity is required to maintain the highest ethical standards in laboratories.

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