

## ETHICS IN LABORATORY MEDICINE

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The professional personnel of a medical laboratory are bound by the ethical codes of their respective profession. Personnel responsible for the management of medical laboratories, as with other health professionals, have responsibilities over and above the minimum required by law. Laboratories shall not engage in practices restricted by law and should uphold the reputation of their profession.<sup>1</sup>

The general principle of healthcare ethics is that the patient's welfare is paramount. The laboratory should treat all patients fairly and without discrimination. The laboratory should collect adequate information for the proper identification of the patient, which enables the requested examinations and other laboratory procedures to be carried out, but should not collect unnecessary personal information. The patient should be aware of the purpose for which the information is collected. Safety of staff and other patients are legitimate concerns when communicable diseases are possible and information may be collected for these purposes.

All procedures carried out on a patient require the informed consent of the patient. Forcing some one to undergo medical testing of any kind is an invasion of privacy and a violation of human rights.<sup>2</sup> For most laboratory procedures, consent can be inferred when the patient presents him or herself at a laboratory with a request form and willingly submits to the usual collecting procedures, for example, venipuncture. Patient in a hospital bed should normally be given the opportunity to refuse.

Special procedures, including the more invasive procedures, will require a more detailed explanation and, in some cases, written consent. This is desirable when there is likelihood of complications following the procedure. Laboratories performing human immunodeficiency virus (HIV) testing shall follow National AIDS Control Organization (NACO) guidelines, which include pre-test and post-test counselling. The laboratory shall not perform HIV test unless the individual has been given pre-test counselling and post-test counselling is ensured. Informed consent of the patient will be taken before the blood is collected. The result of HIV test shall be kept strictly confidential.

In emergency situations, consent might not be possible and under these circumstances it is acceptable to carry out

necessary procedures provided they are in patient's best interest. The laboratory should endeavour to see that results with serious implications are not communicated directly to the patient without the opportunity for adequate counselling.

Adequate privacy during reception and sampling should be available and appropriate to the type of primary sample being collected and information being requested. If the primary sample arrives at the laboratory in a condition that is unsuitable for the requested examination, it should normally be discarded and referring physician notified.

The laboratory shall use examination procedures, including those for collection of specimens, which meet the needs of the users of laboratory services and are appropriate for the examinations. Preferred procedures are those that have been published in established/authoritative textbooks, peer-reviewed texts or journals or in international, national or regional guidelines. If in-house procedures are used, they shall be appropriately validated for intended use and fully documented. Any fabrication of result is completely unacceptable.

The results of laboratory examinations are confidential unless disclosure is authorized. The results will normally be reported to the requesting physician and may be reported to other parties with the patient's consent or as required by law. The results of laboratory examination that have been separated from all patient identification (un-linked, anonymous) may be used for such purposes as epidemiology, demography or other statistical analyses.<sup>2</sup> In addition to the accurate reporting of laboratory results, the laboratory has an additional responsibility to ensure that, as far as possible, the examinations are correctly interpreted and applied in the patient's best interest.

The laboratory shall establish and implement procedures for identification, collection, indexing, access, storage, maintenance and safe disposal of quality and technical records. All records should be legible and stored such that they are readily retrievable. Records may be stored on any appropriate medium subject to national, regional or local legal requirements. Facilities shall provide a suitable environment to prevent damage, deterioration, loss or unauthorized access. The laboratory shall decide the retention time of records as per the national, regional or local regulations. As per National Accreditation Board for Testing and Calibration Laboratories (NABL) guidelines, the minimum period for retention of test reports issued shall be five years for histopathology and cytopathology and one year for other disciplines.<sup>3</sup>

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Medical laboratories should not enter into financial arrangements with referring practitioners where those arrangements act as an inducement for the referral of patients. Rooms used for primary sample collection should be completely independent and separate from referring practitioners' rooms. Laboratories should try to avoid situations that give rise to a conflict of interest.

## References

1. IS/ISO 15189:2003. Medical Laboratories - particular requirements for quality and competence. Bureau of Indian

Standards. Manak Bhawan, 9 Bahadur Shah Zafar Marg, New Delhi - 110 002; 2005. p. 1-39.

2. Arora DR. Textbook of Microbiology: 2<sup>nd</sup> ed. CBS Publishers and Distributors: New Delhi; 2003. p. 563.
3. National Accreditation Board for Testing and Calibration Laboratories (NABL) 112. Specific criteria for accreditation of medical laboratories. 2007. p. 6,26.

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