

Ethical conundrums in the clinical laboratory



Saswati Das

Specialist, Department of Biochemistry, Dr Ram Manohar Lohia Hospital and Atal Bihari Vajpayee Institute of Medical Sciences, New Delhi-110001, India

Submission: 07-01-2021

Revision: 03-02-2021

Publication: 01-03-2021

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 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 a public health crisis.

Key words: Ethics; Clinical Laboratory; Accreditation; Emergency Laboratory; Pandemic

Access this article online

Website:

<http://nepjol.info/index.php/AJMS>

DOI: 10.3126/ajms.v12i3.34113

E-ISSN: 2091-0576

P-ISSN: 2467-9100

Copyright (c) 2021 Asian Journal of Medical Sciences



This work is licensed under a Creative Commons Attribution-NonCommercial 4.0 International License.

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. Professional ethics ought to be given priority in laboratory medicine. Laboratory results deeply impact the decisions of the physician and the well-being of the patient. 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.¹ 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.

Day to day ethical dilemmas in the laboratory

Patient wellbeing is the core value that guides the ethics in laboratory services. Hence, laboratory should treat all patients equally and without any discrimination. The laboratory should use examination procedures which are user-friendly and fulfil the requisite requirements for the examinations. Establishing standard operating procedures (SOP) for all procedures referring to international or national guidelines or peer-reviewed journals minimizes the errors if followed ardently. Repeated training of the laboratory staff on the SOP's and safety protocols will ensure the implementation of ethical practices in the laboratory. Induction training of new staff is absolutely essential in our laboratory. Competency of all staff is assessed six monthly. We also conduct six monthly internal audits to evaluate the adherence to SOPs and good laboratory practices.

Laboratory professionals are responsible for the accurate reporting of the data generated from the tests performed

Address for Correspondence:

Dr Saswati Das, Specialist, Department of Biochemistry, Dr Ram Manohar Lohia Hospital and Atal Bihari Vajpayee Institute of Medical Sciences, New Delhi-110001, India. **Mobile No:** +91-9899091488. **E-mail:** drsaswatidas@gmail.com

in the laboratory. All the results generated from laboratory examinations are confidential unless disclosure is authorized. The results ought to be reported to the requesting clinician. The results of laboratory may be used for any other purpose like research or publication, only if informed consent is available for the same. In our laboratory we have introduced interpretative reporting so that laboratory results can be easily comprehended by the clinician. Turnaround time (TAT) specified by the laboratory on their directory of service should be adhered to at all times.² Dashboards displaying the TAT and alarm systems which alert the laboratory staff in case of delayed TAT may be installed. Implementation of a robust laboratory information system integrated with the hospital information system may improve the TAT.

Patient feedback and clinician feedback regarding satisfaction toward clinical laboratory services should be encouraged and analysed periodically. These feedbacks ensure continuous insight on the agility of laboratory services. Clinician and laboratory communication should be ensured to avoid unnecessary testing and minimum retesting protocol should be followed whenever possible. In our laboratory we have scheduled monthly dialogues between the physician and the laboratorian which has led to better laboratory stewardship implementation and smooth functioning of the lab services. We also have a policy for storage of specimen and archiving of results.

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. Referral Laboratories which are accredited and maintaining good quality practices can mentor smaller laboratories at the district level. Lack of trained staff in remote areas is a major challenge in developing countries. Training of lab professionals on concepts like Risk Management, Patient Based Real Time Quality control, Moving Average, Minimum Retesting Interval will have to

be initiated. Local trainers can be identified in each district who can train others in future. E-resource material and e-learning modules can be prepared for online training in remote areas. Quality standards of the laboratory are should be maintained by enrolling in external quality assurance program, applying for accreditation and conducting audits. Virtual networked centres of referral laboratories may be created within the country or region for knowledge sharing. Laboratories in some regions do not have enough space or the requisite safety design. With repeated inspection by regulatory authorities, the willingness of administration and funding by the civic societies, the design and safety challenges can be overcome. Sustainable and innovative strategies to reduce carbon footprint of laboratories and managing the waste will have to be introduced.

How can accreditation help?

ISO 15189 and College of American pathology are international accreditation standards based on a series of requirements which are adopted by most countries as the national quality standard. The duty of a laboratory professional is to provide reliable and accurate laboratory test results cost-effectively and timely.³ Adhering to accreditation standards ensures laboratories follow the good laboratory practices and adds value to health care quality. It also assigns responsibility to the administration to train each staff to follow the quality protocols round the clock. Regular internal audits and competency training of the staff ensure that quality standards of the laboratory are always upheld.

Ethics considerations in an emergency laboratory during a pandemic

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.² Ensuring ethic preparedness of the laboratories in the midst of a pandemic is of paramount significance. 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, regular team briefings, facilities 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 in place, in case of laboratory staff being infected or quarantined. Judicious maintenance of stock position in view of increased use of personal protective equipment and lab supplies, is advised, to provide a smooth laboratory service. One of the major challenges' laboratories have faced during this pandemic is the introduction of new tests within a short span of time. While it was important for the laboratorians to make the new tests available as fast as possible it was also equally important to conduct robust validations before starting the test. In our laboratory extra workforce who were cross trained in different departments had to be deployed to meet the validation requirements. With COVID-19 samples being received daily in the laboratory the waste management protocol has been revised in many places. The laboratory staff should be provided training and retraining due to change of laboratory protocols and shift to electronic communication systems during this pandemic. Maintaining the TAT of the COVID-19 samples has been a challenge for the laboratories with an increasing workload as the pandemic spread. If there is any delay in the TAT, it is to be communicated to the concerned clinical team immediately.

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. The ongoing pandemic has put the laboratories on the fore front of healthcare, demanding better quality standards from laboratories worldwide. 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.

REFERENCES

1. ISO 15189:2012 Medical Laboratories – Requirements for quality and competence. <https://www.iso.org/obp/ui/#iso:std:iso:15189:ed-3:v2:en> Accessed 30 December 2020
2. Mathur R. Ethics preparedness for infectious disease outbreaks research in India: A case for novel coronavirus disease 2019. *Indian J Med Res.* 2020; 151(2): 124-131. https://doi.org/10.4103/ijmr.IJMR_463_20
3. Schmidt RL and Ashwood ER. Laboratory Medicine and Value-Based Health Care. *Am J Clin Pathol.* 2015; 144(3): 357-358. <https://doi.org/10.1309/AJCPWTDAJGMYLN51>

Author's Contribution:

SD-Conceptualization and Writing of Manuscript.

Work Attributed to:

Dr Ram Manohar Lohia Hospital and Atal Bihari Vajpayee Institute of Medical Sciences.

Orcid ID:

Dr. Saswati Das -  <https://orcid.org/0000-0002-4548-0066>

Source of Funding: None, Conflict of Interest: None.