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ETHICAL CONSIDERATIONS IN GOOD CLINICAL LABORATORY PRACTICE (GCLP)

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ABSTRACTS
Laboratory Medicine is the medical specialty that deals with testing of specimens from patients and consulting with physicians who order the tests, has undergone major transformations during last decade. Many laboratory professional organizations have developed codes of ethics, with common principles of conduct which act as guidelines to professional members of those organizations. The ethical standards are to be followed by the laboratory professional as a good clinical laboratory practice. Maintaining the ethical standards is a big challenge in the resource limited settings. There is always a solution which is depending upon the place. The staff members have to be trained to have the proper SOP and follow ethical standards. This paper is focused to elaborate on the ethical considerations to be followed in pre-analytical, analytical and post-analytical phases of the laboratory.

KEYWORDS: Laboratory, Ethics, GCLP, Ethical considerations.

INTRODUCTION

Laboratory Medicine is the medical specialty that deals with testing of specimens from patients and consulting with physicians who order the tests, has undergone major transformations during last decade. In this field, there is no direct contact with patients or there is a minimal contact with patients by the laboratory physicians, however, their duty is to act in best interests of the patient.[1] The evolution of medical ethics over the years is well documented and evolved through the Nuremberg Code from 1947,[2] the Declaration of Geneva from September 1948, with its continual amendment until October 2017,[3] the Declaration of Helsinki from June 1964, with its continual amendment until October 2013[4] and 'The Belmont Report' from 1978.[5] Created in 1978 by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research of the United States, it outlines ethical principles and guidelines for the protection of human subjects. It identifies three core principles, namely (i) Respect for persons: To ensure autonomy of the subjects/patients as well as to protect autonomy of those with diminished capacity to consent and make decision by themselves. (ii) Beneficence: Acting in the best interests of patients or study subjects as well as maximize benefits and minimize harm. (iii) Justice: Moral obligation to treat all the patients equally disregarding age, sex, and race, and to ensure fair allocation of resources, e.g. treatment facilities and medications/vaccines, what is rightly due in terms of benefits, risks and cost.[5] This paper is focused to elaborate on the ethical considerations to be followed in pre-analytical, analytical and post-analytical phases of the laboratory.

Codes of ethics in laboratory medicine

Many laboratory professional organizations have developed codes of ethics, with common principles of conduct which act as guidelines to professional members of those organizations. The International Federation of Biomedical Laboratory Science advises to maintain strict confidentiality of patient information and test results, safeguard the dignity and privacy of patients.[6] The American Society of Clinical Pathologists advise laboratory professionals 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.

Most of the organizations and codes of ethics focus on many points for prescribing guidelines for Laboratory Medicine professionals. There are several areas in Laboratory Medicine practice where the formulation and implementation of ethical guidelines present challenges.[7] These include (i) Consent from patients including consent for unforeseen complications, usage of Leftover samples and bio-banking; (ii) Considerations in genetic testing, (iii) Reporting implications in Incidental findings, (iv) Error disclosure, (v) Role of laboratories in Test utilization; (vi) Direct to consumer testing and (vii)

Emerging diseases setting.[8] The challenges may be inadequate manpower, lack of training, less availability of latest equipment or methods, lack of adequate facilities for staff and an ever-increasing load of patients.

Ethical issues in the Pre-analytical phase

The ethical standards are to be followed by the laboratory professional as a good clinical laboratory practice. It is the responsibility of all laboratory staff and doctors who are associated with patient specimen. The ethics in pre-analytical phase involve proper identification of the patient, sample collection, labeling, handling and test performance.[9,10]

The patient has to be informed about the test being performed and in some cases the consent has to be taken. Informed consent may pose an ethical problem if the patient is incompetent to make any decision due to age, mental status or critical illness. However, who may be allowed to give consent on behalf of the patient may vary among regions, may be influenced by different cultural practices.[11,12,13]

Children are generally considered as incompetent in decision-making for themselves until and unless they are legally emancipated from their parents; however, the status of children and adolescents under 18 years of age remains an area of controversy and is viewed differently in different parts of the world.[13] There are cases of compulsory testing in certain groups such as intravenous drug users and prisoners. In these exceptional cases, healthcare professionals have an obligation to consult the guidelines provided by the institution in which they practice and they must weigh the risks of loss of a patient's autonomy versus the benefits of the testing.[12] Confidential information about patient demographics, the visit of a patient to a testing facility, which tests were ordered and the reasons for those tests should be given only to appropriate persons. Confidentiality is a must at every step of the process, i.e., specimen transportation, data entry and report delivery.[9,10,14]

All tests should benefit the patient based on best medical evidence. In addition, sample collection should not cause harm. Examples of harm in the pre-analytical phase include infection or pain from the collection process (e.g. inadvertent puncture of an artery and other adverse events). The standard operating procedures and trained personnel should be in place.[9,10] Besides, the collection procedure should be carried out using universal precautions to protect both the patient and healthcare worker. Additional specimens shall not be collected for research procedures without informed consent from the patient and approval from the appropriate Ethics Committee.[15]

The clinical laboratory should, as far as it is able, provide access to a wide variety of laboratory tests at reasonable cost. There should be no preference given to individuals to facilitate or expedite the collection process at the expense of other patients.[9,10,11]

Ethical issues in the Analytical phase

Every laboratory has to maintain confidentiality, quality assurance and competence. In the analytical phase, confidentiality may be maintained through automation that uses automated bar code readers, automated analysis and auto verification, as the patient names are deemed by codes. It has the challenges in small laboratories with manual testing and at point-of-care testing. The patients have the right to decline to have their specimens analyzed even after the specimens have been collected and processed. Confidentiality should be respected and maintained. However, in point-of-care settings, it is really difficult because testing is often conducted in a common room with access by trained and non-trained personnel.[16]

In the analytical phase the best possible analytical result is provided. This is achieved through good clinical laboratory practice (GCLP) and maintenance of professional standards. GCLP involves the good quality assurance program encompassing quality control testing, proficiency testing and laboratory accreditation. The wrong report is not at all accepted. If the sample is lyzed, wrongly labeled, delayed or has any other non-acceptable criteria, it has to be rejected as it affects the report. Laboratories should maintain proper certification and only qualified, properly trained personnel should perform analysis in laboratory and also point-of-care testing.[16,17,18]

Discrimination in the analysis of patient samples based on gender, age or racial origin is an injustice. The Laboratories should have Standard Operating Procedures (SOPs) for every analysis. The accurate report has to be released within the prescribed Turn Around Time (TAT).[18]

Ethical issues in the Post-analytical phase

The post-analytical phase includes reporting and interpretation of results, residual specimen storage and access to data. Laboratories should have a policy for specimen storage and data protection. The results are stored either electronic or as hard copy format.[10,11]

Actually the treating clinician and the patients alone are the recipients of laboratory data. Exceptions are made if the patient is a juvenile or are not capable of receiving or understanding the laboratory results and therefore the patient's family can receive the results. The patient can give consent for accessing the reports by the family members.[13,14] There may exceptions in accessing the results in case of legal aspects. Individuals have the right to decide when and if their records or specimens shall be used outside the normal medical care to which they have consented. Further testing of residual samples (except for method validation or in cases where samples are completely anonymized) should be approved by a local

ethics committee or board and patient consent may be required.[15]

The qualified persons only have to report, verify and interpret reports.[16,17] The results should include the patients name, unique health identification (UHID) number, age, sex, treating physician's name, test name with method, report, unit and reference interval with signature of the signing authority. The access to report has to be within the prescribed timing. In emergency cases the patients report should not be withheld due to non-payment. There should not be any reporting delay. Any error in the report has to be intimated to the treating clinician and amended.[17,18]

The reporting of results should be consistent for all patients. There should be defined TAT for emergency, critical and significant-risk reports. Residual samples are not supposed to be used without patient's knowledge.[19, 20]

CONCLUSION

Maintaining the ethical standards is a big challenge in the resource limited settings. There is always a solution which is depending upon the place. The staff members have to be trained to have the proper SOP and follow ethical standards.

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