



A Review of Ethical Issues Related to Laboratory-Based Diagnostics

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Received: 2021/10/30

Revised: 2021/12/02

Accepted: 2022/01/04



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DOI: 10.29252/mlj.16.2.1

ABSTRACT

The current study aimed to introduce key ethical issues related to laboratory-based diagnostics that any individual may encounter during the provision of healthcare services. In a systematic review, relevant studies published on electronic databases including the PubMed, Scopus, Web of Science, Medline, and Cochrane Library were collected for the years 1975 to 2020. The ethical issues related to clinical laboratories diagnosis and patients, colleagues, and society in different phases of laboratory testing were surveyed in this study. Considering ethical issues must be prioritized in each clinical laboratory for better dealing with clients, collaborators, and the community.

Keywords: [Laboratories](#), [Clinical](#), [Ethics](#), [Medical](#), [Patient Rights](#), [Confidentiality](#).

INTRODUCTION

Medical ethics is a sub-discipline of bioethics, which focuses on different aspects of medical sciences-related ethics, including social and religious values (1). Clinical diagnostic laboratories should follow their own set of ethical practice guidelines, ideally based on the four fundamental areas outlined by the World Health Organization (WHO): autonomy, beneficence, non-maleficence, and justice (2). These principles concern the right of patients to make decisions on their own behalf and obligate the personnel to act in the best interest of the patient, avoiding harm to patients and maintaining fairness and respect (2-6). The main roles of laboratories are to perform biological, biochemical, microbiological, and genetic tests to assist reliable diagnosis and treatment of health-threatening diseases (3, 6, 7).

Given the importance of applying ethical principles, the WHO and the International Organization for Standardization have produced guidelines for clinical laboratory personnel (8). These guidelines provide a framework for performing and reporting diagnostic tests with an emphasis on patient satisfaction and confidentiality, and for storing and retaining medical records (9). Despite the important role of laboratory-based diagnostics in maintaining and promoting health, ethical issues concerning diagnostic laboratories have not been analyzed in detail (10). Clinical laboratories should be updated to reflect current rules and regulations (11). Laboratories must also abide by the newest standards regarding patients' rights, munificence, welfare, and comfort (3). Moreover, laboratories should prioritize and respect a patient's beliefs and culture. Laboratory personnel has to follow the principles of truthfulness, responsibility, conscientiousness, loyalty, equity, discipline, and benevolence while maintaining patient privacy and societal considerations. Laboratories should hire personnel who are trained in and display professional ethics, positive patient relations, diligence to the job, and observation of safety protocols (2, 7, 12, 13).

Laboratory providers are responsible for the quality assurance of presented services. The relationship between patient and laboratory is complex because of the potential of ethical issues arising in the pre-analytic, analytic, and post-analytic phases (14). The pre-analytic

phase includes specimens labeling and handling prior to arrival at the laboratory. Improper labeling and handling of specimens during this phase can result in negative outcomes including incorrect diagnosis, inappropriate treatment, treatment delays, and unnecessary medical interventions e.g. additional surgery. Positive outcomes and patient safety depend strongly on handling specimens in standard ways (15). Regarding the importance of this phase, precise control measures are needed to avoid unintentional errors. Laboratories and specimen collectors must consider and maintain ethical standards (14). The analytic phase includes procedures, diagnostic tests, and the application of related products. Confidentiality, competence, and quality are concerns at this phase. Compared with larger laboratories, small laboratories that perform manual testing and operations often find confidentiality to be a challenging task during the analytic phase (12). Laboratory tests should be carried out according to pre-approved procedures and only by trained personnel. Moreover, a supervisory structure should be in place to monitor employees' performance (7, 14, 16). In the post-analytic phase, interpretation of results, archiving of specimens, accessibility of data, and confidentiality should be considered (2, 3). Different laboratories have different policies for archiving specimens. The use of electronic or hard copy archiving is a basic principle of acceptable laboratory practice (17). Laboratory information should be correctly and securely maintained, and results could be shared only with the patient's consent. The laboratory is responsible for the secure transfer of reports and ensuring that information is not altered or misused (14, 18, 19). Access to medical laboratory records should normally be available only to the clinician requesting the test, the patient, and laboratory/hospital staff for the management of the patient (6). When an authorized person requests access to test results, the laboratory must first confirm the identity of the person making the request. Children and intellectually impaired individuals have the same right of access as competent adults, although this right may be expressed through a parent or authorized agent (20). However, parents do not always have an automatic right to access their children's medical information, and different countries

have different laws and customs in this respect (6). The laboratory should develop protocols on how to handle different requests, taking into account local laws and customs. How this is done, and the stringency with which identities, must be verified by institution and situation. For example, the required degree of stringency for confirming the identity of a person seeking an HIV test result may be much greater than that required of one requesting the results of a routine hemoglobin test (6, 20, 21). The objective of this study was to review and introduce general ethical issues that any person may encounter during the test-requesting, performance, and reporting of laboratory-based diagnostic testing.

MATERIALS AND METHODS

Data resources and search strategy

In order to find ethical issues related to laboratory-based diagnostics, a systematic review of relevant studies published on electronic databases including the PubMed, Scopus, Web of Science, Medline, and Cochrane Library were collected for the years 1975 to 2020.

Inclusion and exclusion criteria

All original articles published in English that discussed ethical aspects of the medical laboratory were included in the review. Studies not approved by ethics committees and irrelevant articles were excluded from the study.

RESULTS

After excluding irrelevant and duplicate articles, out of 145 selected articles for evaluation only 35 articles fulfilled the inclusion criteria. Relevant studies were evaluated in-depth and extracted data were categorized into the following sections.

1) Ethical issues related to laboratory diagnosis and patients

A: 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 (22).

B: Having sufficient scientific or clinical information about the history of communicable infectious diseases such as hepatitis and AIDS is required in each clinical laboratory (2).

C: Organizing and selecting the test, in general, should be done regardless of the patient's economic and social status and in accordance with symptoms of the disease. Also, the laboratory should avoid unnecessarily re-refer of a patient to physician (23).

D: The necessity of testing, required specimens, and sampling procedure should be explained clearly by the laboratory to patients prior to testing. This enables the patient to freely decide for testing, and all procedures will be done with the informed consent of the client (6).

E: Standard and well-known diagnosis procedures should be applied at an acceptable level of professional competence. In the cases of damage to patients, the test should be repeated or replaced by other reliable tests (6).

F: The results of the test must be clear, legible, and without mistakes (2).

G: The laboratory should assure that the results of tests are completely private and not shared with any individual or organizations. Data and results of the tests, even after death, should be kept in good order and protected to prevent loss and any unauthorized use. The information must be archived in a way that is accessible only to qualified individuals (24).

2) Ethics in clinical diagnosis and colleagues

Applying professional ethics among all related clinicians and laboratorians should be prioritized during the diagnosis and treatment of each patient. The important ethical issues concerning the clinicians and laboratorians are listed below:

A: Important ethical principles for the establishment of the laboratory include professional expertise, having the necessary scientific and practical competence, conscientiousness, professional responsibility, and lack of physical or psychological utilization of the patient (21).

B: 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 (25).

C: the most important case of conflict of interest is the establishment of a financial relationship between the referring physicians and the laboratory (26).

3) Ethical topics in clinical laboratories and the society

A: The staff of medical laboratories are responsible for considering the general rights of clients. The principle of justice, non-discrimination between patients, and the need for public access to medical services regardless of religion and political affiliation are the basic issues of medical ethics involving laboratories (27).

DISCUSSION

Ethical issues related to laboratory-based diagnostics were surveyed and highlighted in this study. Precision, speed, observance of ethics and maintaining lending, confidentiality along with the application of scientific and technical methods based on the latest standards are very important features that can pave the way for the advancement of a clinical diagnostic laboratory. Novel pharmaceuticals, genetics, and clinical laboratory technologies not only are used for diagnosis and treatment but also to strengthen human behaviors and capacities (7). 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 (13, 16, 28). Although some laws have been developed at international levels in this regard, the addressed questions and discussions in this field have no easy or agreed-upon response. However, people's satisfaction, confidentiality, and individual access right to gained information should be taken into account. The progress of knowledge and technology in the diagnosis, treatment, and prevention of diseases has significantly changed medicine (13, 29). Instructors of ethics courses should advise medical and pre-medical students about the dignity of patients by discussing their valuable personal experiences. Ethic instructors should also explain the reward of sitting beside the patient and checking the patient's soul and body, so that good and humane behavior of a physician with a patient should be maintained in all professional duties. Ways of logging, collecting, storing, and reporting results should be consistent with general fundamentals (18). Being up to date, explaining the test and results, and keeping the information confidential are important in this regard (7, 19). An awareness of the fundamentals of

laboratory ethics will play a substantial role in the performance of laboratory personnel and encourage them to more readily respect the dignity of their patients. The study of laboratory ethics should be prioritized for medical and allied health students as well as any healthcare staff, particularly laboratory staff, and managers. (16, 28, 29). The growth of pharmaceutical and laboratory sciences in recent years makes the subject of ethics more important and meaningful. During the past decades, implementation of health education programs for the public and laboratory clients was not a priority, but given the recent advancements in modern digitalization and internet technology, many laboratories provide some information about the different stages of laboratory testing procedures. These laboratories informed their clients how to prepare themselves for sampling and laboratory attendance. Undoubtedly, training at this level can change client behavior and is morally acceptable.

Ethical issues should be considered at all phases of laboratory procedures (21). One study in the United States found that laboratory mentors devoted insufficient time to teach ethical issues for laboratorians. The researchers suggested that ethics courses are necessary for students and personnel to improve their skills in ethical topics. (30). Programs to improve education in medical laboratory sciences usually emphasize learning new techniques in different aspects of medical ethics and are necessary for students' professional development (13, 31). However, issues regarding professional ethics may sometimes take place and laboratory providers should be well acquainted with fundamental ethical issues so they can proceed appropriately in such cases (32, 33). Absolutely, education of ethical issues for laboratory providers promotes good communication between patients and physicians (34). Laboratory ethic committees should hold ethical courses for personnel and apply appropriate policies when ethical issues occur (35). Physical and mental conditions, along with data and privacy concerns as patients' rights should be considered in every laboratory (4). Because of the importance of ethical issues, a close relationship is needed between laboratories and related authorities. Indeed, the results of laboratory tests are important for all laboratory providers. These

results help physicians to precisely choose treatments for patients.

Comprehensive training about medical ethics should be scheduled in the laboratory programs and the associated information should be available to the public and other laboratories. Due to the possibility of the emergence of new challenges in medical ethics, the principles of ethical laws should be flexible and ready for a change in the future. All clinicians and laboratorians are required to be up to date and committed to consider all ethical issues in their workplaces.

Although confidentiality is a very important issue in medical laboratories, in the case of public interest and emergencies test results could be taken into account after the patient's awareness. Informed.

Conflict of interest is another issue that needs to be addressed in laboratories. For this purpose, it is necessary to elaborate relevant ethical codes and strategies for preventing and managing conflict of interest in laboratories. With the advent of new technologies, laboratory equipment has become significantly smaller, delicate, and more efficient, but these developments will introduce some challenges for medical diagnostic laboratories. Minimizing manpower is one of the outcomes that can endanger the job security of laboratory staff. Performing laboratory tests using microchip technologies in physician's offices could be another challenge facing medical diagnostic laboratories. The mentioned issues were some of the challenges that new generation-laboratories will face, which must be considered also from the ethical point of view.

CONCLUSION

From the ethical point of view, no discrimination in the provision of laboratory services to society is acceptable. Clients must be aware of their legal rights and the principle of confidentiality in laboratories. The relationship and behavior between the staff/physician and the patient should be well to eliminate or minimize patients' physical and mental harm. Nowadays, consideration of ethical issues is key to professionalize laboratories, and related education and practices are essential when training competent laboratory providers, which will ultimately improve laboratory services (11, 13, 16, 28).

ACKNOWLEDGEMENTS

The authors would like to thank Ms. Catherine Jackson and Dr. Barbara Gastel for their editorial assistance.

DECLARATIONS

Funding

The authors received no financial support for the research, authorship, and/or publication of this article.

Ethics approvals and consent to participate

Not applicable.

Conflict of interest

The authors declare that there is no conflict of interest regarding the publication of this article.

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How to Cite:

Najjari M, Karimazar MR, Ebrahimipour M, M. Budke C [A Review of Ethical Issues Related to Laboratory-Based Diagnostics]. mljgoums. 2022; 16(2): 1-6 DOI: [10.29252/mlj.16.2.1](https://doi.org/10.29252/mlj.16.2.1)