Ethics in Laboratory Medicine: lessons from the COVID-19 pandemic

Mario Plebani
Department of Medicine-DIMED, University of Padova, Italy

ABSTRACT

Professional societies in many countries have developed ethics policies and guidance materials for laboratory medicine which, just like any other area of medicine, must adhere to high ethical standards in order to assure quality and safety in health care. In particular, the International Organization for Standardization (ISO) in the accreditation standard ISO 15189:2012 "Medical laboratories − Requirements for quality and competence" has dedicated a specific section to this issue. However, the COVID-19 pandemic has raised the awareness of the urgent need to reassess and update ethical codes, and has highlighted current challenges and critical issues, such as access to diagnostics and laboratory testing, the value of laboratory information and the need for well-integrated diagnostic information. In the present paper, proposals are made for the updating of ethical codes currently required in laboratory medicine.

Keywords: *Ethics, COVID-19, ISO 15189*

INTRODUCTION

Coronavirus disease 2019 (COVID-19), a major healthcare challenge, is a worldwide threat to public health, social stability, and economic development. The pandemic has not only affected all facets of society, dramatically changing individuals' day-to-day lives and habits, but has also changed clinical practice, including that of clinical laboratories (1). It has, moreover, highlighted stark disparities in access to health care services, laboratory medicine in particular, thus giving rise to the need for a new public health ethics framework based on principles allowing transparency and consistency in public health decision-making, and assuring better clinical outcomes to individuals and the community at large (2). Historically, the crucially important role of diagnostics, particularly laboratory testing, in the provision of good health care has been under-estimated and under-resourced. Yet the COVID-19 pandemic has highlighted the importance of prioritizing diagnostics (3). Without access to affordable, high-quality laboratory diagnostics, it is impossible to allocate effective patient care (preventative, urgent, intensive and acute care included).

The challenges of allocation are particularly apparent in communities persistently deprived of access to care and consequently suffering from an increased prevalence of chronic conditions: in 2018, the Lancet Commission on Diagnostics reported that access to diagnostic testing in Pathology and Laboratory Medicine (PALM) was poor and inequitable in many parts of the world, the diagnostic gap being most severe in primary health care, only about 19% of low and lower-middle-income (LMICs) populations having access to the simplest of diagnostic tests. The authors estimated that a reduction in the diagnostic gap for the six tracer conditions suggested by the WHO (from 35-62% to 10%) would reduce the annual number of premature deaths in low and middle-income countries by 1.1 million, and the annual disability-adjusted life-year losses by 38.5 million (4). A study published in 2021 reported evidence collected on the diagnostic accuracy, cost-effectiveness and utility of laboratory test strategies for COVID-19 in low and middle-income countries, and a proposal was made for rapid evidence synthesis (5). The COVID-19 pandemic has therefore generated the opportunity to better address the fundamental ethical

Per un'ampia fruibilità di questa opinione è fornita la traduzione in Italiano quale materiale supplementare (1S)

Corresponding Author: Mario Plebani, Department of Medicine-DIMED, University of Padova, Italy

Recived: 11.01.2022 Revised: 12.01.2022 Accepted: 12.01.2022

Published on-line: 18.01.2022 DOI: 10.19186/BC_2022.002

principles designed to govern laboratory medicine, with access to affordable, high-quality laboratory diagnostics, and a reversal of the view of the clinical laboratory as a commodity.

In recent years, consolidation, merger, and laboratory downsizing have been driven by the need to deliver economies of scale and to cut costs per test while boosting productivity. Distorted economics, based on payment models rewarding volumes and efficiency rather than quality and clinical effectiveness, have underpinned the entrance of clinical laboratories into the mass production industry, forcing them to relinquish their original mission of providing medical services (6). However, the COVID-19 pandemic has highlighted the challenge of resource allocation and ethical duties, in particular, the duty to act in the best interest of patients, and to ensure respect for individuals, pointing to the need for all laboratory professionals to take these issues into greater consideration. As recently highlighted by Cullen M, et al. (7) *"though select members in the field (laboratory medicine) have advocated for an enhanced presence of these specialists in policy conversations, little work has been done to thoroughly evaluate the moral and ethical obligations of the pathologist and the role they play in healthcare justice and access to care"*.

Ethics in laboratory medicine is a long neglected issue, despite papers in the literature and the valuable work undertaken by the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) Task Force on Ethics. In the last few decades, the focus on technological and analytical issues has caused laboratorians to overlook the role of the profession in the context of medicine and healthcare systems. As already reported (8) *"thanks to the longstanding focus on the analytical performances of laboratory tests, we have lost sight of the outcomes of laboratory information"*.

TOWARDS A NEW CODE OF ETHICS FOR LABORATORY PROFESSIONALS

The publication of ISO 15189:2012 "Medical laboratories − Requirements for quality and competence" by the International Organization for Standardization (ISO) (9) was a milestone in the promotion of ethics in laboratory medicine. Section 4.1.1.3 of this unique, internationally recognized standard for medical laboratories accreditation, summarizes the ethical conduct expected by laboratories, stating that laboratories should have means in place to ensure that:

- there is no involvement in any activities that would diminish confidence in the laboratory's competence, impartiality, judgment or operational integrity;
- management and personnel are free from any undue commercial, financial, or other pressure and influences that may adversely affect the quality of work;
- where potential conflicts in competing interests exist, they shall be openly and appropriately declared;
- there are appropriate procedures to ensure that staff treat human samples, tissues or remains according to relevant legal requirements;
- confidentiality of information is maintained.

These requirements focusing on the need to avoid conflict of interest that can undermine the best interests of patients, protect patient information and comply with national and/or international legal requirements, are similar to other code lists developed by Scientific Societies and Associations, as aptly summarized by Richard X. (10). Basic principles that must also be applied to the field of clinical laboratories and laboratory medicine are: respect for persons; beneficence; and justice, as described in the Belmont report, a pivotal work on ethics and healthcare research (11). The ethical duties of a laboratory professional have been described as distinct from other patient-facing specialties. Indeed, some authors continue to maintain that in a clinical laboratory *"there is no direct contact with patients…and the faceless laboratory physician's first and foremost duty is to act in the best interest of the 'faceless' patient who is often 'just a number' "* (12). According to this viewpoint, the relationship between laboratory professionals and patients is important, but *"the relationship between the laboratory professional and clinician is more important"* (12). Before the pandemic, several documents, papers and initiatives emphasized the importance of laboratory testing in numerous clinical pathways (13), but the pandemic further raised awareness of the essential contribution made by clinical laboratories to diagnostic reasoning and patient management, making the value of laboratory testing more visible to the lay public. Therefore, thanks to the visibility gained from the pandemic, we should not miss the opportunity to provide further evidence of the key role played by the laboratory in modern, personalized medicine, and on the ethical principles pertaining to.

First and foremost, it is important for laboratory professionals to share common medical duties with their "patient-facing" colleagues, thus playing an effective and clinical proper role in the healthcare system, this role being to steward resources and ensure that diagnostic tests are accessible, while preventing any unnecessary, obsolete and/or inappropriate tests being ordered. Likewise, laboratory professionals should provide advice for the right interpretation and utilization of laboratory information, thus contributing to improvement in the effectiveness and sustainability of laboratory services (14,15). This innovative moral stance, which would counteract the vision of laboratory medicine as a simple diagnostic commodity, should restore its true nature as an essential medical service; it is, moreover, the backbone to the implementation of novel programs, such as those undertaken by Diagnostic Management Teams, which should ultimately improve diagnostic-therapeutic pathways and clinical outcomes. As stressed by Cullen M, et al (7) *"the issue of justice in laboratory medicine*

can be understood as a multifaceted and complex issue which requires enhanced advocacy and physician education on selective ordering…, amended reimbursement schemes and growth of the laboratory workforce". Laboratory professionals must inform physicians of changes in best practices, and the appropriate use of innovative tests with evidence-based diagnostic efficiency, thus making it possible to improve on the use of economic resources at a population level.

Laboratory professionals should further raise awareness that 47% of the global population has little or no access to diagnostic services (4). In view of the fact that laboratory testing is central and fundamental to quality health care, a reduced diagnostic gap should lead to a relevant reduction in morbidity and mortality worldwide. Therefore, all laboratorians have the moral obligation to transform and improve access to diagnostics as a fundamental part of a healthcare system, while taking into consideration aspects such as financing, workforce, technology and governance. In striving to improve access to diagnostics, it is of fundamental importance to recognize the role of point-of-care (POCT) and near-patient testing as these technologies, with their many advantages (e.g. patient-centerdness, rapidity, lower staff requirements and avoidance of sample transport issues) are conducive to maximizing access to diagnostics in low- and middle-income countries (3). In addition, smart and user-friendly wearable devices not only help people to pursue a healthier lifestyle, but also provide a continuous flow of healthcare data for disease diagnosis and treatment by actively recording physiological parameters and tracking metabolic state (16). The integration of all diagnostic information represents a challenge that laboratory professionals should take into closer consideration.

Closely related to the above point, is the need to ensure diagnostic safety and quality to prevent the risk of harming patients and washing resources. Extended access to poor-quality laboratory testing is questionable and counterproductive. The lesson learned in the last few decades is that quality should be provided not only in the intra-analytical, but also in the extra-analytical phases (17), all steps being monitored with valuable and harmonized quality indicators (18). In addition, efforts must be made to achieve integration between all laboratory medicine sub-disciplines, according to the PALM concept (19) in order to provide clinicians with comprehensive and complete laboratory reports and all necessary information. Ultimately, integration with imaging information should be promoted. In fact, convergence of imaging, pathology and laboratory tests with advanced information technology, has an enormous potential for revolutionizing diagnosis and therapeutic management of human diseases, including those causing the highest mortality worldwide (i.e. cardiovascular disease, cancer and infectious diseases) (13).

Laboratory professionals, particularly in this era of increased access to molecular and genetic information, should serve as guardians of patient data, should protect patient information and avoid the practice of carrying out tests without the patients' consent, and of using stored samples without obtaining patients' fully informed consent (20-23). Laboratory professionals should ascertain that informed consent has been given by the patient for particularly "critical tests" (e.g. drug screening, pregnancy and genetic tests) in the pre-analytical phase and should guarantee confidentiality of test results within the patient's care circle in the post-analytical phase.

Laboratory professionals are morally obliged to assure the comparability of laboratory information across time, across different laboratories and across different diagnostic systems. Patients must be freed from the recommendation that they should always refer to the same laboratory so as to receive comparable results. In view of reasons such as occupation, family and vacation times, patients should be enabled to receive interchangeable results from laboratories in different locations. In an era of globalization, a patient-centered service should assure comparability of laboratory results through harmonization and standardization programs (24).

Table 1 lists the reported key ethical duties in laboratory medicine.

Table 1

Key actions for ethics in laboratory medicine; laboratory professionals should improve:

- interaction between laboratory professionals, patients and clinicians;
- stewardship for accessibility, correct test requesting and interpretation of results
- access to diagnostics (laboratory testing, in particular), while ensuring quality and safety;
- integration and consolidation of diagnostic data/information;
- guardianship of patient data and ensure correct use of human samples;
- comparability of laboratory results and information (harmonization/standardization).

CONCLUSION

In the present era of "hi-tech" laboratory medicine, it is of crucial importance to maintain high ethical standards in laboratory practice as the ethical dilemmas being faced by laboratory professionals are increasing. The COVID-19 pandemic has provided a window of opportunity to review and update current ethical codes, highlighting current challenges and critical issues, such as access to diagnostics and laboratory testing, the current value of laboratory information and the need for better integration of diagnostic information. In particular, evidence collected confutes the concept that laboratory medicine is inherently isolated from patients; *vice versa*, patient interaction as well as closer interaction between laboratorians and physicians is an increasingly important part of their professional goals and ethical duties (25).

A recently published paper investigating whether the assistance of a technologist in the bedside preparation of bone marrow specimens, demonstrated a significant improvement in sample quality (26), thus reinforcing the view that it is important for laboratory professionals to work as members of multidisciplinary healthcare teams. An accompanying editorial, appropriately entitled "The lab as a driver of quality in the preanalytical realm", reported new evidence of the need to provide advice and cooperation in several phases of the testing process (27). As previously reported in a paper published on ethics in laboratory medicine (28), the Latin aphorism *malum quidem nullum esse sine bono* (not all evil causes harm), should help laboratory professionals learn some lessons from the COVID-19 pandemic, lessons enabling them to enhance their practice, and improve upon ethical aspects. The above reported ethical duties constitute a proposal that national Scientific Societies, International Federations of Laboratory Medicine (e.g. IFCC and EFLM) and other professional organizations should take into account in the interests of developing a more comprehensive and updated code of ethics in laboratory medicine.

CONFLICT OF INTERESTS

None.

REFERENCES

1. Plebani M. Laboratory medicine in the COVID-19 era: six lessons for the future. Clin Chem Lab Med 2021 doi: 10.1515/cclm-2021-0367. Epub ahead of print.
2. Maeckelberghe E. COVID-19: opportunities for public health ethics? J R Coll Physicians Edinb 2021;51:S47-52.
3. Fleming KA, Horton S, Wilson ML, et al. The Lancet Commission on diagnostics: transforming access to diagnostics. Lancet 2021;398:1997-2050.
4. Sayed S, Cherniak W, Lawler M, et al. Improving pathology and laboratory medicine in low-income and middle-income countries: roadmap to solutions. Lancet 2018;391(10133):1939-52.
5. Ouma OK, Ephraim K, Loyce N, et al. Role and utility of COVID-19 laboratory testing in low-income and middle-income countries: protocol for rapid evidence synthesis. BMJ Open. 2021;11(10):e050296.
6. Plebani, M. Clinical laboratories: production industry or medical services? Clin Chem Lab Med 2015;53:995-1004.
7. Lilley CM, Mirza KM. Critical role of pathology and laboratory medicine in the conversation surrounding access to healthcare. J Med Ethics 2021. doi: 10.1136/medethics-2021-107251. Epub ahead of print.
8. Plebani M. Competent well-trained phlebotomists. Am J Clin Pathol. 2021 doi: 10.1093/ajcp/aqab193. Epub ahead of print.
9. ISO 1589.2012. Medical laboratories – Particular requirements for quality and competence. International Organization for Standardization: Geneva 2012.
10. Davey RX. Codes of ethics for laboratory medicine: definition, structure and procedures - A narrative review based on existing national codes. EJIFCC 2020;31:262-73.
11. The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. Ethical Principles and Guidelines for the Protection of Human Subjects of Research. https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/read-the-belmont-report/index.html. (last accessed: January 2022)
12. Wijeratne N, Benatar SR. Ethical issues in laboratory medicine. J Clin Pathol 2010;63:97-8.
13. Lippi G, Plebani M. Integrated diagnostics: the future of laboratory medicine?. Biochem Med 2020;30:010501.
14. Plebani M. Clinical laboratory: bigger is not always better. Diagnosis (Berl) 2018;5:41-6.
15. Plebani M, Laposata M, Lippi G. A manifesto for the future of laboratory medicine professionals. Clin Chim Acta 2019;489:49-52.
16. Xie Y, Lu L, Gao F, et al. Integration of artificial intelligence, blockchain, and wearable technology for chronic disease management: A new paradigm in smart healthcare. Curr Med Sci 2021;41:1123-33.
17. Plebani M. The detection and prevention of errors in laboratory medicine. Ann Clin Biochem 2010;47:101-10.
18. Aita A, Sciacovelli L, Plebani M. Extra-analytical quality indicators - where to now?. Clin Chem Lab Med 2018;57:127-33.
19. Wilson ML, Fleming KA, Kuti MA, et al. Access to pathology and laboratory medicine services: a crucial gap. Lancet 2018;391(10133):1927-38.
20. Emerson CI, Singer PA, Upshur RE. Access and use of human tissues from the developing world: ethical challenges and a way forward using a tissue trust. BMC Med Ethics 2011;12:2.
21. Sancesario G, Pezzati P. Ricerca sul materiale biologico: ritorno al futuro. Biochim Clin 2021;45:299-304.
22. Banfi G. Utilizzo del materiale biologico residuo nel laboratorio clinico. Biochim Clin 2021;45:408-11.
23. Recommendation CM/Rec (2016)6 of the Committee of Ministers to members states on research on biological materials of human origin. https://search.coe.int/cm/Pages/result_details.aspx?ObjectId=090000168064e8f. (last accessed: January 2022).
24. Plebani M. Harmonization in laboratory medicine: more than clinical chemistry? Clin Chem Lab Med 2018;56:1579-86.
25. Joseph L. Your doctor, the pathologist, will see you now. Am J Clin Pathol 2021;156:939-40.
26. Ali SF, Cloe A, Siaghani PJ, et al. Bone marrow collection. Am J Clin Pathol 2021. doi: 10.1093/ajcp/aqab165. Epub ahead of print.
27. Siddon AJ, Kroft SH. The lab as a driver of quality in the preanalytical realm. Am J Clin Pathol 2021. doi: 10.1093/ajcp/aqab180. Epub ahead of print.
28. Plebani M. L'etica in medicina di laboratorio nella terza era della medicina. Biochim Clin 2021;45:176-9.