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Ethics in laboratory medicine: perspectives and challenges in resource limited settings

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ABSTRACT

Currently diagnosis and management of patients in Clinical Practice is very much dependent on laboratory diagnostics. Laboratory Medicine, like any other branch of Medicine, is therefore, mandated with ethical usage of materials and data obtained from patients. Several countries, professional societies and the have developed policies and guidance materials on ethical issues related to laboratory medicine. However, ethical standards and practices vary between different cultures, geographies, legal architecture and according to available resources. In this article, we try to understand the challenges presented in terms of Ethics, where there are constraints of resources.

INTRODUCTION

Like in any branch of medicine, which involves taking decisions about the wellbeing of individual patients as well as catering to the overall wellbeing of the society through continued learning through scientific observation and interventions on patients, Laboratory Medicine is also mandated with ethical usage of patient data and other materials for the optimum utilization of the same for benefit of the individual and the society. "Decisions about diagnosis, prognosis and treatment are frequently based on results and interpretations of laboratory tests. Irreversible harm may be caused by erroneous tests."

Medical Bio-Ethics developed and has evolved over the years starting from the Nuremberg Code in 1947 (1), the Declaration of Geneva in 1948 (2), through the Declaration of Helsinki in 1964 (3) to the Belmont report in 1978 (4). These documents mostly focus on medical research, however, the concepts in the Declaration of Geneva and the Belmont report are also applicable to the practice of clinical medicine. This is because, clinical medicine and medical research are complimentary to each other. This is especially true for laboratory tests, which are developed as a research tool one day goes on to become a diagnostic parameter very fast.

The core ethical principles of all these documents include: (i) Respect for persons, i.e. Acknowledgement of autonomy and protection of those with diminished autonomy; (ii) Beneficence, i.e. the duty to act in the best interests of patients or research subjects with the goal of maximizing benefits and minimizing harm (nonmaleficence); and (iii) Justice, i.e. the duty or obligation to treat patients equally and to distribute, by allocating fairly, what is rightly due in terms of benefits, risks and cost.

Like any other branch of Medicine, Laboratory medicine is obliged to adhere to high ethical standards. Many countries and professional societies have developed policies and guidance materials on ethical issues related to laboratory medicine. The International Organization for Standardization (ISO) has created ISO 15189:2012 "Medical laboratories – Requirements for quality and competence" (5). Section 4.1.1.3 of the document summarizes the ethical conduct expected in laboratories. The core principles outlined in the document mention that (i) there should not be involvement in any activities that would diminish confidence in the laboratory's competence, impartiality, judgment or operational integrity; (ii) management and personnel are free from any undue commercial, financial, or other pressure and influences that may adversely affect the quality of work; (iii) where potential conflicts in competing interests exist, they shall be openly and appropriately declared; (iv) there are appropriate procedures to ensure that staff treat human samples, tissues or remains according to relevant legal requirements; (v) confidentiality of information is maintained.

Despite the importance of ethics in laboratory medicine, there is variability in education and training focused on laboratory ethics. Formal teaching of ethics is absent from many clinical chemistry and laboratory medicine training programs. Recognising this, need for training tools, especially, online ones to facilitate training of laboratory professionals with the convenience of location and timings, International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) has recently constituted a task force on ethics (TF-E) to streamline these documents and spread the ideas on ethics (6). The TF-E has come up with a toolkit for this purpose which serves as a repository of documents developed worldwide in the realm of laboratory ethics (7).

However, it is important to understand that ethical guidelines cannot be uniform over different cultures, geographies and legal architecture. Besides, adherence to the set principles differ

based on available resources and social practices. This article tries to focus on the challenges in setting guidelines and implementation of the same in resource limited settings.

CODES OF ETHICS AND ITS RELEVANCE IN LABORATORY MEDICINE

A Code of Ethics may be described as an expression of basic values - the principles and standards by which we should conduct ourselves. Numerous 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 (8) advises to maintain strict confidentiality of patient information and test results, safeguard the dignity and privacy of patients and above all be accountable for the quality and integrity of clinical laboratory services being provided.

On similar lines 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.

As can be observed from above, most organizations and codes of ethics focus on several points while prescribing a guideline for Laboratory Medicine professionals. There are several areas in Laboratory Medicine practice where the formulation and implementation of ethical guidelines present challenges (9). These include: (i) Consent from patients including consent for unforeseen complications, usage of Leftover samples and biobanking; (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. All of the above considerations relevant to Laboratory Medicine has been addressed elegantly in a recent article by Gronowski et al (10). In this paper we would focus on the challenges faced in resource limited settings.

Resource allocation is not uniform all over the world. Especially in developing countries, healthcare facilities have to work with several constraints. These may range from 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. In these above-mentioned scenarios it is often difficult to conform to the highest standards of ethics.

I. Consent

Most often the laboratories receive patient samples for testing. In such a setting obtaining consent for such exercise is the responsibility of the treating physician. In the hospital setting this is often 'implied', especially when the patient is admitted and sometimes not in a position to give consent. Hence, it is often a practice to take a blanket consent for such diagnostic tests which do not add significant risk to the patient. However, it is a good practice to take consents for such diagnostic procedures which might be adding significant risk to patient's life.

In resource limited settings which includes lack of manpower and time, the ideas of beneficence and non-maleficence should prevail. More importantly, in certain parts of the world, literacy and language issues may be a significant problem. Hence, implementation of a uniform ethics code presents a challenge. The problem sometimes escalates due to some unforeseen complications arising out of some diagnostic procedures and must be accounted for in the informed consent process. The Laboratory, thus, should be able to always abide by the ethical principles of

respect for persons, beneficence, even on a case to case basis.

In resource limited settings, handling of leftover samples becomes yet another challenge. Laboratories often facilitate add-on tests on these leftover samples to minimise turn-around time (TAT). However, the informed consent process must include provisions for the same and abide by the guiding principles of ethical codes. When using leftover samples for research, risk can be minimized by removing patient identifiers. Personal identifiers may be removed and replaced with a code i.e. deidentified or anonymized, i.e. identifiable information, if collected, identifiers are not retained and cannot be retrieved.

Biobanking, defined as a resource that holds human biological samples and/or data to facilitate research over time is also coming up in the developing countries in recent years, especially in the settings of emerging and exotic diseases. Often these are associated with storage of leftover samples in resource constrained parts of the world. However, the process of informed consent should abide by the general principles of ethics. In normal circumstances mostly two options are explored for such initiatives regarding consent: (i) recontacting patients and get consent for each new research study, which is logistically difficult, time-consuming, and expensive, and hence often practically not feasible in resource constrained settings; or (ii) allow patients to give a broad consent that allows for future use of the samples. However, the more general the consent becomes, the less informed it gets.

II. Genetic testing

In principle, the 'right to autonomy' should allow people to decide whether genetic testing is to be performed or not. However, different governments have different policies regarding 'newborn screening', which is performed automatically, without physician orders. Once a disease or risk for disease is detected, patients and physicians face a dilemma whether to disclose the results of the tests to other family members who we now know to have increased risk. This may help individuals and the society as a whole device better preventive and therapeutic strategies and hence the principle of beneficence overrides the individual's right to autonomy. If the disease detected are treatable, the benefit to the public outweighs the autonomy of the individual.

III. Incidental findings

These are results that have potential health or reproductive importance and are unintentionally discovered while processing for other tests. Incidental findings may be carefully evaluated of the benefits against the potential risks and may involve evaluating the result's accuracy, significance to health, and clinical actionability. In the resource limited settings in developing countries it often has other ramifications like cost of treatment and potential benefit of such treatment. Moreover, societal benefits must also be considered simultaneously before ruling in favour of patient's autonomy.

IV. Error disclosure

Disclosure of errors in Laboratory Medicine setting comes with unique challenges related to error reporting because the laboratories usually have no relationship with the affected patient. Hence the disclosure has to happen through the treating counterparts. Several barriers to disclosing error exist viz. unclear definitions of error, fear that patients may not understand the error, worry that clinicians may not be able to properly explain the error, and disclosure of error that was actually committed by someone else. The process of disclosing medical errors is

gradually becoming formalized into the health care process.

Clinical laboratories should have policies and procedures for detecting errors that affect patient care and for informing both providers and patients. But several apprehensions exist among professionals inhibiting them to participate in the process. The most important amongst them is the fear of retribution from their colleagues, peers, supervisors, treating physicians and above all their patients. Sometimes there is inadequate understanding of the consequences of the error leads to the belief that eventual outcome would have been the same. The fear of being penalised because of disclosure is another barrier hence often people risk being caught. Fear of improperly conveyed error disclosure by physician colleagues also act as a barrier of appropriate error disclosure. Hence, appropriate mechanisms for error disclosure and mechanisms to protect the lab professional may increase the effectivity of error disclosure.

V. Test utilization

One of the major problems in resource limited settings is inappropriate test utilization. In developing countries like India healthcare system is run parallelly through government and private mechanisms. In the private setting patients generally pay from out of their pocket to meet the expenses incurred during their treatment etc. Only a small percentage of patients are covered under insurances. On the other hand in the government facilities the services are either free or at a subsidized rate. However, the waiting periods in those systems are long and often the ancillary facilities are inadequate, hence not preferred by people who can afford. Hence, inappropriate test utilization is a problem in both the scenario: in the private set-up unethical practices for profiteering might be discouraged by the labs; in government set up inappropriate test utilization should be discouraged as it leads to mis-utilisation of public money. Laboratorians should advocate for proper test utilization and communicate with physicians when they feel testing has been ordered inappropriately.

Inappropriate laboratory testing can potentially lead also to false-positive results that can lead to unnecessary testing and intervention or even misdiagnosis, and increased costs for the patient and society as a whole. A lot of factors lead to poor test utilization: large and growing number of tests, lack of proper physician training, difficult to use direct order entry and electronic medical record systems, and demand from patients themselves as exposure to internet information leads patients to demand certain tests.

VI. Direct-to-Consumer (DTC) testing

DTC laboratory testing is growing rapidly all over the world along with the developing world. DTC allows consumers to order their own laboratory tests providing greater autonomy in some cases, is more accessible than going through standard healthcare providers and may be less expensive, which is also a source of justice for patients with limited financial means. However, it has several limitations; consumers are less likely to properly interpret their own laboratory tests and may find erroneous information without expert guidance. This becomes even more evident in low-prevalence disease which increases the chances for false positive results. Hence, although not directly under the perview of the laboratories ethically laboratories are bound to provide support to their customers.

VII. Emerging disease setting

The emergence of COVID-19 and some other novel diseases in recent years have presented a new challenge to ethical principles. A lot of questions have come up in these unusual circumstances like how the decisions are taken to ascertain which risks are acceptable for laboratory workers? Who decides what risks to

patients are acceptable to protect laboratory workers or to protect other patients? But most importantly in resource limited settings where there is shortage of appropriate personal protective equipment (PPE) creating awareness among lab staff about the level of PPE required for each lab activity. Importantly, there should be initiatives to spread awareness among staff to mitigate their apprehensions.

On the other hand laboratories should ensure access to laboratory testing for all patients who require testing. However, the low capacity of resource limited settings in analyzing samples through appropriate testing methods often leads to unethical practices. However, development of a policy in sync with legal requirements and local needs often addresses the issue.

OVERCOMING CHALLENGES

Overcoming the above-mentioned challenges in Laboratory Medicine in resource limited settings is difficult, but not impossible. The most important step to ensuring ethical standards and practices in the laboratory must be recognised as a shared responsibility between all the laboratory staff. It is important that the roles of each of them are defined and all are made to understand the accountability associated with their jobs. This would be possible through repeated training of the staff at all levels.

Ethical issues in the pre-analytical phase

The responsibility of the laboratory starts with proper identification of the patient or subject, collection of the appropriate sample using the appropriate technique, appropriate identification and labelling of the sample so that the right tests are performed and appropriate handling of the specimen until testing is performed. In the whole process respect for the persons must be maintained through obtaining proper consent: informed, implied. Besides, the right to refuse to be tested, should be respected unless there are legal obligations, as has happened during the COVID-19 pandemic. Most importantly, confidentiality must be maintained at every step of the process including specimen transportation and data entry. Finally, the tests should benefit the patient based on the best medical evidence and should be done using universal precautions to protect the patient and the healthcare worker. And all these should be available at a reasonable cost to ensure access to the population as a whole.

Ethical issues in the analytical phase

The most important issue during the analytical phase is to provide the best possible analytical results through good laboratory practice and maintenance of rigorous quality assurance program which becomes a challenge in resource limited settings. However, the guiding principle should be: “a wrong result is worse than no result”. Besides, all patient samples need to be treated equally. Discrimination based on gender, age, racial origin, or even socio-economic status is an injustice. However, specimens designated as STAT or priority must be analysed promptly to meet the medical need.

Another aspect of good laboratory practice (GLP), often ignored in the setting of resource-poor settings, is the refusal to analyse or report a result when there is evidence of: improper patient preparation, poor sample integrity, incorrect or poor labelling and other deficiencies that may compromise the test result. Lab staff are sometimes persuaded to accept ‘otherwise unacceptable samples’ due to patients coming in from remote areas with limited access to similar healthcare facilities in their vicinity. But this should be avoided.

Acceptability criteria of samples that are classified as “difficult to obtain” (such as cerebrospinal fluid) may be relaxed sometimes based on

clinical judgement; however the responsibility of the same is to be defined on persons with experience and laboratory should develop an appropriate policy on analysis. Besides, documentation of the specimens when specimen integrity or identification is compromised may be developed as a policy.

Ethical issues in the post analytical phase

The post analytical phase poses certain other challenges in resource limited settings and includes reporting and interpretation of results, residual specimen storage, and data access.

Even in resource limited settings with limited manpower, identification of authorized personnel allowed to access medical records such as doctors, patients, and laboratory staff should be documented. This would ensure quality of reports as well as confidentiality of results. However, these policies should abide by legal requirements, insurance rules, and government regulations. Disclosure of errors if any needs to be notified as soon as they are identified, and test results should be corrected as soon as possible.

Maintaining confidentiality presents the biggest challenge in this phase. It is important to keep all client/patient information secure and restrict access to testing areas. In resource limited settings where records are not maintained electronically with appropriate access control, all physical documents need to be secured. Repeated reinforcements by training for maintenance of ethical standards need to be done because people often violate ethics not because they mean to, but because they are careless; sometimes even acting with good intentions.

The major managerial issues which needs to be addressed in all settings and is equally applicable in resource-poor settings is Conflict of Interest issues involved in procurement etc. of the lab. All work or travel-related payments from a diagnostic or pharmaceutical company, or receipt of fees as a consultant, member of an advisory board, lecturer, speaker, or expert witness; grants, either financial or reagents, received from governmental sources, foundations, non-profit granting agencies, diagnostics or pharmaceutical companies come under the purview of the same and need to be disclosed during management review meetings.

CONCLUSION

It can be well appreciated that ensuring adherence to ethical standards is a challenge in the resource limited settings. The challenges vary from place to place and the solutions need to be tailored to practical situations. Addressing these issues in the form of policy at the level of the country, local administration or even at the hospital/laboratory level may help in providing a guideline improving ethical practices. Framework for addressing ethical issues encountered in the practice of laboratory medicine need to be addressed and training of staff in this regard needs to be undertaken to ensure compliance to ethical requirements. We must constantly remind ourselves of the code of conducts and ensure we do the right thing because ethical issues are often hard to deal with because they create dilemmas.

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