

Ethical practice in laboratory medicine; a glimpse of the current issues

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Introduction. Ethics in medicine describes moral principles that should underpin all actions taken in medical practice. The four pillars of medical ethics are beneficence (doing good), non-maleficence (doing no harm), autonomy (giving the patient freedom to make informed decisions) and justice (ensuring fairness) (1). These basic principles, which have been established through experiences encountered over many decades, will stand true at all times. These principles are applicable to every field of medicine including laboratory medicine. Ethical issues may change with time due to many reasons, especially with the advances in medicine. The exponential expansion in the field of laboratory medicine demands ethical practice in laboratory medicine be revisited. This article intends to discuss some common ethical issues encountered in laboratory medical practice on a day-to-day basis and to identify the extent of accountability of professionals in laboratory medicine towards ensuring ethical laboratory practice with special reference to histopathology.

Keywords. Ethical practice, Laboratory medicine, Medical ethics

ETHICS IN RELATION TO SAMPLE PROCESSING CYCLE

Ethical principles are applicable throughout the three phases of the sample processing cycle: pre-analytical, analytical and post-analytical phases. It extends beyond this processing cycle which includes how the laboratory attends to the remaining sample, record keeping, and archiving tissue blocks/slides and other records.

Most of the potential ethical issues do not arise if the laboratory staff strictly adheres to the established laboratory standard operating procedures (SOPs). Patient's consent to have laboratory tests performed on their samples is a requirement (2). Consent is often implied when the patient provides samples for testing e.g. blood, urine and other body fluids. When the patient is to undergo a biopsy/surgical procedure to diagnose or as treatment, consent may be obtained by the clinical staff, or it may be implied in certain situations. (2) However, pre-test counselling should be performed for potentially stigmatizing investigations, e.g. tests for certain infectious diseases, screening for prohibited drugs and genetic tests, which should then be followed by post-test counselling where appropriate (3). It is mandatory to maintain confidentiality of such test results and should only be shared with the healthcare team managing the patient

unless it is a requirement by law or public health regulations. (2,3,4) Anonymizing samples at the time of collection using a bar code or assigning a laboratory reference number to the sample prevents the identity of the patient from being disclosed. Confidentiality of information is well assured if limited access is provided to the password-protected electronic database of the laboratory/hospital. At every step of sample handling, from sample collection to the issue of the report and thereafter in archiving, confidentiality and anonymity should be maintained (5).

Adherence to SOPs in the collection and transport of samples, performing the test, clinical validation and entering results will ensure accuracy, reliability and validity of results which is a requirement in quality assurance. Engaging in a standard quality assurance process itself enhances ethical practice as it ensures the accuracy, validity and reliability of the tests performed and hence, addresses the concept of beneficence and non-maleficence. Additional samples should not be obtained from the patient without informing and getting permission from the clinician or the laboratory specialist concerned (5).

Since the specimens are assigned a unique reference number on acceptance to the laboratory, confidentiality of the results and anonymity of the patient is generally well

maintained until the report is completed. However, laboratory and ward/clinic staff should be well aware of the patients' right to confidentiality and anonymity. This may be breached in some instances if the staff performing the test, messengers delivering the reports, or ward or clinic staff who file the reports are not sufficiently informed of the patients' right to confidentiality and anonymity.

In performing the tests of different patients, the laboratory may prioritize certain specimens /patients based on the relevant clinical context e.g. prioritizing a biopsy over a resection specimen received at a histopathology laboratory, random blood glucose of an unconscious patient over a routine clinic request when the routine workload for the day is a limiting factor. This prioritization cannot be considered unethical, it is rather a necessity in the clinical context. Reflecting beyond this, it is important to state that laboratory professionals are accountable for setting priority policies on making good use of publicly funded services (3). This can be achieved by taking measures to prevent unnecessary testing and duplication of tests ensuring judicious use of the laboratory.

Proper storage of histopathology blocks and slides will ensure patients' rights to request tissue blocks for any further test on the sample even after years of issuing the report, e.g. for molecular testing, ensuring beneficence. Patients generally do not expect their specimens to be used beyond the testing prescribed by a clinician (5). If the archived material or laboratory data of patients are to be used for research purposes the concerned researcher should obtain ethical and administrative clearance before commencing the study ensuring the autonomy of the patients.

During the whole cycle of sample processing, how the laboratory staff should conduct themselves has been discussed in different forums. Adhering to hospital infection control practices for their own beneficence and avoiding the use of mobile phones during laboratory work are good practices expected from the laboratory staff of all categories. Mobile phones and other electronic devices may interfere with the electronic circuits of very sensitive laboratory equipment and more often distract the laboratory personnel carrying out their duties. Such practices can easily lead to the generation of erroneous results which can be detrimental to the

patient. Beneficence and non-maleficence are breached in such situations. Discussing the patient's test results with people who are out of the circle of patientcare is not acceptable as it breaches confidentiality.

THE HISTOPATHOLOGIST'S DILEMMA

Obtaining a second opinion has been emphasized in reporting on histopathological samples of cancers due to the complexity in the classification of tumours (6). This process is expected to avoid misdiagnosis and/or refine the diagnostic process in terms of confirming the first pathologist's diagnosis or offering more information to improve the treatment plan which will benefit the patient (6). The process of obtaining a second opinion will be effective if there is an opportunity for discussion between the first and the second pathologist. In Sri Lanka, patients sometimes request tissue blocks/slides for further testing or for a second opinion. It is considered a right of a patient, in terms of beneficence (7). Histopathologists often release this material without hesitation. However, the first reporting histopathologist may not get feedback on the second opinion or further test, for which he /she has the right to know. As there is no discussion taking place between the two pathologists in this instance, the patient could be deprived of a more refined diagnosis

Inter-observer variation in histopathological interpretation is well recognized, especially when assigning scores or grades and in interpreting difficult cases. There are measures established to minimize such errors. Obtaining a second opinion or an expert opinion is one such measure to assure a "safe" diagnosis (4,7). In the current practice, requesting a second opinion on difficult cases by the histopathologist often happens on a personal basis and if it is intra-departmental, a note on this may or may not appear in the final report. Although many histopathologists practice obtaining a second opinion, as and when necessary, the fact that a second opinion has been obtained is not often stated in the report. Therefore, neither the clinician nor the patient is aware of the enhanced validity of the report and may resort to further obtaining a second opinion on their own. The practice of stating the opinion of a second pathologist in the report sometimes leads to issues of losing confidence in the first reporting

histopathologist by the clinicians and may be a reason why it is not stated. However, having intra-departmental reviews of cases is a well-recognized concept recommended by quality assurance guidelines and practiced by many histopathologists although clinicians and patients may be unaware of such quality improvement practices which ensures giving the best care for the patient.

In some instances, an excised tissue sample is divided and sent to two different pathologists leading to differences in the diagnosis. This happens due to the variation in the pathological changes in the two tissues, e.g. one tissue contains an invasive malignancy but the other has its in-situ component only. This disparity in diagnosis is not due to any incompetencies of the histopathologist but due to the unwise decision taken creating confusion on the correct diagnosis. Issues of this nature are much less in the current medical practice assuring beneficence towards patients.

Such issues may cause unnecessary lengthening of the process of issuing a report with a definitive diagnosis. They can be avoided if a forum to discuss such dilemmas among laboratory professionals and clinicians is established. Multi-disciplinary meetings and pathology peer review meetings are good options to address such issues which are currently being practiced to varying extents in Sri Lanka. Such measures address the professional's responsibility in assuring beneficence and non-maleficence.

IMPROVING COMPETENCE AND SKILLS

Medical laboratory professionals are accountable for the quality of the services they provide (2). Therefore, it is an obligation to maintain and enhance individual competence via engaging in continuous professional development activities. Medical laboratory professionals have significant opportunities in this respect owing to the academic activities organized regularly by the respective professional colleges in Sri Lanka. However, the opportunity for the other categories of laboratory staff other than the specialists may not be sufficient. On the other hand, much more information is available via online platforms which are easily accessible due to the enhanced internet facility, provided that the desire for self-improvement prevails among laboratory personnel.

Unlike in the past, diagnosis of medical conditions relies on laboratory investigations to a great extent. It reaches 70% of patients seeking medical attention in the United Kingdom (3). This emphasizes the critical role played by the laboratory in patient care by providing timely, reliable and accurate reports on the samples received. Therefore, it demands the recognition of the ethical aspects of a laboratory service in day-to-day practice including the obligation to enhance skills and competencies. Laboratory staff need to identify their role in terms of the impact that they have on the patient's outcome.

RESPECTING TEAMWORK

The contribution of the laboratory to patient care implies 'shared decision-making' between the clinician and the laboratory specialist which sometimes is considered the hallmark of laboratory medicine (3). Sharing necessary information is extremely important in reaching the correct diagnosis and in offering the best management for the patient. Wrong diagnoses may be made, or inappropriate management decisions may be taken unless the importance of each other's contribution to the 'shared decision-making' is not understood and practised. If the relevant clinical details are not provided to the laboratory specialist to interpret the results of laboratory investigations beneficence and non-maleficence will not be assured for the patient. The clinician who obtains the services of the laboratory and the laboratory specialist who provides the laboratory service is required to understand each other's expectations and limitations in providing the best care to the patient. Therefore, interpersonal collegiality and teamwork at the professional level are much emphasized (3). The understanding between the clinician and the laboratory medicine specialist is of paramount importance for the test result to be of use in providing the best care to the patient. Multi-disciplinary team meetings practised in most countries are well suited to Sri Lanka too in this respect and are getting popular in some centres although not practised much in other centres due to varying reasons. Providing a laboratory service entails teamwork from the acceptance of a sample until the report is

dispatched. A well-designed workflow in a laboratory becomes productive in terms of validity, reliability, and timeliness of generated reports only with the optimal contribution by individual laboratory staff and teamwork ensuring beneficence and non-maleficence towards patients.

The laboratory professional's responsibility towards society as a whole requires consideration, especially in resource allocation in a resource-limited setting like in Sri Lanka. Equitable access to laboratory facilities is one aspect of ensuring justice for the patient. Judicious fund allocation to different levels of laboratories and to costly laboratory tests is a dire need. In offering tailor-made therapy to patients with certain cancers costly high-tech investigations are required. However, due to the restrictions in funds, some of these are either not available in the state sector laboratories or restricted to reference laboratories and private sector laboratories. Assuring fairness in access to such facilities is not easy due to budgetary limitations.

CONCLUSIONS

Just as in other fields of Medicine, it is one of the responsibilities of laboratory professionals to strive to maintain a high standard of ethics in medical laboratory practice. This article is not a complete account of ethical issues encountered while practising laboratory medicine. However, some of the common issues that need attention are discussed in order to raise awareness among those who are engaged in and those using medical laboratory services. Paying sufficient attention to ethics is important as it prevents someone from

committing an unethical action knowingly or unknowingly.

It is recommended to develop standard operating procedures giving due consideration to the underlying ethical principles as well. The ethical practice of laboratory medicine and the ethical use of the laboratory should be sufficiently addressed in undergraduate and postgraduate training programmes of healthcare workers to ensure the basic moral principles of beneficence, non-maleficence, autonomy and justice to be upheld in providing patient care.

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