The basic tenets of medical ethics, as applied to laboratory medicine

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Acknowledgements – None

Brief title – Ethics in laboratory medicine

Disclaimers - None

Key words – medical ethics, misconduct, autonomy, beneficence, non-maleficence, justice, informed consent, medical research

The significance of pathology and laboratory medicine in medical practice is shown by the fact that a recent study showed that 66 % of clinical decisions were based on laboratory tests1. Laboratory investigations also form an important component of biomedical research that is carried out on human participants. The basic principles of medical ethics are autonomy, beneficence, non-maleficence and justice2; though these are thought of largely in the context of clinician-patient interaction and patient care, they also include the pathologist-patient relationship. Baron has pointed out that the pathologist’s ethical responsibilities extend well beyond the primary patient, and also include responsibilities to other patients, the referring physician, colleagues and staff, students, research subjects and animals and the general public3. Ethical issues related to pathology and laboratory medicine are not as commonly addressed as in other spheres of medicine. This is probably because of lack of direct contact of pathologists with patients.

There is limited literature devoted to the specific topic of ethics in laboratory medicine3-8. There is also a need to sensitise medical students to ethical issues in laboratory medicine and to generate more teaching resources to add to the existing material.

The fundamental bioethical principles and the core values and virtues of honesty, integrity and reliability must be practised by a pathologist for safeguarding the health as well as rights of patients and research participants7. It is obvious of course, that these principles of ethics are not mutually exclusive; some concepts (eg. beneficence and non-maleficence) overlap with each other. Further, there are occasions when one principle may conflict with the other – the physician, then, has to take a measured decision, after considering the possible harms versus the expected benefits of the decision that she takes in the best interest of the patient4.

Wijeratne and Benater add that certain virtues are essential in the quest to achieve the high standards that good medical and laboratory practice must reach. These virtues include compassion, discernment, trustworthiness, integrity and conscientiousness5.

We discuss the basic tenets of medical ethics as applied to pathology and laboratory medicine.

1. **Autonomy of the patient /research participant:**

Autonomy is the right to decide for oneself. Informed consent is the expression of the principle of autonomy2

The various laboratory tests that are carried out require the patient/ research participant to undergo those investigations voluntarily. Any kind of coercion in this matter is a violation of human rights.Implied consent is a consent which is not expressly granted by a person, but rather implicitly granted by a person's specific actions and the circumstances of the situation. Thus, implied consent is usually considered sufficient for most investigations as the patient presents himself/herself willingly to the laboratory for tests to be performed. It is assumed that the patient has given consent for procedures such as phlebotomy and that the referring physician has explained the need for performing the laboratory tests. An exception to the idea of implied consent is in HIV testing, where, as per WHO guidelines, written consent and counselling is essential prior to testing9.

*Autonomy and research samples*

A research study which involves collection of body specimens or tissue also requires informed consent of the research participant. This consent must clearly explain the purpose of the study as well as benefits and harms of participating in the research study4. Approval from the Institutional Ethics Committee (IEC) is necessary in all such studies. However, some issues arise after the completion of the study.

Can research be performed on the residual samples or tissue? Should the research be restricted to the disease that the patient has had? Or can it be used for research on other diseases? Does the biological material belong to the patient once it is removed from the body? The ownership of the paraffin blocks (and indeed, any biological material) is among the trickier and more contentious of ethical issues in the laboratory10-22. Ideally, any research on the tissue samples should be done after informed consent of the patient to whom the tissue belongs and/or after approval from the IEC, as per the laws existing in the country concerned.

If the patient (or the IEC) denies permission for the storage of his or her tissue for research purposes, the right of the patient must be respected. It goes without saying that confidentiality must always be maintained. The pathology laboratory thus plays a role of guardian rather than proprietor of these stored body samples12,17, 21 **.**

Much has been written in the literature about the pros and cons of both sides – those who believe that patient consent is essential before the scientist uses surplus material and those who believe that it isn’t 19,20 .

van Diest argues that the time and expense involved in getting repeat consent would be better spent in research19. The excess material must be used to benefit science. He adds this can be done, provided confidentiality is maintained and all of the excess sample is not used up (in the eventuality that the patient may need it in the future). He adds that the principle of solidarity (i.e. helping others) is of greater importance than the right of self-determination (of the patient deciding what needs to be done with one’s own excess tissue). On the other hand, Savulescu’s stance is that consent is a must because of the importance to maintain confidentiality as well as to defer to the principle of patient autonomy. He also makes the case that seeking consent would help build public confidence in science and research and acts as a check against the abuse or misuse of samples20.

However, it is often not practical or possible to contact patients years after their surgical procedure or diagnosis. In addition, contacting a family long after a medical event (particularly if it involves an adverse event ) may bring back painful memories of the suffering of a loved one – thus not only violating medical ethics but also common sense humanity22.

Our own belief is that we should follow the principle of solidarity19 or altruism. Just as today, we benefit from the largesse of research participants of the past (albeit involuntarily and without their consent, in a large number of cases), we owe it to the next generation to contribute our residual biological material for future use. Because no harm can come to the individuals (as there is no further invasive procedure and because confidentiality is maintained), it is exigent on us to do so.

One way of tackling this issue is to consider changing the current Informed consent process ( which takes permission only for the current study) and to seek a broad consent which may be applicable in future, provided an IEC permission is sought as well, to act as an appropriate check. Furness and Nicholson suggest, based on their findings in a study performed to seek opinions from patients, that it may be more practical to assume implied consent) in most cases and to avoid using tissue only from those who specifically record their objections.22

*Autonomy and autopsies*

Medicolegal autopsies, by their very nature, do not require consent from family members. However, in clinical autopsies, consent from the family is mandatory. Because the autopsy is an invaluable teaching tool and its benefits could be passed on to future generations of patients and their doctors, one can easily make the case that autopsies should be made compulsory in many cases. This would be consistent with a Cartesian approach, which posits that because the body is no longer alive, thinking has stopped and the body has merely become an object. However, sociocultural values predominate and it is the practice to follow the wishes of the relatives of the deceased, regarding autopsy23. The family must be informed, and consent taken, about tissues being retained for academic and diagnostic purposes.Procedures for obtaining written informed consent for organ removal and retention should be continuously monitored. That autopsy rates have declined is in itself a serious issue24. The reasons for this decline include financial, medical and potential medicolegal matters. One could argue that by the act of not promoting autopsies, physicians and pathologists are doing a disservice to science, to learning and to society, and by implication, are behaving unscientifically.

Ethical issues regarding autopsy and organ retention have achieved great importance and have changed autopsy practice in the UK and possibly in other countries after the Alder-Hey episode and its aftermath ( where children’s organs were removed from the body and retained by the pathologist, without parental consent), early this century25.

*Autonomy and legal issues*

Healthcare providers must keep a patient’s personal health information private unless directed by a court of law to release the information26 or if it is a notifiable disease like cholera which is mandated by law, to be reported to government authorities**.**

Care should be taken not to discuss the test results in public places such as the hospital cafe or elevators. Disclosure of certain reports may have serious personal and social consequences in the form of psychological trauma and social stigma. These include, but are not limited to, HIV testing, paternity testing and testing for genetic disorders and for drugs of abuse. In these situations adequate counselling is required before the results are revealed. The results of genomic and DNA testing should be revealed only to the patient and the attending physician. The information must be revealed to parents when the patient is a minor. There must be clear policies for securing the confidentiality of results including restricted access to electronic data.In research settings, confidentiality of laboratory results of the research participants should be ensured by maintaining anonymity. This is true even when the data is to be used for epidemiological purposes.

While all journals agree that IEC is essential for experimental studies and most journals desire patient consent for case reports, editors are often flexible about the latter, if patient consent is not possible due to logistic reasons. In fact, The BMJ states that “Images – such as x rays, laparoscopic images, ultrasound images, pathology slides, or images of undistinctive parts of the body – or multimedia files (e.g. video, audio) may be used without consent so long as they are anonymised by the removal of any identifying marks and are not accompanied by text that could reveal the patient’s identity through clinical or personal detail.”

[<https://authors.bmj.com/policies/patient-consent-and-confidentiality/>   accessed 6th July 2019]

This, to us, echoes what Tranberg et al, as well as we believe in - that patient consent is not necessary for the vast majority of images used for teaching and research in pathology provided confidentiality is maintained27.

The advent of social media has led to further issues. The ease and the speed with which images can be disseminated and the easy availability to the images – not only to physicians, but also to the general public – makes it crucial to take great care while using Facebook, Instagram and WhatsApp. Common sense and the routine principles of privacy are sufficient to address this. The wide reach of social media can be used to reach out to many more people than conventional media, but, as has been pointed out, there is no formal peer review system. This could result in unscientific information being put out – which, by itself, is unethical. There is, of course, exchange of ideas after the posting of an image or an idea and posts have been known to be taken down28. However, once published on the web, it is likely that some files will remain on some sites, in their uncorrected versions. Crane and Gardner recommend that patient-specific data must be modified (eg. alter the age or the site of the lesion) if it does not alter the context of the message being transmitted28. They point out that generations of textbooks have carried images for educational purposes and rightly conclude that the benefits of sharing images outweigh the risks.

1. **Beneficence:**

Healthcare providers have a duty to be of benefit to the patient as well as to take positive steps to prevent and remove harm.

*Beneficence and laboratory reports*

Laboratory investigations should be performed in a manner that will ensure maximum benefit to the patient. An accurate and timely laboratory diagnosis is essential for treatment. Beneficence implies that the laboratory physician has to be proactive and offer medical advice that extends beyond the mere act of diagnosis. Thus, a report must be appropriately worded and may recommend the taking of a second opinion or seeking help or advice of experts in a particular subspecialty.

Informing a physician about a critical value in a patient is not only sound medical practice but is also a moral requirement. Failure to inform a critical value could violate the principle of *Primum non nocere*.

*Beneficence and financial issues*

“Kickbacks” or “cuts” or fee-splitting by pathologists with physicians who refer patients or specimens to them are a common problem in India and probably in other countries. Kickbacks are, without a doubt, unethical and there should be no place for such a practice in any ethical health system. No patient benefits from fee-sharing between physicians, a practice which only results in the patient ending up paying more. Thus, the concept of beneficence also overlaps with the idea of non-maleficence.

*Beneficence and research and education*

Besides the examples mentioned above which are unique to laboratory medicine physicians, there are areas which are relevant for all physicians. While undoubtedly, it is component of medical service to which the principles of medical ethics apply best to, areas such as research and teaching must also be seen through this ethics lens. Failure to publish a paper when a researcher is in the know of an important finding, even if it is a negative finding, is now considered unethical because it could lead to a waste of resources and time and also potentially puts other patients at risk, if some other researcher decides to pursue the same hypothesis subsequently. It behooves all physicians to have an inquiring mind and to publish the fruits of their research, so that other physicians and their patients benefit from the research. This research must be published only in legitimate scientific journals; predatory journals (pseudojournals) often stoop to unethical practices. An ethical physician-researcher must not associate with them or publish in them. Besides the fact that these journals do not follow peer review, is the part that because these journals are often not indexed in standard or recognised indexing bases, the data – often on patients or animals who have undergone potentially dangerous procedures – is often lost to the scientific world29, 30.

Likewise, we believe that it is a professional obligation for pathologists/ physicians to teach not only students but also colleagues and staff as well as the general public. After all, the word “doctor” is derived from the Latin word *docere*, to teach.

3. **Non-maleficence:**

This is the principle of *Primum non nocere*. No intentional harm or injury should come to the patient or research participant either through acts of commission or omission. Manipulation of data for any purpose is a violation of the principle of non-maleficence and is contrary to the basic tenets of medical ethics and good medical practice.

A wrong diagnosis may lead to inappropriate and unnecessary treatment and may include unwarranted surgery or chemotherapy or radiation therapy.Any errors in analysis and interpretation should be disclosed to the clinician concerned. While all samples must be treated as precious samples, it goes without saying, of course, that certain samples are more precious than others because repeat samples may simply not be available. Most anatomic pathology material , as well as certain other samples such as CSF fall into this category.

*Non-maleficence and communication*

Good and appropriate communication between the pathologist and clinician colleagues is essential for patient safety and sound medical practice31 Because no “one size fits all” in medicine, it may be appropriate for a pathologist to individualise and modify the contents and style of her style of reporting, in order to reduce the chances of misinterpretation of a report. This is particularly true in diseases and in organ systems which have more than one classification or terminology or units of measurement.

Direct communication between pathologist and the patient is rather limited. A recent report on this subject raises the subject of a fee for service for a patient-pathologist meeting32. with the editorial that such an act would be unprofessional. That financial considerations may adversely influence practice of anatomic pathology have also been raised by Murphy33

*Nonmaleficence and error in medicine*

The topic of error in medicine – both, in general, as well specifically in laboratory medicine - has been addressed now for the past two decades. There have been specific references to error in medicine, ever since the report by the Institute of Medicine ( now known as National Academy of Medicine) in 199934. The initial report, has been followed in 2015, with a report which dealt with error in diagnosis35.

Errors do take place in laboratory medicine and may be preanalytical, analytical or post-analytical. Because of the complex nature of laboratory medicine and the fact that there are multiple steps and many people involved in the processing of a patient sample and the eventual laboratory report, occasional errors are inevitable. How must these errors be dealt with – and who must the error disclosure be made to? Error in pathology has been the subject of research and commentary in the recent past.36-39. In one study of laboratory directors, while most admitted to having made errors and having admitted them to their clinical colleagues, very few disclosed them to the patients themselves36.

Whereas ideally, the pathologist must disclose the error to the patient, the practice is generally for the treating physician to do so. There are unresolved issues, which cloud the matter. The exact definition of error itself – as interpreted by pathologists – is sometimes nebulous37. While an error of commission (eg. labelling a benign lesion as cancer) is clearly an error, does the same apply for an error of omission ? (eg. missing vascular wall invasion in a cancer, a feature that could lead to change in treatment and prognosis). Pathologists also believe that many patients may not be in a position to understand the context and the mechanics of the medical error. Likewise, they believe that physicians too may not be able to appreciate the subtleties of laboratory practice.

Lack of training in communicating with patients – and of course, the fact that pathologists often do not meet their patients and hence are unable to build a patient-doctor relationship only makes the issue more complex37. Indeed, given the ground realites, it is likely that the first – and only – time that a pathologist may establish contact with a patient will be at the time the error is to be admitted. Regional practices and different social structures across peoples around the world also add to the complexity of the issue.

Given the fear and the reality of litigation as well as trial by media and social media and of the rising problem of violence against doctors40, it is not surprising that there is no clear consensus among pathologists as to what the appropriate approach should be. The implementation of tumor boards and other speciality case conferences as well as intradepartmental consensus meetings helps in the reduction of error. Such meetings are now standard practice in an evidence-based medical practice.

When one conducts a retrospective study in pathology, it is not uncommon to unearth erroneous diagnoses made in the past. There are also obvious ethical concerns, which arise when one retrospectively learns of an error committed by an earlier colleague - or by oneself. How does one deal with such error – particularly if the event has taken part in the recent past? Should one inform the patient of the earlier error? What are the legal implications of such disclosure? What does one do if one realizes that a particular colleague is responsible for a significantly large number of errors?These are no easy or practical answers to these difficult questions41.

Nonmaleficence and screening for disease

Screening for disease is another example of an activity that, while it has the potential to benefit some, also offers the possibility of actually causing harm to some. Physicians inviting the general public for screening tests should communicate the benefits as well as the risks of the procedure. A perfect example is breast cancer screening, which not only detects cancers, but also often picks up small lesions that would likely not have been clinically significant and not been detected in routine practice. However, the detection of the mass on imaging leads to anxiousness and worry, subsequent surgery and occasionally a problematic borderline breast lesion. False positive and false negative results exist in all screening (and, of course, in routine) investigations and it is necessary to counsel patients about them.

In a similar vein, the ubiquitous annual health check –which has a substantial laboratory component - needs a judicious approach. Whereas they have been the norm for much of the past half century, relatively recent evidence from the Cochrane library and from others suggests that the routine health check makes little difference to mortality from cancer and cardiovascular disease42,43. Yet, doing away entirely with all health checks is also likely to be an erroneous step. A balanced view - which from the point of view of laboratory medicine, would imply the selective use of clinically indicated investigations, rather than uniform panels of tests for all – maybe the most appropriate step.

*Nonmaleficence and overdiagnosis*

Other related and unexpected ethical issues have also surfaced in recent years. The easy availability of ultrasound has led to a marked increase in diagnosis of small thyroid nodules with the result that there has been a veritable ‘epidemic’ of cases of papillary carcinoma of the thyroid. How many of these papillary carcinomas are biologically malignant? How many are incidentalomas which would have been asymptomatic and ideally should have never been detected? Schnadig44 advises that the concept of overdiagnosis must be included in pathology education as well as to the public and that limits must be set, by consensus with the physicians concerned, for screening by ultrasound and fine needle aspiration as well as mutation analysis.

Similarly, genetic testing also often yields unexpected findings and raises challenging ethical issues pertaining to autonomy and consent45.

*Other issues*

Overinvestigation and the performance of unrequired tests also leads to unnecessary expenditure for the patient or for the institution. Wastage of resources is an ethical issue and must be addressed by pathologists3

Finally, it must be noted that while the concept of “harm” or non-maleficence usually refers to the living, it is paramount that we offer the same principles of respect to the body, while we deal with the dead, at autopsies.

1. **Justice:**

Justice is fairness and equality and fair distribution of resources in society.

The laboratory and its personnel should treat all patients fairly and without discrimination. Healthcare personnel have duties not only towards the patient but also towards society.4 Distributive justice in the allocation of scarce resources is achieved by preventing unnecessary laboratory investigations which are often not indicated in a particular clinical condition thus leading to wastage of manpower, reagents, cost and time. This may additionally hamper the quality of the test results.

Hence, there should be provision of equitable access to laboratory investigations for all patient groups. The approach will, of course vary vastly between countries with Universal health coverage and those where private heath care is the common modality of treatment. In an ideal world, all laboratory tests, including expensive ones, should be available to all without discrimination either because of race or gender or sexual orientation or cultural /socioeconomic/ personal beliefs. However, this is a utopian idea and the reality is quite different. However, there should be balance between individual good and societal common good. Occasionally, healthcare professionals including laboratory personnel are pressurized to deviate from the routine workflow to favour and give prompt reports and attention to celebrities and other “very important persons”. Such situations should be handled in a balanced manner so that no harm is caused to other patients and there is no violation of justice as far as healthcare resources are concerned46.

Equally difficult are situations where clinical colleagues request unwarranted investigations, possibly due to a lack of understanding of the complexity of the test and its attendant merits and demerits or as a part of defensive medicine47. While this is admittedly a difficult problem to solve, attempts must be made to communicate with and educate the clinician, in the best interest – scientifically and financially – of the patient. As Baron points out, overinvestigating one patient may result in another patient being underinvestigated3. Waste of resources and of time is unethical.

Though strictly not within the purview of ethics, professionalism is related to the field of ethics48,49. A surveyconducted by Domen indicates that formal education in ethics was being provided by about 62% of pathology residency training programs while 94% provide informal ethics education in the USA10. Training in ethics is lacking in many undergraduate and postgraduate courses in India and elsewhere12. Bruns et al performed an online survey among 80 directors in 24 countries and showed that formal teaching of ethics was lacking in many training programmes. The time devoted and areas covered were also variable50.

We performed an email/Whatsapp survey to get an idea about the situation in India. We asked heads of departments of pathology in 30 medical colleges in the states of Maharashtra and Karnataka in India and learnt that only 2 colleges, of the 22 which replied, have incorporated ethics education in the postgraduate course in pathology either in a formal manner or informal manner. (It must be noted though, that 15 of the colleges have ethics in the pathology curriculum for undergraduate students).

Thus, we illustrate how the basic tenets of medical ethics are directly relevant to the practice of laboratory medicine.

One of us [ SAP ] has earlier co-authored an article on a Revised Hippocratic oath for medical students for the 21st century.51. In a similar vein, we end with an oath for pathologists, inspired in part, by Ralph Crawshaw’s Physician’s oath for self-insight52.

**A pathologist’s oath**

I promise to use my knowledge of medicine and of pathology to diagnose the patient’s condition, using my training and whatever means that I have in the laboratory. I shall, however, not perform unwarranted tests.

Because one's life is one’s most valuable possession, and because a patient has chosen to trust me with his or her life, I shall respect that trust and shall be grateful to the patient forputting his or her trust in me. Because trust is a two way affair, I would likewise expect the patient to trust me as I endeavor to care and heal.

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I shall follow the laws of the land. Where such guidelines are in direct conflict with my personal beliefs, I shall guide the patient appropriately, even if it means referring the patient to another physician.

I shall respect the patient’s right to confidentiality and autonomy and shall not discuss his or her condition with anyone unrelated to his treatment protocol, without his permission.

​ I shall always endeavor to prevent any kind of harm, whether physical or mental or financial and thus practice non-malefeacence.

The patients beneficence takes priority and I shall, thus, practice the Hippocratic ideal of *Primum non nocere.*

​I shall be scrupulously honest in my dealings with my colleagues. I know that some colleagues can be difficult to get along with; conversely, it is possible that, at least on occasion, I may be unreasonable. Either way, I shall never let my personal likes and dislikes come in the way of patient management.

I shall remain true to my chosen profession of medicine and pathology in particular. I shall not demean myself by offering cuts or kickbacks to anyone. I shall also not accept commissions or freebies or company junkets or other arrangements that might compromise my opinion of people or companies of any kind, which could bias my objective thinking and clinical practice.

I understand that these are my personal beliefs and may not be shared, in full, by every colleague or organization that I may be associated with. Thus, I shall attempt to balance the best interests of all parties involved, with patient safety and care being the prime consideration.

​​I shall keep up with the advances in medical literature and try my best to use the knowledge in a dispassionate and scientific manner. I shall evaluate carefully, all new tests before accepting them as reliable and useful. Thus, I shall not blindly recommend “routine” health checks.

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I shall attempt to spread relevant medical knowledge to the community in whatever manner possible, either by writing in the lay press or at lectures.

I shall attempt my best to work in as scientific and ethical manner as possible. I shall take care not to waste precious resources, and shall continually attempt to reduce costs, without, in anyway, compromising on patient safety.

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I take my work seriously, but not myself. Because laughter is the best medicine, I shall try to see good humour in situations that warrant it.​

I shall treat my technologists as colleagues and try to raise their awareness and understanding of their science.

Were I to perform an autopsy, I would treat the cadaver with the same respect befitting a live person.

​​I am aware that error of one kind or the other, including erroneous diagnosis, is inevitable in my field; I shall take the utmost care to reduce the possibility of error. When I am not certain of a diagnosis, I shall attempt to offer a clinically useful differential diagnosis. Further, when indicated, I shall recommend that the patient seek an expert opinion on the case. Depending on the specific circumstances, I shall help the patient get a second opinion.

​​I shall not venture into areas that I am not qualified to practice. However, given my basic background as a physician, I shall endeavor to offer my opinion, when needed, on matters beyond pathology.

Because medicine consists of life-long learning, I expect to be in a position where I will benefit from the learning of others. Similarly, I hope to be able to learn from the vast experience of my colleagues.

​​I believe that research is an important component of my role as a physician-pathologist. I shall attempt to investigate and find the answers to questions that are of importance, without wasting resources or putting patient safety in jeopardy. I shall concentrate on diseases of local, regional and national importance.

I shall use the most appropriate journal to spread the fruit of my research. I shall not fall prey to predatory journals by either publishing in them or by refereeing their articles.

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I shall not manipulate data or plagiarise or indulge in other unethical publication practices. I shall do my best to encourage my younger colleagues and friends, including those from other departments; this, I shall do, by allowing them to make the effort and earn first author position, where feasible. Because I believe in the circle of life, I would expect them to do the same subsequently with their younger colleagues.

I take this oath voluntarily, not because it is mandatory or fashionable or politically correct, but because I truly believe in it.

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