INTRODUCTION

The practice of Medicine in general and Pathology particularly is prone to human error and it is the constant endeavor of all medical professionals to minimize this error to provide our patients the highest standard of care. The fallout of gross negligence in medical care delivery is often a lawsuit which can be arduous and traumatic for all parties involved. In the West, where the fear of litigation looms large over medical professionals, care delivery systems are more streamlined and transparent, when compared with our country which is traditionally not as litigious a society. However, with the “Glocalization” of the global community and the entry of insurance players in the medical scene, this scenario is fast changing and more informed patient base means greater answerability of the medical professionals and therefore a greater responsibility to provide minimum standards of care. This means that each one of us involved in Surgical Oral Pathology reporting should be aware of our responsibilities and the medicolegal repercussions of our actions.

Alarming but true

The PubMed search engine could not retrieve even a single article with the combined key words search of Medico-Legal issues, Surgical Pathology, and India. When Medico-Legal issues and India were used as key words, seven articles were found but none of them were on practice of Surgical Pathology. Medico-Legal issues and pathology when used as key words, about 112 articles were found. None of the leading textbooks used by the postgraduate students of Oral Pathology speak of the subject of Medico-Legal issues, reflecting the scarcity and negligence towards this subject. Errors in diagnosis not only put patient’s life in danger, but also puts the Oral Pathologist at risk for facing a medico-legal lawsuit. All these statements underline the importance of the present review.

Objectives

This paper focuses on standardized procedures for the various histopathology laboratory exercises. The paper highlights the importance of proper record maintenance with reporting protocols. A list of do’s and don’ts for an Oral Pathologist is provided to help him/her in reducing the probable Medico-Legal issues. It does not in any way address the issue of individual competence and diagnostic abilities: That is an aspect for each individual to introspect upon and take remedial action.
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Medical negligence and the law

Medical negligence means negligence resulting from the failure on the part of the doctor to act in accordance with medical standards in practice, which are being practised by an ordinarily and reasonably competent man practising the same profession.[1]

Liability under the Consumer Protection Act

Services rendered by the doctors and hospitals have been held to be within the jurisdiction of this act.[1] The Consumer Protection Act, 1986 is a benevolent social legislation that lays down the rights of the consumers and provides promotion and protection of the rights of the consumers.[1] The Consumer Protection Act will not come to the rescue of patients if the service is rendered free of charge, or if they have paid only a nominal registration fee. However, if patients’ charges are waived because of their incapacity to pay, they are considered to be consumers and can sue under the Consumer Protection Act.[2] Punishment can vary from case to case; compensation would depend upon damages suffered by the patient.

Liability under tort law

Under civil laws, at a point where the Consumer Protection Act ends, the law of torts takes over and protects the interests of patients. This applies even if medical professionals provide free services. In cases where the services offered by the doctor or hospital do not fall in the ambit of ‘service’ as defined in the Consumer Protection Act, patients can take recourse to the law relating to negligence under the law of torts and successfully claim compensation. The onus is on the patient to prove that the doctor was negligent and that the injury was a consequence of the doctor’s negligence.[2]

Liability under criminal law

In certain cases, negligence is so blatant that it invites criminal proceedings. A doctor can be punished under Section 304A of the Indian Penal Code (IPC) for causing death by a rash or negligent act, say in a case where death of a patient is caused during operation by a doctor not qualified to operate.[3]

Using Right to Information (RTI) Act, a personal query from the author to Karnataka State Consumer Disputes Redressal Commission, (Basava Bhavan, High Grounds, Basaveswara Circle, Bangalore-560001) regarding the number of registered consumer cases was made. Around 162,882 cases in about 13 categories were filed from the time of inception of the act and medical category stands at ninth position and public awareness of medical negligence in India is growing and hospital managements, doctors are increasingly facing complaints regarding the facilities, standards of professional competence, and the appropriateness of their therapeutic and diagnostic methods. As the Figure 1 depicts, the number of cases have increased over the time to present number of 2,474 cases (as on 31st March 2010).

According to Bong,[3] in order for medical negligence to be proven against a medical practitioner, the aggrieved patient must show that:
1. The doctor owed a duty of care towards the patient,
2. The doctor was in breach of that care, and
3. The patient suffered damage as a result of that breach of care.

A duty of care is assumed towards the patient once a pathologist embarks upon a laboratory task on behalf of the patient (e.g. trimming of a specimen and subsequent reading of the histopathology slides). An incorrect diagnosis in a laboratory test which subsequently causes damage to the patient raises the question of medical negligence on the part of the pathologist.[3]

Quality control in histopathology

Surgical Pathology has numerous steps in receiving, processing, and reporting a specimen. It has been estimated that if there is a 1% error rate at each step, with 25 steps the risk of error goes up to 22% and 50 steps goes up to 39%.[4] An article on errors in anatomic pathology concluded that errors in specimen identification accounted for about one-third, defective specimens accounted for 4-10%, analytic misinterpretation accounted for about one-fourth, and defective reports were about one-third to two-fifths of the errors.[5]

Quality control in histopathology can reduce the possibility of misdiagnosis and thus the risk of Medico-Legal issues. Implementation and assessment of quality control is difficult in histopathology because of lack of objective numerical data, descriptive nature of reports, subjectivity, individual judgment,
bias, and nonuniformity of reporting patterns. The concept of quality and its control is applicable to pre-analytical, analytical, and post-analytical processes; and corresponding steps are shown in the Table 1.

The quality control measures proposed here are the ones originally discussed by Iyengar.

**PREANALYTICAL ASPECTS**

Various studies indicate that the majority of errors in the laboratory relate to the preanalytical phase. The same can be said of the histopathology laboratory as well. Correct patient identification by a unique accession number that is traceable to the specimen and report all through the process is of prime importance. There is immense benefit in using barcode technology to minimize errors in sample accession and identification. Dialogue with the clinician about the importance of properly filled forms is needed. As far as possible, diagnosis should conform to clinical, radiographic, and pathological correlation. In cases with missing/incomplete clinical and radiographic data, pathologist should make an effort to extract such information from the clinicians and surgeons.

Listed below are few of the steps one may implement to achieve proper control of the pre-analytical process.

a. The standard operating procedure (SOP) for sample accession, identification, acceptance/rejection, gross examination, and sampling and all the steps that follow should be written in simple language and hence, it can be understood by all. The SOP should be available at the workplace and all technical staff should be aware of its contents. Each step should be well-documented.

b. Usage of standard chemicals and planned changing of chemicals used for processing based on the number of tissues passed through. The limit on number of tissues may be set based on the laboratory’s experience (average 200-300 cassettes is standard number followed in most of the laboratory). The same also applies to the deparaffinization, staining, dehydration, and clearing steps for sections.

c. Usage of controls for routine and special stains daily is strongly recommended. For routine hematoxylin and eosin (H and E) staining, the laboratory may identify one tissue block with a good mixture of hematoxyphilic and eosinophilic tissue as a control. The control slide should be stained before the routine batch of slides and the staining character should be compared with that of the previous day. A record of the staining character should be maintained.

d. Recording the temperature of the paraffin bath, water floatation bath, and slide warming table should be done on a daily basis. These and other equipment should be of standard quality and calibrated at periodic intervals.

e. The microtome should be of good quality and serviced regularly. Periodic calibration of the micrometer should be made to ensure consistency of section thickness. The importance of proper maintenance of the knife need not be reiterated. The use of disposable blades is recommended.

f. The label affixed on the stained slide should be of an appropriate size. The identification should be legible and should ideally carry the name of the laboratory. Using barcode labels, one can incorporate demographic data such as the name of the laboratory, the name of the patient, the laboratory ID number, and the date.

g. All the above steps when performed should be signed by the person performing the individual steps, thus bringing about accountability which makes the person more vigilant and thus lesser chance of negligence.

**ANALYTICAL ASPECTS**

1. For departments with more than one pathologist:
   a. Intradepartmental consultation (review of selected cases by colleagues).
   b. Comparison with other reports (frozen/cytology/histopathology).
   c. Random case review (blinded re-reporting of random cases every 3 months) + by the same person (to check for precision) + by a different person (to check for accuracy).
   d. Hierarchical form of reporting Cases are reported starting from junior most to senior most. This can not only train the junior staff, but also keep the seniors on their toes.
   e. Attending, intra- and interdepartmental conferences (clinicopathological conference).

2. For laboratories run by single pathologist: Though this is a disadvantageous situation, reasonable quality may still be achieved by implementing the following:
   a. Random blinded review of reported cases (precision check).
POSTANALYTICAL ASPECTS

This phase involves report generation without transcription errors, report transmission/dispatch to the right person(s), storage of reported material as well as reported data, and safe disposal of specimens thereafter. Newer models include billing issues, patient safety issues (reporting of critical results), turnaround time (TAT). Monitoring of TAT is of vital importance and laboratories should strive to achieve the goal of signing out the majority of cases within 48 hours of receipt of the specimen. The use of microwaves may assist in improving the TAT especially for small biopsies.

Communication

“Poor communication between pathologist and clinician is a recognized issue leading to the increased risk of a case resulting in malpractice”, and in a study of specimen accessioning and identification deficiencies, “the most common deficiency was the absence of clinical history or a clinical diagnosis”. So communication and maintaining a rapport with the surgeon becomes very vital for arriving at a correct diagnosis and providing adequate treatment to the patient. It is like a continuous cycle that a pathologist would render his duties to best of his efforts and by doing so the impressed surgeon would trust the pathologist and also listen to the suggestions and be open about data regarding the patient, thus resulting in better communication.

Histopathological report

The surgical pathological report is a potentially legal document. The basic style of reporting is individual and this is developed over a period of time with experience and we tend to follow the footsteps of our seniors or professors, but here are the few recommendations of The Association of Directors of Anatomic and Surgical Pathology (ADASP) and following it would make this process of reporting more standardized which may contribute to patient care.

1. Placing all demographic information (patient’s name, location, gender, age, date of birth, as well as the requesting physician’s name,) in the top portion of the report.
2. Printing the name, address, telephone, and fax number of the laboratory at the top of the surgical report.
3. Placing the Surgical Pathology number in the top portion of the report on every page, set off from other information so that it can be easily and quickly identified.
4. Including a summary of the pertinent clinical history as part of every Surgical Pathology report.
5. Including a separate “specimen submitted” section and an adequate gross description in every report.
6. Including in the pathology report, when slides or blocks are received, number of slides and blocks should be mentioned.
7. Recording microscopic features whenever the responsible pathologist deems it appropriate, but a microscopic description need not be part of every report.
8. If technology is available, a photograph of relevant field should be published in the report.
9. Designating those “special” stains that have been performed, listing each stain and results of the staining in the microscopic section.
10. Grading all the tumors for which grading has been shown to be a significant prognostic variable. When a grade is given, the grading criteria or scheme should be recorded.
11. The condition of resected margins should be recorded whenever necessary and using a checklist approach for recording information needed for the patient treatment and prognosis (like grade, depth of invasion, presence or absence of vascular invasion, size of the tumor, type of tumor, etc.) is recommended.
12. All information needed to formulate the pathologic state of a cancer should be present in the report.
13. Documenting intradepartmental consultations in the report, either by identifying the consultant or having the consultant cosign the report.
14. Citing references in the report when pertinent.
15. It is acceptable for the responsible pathologist to make suggestions for additional studies or procedures in the Surgical Pathology report if the pathologist thinks he/she might contribute to the case.
16. Including the date, when the specimen was received and the date of the final report should be present in all Surgical Pathology reports.

Retention and ownership of specimens

There are no defined guidelines, but most of the institutions follow the guidelines put forth by The Royal College of Pathologists of the United Kingdom.

1. Wet tissue: Four weeks after final report.
2. Paraffin blocks: Permanently or at least for the lifetime of the patient.
3. Stained slides:
   a) Histology: Ten years; permanently if practicable.
   b) Cytology: Ten years minimum, longer if possible, to cover at least one recall visit.
Use of human tissue blocks for research

Unfortunately for us, pathologists in India, there are no guidelines or legislations regarding the use of human tissue in research and in the biomedical industry. It is best practice to obtain explicit consent from the patient for most of the cases and the use of tissue blocks to build commercial tissue arrays must be critically reviewed keeping in mind patient privacy, autonomy, and intellectual property rights. The tissue blocks should be promptly returned back to the store once necessary sections are cut and such transaction should be recorded and updated.

Do’s and don’ts for the Oral Pathologists

Every profession has its own trade secrets and one gets more and more refined and experienced with passage of time and constant practice. Here are few suggestions put forth by Kaushal [1] and few from the author himself to obviate some of the avoidable irregularities and save from a possible Medico-Legal issue.

1. Every Oral Pathologist should be a registered practitioner and registration should be renewed regularly.
2. Detailed records in respect to the patient should be methodically maintained and liable to be furnished on demand within 72 h of such request.
3. Consent of the patient whenever the situation demands must be obtained in writing.
4. Do not go beyond the point of your skill.
5. Do not delegate that part of your duty which is within your professional competence and always keep constant supervision over juniors and assistants.
6. Keep yourself informed about the latest developments in various branches of the medical field.
7. Never overstate your qualifications.
8. Give complete details of fees charged from a patient.
9. Remember, publicity is prohibited.
10. Issue genuine certificates and bills.
11. In case the patient comes from another doctor his previous treatment record should be taken.
12. Do not hesitate to treat or diagnose the case for the fear of the law. Every patient is not a potential litigant.
13. In case of errors do sympathize with your patient and explain realities.
14. Without concealing try to improve the condition of the patient if something has gone wrong.
15. In case of doubts and enhanced risk, seek second opinion.
16. Professional indemnity insurance
   It is advisable to take an insurance cover for professional pursuits. The doctor gets an insurance cover so he can practice his profession with more confidence and security. In case of litigation in court, many a time it is the insurance company which gives legal help to the doctors, as the companies maintain a regular fleet of practicing lawyers who are expert in the field.
17. One should judge the case and if any feeling of a mishap is in the mind then should not wait until a lawsuit is filed or even notice letter has been received. Early communication maximizes the pathologist’s chance of successful resolution of the situation, possibly even avoiding a lawsuit altogether.
18. When an indication of a potential problem arises, one should not under any circumstances alter the patient’s records – including glass slides.
19. On receipt of any notice, pathologist should immediately notify the appropriate risk management individual or his legal adviser.
20. The pathologist, even in an understandably agitated frame of mind, should not talk about the case to anyone other than the pathologist’s attorney or an agent of the attorney for whom attorney-client privilege attaches. Under no circumstances whatsoever, should the pathologist get in contact with or discuss the case with the plaintiff or the plaintiff’s attorney and should always communicate through the lawyer. [11]

CONCLUSION

Be it Sports or Medicine, professional ethics is a subject poorly followed and understood in India. Albeit as a Pathologist, one is not often in direct contact with the patient, the clinical impact of a Pathologist’s word is far reaching and tissue diagnosis has to be taken seriously considering its Ethical & Medico-Legal ramifications. Administration should make it a point to include subjects of Ethics and Medico legal issues more stringently in the syllabus and encourage the Oral Pathologist to make this a way of life. A defined role of an Oral Pathologist should be put up by the central authority and monitor the practicing pathologist for quality. But, finally no matter what precautions we take to avoid Medico-Legal issues, there will be mishaps and mistakes and we are bound to learn from such mistakes.

To err is human but to repeat the same mistakes because of negligence and ignorance is unacceptable and punishable. A duty of care and genuine concern towards the patient itself will guide us towards an efficient practice.

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Anand Diagnostics Laboratory, No 11, Blue Cross Chambers, Infantry Road Cross, Bangalore- 560 001 India.

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