

EDITORIAL

Medico-legal aspects of histopathology practice

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Abstract

Medico-legal problems experienced by histopathologists differ from those of other clinicians as they are rarely in direct contact with patients. Nevertheless, the pathologist owes a duty of care to the patient and is liable for medical negligence. In the absence of local guidelines, it is prudent to follow guidelines published by learned Colleges elsewhere. This is also true when delegating duties to non-pathologists, technical and other support staff. Errors in diagnosis and documentation pose the most common problems in histopathology. In this, liability also depends on many factors including the provision of adequate clinical information by clinicians and competence of laboratory staff. Clinicopathological discussions, participation in quality assurance programmes and adherence to standard operating procedures are important audit activities to minimize and detect errors as well as prevent grievous outcome to patients.

Issues also arise over the retention of specimens and reports. In general, wet, formalin-fixed tissues should be kept until histopathological assessment is finalized and preferably after clinicopathological sessions, and even longer if there is potential litigation. Reports should be archival. Paraffin blocks should be kept for at least the lifetime of the patient, and histology slides for at least 10 years, to facilitate review and reassessment. Despite adverse publicity in the foreign press over the use of human organs and tissues for research and education, it is accepted that processed tissues can be used for research and educational purposes provided the patient's identity is kept confidential. Nevertheless, it would be prudent to revise consent forms for surgery and autopsies to include the possibility that tissues removed can be stored or used for research and education.

Good medical practice in pathology encourages a willingness to consult colleagues when in doubt, but advises that the treating clinician be informed if histopathological material is referred away for a second opinion. The Telemedicine Act of Malaysia (1997) requires practitioners outside Malaysia providing diagnosis through telepathology to hold a certificate to practice telemedicine issued by the Malaysian Medical Council. It is likely that the medico-legal scene in histopathology will change in the coming years with the advent of other new ancillary investigative techniques.

Key words: laboratory practice, medico-legal, medical negligence, telemedicine

INTRODUCTION

Compared to ward or clinic-based medical practitioners, the histopathologist is not in the front line when it comes to allegations of medical negligence. However, with the upward trend in medical negligence allegations in Malaysia, histopathologists can no longer expect to be exempted. Moreover, in some subspecialties, for example, cytopathology and neuropathology, pathologists are often in direct contact with patients and may perform invasive diagnostic procedures. There is now an increased awareness of the legal aspects of the practice of diagnostic

pathology, more so with the rapid increase in number of private pathology laboratories throughout Malaysia.

The legal problems experienced by pathologists are slightly different from those of other clinicians. Published articles on the legal problems faced by histopathologists have largely highlighted issues unique to the particular country of the authors' practice.' In this paper, we focus on various legal problems peculiar to the practice of histopathology in Malaysia.

MEDICO-LEGAL ISSUES IN HISTOPATHOLOGY

Errors in diagnosis

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 toward 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.

Although the pathologist is somewhat different from his other clinical colleagues in that he does not normally come into direct contact with patients, he still owes a duty of care to the patient and is liable for negligence. 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), a duty of care is assumed towards the patient. 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. An example is incorrect diagnostic interpretation of a non-malignant lesion as malignant resulting in the patient undergoing potentially damaging chemotherapy or needless surgery. An incorrect diagnosis, however, is not the only reason for medical litigation. Among the common reasons for histopathology-related medical negligence claims in the United States of America are: (1) mistaken diagnosis due to misinterpretation of the slide, (2) a missed important lesion or feature in the specimen either through oversight and failure of sampling and (3) poor wording or omissions in the report leading to failure of the clinician to have an understanding of the nature or extent of the lesion or adequacy of the sample.²

The pathologist, however, is in a different position when it comes to misdiagnosis, compared to his other clinical colleagues. To begin with, the pathologist depends on his clinical colleague for information from the medical history, physical examination and investigations (biochemical results, x-rays or other diagnostic imaging) of the patient, which are relevant for making a pathological diagnosis. Furthermore, the specimen sent to the laboratory would normally be registered and processed by other laboratory staff. In some laboratories, the specimen may even be sampled by a non-pathologist or a pathology trainee. The

interpretation would therefore be dependent to a certain degree upon many factors not of the making of the pathologist, although the pathologist as the person issuing the histopathology report is regarded as responsible for the misdiagnosis. It would be interesting to see if some of the blame can be shifted to other persons, particularly the clinician if there is failure of adequate and accurate provision of clinical information, which resulted in an incorrect diagnosis. However, it must be pointed out that it may be held as the pathologist's responsibility to obtain certain clinical information when it is not provided, e.g. x-ray and mammogram findings, etc.¹ The liability of other laboratory staff will be discussed below.

Notwithstanding the above, an incorrect diagnosis does not always imply that the pathologist is liable, although there may only be a fine line between liability and acceptable error. As with his other clinical colleagues, the pathologist is subjected to the 'Bolam' judgment, named after a famous case (patient) in 1957.⁴ The judge in that case stated that a doctor is not guilty of negligence if he has acted in accordance with a practice accepted as proper by a responsible body of medical men skilled in that particular art. This means that it has to be shown that the incorrect diagnosis was due to negligence and not an acceptable error in each individual case. The decision for negligence would be based on peer review, i.e. upon the opinion of other practicing histopathologists. As far as we are aware, this view will also hold for Malaysia.

Recently there had been an upsurge of interest in medical errors. The Institute of Medicine of the United States of America has estimated that as many as 98,000 hospitalised Americans die every year due to medical mistakes.⁵ In this, histopathology is not exempted. Foucar and Foucar quoted an article in *The New York Times* estimating as many 30,000 cancer diagnoses a year were "wrong" because of pathology errors.⁶ Making a diagnosis is subjective and prone to human error. Inconsistencies have been reported in diagnoses between various pathologists and the diagnoses by individual pathologists studying the same histopathological material (slides) at different times.⁷ It has been shown in various audits held by histopathology departments that serious errors in diagnosis occur at a rate varying from zero to 1.2%.⁸ Evidently, pathologists are not infallible and are capable of making mistakes.

One of the ways to detect and reduce these errors is through an audit process.⁹ Interaction with clinicians, for example in clinico-

pathological conferences, can help by providing clearer insight into the clinical problem, to minimize and detect diagnostic errors and also prevent grievous outcome. Subscription to quality assurance programmes also helps the pathologist to maintain diagnostic acumen and keep up-to-date with reporting practices. It would be interesting to see, in the future, if a laboratory is held liable for errors due to non-subscription to or inadequate quality assurance programmes.

Errors in diagnosis may not only lead the pathologist to a potential medical negligence suit. In some countries, they have resulted in the suspension of the pathologist from practice on the grounds of incompetence. An excellent example is Dr. Samuel Kiberu who, while working as a locum consultant histopathologist in two hospitals in England between 1991 to 1993, made a total of 531 errors in 4230 cases. He was subsequently suspended from practice.¹⁰ Although the suspension of a doctor for incompetence in work performance is unusual in Malaysia, there is no reason why this may not be more seriously considered in the future.

Retention and ownership of specimens and reports

Currently, there are no local guidelines for the duration whereby specimens are to be retained. It is noteworthy that the period of limitation in Malaysia is 6 years.

It is reasonable to keep wet, formalin-fixed, tissue specimens for a duration of time sufficient for the consulting clinician to study the report and for the pathologist to take further samples if this is deemed necessary after a clinicopathological discussion. Certainly if the clinician has informed the pathologist that the case is a potential medico-legal one, it would be wise to keep the specimen for longer, perhaps for a period of a year.' Although it has been recommended that histopathological slides be kept for a period of 10 years, it should ideally be kept longer or even permanently as they may be essential for the follow-up review of the patient. The Royal College of Pathologists of the United Kingdom has issued a guideline on the period of retention of specimens." The following is a summary of the length of time that essential reports or specimens are to be kept:

Documents and paper records

Day book – two calendar years

Protocols for standard operating procedures – both current and outdated protocols should be

dated and kept permanently on file.

Surgical reports – hard copy to be lodged in patient's notes; bound copies to be kept permanently by laboratory.

Post-mortem reports (hospital autopsy) – report should be lodged in patient's record; bound copies of reports to be kept permanently.

Specimens and preparations

Wet tissue – four weeks after final report.

Paraffin blocks – permanently or at least for the lifetime of the patient.

Stained slides –

a) *histology* – ten years; permanently if practicable.

b) *cytology* – ten years minimum, longer if possible, to cover at least one recall visit.

It is debatable as to who would be held responsible for non-retention of specimens should the question of liability arise. Space constraints may lead to specimens, blocks or slides being discarded earlier. Even though the decision for duration of storage may be an administrative one made by a higher authority, the pathologist as the 'captain of the ship' may still be viewed as responsible. Hence, if the pathologist feels that a practice is against the guidelines of the profession, he has the duty of informing this to the administrators. It is very likely that the pathologist will be absolved of any liability if it can be shown that he has informed his administrators about the matter earlier.

Although this has not been a major legal issue, any part of a patient should technically belong to the patient. Therefore, it can be argued that all parts of the body whether it is an amputated limb or an organ, should be returned to the patient when requested for after all the investigations are completed. This is, however, an uncommon request in Malaysia, and is best discouraged as it opens a Pandora's box of issues related to proper disposal of tissues and body parts by patients and their relatives. A problem that more frequently arise is when the patient requests for blocks or slides for referral purposes. It is unsure to whom the blocks or slides belong, although The Royal College of Pathologists, UK, in 1999 stated that 'the durable material thus produced can be considered the property of the entity which produce them,' which essentially means that they belong to the laboratory or institution.¹² However, there is no reason for the pathologist not to return referred slides or to recut new slides for referral when so

required. It must be kept in mind that only original slides (or slides on which the report is based) are considered to be legal evidence in a medical negligence case and thus it is advisable to send away recuts rather than original slides.

The use of organs for research and education is a major issue that has caught the public eye in the Western world. Using the definition by the Royal College above, processed tissues can be used for research even without prior consent of the patient. However, the pathologist should ensure that there is sufficient tissue left for diagnostic review or subsequent prognostic assessments.¹³ It is also the pathologist's and laboratory's responsibility to ensure that sufficient safeguards have been placed to ensure the patient's confidentiality. It would be even more prudent to ensure that future consent forms for surgery/biopsy and autopsy include the possibility that tissue removed be stored or used for medical research and education.

Liability of laboratory staff

In any laboratory, certain duties are delegated to the technical and other supporting staff. Certain mistakes on their part may have profound implications on patients and may lead to a negligence suit, e.g. mislabeling of specimens, mis-typing of names or reference numbers of patients. The pertinent question is who should be held responsible for their mistakes. In Ministry of Health public hospitals, the principle that the "master is responsible for the errors of his servants" usually applies, i.e. all employed staff, from attendants to consultants are the responsibility of the Ministry of Health. Hence, the government would assume financial responsibility for the errors of its employed staff. However, the pathologist as the leader of the laboratory team is expected to assume some responsibilities and may be censured for mistakes of the general laboratory staff.

The situation is not so clear in private pathology laboratories. It would be to a certain extent dependent on the actual contractual agreement between the pathologist and the management. However, it would not be wrong to assume that once again, the pathologist would be held responsible for professional matters as the person in charge of the laboratory.

According to Knight, there should be written practice codes or procedures which the pathologist must ensure all members of his staff are aware of and adhere to.² Once these operating procedures are in place, any mistakes resulting

from deviation from these procedures would exonerate the pathologist from assuming any vicarious liability. A particular pertinent point to consider would be the procedure for trimming (cut-up) of specimens. Many busy histopathology laboratories have delegated the trimming of certain surgical specimens to non-pathologists such as medical officers-in-training or even technologists. In principle, the pathologist is responsible for the macroscopical examination and dissection of tissue specimens including selection of tissue for histological examination, even though it had been delegated to a non-pathologist. According to the Royal College of Pathologists of Australasia,¹⁴ the pathologist should ensure these few steps; -

1. a pathologist must be available to inspect these specimen(s) and provide advice,
2. the non-pathologist performing the task must be appropriately trained to undertake the responsibilities delegated to him or her,
3. a procedure manual covering, in adequate detail, all the delegated tasks must be readily available within the laboratory, and
4. both non-pathologist performing the cut-up and the supervising pathologist must be identified in the final report issued by the laboratory.

Whilst this is only a guideline, in the absence of any similar instructions in Malaysia, it may be of use as a guide to the courts in this country should a medical malpractice suit arise in this particular circumstance. If the pathologists can show that the procedures provided have not been adhered with, then the responsibility may fall upon the non-pathologist. On the other hand, if the policy had been adhered with, a genuine mistake by the non-pathologist would be acceptable as protocols have been followed.

Referrals to other pathologists

As in other disciplines of medicine, there may be referral of cases from a pathologist to another pathologist for further interpretation or opinion. Unlike other branches of clinical medicine where the patient is being referred and therefore he or she is fully aware of that fact, it is usually the histology slides or blocks which are being sent to another pathologist for consultation together with a summary of the patient's medical history. This may pose a problem if the patient has not consented to the referral and especially when the patient has to pay for the consultation. In this, the pathologist is in a more difficult position

than his other clinical colleagues, as he does not come into direct contact with the patient and as such, will have no opportunity to obtain consent from the patient. Traditionally, the pathologist is viewed as having acted in good faith and in the interest of the patient. The Royal College of Pathologist's (UK) document on Good Medical Practice in Pathology encourages a willingness to consult colleagues when in doubt, but advises that the treating clinician be informed if histopathological material is referred away for a second opinion.¹⁵

Post-mortem examinations

In Malaysia, histopathologists are expected to perform medico-legal as well as hospital post-mortem examinations. Once again, the issue of consent is important. In medico-legal post-mortem examinations, authorisation for the examinations is given by the police officer on behalf of the magistrate conducting the inquiry into death.¹⁶ This authorisation overrides the relatives' objections. The pathologist is duty bound to proceed with the post-mortem examination once the authorisation has been issued for failure to do so would be considered a breach of the Criminal Procedure Code and General Orders." It would be interesting to see if the histopathologist can refuse to perform certain medico-legal post-mortem examinations which require specialised expertise citing inadequate training as a reason.

The Criminal Procedure Code also states that the post-mortem examination is to be undertaken by a Government Medical Officer." There has been an occasion when the post-mortem report from a pathologist from one of the local medical schools was rejected by the Court as he had not come within the definition of a Government Medical Officer. Subsequently the Medical Act 1971 was amended to broaden the definition of a Government Medical Officer. As a result, the Director-General of Health was empowered to appoint any fully registered medical practitioner to perform post-mortem examinations and the practitioner was then deemed to be a Government Medical Officer.¹⁸

The problem of confidentiality in post-mortem reports has already been discussed in an earlier article.¹⁹ Basically, the problems of confidentiality and release of autopsy findings are different in both medico-legal and hospital autopsies. In the former, the police on behalf of the coroner requests for an autopsy and therefore, the confidentiality is owed to the authorities. In

the latter, the situation is more straightforward for the ethical responsibility lies towards the next-of-kin who consented to the autopsy. Medico-legal issues may arise when medico-legal autopsy reports are released for insurance or litigation purposes without the consent of the investigating authorities.

Lately, as a result of inquiry into the high death rates of children undergoing heart surgery at Bristol Royal Infirmary, United Kingdom, the practice of retention of organs for research by pathologists without parental consent was brought to light.²⁰ There has been a large public outcry which resulted in the Royal College of Pathologists of UK and Australasia issuing guidelines on the retention of organs obtained from post-mortem examinations.^{21,22} It is prudent that the College of Pathologists in Malaysia adopt similar guidelines to prevent similar adverse publicity locally.

Applications of modern technology in histopathology

Telemedicine is one of the important flagship applications of the Malaysian Multimedia Super Corridor Project. The Telemedicine Act has been gazetted as a result.²³ Here we would like to highlight a few pertinent points with regards to telemedicine in the practice of histopathology.

Telepathology i.e. the practice of pathology through telemedicine has been used for remote diagnosis of frozen sections, histology and cytology samples in many countries. Other potential applications currently in research are consensus diagnosis, implementation of multimedia databases, teaching and quality control.²⁴ Among the legal aspects of telepathology would be the liability for negligence as a result of incorrect diagnosis. It would be prudent for the pathologist giving an opinion to store the images on which his opinion was based, as arguments may arise later as to which images were included in the transmission. Ultimately who is responsible for the pathological diagnosis of a case remains unclear. It would be reasonable to hold as responsible, the pathologist providing a primary diagnostic service through telemedicine. However, if a second opinion is sought through telemedicine, responsibility is likely to lie with the referring pathologist as he would be the one issuing the report. Consent would be another problem to be cognizant of. The Telemedicine Act explicitly requires that the written consent of the patient be obtained, and confidentiality safeguards apply.

In the situation of making a diagnosis by telepathology, the problems of registration for practice by a pathologist in another country appears to be resolved as there are provisions in the Telemedicine Act requiring the medical practitioner outside Malaysia to be issued a certificate to practice telemedicine by the Malaysian Medical Council. Alternatively the pathologist can practice through a locally registered medical practitioner holding a valid practising certificate.²³

Guidelines to reduce medical malpractice

1. Ensure there are written protocols not only for all technical procedures but also for day-to-day work processes (labeling of specimens, typing of reports etc.). Make sure that the staff adhere to them.
2. Ensure your laboratory participates in a recognised quality assurance programme and uses audit to reduce errors.
3. Ensure good communication with clinicians, especially in the case of frozen section diagnoses.
4. Consult other colleagues when faced with a difficult case or in doubt.
5. Adopt recommended guidelines or consensus developed by learned societies in the practice of histopathology.^{25,26}

Concluding remarks

With the changing scene in the practice of medicine, pathologists are no longer exempted from medical negligence. The pathologists too have to maintain a good standard of practice, ensure that laboratory staff follow appropriate guidelines and protocols, have good communication with clinicians, ensure clear documentation of procedures and results, maintain records and subscribe to appropriate, recognised quality assurance programmes. It is likely that the medico-legal scene in histopathology will change in the coming years with the advent of laboratory information systems, new information technology and other new ancillary diagnostic investigation techniques.

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