LEGAL IMPLICATIONS IN ROUTINE CLINICAL PRACTICE

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Introduction

Medico-legal management forms an important part of the total patient care. With the rapid progress of medical science and technology, the law and ethics pertaining to clinical practice have become more complicated in order to meet the various complex issues that have arisen. Medical ethics is a code of behavior accepted voluntarily within the profession, as opposed to statutes and regulations that are imposed by official legislation. Much of medical ethics consists of good manners and civilised behavior in the general sense, but there are certain matters, which are particular to the practice of the profession of medicine. Matters of immediate concern in routine clinical practice are pertaining to consent, confidentiality and negligence.

Strictly ethical issues generally involves the respective professional bodies, medical council in the case of the doctors and the dental council in the case of dentists. This kind of self-regulation is essential in order to safe guard the interest of the public. On the other hand medical practitioners could be taken to task and may end up in litigation for failure to follow the fundamental principles involved in the day to day practice of medicine or dentistry. There are occasions where even criminal charges are being brought against doctors in the course of their routine duty. In the western countries, particularly in the United States of America, there is so much pressure on the medical practitioners owing to the high possibility of civil litigation, the practice of medicine has become quite challenging. What they call, "defensive medicine" is practiced in that part of the world with the main intention of safe guarding the interest of the doctor. Every doctor should compulsorily enroll himself with a medical protection society and the premium for indemnity goes on increasing owing to more and more litigation. There are law firms specialising in litigation cases, and looking for possible victims to be used on a fee-sharing basis. As a result health care becomes expensive and doctors are reluctant to undertake borderline cases for treatment due to fear of litigation in the event of failure. The high chance of developing residual impairment in certain specialties such as orthopaedic surgery and plastic surgery has made these specialties very expensive. The medical practitioners will develop a cautious attitude and always tend to safeguard themselves. They may carry out unnecessary investigations to safeguard themselves. Such a scenario is certainly a very unhealthy situation. It does not help the patient or the medical profession in any way. There is no doubt that the medical profession should have the freedom and right to pursue its professional duty without undue interference, but that professional freedom should have its limits, and the interest of the public must be paramount in the provision of services.

The present day medical practice, though scientifically very advanced has become more technically oriented. The concern and respect for human feelings and human values are slowly but steadily disappearing. There is a serious break down in communication between the doctors and the patients. In spite of increased efficiency in the system of health care delivery in the developed countries, the practice has become less intimate and less compassionate. The earlier period family practitioner system that maintained a very close personal relationship is fast disappearing. The traditional family practitioner had all the time for the patients and their families and he was more a family friend than a physician on whom public had great faith. In modern day medicine, with busy hospitals and so many specialisms, the patients are just part of the system, mere cases, who are moved from one place to another, similar to a factory production line. There is less and less personal communication and understanding and hence the public too has no reluctance in suing the doctors. In today's context proper and efficient health care delivery is broadly regarded as a right rather than a privilege in the developed world. So it is not surprising that the incidence of litigation against doctors will continue to rise.

Malaysia is basically an Asian country with its own culture, traditions and values. Over the last few decades there has been tremendous economic and social developments and naturally this will also have an influence on the traditional beliefs and values. Anything-untoward happening to patient was earlier accepted as fate, ill lucks, destiny or karma and rarely the doctors were blamed. The present urbanisation, modernisation and mass communication has created a better awareness and this has lead to less tolerance to accept any failures on the part of the doctors by the patients and their relatives. Already many practitioners have been taken to task.

The objective of this article is not to go into the intricacies of all aspects of unethical and unprofessional is-

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sues that are involved in medical practice. It is intended to high light some of the very fundamental principles involved in the day to day clinical practice, which is often the underlying cause for civil litigation.

Consent in medical practice

Touching some one without the authority may be an assault. An assault can take the form of a criminal or civil offense or both. It is obvious that in a doctor patient relationship there is almost always a physical contact. From a casual examination at the out patient department to an internal examination and other kinds of invasive and non-invasive treatment, involve physical contact. It is a person's right to decide what is to be done to his or her body. This right is protected by the criminal law by making unauthorised interference against the human body punishable as crimes with either fine or imprisonment or both (1). In civil law unauthorised interference with a person's body is considered as trespass, and action may result in awarding of damages. Therefore the primary objective of consent is to protect the interest of the doctor from unnecessary allegations and civil and criminal litigation. On the other hand it is also intended to protect the interest of the patient by making him or her fully aware of the steps that are taken by a clinician prior to agreeing on these medical procedures.

For routine history taking and basic clinical examination in an out patient department implied consent is generally applicable. By the patient's behavior the doctor is given to understand that the patient has no objection to such procedure and hence the consent is implied. But for more intimate examination and other procedures for investigative or therapeutic purposes, an express consent has to be obtained. This can take the form of verbal or written consent. Written consent has the advantage in the event of a contest.

In any situation consent has to be "informed consent", before it becomes valid. Taking the patient's signature on a consent form does not amount to a valid consent. Before obtaining consent, it is the doctor's responsibility to provide the patient sufficient details and information regarding the patient's condition, expected procedure, may be investigation or even treatment. The patient should be told in clear manner and in a language that the patient understands the various advantages and disadvantages of the proposed course of action and the possible expected results, and then it is the patient's responsibility to make the final decision. The patient who gives consent should be in a clear state of mind and have the intellectual capacity to understand all the implications and the doctor should satisfy himself about this point. Consent should always be for a specific procedure or a course of action. However, exception to this rule does exist under certain situations. Some time a doctor may have to obtain a "blanket consent", if he is not certain about the patient's medical condition, for example undertaking an explorative operation where no definite diagnosis has been made. Under such a situation a doctor should have the freedom and flexibility to decide what is best for the patient.

If the patient is unconscious or in a confused state of mind then a consent has to be obtained from the next of kin. Same principle is applicable to minors and mentally retarded patients. Age of consent for medical treatment is 18 years. For minors and mentally retarded generally parents or guardians could provide consent. This is referred to as "consent by proxy"(2). However, under life threatening or emergency situation a doctor can carry on with the necessary treatment if there is no way of immediately obtaining a valid informed consent. In such a situation the procedure should be very specific, pertaining to the emergency or life threatening condition. In the above event, however, all relevant details and circumstances have to be carefully and methodically documented in the patient's clinical notes. There are unusual situations where sometimes parents may refuse to give consent for blood transfusion or surgery on their children who are minors. Those who follow the faith of Jehovah's Witness are against blood transfusion. In an emergency situation if the parents refuse blood transfusion, a doctor in good faith can ignore the refusal of consent and go ahead with the necessary treatment. It is widely recognised in both criminal and civil law that there are certain circumstances in which acting out of necessity legitimates an otherwise wrongful act. However, in order to protect himself, the doctor should have another doctor to be a witness to his course of action and the entire details have to be carefully documented in the clinical notes. No junior doctor should resort to such a course of action. As an alternative, if time permits, it may be possible to obtain a court order to render the necessary treatment. In the case of adults who refuse consent the course of action to be taken could be different. In spite of explanation, if there is refusal then the patient should be made to sign a written declaration of his refusal(3).

Consent regarding donation of organs in the living is different. Various countries have various regulations pertaining to living donors and cadaver donors. In the case of minors, there are many safeguards introduced in spite of parental consent for donating an organ (4,5). In some countries such as in Canada, minors cannot be donors (6). Owing to various mal-practices many countries have brought in restrictions even for adult living donors (7). Cadaver donation is governed by the Human Tissue Donation Act and here too the regulations vary from country to country.

Medico-legal postmortem examination is covered under the Criminal Procedure Code. According to sec-

tion 329, 334 and 337 of the Malaysian CPC, sudden, unnatural and unexpected deaths could be subjected to a medico-legal postmortem for which no consent is necessary from the next of kin (8). On the other hand the next of kin has no right to object to such a procedure and if they object it will amount to contempt of court. The situation with clinical postmortem is different. Clinical postmortem does not come under the purview of the criminal procedure code and is conducted usually at the request of the clinician who has treated the patient. Clinician may be interested in knowing the exact nature and extent of the disease, efficacy of the treatment that was rendered, circumstances for failure and so on, in other word it is purely an academic exercise. In such a situation consent from the next of kin is essential.

Another situation is when police produce patients, victims and suspects to be examined in a medico-legal context. No medico-legal examination should be undertaken without a valid consent. The person should be told that he could object to the medical examination. Further more the findings will be divulged to the police and courts. In the case of minors and mentally handicapped, parental or guardian's consent is needed. If the law enforcement agency feels that a medical examination is essential but the person refuses consent, then an order may be obtained from court so that examination could be carried out without consent. There may be a situation when a person could be brought in for examination by the police who is heavily intoxicated and not in a fit state to give a valid consent. Usually such cases are admitted to ward. In such cases the doctor can carry on with the observation, examination and even undertake certain basic investigations such as blood alcohol estimation but should withhold all such information until the person had fully recovered and is in a fit state to make up his mind about consent. This is beside the immediate treatment that is rendered for his clinical state.

There is also exception to examination without consent under certain situations such as new admission to prisons, recruiting personnel into the armed forces, at the port of entry and so on.

Confidentiality

One of the most important principles of a doctor patient relationship is the maintenance of secrecy on the part of the doctor and this is referred to as confidentiality or professional secrecy (9). By virtue of the nature of the duty, the doctor gets knowledge of many personal and intimate details about a patient and the patient's family. For medical reasons the patient is often obliged to divulge all kinds of personal information to the doctor and from the doctor's point of view such information may be of relevance to advise and decide on the appropriate course of treatment and so on. Hence, one can understand the importance of confidentiality and the dangers of violating such a code of conduct. The original Hippocratic Oath and the subsequent International Code of Medical Ethics emphasise the importance of confidentiality(10). According to the international Code of Medical Ethics, "a doctor shall preserve absolute secrecy on all he knows about his patients because of the confidence entrusted in him". A breach of this confidence may lead to civil litigation. However, this principle at times gets the doctors involved in unnecessary conflict with the police and the lawyers. In the legal profession, whatever that is being conveyed by the client, the lawyer is not obliged to divulge, and no one can force him to do so. Such absolute immunity usually does not exist in the case of doctors with regards to cases pertaining to clinical practice. However, there are countries where there are laws preventing doctors from violating confidentiality.

In the day to day practice of a doctor there are instances where doctors may have to divulge certain confidential information about patients to third parties. This is done under certain circumstances and the information are always passed on to responsible persons who are in some way officially involved, or covered by statute or in the larger interest of the community. Divulging information under such special circumstances is termed as "privileged communication".

There are many instances where the doctor by virtue of various statutes is expected to divulge information. Statutory notification of deaths and births, infectious diseases, notification of poisoning, abortions are all such examples. Information can be released with the patient's consent. In insurance claims or compensation claims once the patient gives consent there is no difficulty in releasing the information. In the event of death, the next of kin or the lawyer who looks after the interest of the deceased can authorise the release of such report. Necessity may arise for the doctor to disclose certain information to immediate family members about the patient's illnesses in the larger interest of the patient. Certain sensitive and distressing issues may be better discussed with relatives rather than the patient. In the course of clinical management, information about patient can be shared among professional colleagues including dentist and nurses who are involved in the patient care. Information can also be shared in ethically approved research projects.

Courts of law can always request for confidential reports about patients and the doctor is obliged to abide. But the order should originate from the presiding judge. If the details are harmful to the patient, the doctor may politely appeal to the Judge about non-disclosure of such information and explain to him the harm it could cause to the patient. Some judges may agree with the doctor

and some may decide to take up such matters in the chambers rather than in open court. If the judge still persists then the doctor has no alternative but to comply. There are also certain special legal provisions where information has to be divulged. For example under the prevention of terrorism acts any person who has been injured in suspicious circumstances, it is the doctor's duty to notify the police. Failure to do so may lead to criminal charges being brought against the doctor. In Government medical institutions all traumatic cases are as a routine notified to the police. However, in the private sector the doctor will have to obtain consent before doing so. In certain suspicious cases, if the patient refuses consent in the private sector, the doctor can refuse to treat that patient altogether. The doctor is not obliged to take any one as his patient in the private sector even in a life threatening emergency. The situation in the government sector of course is different, and the doctor is under an agreement with the hospital to treat all cases and to abide by the hospital manual of procedure.

Another sensitive area where certain information has to be divulged are in the larger interest of the public. While providing respect for confidentiality it is important that the public interest too should be protected. For example there is no doubt that the public has to be protected from drivers who are colour blind or suffering from epilepsy particularly if they are driving public vehicles, or food handlers who are suffering from infectious diseases like typhoid. But there are certain protocols that have to be followed in handling such cases. Initially the doctor may advise a colour-blind driver to change his job and if he fails to do so then his employer should be notified. Similar cases have to be handled in a responsible manner and authorised officers should be informed about various medical conditions for necessary action, the objective of this exercise being to protect the interest of the public.

Negligence

There is nothing more disastrous in a doctor's professional career than an action for negligence against him. The concept of medical negligence is comparatively new. It did not come into prominence until the early 19th century. With the industrial revolution and urbanisation in the West, people gradually began to understand their rights and privileges. Surgeons, apothecaries and lawyers were the earliest to get involved in cases of negligence.

It is common law that for liability to occur in medical negligence there must be a duty of care owed by the doctor to the plaintiff, the defendant doctor must be in breach of that duty, and there must be damage to the plaintiff of a form recognized by the law as compensable, and which is caused by, and is not too remote a consequence of, the breach of duty (11). So first and foremost there should exist a doctor-patient relationship in a professional sense. In the private sector no doctor is compelled to take any one as his patient, but once he or she is under his care as a patient, immaterial whether it is for a fee or otherwise, the doctor-patient relationship is in force. From that moment the doctor will be compelled to treat him unless the patient on his own breaks that contract. As indicated earlier in government hospitals the situation is different and the doctors will have to treat all the patients who come to the hospital, owing to their agreement with the institution.

Basically most cases of medical negligence arise out of breach of duty. Here the test of a "reasonable man" is applied. A practitioner is expected to exhibit reasonable skill and care in the over all management of his patient. Accordingly, he should not do some thing that an average doctor would not have done and will do some thing that an average doctor would have done. What is expected out of a doctor is the reasonable skill and care. However, according to the seniority and specialisation the court may expect different degrees of skill.

In medical practice negligence can take the form of civil or criminal negligence. But the majority of cases are civil in nature. Civil negligence is a tort or civil wrong and the punishment will be in the form of compensation. To prove civil negligence the three elements namely, duty of care; breach of that duty; and a damage directly arising from it, should exist. Proof of guilt is the balance of probability, the usual civil test. Criminal negligence is very rare and the offence is so great as to be an offence against society. For example a doctor under the influence of alcohol operates on a patient and if some thing goes wrong, then the doctor could be charged for being criminally negligent. In such cases the state undertakes the prosecution unlike in civil cases and the proof is beyond reasonable doubt, the criminal test. If found guilty the doctor may end up in prison and may even have to pay compensation.

A doctor is not liable simply because of failure to cure or for bad results, provided that he has exercised reasonable skill and care. His reasonable skill, care and judgement should conform to the accepted medical practice(12). No procedure is free of risks. Even an ordinary, routine procedure can turn out to be a disaster. When some thing untoward happens, the doctor cannot be held liable, provided that he has followed the correct procedure and taken proper precautions. If the doctor has secured all necessary data on which he has made the judgement, then he is not liable even if there is an error of judgement. At this point it is very relevant to emphasise the importance of an informed consent. If something goes wrong which may be considered as unexpected or unusual could become negligent if there is no valid consent.

Often the doctors are sued for making very ordinary mistakes and failure to follow basic instructions and guide lines. Many cases are instances of carelessness or recklessness. Improper instructions over the phone, illegible writing, not carefully reading the notes, mixing up of specimens and drugs, not obtaining proper consent, poor communication with the patients and other para-medical staff are some common causes. Some time no proper clinical ward rounds are performed. Consultants, registrars and junior doctors may not do the rounds together and hence instructions may not have been properly passed down the line for necessary action. Negligence is rarely due to technical malfunction but much more often due to human errors in communications and understanding (13).

In civil negligent cases, the patient or the patient's relatives take the doctor to court. Usually the plaintiff has to prove that the defendant doctor had been negligent. But under the doctrine of "res ipsa loquitor", which means in Latin "the fact speaks for itself", the balance of proof may be shifted from the plaintiff to the defendant. Sometime the mistakes that are made by doctors are so obvious that the plaintiff will not have any difficulty in proving the case. For example amputating a wrong limb may come under this doctrine. Leaving behind swabs or instruments in body cavity is another instance. Under such circumstances the defendant doctor may have to fight his case and try to prove that he was not at fault. The doctor may take up the position that the patient's condition was so serious that he had to finish surgery as soon as possible. This time constraint could have inadvertently given rise to the above situation (14).

- Precaution against negligence:
- There should be a good doctor patient relationship
- Always obtain valid informed consent
- Keep accurate and complete medical records
- Do all relevant investigations
- Do not guarantee a cure
- You are responsible for the supervision of your subordinates
- Communicate well with the patient
- You must be sure about your limitation
- Never hesitate to consult other professional colleagues if in doubt
- Never undertake procedures in specialties in which you are not competent
- Keep reasonably informed of recent development in your specialty
- Be considerate about human life and human suffering

Conclusion

As already mentioned medical ethics has become more and more complicated and the medical profession is in a dilemma at times to take a correct and an acceptable course of action. But still, if the medical litigation cases are analysed, most of them have not originated from ethically complicated situations but from very basic fundamental principles of clinical practice. The objective of this article is to educate an average medical practitioner regarding the legal implications that he may be encountered in his day to day practice. It is always presumed that a doctor acts in good faith. But if he fails to follow the fundamentals of clinical practice especially pertaining to consent, confidentiality and negligence then he runs the risk of litigation. It is also important to remember that a practitioner in a hospital differ in many respects from that of a private practitioner. Medical doctors some time forget this difference and get involved in unnecessary embarrassment.

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