Open Disclosure

Dr Milton Lum FRCOG
Elected Member, Malaysian Medical Council

Hipocrates enunciated the fundamental principle of medical practice *Primum non cere* (First do no harm) when he stated "The physician must...have two special objects in view with regard to disease, namely, to do good or to do no harm...I will follow that system of regimen which, according to my ability and judgment, I consider for the benefit of my patients, and abstain from whatever is deleterious and mischievous."

Medical care today can and does pose harm to patients. This was put succinctly by Prof Cyril Chantler, who stated that medical care "used to be simple, ineffective and relatively safe; now, it is complex, effective and potentially dangerous." (*The Role and Education of Doctors in the delivery of Healthcare The Lancet, 3 April 1999; 353 (9159): 1178-81*)

Harm data

The harm data from various countries bears this out. It is estimated that in the United States (US), potentially preventable adverse events comprise about 10% of admissions and there are about 50,000 preventable deaths annually i.e. one every 10 minutes. The potentially preventable costs comprise 5% of the US budget.

Medical error is the third biggest cause of death in the United Kingdom. The potentially preventable adverse events constitute about 10% of admissions i.e. about 850,000 annually. There are about 40,000 deaths annually and the estimated cost to the health system of adverse events is £7.2 billion (16% of budget).

There is similar data from Australia where adverse events were found in 10% of reviewed admissions, with each adverse event accounting for 7.1 extra bed days. 51% of the adverse events were highly preventable; 13.7% of total adverse events led to permanent disability and 4.9% resulted in death.

Whilst there is no published local data, it can reasonably be estimated that the numbers do not differ much from the data from other countries.

Information about the relationship between the timing of the adverse events and adverse events due to negligence was provided by Brennan et al from the Harvard Medical Practice Study *(Qual Saf Health Care 2004; 13: 145*)

Category	Timing of adverse event	**Adverse event***	**Adverse event due to negligence***
1	Occurred and discovered during index hospitalization	647 (50.6) 55,046 (49.4)	156 (51.0) 15,257 (51.2)
2	Occurred during index hospitalization, discovered during subsequent outpatient care	78 (6.1) 6,327 (5.7)	7 (2.3) 776 (2.6)
3	Occurred during index hospitalization, discovered during subsequent hospitalization	67 (5.2) 6,526 (5.9)	19 (6.2) 1,857 (6.2)
4	Occurred during outpatient care before index hospitalization but discovered during index hospitalization	167 (13.1) 16,142 (14.5)	59 (19.3) 6,019 (20.2)
5	Occurred during earlier hospitalization but discovered during index hospitalization	319 (25.0) 27,420 (24.6)	65 (21.2) 5,903 (19.8)

*For each category the first row of values indicates the sample count, and the second row the weighted population total. Data are presented as number (%).

Various definitions

When patients suffer harm in the course of receiving medical care, doctors are under legal and ethical obligations in many jurisdictions to disclose it to the patients. This obligation has been termed "open disclosure."

There are various definitions of open disclosure. The Australian Council for Safety and Quality in Health Care (2003) define it as "*the open discussion of incidents that result in harm to a patient while receiving health care*." The Joint Commission on Accreditation of Health Care Organizations (2001) of the United States require that "*Patients and, when appropriate, their families are informed about the outcomes of care, including unanticipated outcomes*." The Chief Medical Officer, England (2003) reminded staff of the National Health Service of their "*Duty of candour requiring clinicians and health service managers to inform patients about actions which have resulted in harm*." The Canadian Patient Safety Institute (2008) define it as "*the process by which an adverse event is communicated to the patient by health care providers*."

The Law

There are two types of law i.e. Statute law, which is enacted by Parliament and the Common law, whose roots are in English common law which originated in the 13th century. It is premised on the doctrine of precedent i.e. lower courts are bound by earlier judicial

decisions made by higher courts. The process progresses from one decided case to another. Sometimes, common law principles are redefined or declared by statute law.

Private Health Care Facilities and Services Act (PHFSA)

There are provisions in the PHFSA regarding patients' rights. Section 35 states that "*A licensee of a private healthcare facility or service or the holder of a certificate of registration or the person in charge of a private healthcare facility or service shall make available, upon registration or admission, as the case may be, its policy statement with respect to the obligations of the licensee or holder of the certificate of registration to patients using the facilities or services*" and that "*A policy statement shall cover such matters as may be prescribed*."

Section 36 provides for the grievance mechanism. It states "*The licensee of a private healthcare facility or service or holder of a certificate of registration shall establish a plan for grievance mechanism for patients using the premises of the private healthcare facility or service*" and "*A grievance mechanism plan and grievance procedure shall be as prescribed*."

There are provisions in the Private Health Facilities and Services (Private Hospitals and other Private Health Care Facilities) Regulations regarding the provision of information to patients. Section 27(a) states that "*The licensee or person in charge of a private healthcare facility or service shall take reasonable steps to ensure that a patient is provided with information about the nature of his medical condition and any proposed treatment, investigation or procedure and the likely costs of the treatment, investigation or procedure."*
Contravention of this regulation will, upon conviction, lead to a fine not exceeding RM10,000 or to imprisonment for a term not exceeding three months or to both.

Section 40 of the Private Health Facilities and Services (Private Hospitals and other Private Health Care Facilities) Regulations specifies that the process for addressing any grievance against a private healthcare facility or service.

There are similar provisions in sections 18 and 27 of the Private Health Facilities and Services (Private Medical Clinics and Private Dental Clinics) Regulations.

There are no such statutory provisions for government health care facilities and services. However, they have similar administrative directives in place.

Common Law

One of the landmark cases in Malaysian law was the *Foo Fio Na v Dr Soo Fook Mun & Anor* case. The judgement made, on 30 December 2006, changed the landscape of medical practice.

The question posed to Federal Court was "Whether the *Bolam* test as enunciated in *Bolam v Friern Hospital Management Committee [*1957] 2 All ER 118, in the area of medical negligence should apply in relation to all aspects of medical negligence."(*Steve Shim CJ (Sabah and Sarawak) in Foo Fio Na v Dr Soo Fook Mun & Ors* [2002] MLJ 129 : 130C)

The answer was "…we answer the question posed to us in the negative and order that this appeal is allowed with costs…"*(Siti Norma Yaakob FCJ in Foo Fio Na v Dr Soo Fook Mun & Anor* [2007] MLJ 593 : 612)

The decision of the Federal Court was "We are of the view that the *Rogers v Whitaker* test would be a more appropriate and viable test of this millenium than the *Bolam* test… 'Doctor knows best' should now be followed by the qualifying words 'if he acts reasonably and logically and gets his facts right" quoting from Lord Woolfe's Inaugural lecture in the Provost series [2001]

The Federal Court stated that "The *Bolam* test has no relevance to the duty and standard of care of a medical practitioner in providing advice to a patient on the inherent and material risks of the proposed treatment…The practitioner is duty bound by law to inform his patient who is capable of understanding and appreciating such information of the risks involved in any proposed treatment so as to enable the patient to make an election of whether to proceed with the proposed treatment with knowledge of the risks involved or decline to be subjected to such treatment."

The *Bolam* test states 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…Putting it the other way round, a doctor is not guilty of negligence if he is acting in accordance with such a practice, merely because there is a body of opinion which takes a contrary view." (*McNair J in Bolam v Friern Management Committee* [1957] 2 All ER 118)

By contrast, the *Rogers v Whitaker* test states "Except in the case of an emergency or where disclosure would prove damaging to the patient (therapeutic privilege), a medical practitioner has a duty to warn the patient of a material risk inherent in the proposed treatment… A risk is material if in the circumstances of the particular case, a reasonable person in the patient's position, if warned of the risk, would be likely to attach significance to it; the medical practitioner is or should reasonably be aware that the particular patient, if warned of the risk, would be likely to attach significance to it….The fact that a body of reputable medical practitioners would have given the same advice as the medical practitioner gave does not preclude a finding of negligence. Generally speaking, whether the patient has been given all the relevant information to choose between undergoing and not undergoing the proposed treatment is not a question the answer to which depends upon medical standards of practice."

The rationale for the Federal Court's decision was "…it is for the courts to adjudicate on what is the appropriate standard of care after giving weight to "the paramount consideration that a person is entitled to make his own decisions about his life." (*Rogers v Whitaker* [1992] 175 CLR 479: 487, *F v R* [1983] 33 SASR : 193)

That the court has the right to set the standards of care has already been stated in some Malaysian court judgements i.e. "…while evidence of acceptable medical practice is a useful guide for the courts, it is for the courts to adjudicate on what is the appropriate standard of

care after giving weight to the "paramount consideration that a person is entitled to make his own decisions about his life" (*Kamalam v Eastern Plantation Agency* [1996], *Tan Ah Kow v Government of Malaysia* [1997])

Although the Federal Court stated "The *Bolam* test has no relevance to the duty and standard of care of a medical practitioner in providing advice to a patient on the inherent and material risks of the proposed treatment" it made no specific pronouncements on diagnosis and treatment.

The question arises as to whether there is a difference between disclosure, diagnosis and treatment.

The judgement in *Rogers v Whitaker* states "There is a fundamental difference between, on the one hand, diagnosis and treatment and, on the other hand, the provision of advice or information to a patient." *(Rogers v Whitaker* [1992] 175 CLR 479)

It clarifies further "Whether a medical practitioner carries out a particular form of treatment in accordance with the appropriate standard of care is a question in the resolution of which responsible professional opinion will have an influential, often a decisive, role to play; whether the patient has been given all the relevant information to choose between undergoing and not undergoing the treatment is a question of a different order. Generally speaking, it is not a question, the answer to which depends upon medical standards of practice." (*Rogers v Whitaker* [1992] 175 CLR 479)

The answer to the question as to whether there is a difference between disclosure, diagnosis and treatment was provided in another Australian case, *Naxakis v Western General Hospital*. The judgement was explicit i.e."To allow that body of opinion to be decisive would re-introduce the *Bolam* test into Australian law. In *Rogers v Whitaker*, this Court rejected the *Bolam* test and held that a finding of medical negligence may be made even though the conduct of the defendant was in accord with a practice accepted at the time as proper by a responsible body of medical opinion. To many doctors, judges and lawyers, it must seem unsatisfactory that a doctor can be condemned as negligent by a jury when he or she has acted in accordance with a respectable body of medical opinion. But as long as there is evidence that other respectable practitioners would have taken a different view concerning what should have been done by the defendant, the issue is one for the jury, provided of course the evidence is reasonably capable of supporting all the elements of a cause of action in negligence." (*Naxakis v Western General Hospital* [1999] HCA 221)

The rejection of *Bolam* in Australia was total until legislation was enacted to reintroduce a modified *Bolam* test for diagnosis and treatment and the *Rogers v Whitaker* test for the provision of information.

The Federal Court judgement discussed the *Naxakis v Western General Hospital* case but did not make any pronouncements. However, it is pertinent to note that the discussion took up about 13% of the Federal Court's judgement. One should ponder on its statement "In the realm of diagnosis and treatment and the duty to warn, the ruling of the High Court of Australia in *Naxakis v Western General Hospital & Another* [1999] HCA 221 was able to

settle the ongoing doubt which existed in *Rogers v Whitaker*, as to whether, *Rogers* was restricted to cases relating to negligent advice only." (*Foo Fio Na v Dr Soo Fook Mun & Anor* [2007] MLJ 593: 612)

Unfortunately, the Federal Court did not provide guidance on the materiality of the risks i.e. the extent of information that has to be provided to patients, particularly the types of risk, and how detailed the information should be.

A search for guidance from the Australian cases throws some light. For example, it is stated in *Rogers v Whitaker* [1992] *"*A risk, even if it is a mere possibility, should be regarded as material if its occurrence causes serious consequences" and in *F v R* [1983] "the nature of the matter to be disclosed, the nature of the treatment, the desire of the patient for information, the temperament and health of the patient, and the general surrounding circumstances."

Ethical aspects

The Malaysian Medical Council's (MMC) Code of Professional Conduct (Code) states "The public is entitled to expect that a registered medical practitioner will provide and maintain a good standard of medical care. This includes:-
a. conscientious assessment of the history, symptoms and signs of a patient's condition;
b. sufficiently thorough professional attention, examination and where necessary, diagnostic investigation;
c. competent and considerate professional management;
d. appropriate and prompt action upon evidence suggesting the existence of condition requiring urgent medical intervention; and
e. readiness, where the circumstances so warrant, to consult appropriate professional colleagues."

The MMC's Code is supplemented by its guideline Good Medical Practice which states "A patient who complains about his treatment has a right to expect a prompt and appropriate response. The doctor has a professional responsibility to deal with complaints constructively and honestly. The patient's complaint must not prejudice his further treatment…If a patient has suffered serious harm for whatever reason, the doctor should act immediately to put matters right. The patient must receive a proper explanation about the short and long term effects. When appropriate the doctor should offer an apology."

Duty of disclosure

It is apparent from the preceding paragraphs that a doctor has a legal as well as an ethical duty to provide advice or information before treatment.

But what should a doctor do after an adverse event occurs? There is an ethical duty of disclosure if one reads the MMC's documents referred to in a previous paragraph. Whether there is a legal duty of disclosure is less clear. The courts have not made a categorical statement on this. However, in the light of the current medico-legal climate, it would be imprudent for a doctor to assume otherwise.

Consequences of adverse event

Patient dissatisfaction after an adverse event is expressed in many ways. The patient could sue the doctor and/or health care facility in the worst case scenario. Whilst the reasons why patients sue doctors have not been studied in Malaysia, it has been done elsewhere. Vincent C et al's study in the United Kingdom (*Why do patients sue doctors. Lancet 1994; 343: 1609-1613)* was illuminating. There are five main reasons stated viz :

- Reactions to incidents
  - Anger 90%
  - Bitterness 80%
  - Betrayal 55%
  - Humiliation 40%
- Standards of care – "So it would not happen to anyone else" 91%
- Explanation – "I wanted to understand what happened" 91%
- Compensation – "To get an admission of negligence" 81%
- Accountability – "So that doctors would know how I felt" 68%

Adverse events also impact on doctors. Newman MC reported on the emotional impact of mistakes on doctors *(The emotional impact of mistakes on family physicians, Archives of Family Medicine 1996;5(2):71-75)*. They were:

- Self doubt 96%
- Disappointment 93%
- Self blame 86%
- Shame 54%
- Fear 50%
- All but one doctor stated they needed support.

Waterman reported on the emotional impact of medical errors on doctors in the United States and Canada (*Jt Comm J Qual Pat Saf 2007; 33(8): 467-476)* in a survey completed by 3,171 of 4,990 physicians in internal medicine, pediatrics, family medicine, and surgery (64% response rate). The findings were:

- Increased anxiety about future errors 61%
- Loss of confidence 44%
- Sleeping difficulties 42%
- Reduced job satisfaction 42%
- Harm to their reputation 13%
- 1/3 of physicians involved with near misses only also reported increased stress

The doctors were more likely to be distressed:

- after serious errors when they were dissatisfied with error disclosure to patients (OR 3.86, CI 1.66, 9.00)
- perceived a greater risk of being sued (OR 0.28, CI 1.50, 3.48)
- spent greater than 75% time in clinical practice (OR 2.20, CI 1.60, 3.01)
- were female (OR1.91, CI1.21, 3.02)

Only 10% of the respondents agreed that health care organizations adequately supported them in coping with error-related stress

The views expressed in this article are personal and do not represent that of any organization the writer is associated with.

To be continued in the next issue of the MMC Bulletin