Recent developments in informed consent: the basis of modern medical ethics

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Abstract
Informed consent is today of paramount importance to the dental and medical professions because of modern ethical issues and medico-legal consequences. This paper looks at the risk communication by medical and dental practitioners as the patient's right to know constitutes the basis of modern medical ethics. The paper discusses informed consent for both clinical practices as well as for clinical research study.

Key words: medical ethics and informed consent.

INTRODUCTION
Patients' rights to know and to decide, using free will, is based on the ethical concept of patient autonomy. The 'basis of consent' to medical or dental treatment is expressed by an American judge, Cardozo, in the case of Schloendorff v Society of New York Hospital (1914), as:

Every human being of adult years and sound mind has a right to determine what shall be done with his own body; and a surgeon who performs an operation without his patient's consent commits an assault.

Patients have the decisive role in the medical decision-making process. Their right of self-determination is recognized and protected by the law of informed consent.

Disclosure of information: doctor's legal duty

What needs to be disclosed? What is the level or standard of disclosure? In recent times, there has been much judicial activity in medical negligence for doctors on the standard of medical care in England, Australia, USA, Singapore and Malaysia. Let's examine some of the different jurisdictions for a comparative analysis.

The American position

The doctrine of 'informed consent' started in the American case of Salgo in 1957. The court decided that, for there to be an intelligent consent by the patient for the proposed treatment, the doctor had a duty to disclose all necessary facts. A patient requires sufficient information of risks, benefits, limitations and alternatives to make a true choice on treatment. In the American case of Canterbury v Spence the court held that:

...The patient's right of self-decision shapes the boundaries of the duty to reveal. That right can be effectively exercised only if the patient possesses enough information to enable an intelligent choice...
The Canadian position

In the case of Reibl v Hughes,^8 the Canadian court held that a doctor had a duty to disclose ‘material’ risk. But it is for the court, and not for medical doctors, to decide what is ‘material’.

The Australian position

In Australia, the landmark decision of Rogers v Whittaker^9 strongly attacked Bolam and firmly rejected the English Bolam test. Patients must be informed of the material risks of the proposed medical treatment. In the Rogers case, the High Court stressed the importance of good communication between doctor and patient, and the right of the patient to receive information about his medical care. The majority was of the opinion that:

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 the patient . . . because the choice to be made calls for a decision by the patient on information known to the medical practitioner but not to the patient, it would be illogical to hold that the amount of information to be provided by the medical practitioner can be determined from the perspective of the practitioner alone or, for that matter, of the medical profession.

The judgement in Rogers v Whittaker stated:

In Australia . . . the standard of care . . . is not to be determined solely or even primarily by reference to the practice followed or supported by a responsible body of opinion in the relevant profession or trade. Even in the sphere of diagnosis and treatment, the heartland of the skilled medical practitioner, the Bolam principle has not always been applied. Further . . . particularly in the field of non-disclosure of risk and the provision of advice and information, the Bolam principle has been discarded and, instead, the courts have adopted the principle that . . . it is for the courts to adjudicate on what is the appropriate standard of care.

This is reasserting the ‘prudent patient’ and the ‘therapeutic privilege’ American test of Canterbury v Spence, relating to risks that are material to the prudent patient making an informed decision.

The Singapore position

Until 2002, the Court of Appeal decision in Singapore on medical negligence – Dr Khoo James & Anor v Gunapathy^10 – there were inconsistencies in the application of the Bolam test in the Singapore courts. The Gunapathy case has finally explained the working of the Bolam test, as well as indicating the policy considerations of the Singapore courts vis-à-vis the medical profession. Referring to the House of Lords decision in Bolitho v City and Hackney Health Authority^11, the Court of Appeal explained that the Bolam test is supplemented by the Bolitho ruling. So the Bolam test did not represent immunity from judicial inquiry over the medical process. An expert view, in order to qualify as representative of a responsible body of medical opinion, had to satisfy the threshold test of logic. The testimony must have a logical basis, and the experts had to direct their minds to the comparative risks and benefits and reach a ‘defensible conclusion’ on the matter. The Singapore court affirmed that the Bolitho ruling was a timely addendum to the Bolam test, giving it a commonsense understanding which was hitherto unexpressed.

The English position

The majority of the House of Lords in Sidaway v Board of Governors of Bethlem Royal Hospital and the Maudsley Hospital^12 held that the Bolam test applied to advice about medical treatment. But if a proposed treatment has a risk of serious consequences, a court can decide that the prudent doctor should warn of it. Thus a risk, even if it is mere possibility, should be regarded as ‘material’ if its occurrence causes serious consequences such as death or paralysis.

In a dissenting judgement, Lord Scarman in the Sidaway case stated that whether a doctor had breached his duty of care in information disclosure was a question for the courts to determine, and should not be based upon professional practice. He was of the view that a patient had a right to be informed of a ‘material’ risk of medical treatment.

The ‘prudent patient’ test determines what risks are ‘material’: that is, what significance would a reasonable patient attach to advice given in deciding on treatment.

However, there was a movement away from Bolam and evidence that the English courts will not rigidly apply the Bolam standard in disputes over information disclosure as seen in cases such as Newell and Newell v Goldenberg^13 and Williamson v East London and City Health Authority and others. ^14

In the 2000 case of Penny & Anor v East Kent Health Authority,^15 the English Court of Appeal held that the Bolam test applied, subject to the qualification that expert evidence of the defendant’s conduct accorded with sound medical practice and was capable of withstanding logical analysis.
Implications of a new English case: Chester v Afshar

The Bolam test has been challenged in jurisdictions such as the USA, Canada, Australia, South Africa and Malaysia. With the modern trend toward patient’s rights and self-determination, there is now a much greater evidence of a shift in the patient–doctor relationship from a ‘traditionally paternalistic philosophy’ to a ‘partnership relationship’ between medical practitioner and the patient.

In October 2004, the English House of Lords ruling in Chester v Afshar changes the law on informed consent. This affects jurisdictions, especially Commonwealth countries that base their legal systems on English law. In the Chester case, Miss Chester had a discectomy to treat her low back pain. Her surgeon had performed the procedure competently. However, Miss Chester was one of the 1–2% of patients that suffers the risk of cauda equina syndrome. Miss Chester sued her surgeon for failing to warn her about this particular risk. As the surgeon lacked documentary evidence that he had warned her of the risk, the court then accepted Miss Chester’s claim and liability was proven. Miss Chester agreed that she might still have had surgery if she had been made aware of the risk. But Miss Chester said that she would have taken some time to think and may have had the procedure on another day and by a different surgeon. The Court by a majority viewed that the test of causation (i.e. the negligence not to inform about the risk had led to the injury) had been satisfied on policy grounds. That policy is the patient’s autonomy and dignity which should be respected by allowing her to make an informed decision.

Lord Hoffman said this argument ‘was about as logical as saying that if one had been told, on entering a casino, that the odds on No.7 coming up at roulette were only 1 in 37, one would have gone away and come back next week or gone to a different casino.

The Chester case makes it more crucial now than ever to warn patients about significant adverse outcomes, risks and complications for any procedure. Doctors must ensure that patients are fully informed and understand the information given. The patients must also be given sufficient time to digest the risks disclosed. It is also important to document in the medical notes, if treatment is refused after information disclosure.

Informed consent: the medical duty to inform

Empowering the patient will mean that the patient is part of the team in control of his medical and dental health. This will make it much easier for the doctor to communicate risk information to him. Informed consent is not simply the patient signing a consent form but more importantly, is a process of a detailed discussion between the doctor and his patient.

Informed Consent is enforced by both medical ethics and the common law. The common law places a medical duty on doctors to inform and warn. Failure to communicate is a failure in duty and thus resulting in a breach of the medical standard of care. But in an emergency situation where a patient is unable to consent, due to unconsciousness, a doctor may perform emergency treatment based on the doctrine of necessity or implied consent to save life.

Standard of care for medical practice: the Bolam principle

The question is: ‘How much risk information to tell?’ The standard of medical care has been formulated by the court in the English case of Bolam v Frien Hospital Management Committee (1957), known as the ‘Bolam test’. In this case, a patient, Mr Bolam, sued the hospital and its doctors for damages, claiming negligence on the part of the doctors in performing electroconvulsive therapy on him which resulted in fractures. The patient also claimed that he did not give informed consent to the hospital doctors. Judge McNair stated the now famous ‘Bolam test’ in his judgement:

‘... (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... a man is not negligent, if he is acting in accordance with such practice merely because there is a body of opinion who would take a contrary view. At the same time that does not mean that a medical man can obstinately and pig-headedly carry on with some old technique if it has been proved to be contrary to what is really substantially the whole of informed medical opinion...’

From the Bolam test arise the three essential elements, namely:

• the method which the doctor practices must be accepted as proper;
• with this practice ‘accepted’ as proper by a ‘responsible body of dental men skilled in that particular art’;
• the fact there exists another body of opinion which takes a contrary view of the doctor’s practice does not make the doctor negligent.

The Bolam test which clearly sets out the standard of medical care for professional practice has been accepted by Singapore courts for a long time. Recently, in the...
Singapore Court of Appeal case of Dr Khoo James & Anor v Gunapathy (2002) affirmed the Bolam principle and explained that the Bolam test is supplemented by the Bolitho case. This involves a two-stage inquiry:

- whether the medical expert directed his mind to the comparative risks and benefits (bare and unsupported assertions would fail this test) and;
- whether the medical expert had arrived at a ‘defensible conclusion’ after the balancing process (‘defensible’ in that it is internally consistent and does not controvert proven extrinsic facts and does not ignore advances in medical science).

The opinion of a responsible body of medical men is subject to the court’s scrutiny to ensure that it can withstand logical analysis.

Further, the Bolitho case does not allow a court to decide which competing view of medical evidence should apply. Whether a dental practice is or not acceptable should be decided against the opinion of a responsible body of medical opinion. Applying the Bolam test, the judge must rely on medical experts – the Bolam standards of medical men. There are many cases in the Singapore High court accepting the Bolam principle such as Supuletchimi d/o of Rajoogopal v Tay Boon Keng Suit no. 210 of 2000; Vasuhi d/o Ramasamypillai v Tan Toch Seng Hospital Pte Ltd (2001) 2 SLR 165; Yeo Peng Hock Henry v Pai Lily (2001) 4 SLR 571; and Re An Infant (Suit no. 1554 of 2001).

With Bolam, it would mean that whether a doctor was negligent or right in not informing a patient of a material risk is a matter to be assessed by the standards of ‘opinion of a responsible body of medical men’ and not by the court. However, if the patient specifically asks about the risks of a medical procedure or treatment, the doctor must answer the inquiry fully.

It is therefore necessary for doctors to communicate risk information to patients so that the patients can make his decision. The patient’s consent to medical or dental treatment will then be considered in law as ‘real’ and ‘valid’ because sufficient information is given to him to make a decision for an ‘informed consent’. Communication skills should match with the technical competence. Thus, risk and information communication must be accurate to keep up with biotechnology advances and any recent developments.

Checklist – duty to inform in medical practice
A useful checklist for medical practice is as follows:

- the name of the operation;
- the nature of the proposed treatment;
- what the operation involves;
- other treatment options of alternatives;
- the potential complications;
- side-effects;
- the risks, including risks of no treatment;
- the special precautions required postoperatively;
- the benefits of treatment;
- the limitations of treatment;
- the success rate and failure rate of operation;
- what happens on admission; and
- how the patient will feel after treatment.

Informed consent in clinical trials
Informed consent in clinical studies is much stricter, as the human subject or volunteer may not receive any direct benefit from the clinical research trial. Singapore’s regulatory framework on informed consent is governed by international codes (such as Declaration of Helsinki, Belmont Report and Nuremburg Code) and the Singapore Guidelines for Good Clinical Practice, the Medicines (Clinical Trials) Regulations and the Medicines Act.

Clause 23 of Declaration of Helsinki states that when obtaining informed consent for research projects, the doctor should be particularly cautious if the subject is in a dependent relationship with the doctor or may consent under duress. In such a case the informed consent should be obtained by a well-informed doctor who is not engaged in the investigation and who is completely independent of this relationship. People who are ‘in a dependent relationship’ could also include students, trainees and subordinates.

Section 11 of Medicines (Clinical Trials) Regulations set out the legal requirements to obtain informed consent. Section 14 lists the matters which must be discussed with the subject. Before a clinical trial is conducted, the following 21 matters must be discussed fully with explanation, on pain of a maximum fine of $5000 or to a maximum imprisonment of 12 months or both:

1. that the clinical trial involves ‘research’
2. the purpose of the clinical trial
3. the treatments to be administered in the clinical trial and the probability for random assignment of each treatment
4. the procedures to be followed in the clinical trial including all invasive procedures
5. the responsibilities of the subject
6. which aspects of the clinical trial are experimental
7. the reasonably foreseeable risks or inconveniences to the subject, embryo, fetus or nursing infant
8. the reasonably expected benefits, including whether there is any intended clinical benefit to the subject
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9 any alternative procedures or treatments available to the subject, and their potential benefits and risks
10 any compensation and treatment available to the subject in the event of research-related injury
11 any pro-rated payment to the subject for trial participation
12 any anticipated expenses to the subject for trial participation
13 that the subject’s trial participation is voluntary and that he may refuse to participate in or may withdraw from the clinical trial at any time without penalty or loss of benefits which the subject would otherwise be entitled
14 the licensing authority and people who will be granted access to subject’s medical records
15 the extent to which records identifying the subject will be kept confidential
16 that the subject will be informed timely of any relevant information affecting his willingness to continue participating in the clinical trial
17 the people to contact for further information about clinical trials and rights of subjects and in the event of injury relating to trial participation
18 any foreseeable circumstances or reasons for which the subject's participation may be terminated
19 the expected duration of the subject’s participation in the clinical trial
20 the approximate number of subjects involved in the clinical trial
21 any other information which the licensing authority may require to be given.

Further, section 4.8.6 of Singapore Good Clinical Practice (GCP) requires the language used regarding information about the trial should be as non-technical as practical and should be understandable to the subject.

Other consequences of non-compliance with regulatory requirements would include the breach of terms of the sponsor’s Clinical Trial Agreement and the non-publication of research results as seen in clause 27 of Declaration of Helsinki (which the Singapore GCP prescribes to). Human experimentsation not in accordance with ethical principles are unlawful.

Surveys on quality of informed consent of medical professionals

Three known surveys were done in Canada, USA and Singapore. The Canadian survey which was monitored at St Mary’s Hospital Centre, Montreal published the results in the article ‘Monitoring clinical research: report of one hospital’s experience’. This survey revealed many problems in obtaining informed consent, for example, consent form missing, witness signature missing, and subject signature missing.

In the American survey on ‘Quality of Informed Consent in Cancer clinical trials: a cross-sectional survey’ which was published in Lancet revealed major deficiencies in patients not being aware of non-standard treatment, the potential for incremental risk or discomfort, the unproven nature of treatment and the uncertainty of benefits to self. These problems are referred to as the ‘therapeutic misconception’. Lower knowledge scores were associated with use of languages other than English. Efforts are needed to ensure that their consent is adequately informed by expanding the use of interpreters and translated consent forms.

In Singapore, a survey of 100 medical professionals was carried out using a self-administered questionnaire comprising 34 questions. These questions were designed to cover the eight basic elements of informed consent, namely, methodology, risks, benefits, alternatives to treatment, confidentiality of data, compensation, contact information and voluntary participation, as it is applied in clinical trials. The objective of the survey was to investigate the perceptions and practices of medical professionals (both in medicine and dentistry) in matters relating to informed consent. The highlights of the results were presented under the eight elements of informed consent. (This research survey won the best poster presentation award in the category of ‘Allied Health Sciences’ at the Singapore National Healthcare Group (NHG) Annual Scientific Congress 2004, 9th–10th October 2004. and its abstract is published in the supplement issue, Vol 33 No 5 September 2004. Annals, Academy of Medicine, Singapore. This poster presentation on ‘Understanding the Basic Elements of Informed Consent: A Survey of Medical Professional’ is written by Associate Professors Giam Yoke Chin, and Catherine Tay Swee Kian, Professor Goh Chee Leok, Eugene Tan, and Drs Chan Yiong Huak and Martin Chio.)

The statistical results showed that 17.4% of those surveyed fail to ensure patients and volunteers fully understand the methodology of the clinical trial, and 17.3% do not disclose the risks completely. 16.1% do not explain the benefits of the proposed treatment, with 17% not discussing the alternatives available. 29.8% fared poorly in assuring patients of confidentiality of medical records, while 17.1% fail to convey the idea that participation in the trial is voluntary. The worst performing areas were in the elements of compensation and contact information, where 51.9% do not inform patients that compensation is available in
the event of a trial-related injury, while 51.3% do not provide patients with contact information for the trial.

This survey found that most medical professionals comply with the elements of informed consent. But in general, there was a significant proportion of medical professionals with inadequate understanding and are unaware of the eight elements of informed consent, especially in clinical trials. Therefore, training of doctors on the proper way of taking informed consent is strongly needed.

CONCLUSION

It is submitted that logically as part of the patient’s contributions to a shared clinical decision, a patient should make his own informed consent or refusal to the doctor’s information disclosure and dental recommendations. This process of informed consent will truly reflect the fundamental medical ethics of autonomy and self-determination thereby respecting the patient’s choice of dental interventions. It surely has greater ethical support for a good medical and dental law on informed consent.

To avoid negligence and breaching the medical and dental standard of care in informed consent, the doctor should in giving medical or dental advice, exercise his skill with competence in accordance with accepted practice. He should discuss his diagnosis and treatment plan with the patient. If the patient inquires about the risks of proposed medical or dental treatment, the doctor must disclose the material risks to the patient. It is good practice to document contemporaneously his advice to which the patient has consented. In doubt, it is prudent for the doctor to seek a second opinion from his colleagues professing a similar skill. This is to ensure that the doctor’s professional practice is in accordance with the opinion of a responsible body of medical men.

Better communication between the doctor and his patient and with a proper informed consent taking as reviewed above, will avoid claims based on perceived rather than actual negligence on the part of the doctor.

Therefore, doctors familiarizing themselves with the essential eight elements of informed consent is not only respecting biomedical ethics but is essential to protect the safety and welfare of patients, as well as maintaining good clinical practice and ethical research studies. Dr H Beecher20 in his article said that ‘... A far more dependable safeguard than consent is the presence of a truly responsible investigator’. Informed consent has today emerged as a significant ethical and legal standard of medical and dental practice.

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