

Recent Developments of Informed Consent in Eye Research

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Abstract

Introduction: Informed consent is a very important ethical concept in medical and research ethics. The law of informed consent in medical negligence cases has developed over the years. Today, it is impossible to ignore the legal aspects of informed consent given the new ruling in the English case of *Chester v Afshar* [2005]. This landmark case has made significant inroads into the development of the concept and may have great impact on all Commonwealth jurisdictions including Singapore. The court in *Chester's* case considered the modern basis of medical ethics in informed consent situations. In this article, I review legal developments in informed consent, and compare these with the more recent developments in *Chester's* case and the Malaysian case of *Foo Fio Na* [2006]. In particular, I note that *Foo's* case clearly followed the approach in the Australian case of *Rogers v Whitaker* case. **Methods:** Literature review. **Results:** I reviewed 2 recent cases – the English *Chester* case and the Malaysian *Foo Fio Na* case (wherein the Federal Court followed the Australian court in *Rogers v Whitaker* which involved an ophthalmology medical negligence lawsuit). **Conclusion:** There is a rising global trend of relying on medical ethics principles in giving more respect to the individual patient or research human subject in the area of informed consent before they participate in clinical research studies. Following the recent legal cases on informed consent – *Chester v Afshar*, *Foo Fio Na* and *Rogers v Whitaker* – it has become more crucial than ever to exercise extreme care in obtaining informed consent from clinical trial subjects.

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Introduction

Two recent court rulings¹ have underlined the global trend of relying on the principles of medical ethics of autonomy or self-determination of the individual when determining whether informed consent has been given by the relevant subject. This article discusses the importance of respecting the individual person, especially in cases where he or she is the human subject in clinical research studies. The applied ethics of giving and obtaining informed consent and the need to protect the human subject's confidentiality are very important ethical issues given the increasing number of human clinical studies in recent years.

The Case of *Chester v Afshar*

I shall deal with the first new English case of *Chester v Afshar*¹ which has somewhat changed the law on informed consent. In this case, the defendant neurosurgeon had

performed surgery on the patient plaintiff who was suffering from low back pain for some time. Her consultant rheumatologist had given her epidural and sclerosant injections. A magnetic resonance imaging (MRI) scan showed disc protrusions. She was referred to a neurosurgeon for elective lumbar surgical procedure. Prior to the surgery the defendant neurosurgeon had negligently failed to warn the patient plaintiff of the small 1% to 2% risks of *cauda equine* syndrome (CES). The patient had a discectomy to treat her low back pain. The surgeon performed the procedure competently without negligence. Unfortunately, the patient suffered *cauda equine* damage as an unavoidable complication of this surgery, and subsequent disability. She sued the surgeon claiming that he failed to warn her about this particular risk.

As the surgeon lacked documentary evidence that he had warned her of CES risk, the court accepted the patient's allegation, and the surgeon's liability for his failure to warn

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was established. Under traditional causation principles, the next step was to convince the court that the patient would not have undergone procedure if she was aware of risk (i.e. causation). But the patient took a different approach in this case. The patient agreed that she might still have had the surgery, but said that she would have taken time to think and she would have had the surgery on another day and possibly be operated by a different surgeon. Therefore, had an appropriate warning of the risk of *cauda equine* damage been given by the surgeon, the patient would not have agreed to undergo surgery on that day but she would have obtained a further opinion as to whether surgery was necessary.

Lord Hoffman said:

“[It] 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”.

By a majority, the judges found that the patient had established a causal link between the breach (i.e. failure to warn of CES risk) and the injury (i.e. nerve damage) sustained by the patient, and held that the surgeon was liable in damages. But for the surgeon’s negligent failure to warn the patient of small risk of serious injury, the actual injury would not have occurred when it did and the chance of it occurring on a subsequent occasion was very small. The patient’s injury was the product of the very risk that the patient should have been warned against before she gave her consent. As a result of the surgeon’s failure to warn the patient, the patient could not be said to have given informed consent to the surgery in the full legal sense.

The Court took the view that the negligence to inform of the risk which led to injury was proved on policy grounds; the policy being that the patient’s autonomy and dignity should be respected by allowing her to make an informed decision.

The patient’s right of autonomy and dignity could and should be vindicated by a narrow and modest departure from traditional causation principles. Therefore, legally, the patient’s injury was considered to have been caused by the breach of the surgeon’s duty of medical care for not giving a proper informed consent.

The implication of *Chester’s* case is that it is now more important than ever to take extreme care in ensuring that patients including human subjects in clinical trials are given full information, that they fully understand the information and that they have been given sufficient time to digest the said information. Comprehensive and comprehensible warnings regarding all significant possible adverse outcomes must be given to the patient or subject.

The Case of *Foo Fio Na*

A landmark ruling was made in the second case i.e. the Malaysian case of *Foo Fio Na*,¹ which has raised the benchmark of service that medical specialists owe their patients.

In this case, the patient was involved in an accident on 11 July 1982 and was subsequently warded at the second defendant hospital. The patient suffered, *inter alia*, a closed dislocation C4 and C5 vertebrae with bilaterally locked facets. The first defendant who was the orthopedic surgeon on duty had treated the patient. The surgeon failed in 3 attempts to reduce the dislocated cervical vertebrae. On 19 July, he performed the first of 2 operations to place the dislocated vertebrae into their original positions. This involved an open reduction where the nape of the patient’s neck was surgically opened and the dislocated vertebra moved to their normal positions and secured by bone grafting and the insertion of a loop of wire to stabilise the spinal cord. X-rays were taken after the surgery. Unfortunately, this procedure was unsuccessful and the patient became paralysed.

Subsequently, the hospital’s neurosurgeon found that the wire loop, which was placed to correct the dislocation of C4 and C5 vertebrae during the first operation, was pressuring the spinal cord thereby causing the total paralysis. The first defendant orthopedic surgeon performed a second operation on the same day to remove the wire loop. However, the patient remained paralysed and she sued the defendants for medical negligence in the High Court. She succeeded in proving that her paralysis was caused by the first operation performed by the orthopedic surgeon and was not due to the motorcar accident. She also proved that the orthopedic surgeon was negligent in tying the wire loop, which compressed the spinal cord leading to the paralysis. The Court held the hospital to be vicariously liable for the negligent acts of the orthopedic surgeon. The defendants appealed successfully to the Court of Appeal who allowed their appeals. The patient then appealed to the Federal Court with the question of law: “Whether the *Bolam* test should apply to all aspects of medical negligence.”

The Malaysian Federal Court held 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 doctor 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 informed decision on whether to proceed or refuse the medical treatment. The Federal Court has clearly chosen to follow the Australian case of *Rogers v Whitaker*. The Court viewed that the *Rogers v Whitaker* test

would be more appropriate and a viable test to be used in this millennium than the *Bolam* test.

Comments

From the above 2 cases, it is hard to ignore what appears to be a growing modern trend that, in informed consent cases, the standard of medical care has moved. With the English *Chester* case, it was the reliance on medical ethics, while in the *Foo Fio Na* case, it was an outright rejection of the *Bolam* test, (when the Federal Court chose in preference the Australian approach in *Rogers v Whitaker*² case.

In the Australian case of *Rogers v Whitaker*, Whitaker who was almost totally blind in the right eye consulted Rogers, an ophthalmic surgeon. The surgeon advised Whitaker that an operation on her right eye would not only improve its appearance but would probably restore significant sight to it. Whitaker agreed to the surgery which developed inflammation to her left eye and this led to the loss of sight of that good left eye. The Supreme Court of New South Wales held that Rogers was liable as he failed to warn Whitaker that as a result of the surgery she might develop a condition known as sympathetic ophthalmia in her left eye. The High Court said:

“In Australia, it has been accepted that the standard of care to be observed by a person with some special skill or competence is that of the ordinary skilled person exercising and professing to have that special skill. But, that standard is not 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...Further, and more importantly, 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, 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”.

It is interesting to note that in another Malaysian case of *Kamalan v Eastern Plantation Agency*,³ the court did not apply the *Bolam* test. But it instead followed the Australian case of *Rogers v Whitaker*. In another Malaysian case of *Hong Chuan Law v Dr Eddie Soo Fook Mun*,⁴ the court held that it is for the court, and not a body of medical opinion, to judge the adequacy of information disclosure

for an informed consent. In the recent English case of *Penney & Anor v East Kent Health Authority*,⁵ the Court of Appeal held that in areas of conflict between 2 competent experts holding genuinely different opinions, the judge can decide which evidence to prefer, with the *Bolam* test being not applicable.

It follows that in research studies, extreme care in obtaining informed consent becomes even more crucial than ever, especially after *Chester* case. This is particularly so for non-therapeutic research that may not directly benefit the human participants in clinical trials.

Informed Consent in Singapore

The most authoritative Court of Appeal decision in Singapore on medical negligence is the case of *Dr Khoo James & Anor v Gunapathy* (2002), which has finally resolved and approved the application of the *Bolam* test as supplemented by the *Bolitho v City & Hackney Health Authority*.⁶ It affirmed that the *Bolam* test applied to the issue of advice in the *Gunapathy* case but did not decide on the extent of the applicability of the *Bolam* test in informed consent cases. Yong Pung How CJ said:

“We would emphasise that this is not the appropriate place to address a fully argued appeal on the merits of a doctrine of informed consent. The issue did not arise in the submissions before us and we would not pronounce on it as such. We, however, feel compelled to address the judge’s inexplicable assumption that *Bolam* had been unceremoniously evicted from the issue of medical advice, and to make the observation that were this argument ever to arise in our jurisdiction, it would find *Sidaway* to be somewhat shaky ground on which to stand. Accordingly, in affirming that the *Bolam* test applied to the issue of advice in the present appeal, we found that the defendant doctors’ disclosure of the relevant percentage risks of radiosurgery was supported by a respectable body of medical opinion. They had not given negligent advice to *Gunapathy*.”

Under the *Bolam* test, a doctor is not negligent if he is acting in accordance with a practice accepted as proper by a responsible body of medical men skilled in that particular art, merely because there is a body of such opinion that takes a contrary view.

Under the *Bolitho* case, the Court must be satisfied that the exponents of a body of professional opinion has a logical basis and had directed their minds to the comparative risks and benefits in reaching a defensible conclusion. The

opinion of the expert witnesses must be founded on logic and good sense.

However, in 2004, the Singapore Medical Council fined a neurosurgeon \$2,000 for professional misconduct when he performed radiosurgery on a patient without explaining sufficiently its risks, side effects and the then experimental nature of such treatment for this type of brain tumour. The neurosurgeon had therefore failed to obtain the patient's informed consent for radiosurgery.

The SMC Ethical Guidelines has recognised the importance of informed consent.⁷

a) Untested Practices and Clinical Trials: Paragraph 4.1.4

A doctor cannot treat patients according to management plans or remedies that are not generally accepted by the profession. Evidence-based medicine must be practiced, except in a formal and approved clinical trial. A doctor participating in clinical research must exercise due care and safety towards the patients. Before a doctor enrolls a patient into a clinical trial, he must ensure that the trial is approved by an ethics committee or an institutional review board and conforms to the Good Clinical Practice Guidelines. The doctor must obtain informed consent from the patient. Further, under clause 23 of the Declaration of Helsinki (which the Singapore Guidelines of Good Clinical Practice ascribe to), if a human subject is in a dependent relationship with a doctor, the informed consent must then be obtained by another well-informed doctor who is not engaged in investigation and who is completely independent of this relationship. A doctor cannot experiment or authorise research which are not part of a formal clinical trial and which are not part of treatment or in the best interest of the patient or which could cause undue suffering or threat to a patient's life.

b) Self-Determination – Patient's Right to Information: Paragraph 4.2.4

Under medical ethics of autonomy or self-determination a patient has a right to information. A doctor must give information to the best of his ability, communicate clearly and in a language that the patient can understand. Most importantly, a doctor should facilitate a patient obtaining a second opinion if he wishes it.

c) Informed Consent: Paragraph 4.2.2

It is the doctor's responsibility to ensure that a patient is adequately informed about his medical condition and options for treatment so that the patient is able to make an informed decision about his treatment. The patient must be told of the risks, possible complications and benefits of the procedure and any alternatives available to him. If the patient is a minor, or has diminished ability to give consent, this

information must be explained to his parent or guardian. However, the taking of informed consent is always much stricter in the case of clinical trials, as detailed in the below section.

Legal Requirements of Informed Consent in Research Study

In Singapore, the Singapore Guideline for Good Clinical Practice (SGGCP) which has statutory force under the Medicines Act (Clinical Trials) Regulations was adapted from the ICH Harmonised Tripartite Guideline.^{8,9} Its compliance by researchers will give public assurance that the person's rights, safety and well being as trial subjects are protected and consistent with the ethical principles which have their origin in the Declaration of Helsinki (DOH).

The first principle of the Nuremberg Code says: "*The voluntary consent of the human subject is absolutely essential.*" For a legally valid consent, the research subject must have sufficient knowledge and comprehension of the elements of the subject matter involved so as to enable him to make an understanding and enlightened decision.

Paragraph 22 of the DOH and paragraph 4.8.10 of the SGGCP specifies what the research subject needs to know in order to make an informed decision about trial participation. The consent should be voluntary with the subject being able to withdraw at anytime without penalty and without thereby compromising their healthcare. Further, under paragraph 23 of DOH, when obtaining informed consent for the research project, the physician should be particularly cautious if the subject is in a dependent relationship with the physician or may consent under duress. In that case the informed consent should be obtained by a well-informed physician who is not engaged in the investigation and who is completely independent of this relationship. Persons with diminished responsibility such as the vulnerable subjects (minor children, mentally handicapped and unconscious persons) may be allowed as research subjects but only under certain strict conditions.

The process of obtaining informed consent should involve a careful verbal explanation of the research study and what it means to the subject. Informed consent should be re-obtained should any new additional information during a trial emerge which may affects the subject's decision to continue with the trial project.

Conclusion

Since every proposal for medical research on human subjects must be reviewed and approved by an independent ethics committee or institutional review boards, researchers must show how a trial participant's consent will be obtained. Legally, the Patient Information Sheet (PIS) and consent form are very important legal documents in relation to the

research subject. Failure to adhere to the legal requirements of obtaining a valid and proper informed consent in research studies may potentially lead to a civil negligence action by the trial participant, as it constitutes a breach of the medical duty of care. The trial participant may even claim legal remedies by alleging that there had been fraudulent misrepresentation, and a criminal offence under Penal Code and/or civil negligence actions in that there was a failure to obtain informed consent resulting in injury.

The rulings in the 2 recent cases serve only to further emphasises the need to respect medical ethics of informed consent in Singapore today, especially given the increasing number of clinical trials in Singapore. In Singapore, the *Bolam* test as supplemented by the *Bolitho*⁶ case (i.e. the current accepted practice must be supported by a logical

opinion e.g. based on evidence-based medicine supported by clinical trials) also applies to the standard of medical care in giving informed consent to research subjects.

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