

Informed Consent in Obstetrics and Gynaecology

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Hong Kong J Gynaecol Obstet Midwifery 2007; 7:43-7

Keywords: Informed consent

Introduction

Consent from patients and counselling by doctors are critical in obstetrics and gynaecology. Informed consent is divided into two stages. Stage 1 is a detailed discussion and an explanation of the risks and treatment options provided by the doctor to the patient. Stage 2 is the signature of the patient to the written consent form. Stage 1 is more important; if the disclosure of risks is not understood by the patient, the doctor is still liable for damages for negligence for the breach of medical duty of care in not explaining fully to the patient. Further, there may be legal challenges especially when consent to obstetric treatment is sought from women in labour who may lack the mental capacity to give a valid consent because of pain or fatigue.

The medical ethics of autonomy or self-determination require the patient to consent to treatment. Often, an ethical dilemma may occur when the patient and doctor disagree on the proposed obstetric treatment. The purpose of consent is to give a defence to a civil lawsuit for damages for trespass to the person or a criminal offence of battery or assault¹. However, most civil actions are negligence and trespass to the person. In this article, negligence in consent taking is discussed first, before dealing with trespass to the person.

Negligence and Consent

Under the law, a patient can only consent to any obstetric treatment if she is competent and consents voluntarily to the proposed treatment, based on the adequate information given to her about that proposed treatment. The four essential elements in informed

consent are: (1) 'disclosure' of information by the doctor (it is a medical duty of care to disclose), (2) adequate 'understanding' of information by the patient, (3) patient's 'voluntariness' during the consent process, and (4) the patient has sufficient mental 'competence'.

Doctor's Duty to Disclose Risks to Patients

Consent is an ethical principle. Medical treatment can only be performed with the consent of a competent patient. Administering medical treatment without consent is a failure to respect a patient's autonomy, thereby violating her right to self-determination. A good medical law respects autonomy by demanding a 'real' consent from the patient.

Patients have the decisive role in the medical decision-making process, and their right of self-determination is recognised and protected by the law². However, in an emergency situation where a patient is unable to consent, e.g. due to unconsciousness, a doctor may be justified in carrying out emergency treatment based on the doctrine of necessity or implied consent. It is presumed that a patient would have consented to the treatment as it was necessary to save her from serious harm.

What is 'Adequate' Information for the Patient to Consent?

In a negligence action, the plaintiff must prove four elements. Firstly, the patient must prove that a duty

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of care is owed to her by the doctor. Secondly, the patient must prove that the doctor breached that duty by failing to meet the standard of care required by law under the *Bolam* test. Thirdly, that the breach of duty caused the injury. Fourthly, that the damage must not be too remote, in that it was foreseeable by the doctor. Under the law, the doctor has a duty of medical care to give ‘adequate’ information about the proposed medical treatment. From an ethical viewpoint, under the principle of respect for autonomy, no person should be exposed to risks without knowing such risks.

In negligence cases which arise from the issue of consent to obstetric treatment, it usually happens when the patient claims not to have been given adequate information by her doctor, for her to make an informed decision to consent to the medical treatment. For instance, uterine perforation is a common complication, which may happen in the course of a dilatation and curettage. And the claim for negligence may be based on the failure to diagnose the uterine perforation, where a more serious secondary complication occurs from the perforation such as bleeding or bowel injury. Thus it is important to mention the most common complications and difficulties of that particular procedure. Saying anything less is failure to meet the legal requirements for an adequate informed consent.

The question is how much risks should be disclosed to the patient by the doctor? The doctor must comply with the standard established by the *Bolam* test³ as supplemented by the *Bolitho* case⁴.

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 have 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.

A leading English case on negligence in informed consent is *Sidaway v Board of Governors of Bethlem*

*Royal Hospital*⁵, where Mrs Sidaway claimed that she was not given sufficient information about the risks of the surgery before she consented to it. She alleged that she suffered injury because she had not been informed of the small risk of harm. This *Sidaway* case confirmed that the doctor is judged by the standard of care laid down by the *Bolam* test, which applied to all medical negligence cases of misdiagnosis, wrong treatment and the failure to give informed consent. As long as the doctor can prove that he acted in accordance with a responsible body of medical opinion when obtaining informed consent from the patient about the proposed medical treatment, he will not be liable for negligence. However, the *Bolitho* case explained how *Bolam* test is to be applied and interpreted, in that the medical opinion is now subject to the logical analysis under the courts’ scrutiny⁶.

This reflects a paternalistic view of the English and Hong Kong courts which is for the doctors to decide on ‘how much to tell the patient’ under the *Bolam* principle, as supplemented by the *Bolitho* case. However, if the patient has asked about the risks and side-effects, then the doctor must explain them all.

The *Sidaway* approach, however, has not been followed by a number of other jurisdictions. Half of the United States, Australia, South Africa, Malaysia, and the Canadian courts have rejected the professional medical standard. The test is “what would a ‘reasonable patient’ want to know about the ‘material risks’?” Rejecting the *Bolam* test, the issue in these countries is whether the doctor’s conduct conformed with the standard of care required by the law. It was held in the Australian case of *Rogers v Whitaker*⁷ that if the patient asks for details of risks, she must be informed of such risks; and that doctors have a duty to warn of material risks to which a reasonable person in the plaintiff’s position would be likely to attach significance or which the doctor is aware that the patient, if warned of the risk, would probably find significant.

Further, Bristow J in the English case of *Chatterton v Gerson* (1981)⁸ said: “When the claim is based on negligence the plaintiff must prove not only the breach of duty to inform, but that had the duty not been broken she would not have chosen to have the operation...”

However, the recent ruling of the English case of *Chester v Afshar*⁹ (2004) has brought medical ethics to the forefront once again, where it was held that the failure to inform the patient of the risks did lead to her injury. 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 procedures. Before 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 the surgery, and subsequent disability. The patient sued the surgeon claiming that he failed to warn her about the CES risk.

The court accepted the patient's allegation, because the surgeon lacked documentary evidence that he had warned her of CES risk. Therefore the surgeon's liability for his failure to warn was proven.

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 the risk (i.e. causation). But the patient took a different approach in that 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 been 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."

The majority of 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 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 consequence 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 in *Chester* case 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 obtaining a proper informed consent.

The legal implication of the *Chester* case is that it is more important than ever to take extreme care in ensuring that patients are given full information; that the patients fully understand the information by giving them oral or written tests (no usage of Latin words); and that patients are given sufficient time to digest the said information. Comprehensive and comprehensible warnings regarding all significant possible adverse outcomes must be given to the obstetric patient.

From the *Chester* case, it appears to be a growing global modern trend that, in informed consent cases, the standard of medical care has changed and moved. The *Chester* ruling serves only to further emphasise the need to respect medical ethics of informed consent. It is the reliance on medical ethics of autonomy or greater self-determination for patients. The case for this is very strong in obstetrics, now that the emphasis is on medical consumerism in this new climate.

In the English case of *Wells v Surrey Area Health Authority*¹⁰, a 36-year-old woman, who has two

children, was advised after a long and difficult labour to have a caesarean section. She was in a drugged and exhausted state when the consultant suggested that she be sterilised during the caesarean section operation. The consent form was signed by her and the procedure was done. Upon recovery, she complained that as a Roman Catholic she would never have agreed to the sterilisation. She claimed that her consent was not valid because it was signed when she was in a weak and confused condition. She sued the doctor for assault and battery because the operation was done without her consent and for negligence because she was not given information about sterilisation and its consequences. The judge held that her action for battery and assault must fail because he found that the patient was capable of understanding and consenting to the procedure. But the judge allowed her action for negligence because she was not given sufficient information and counselling to enable her to make an informed decision.

There should be proper antenatal counselling and continuing advice during labour about pain relief, delivery methods, and caesarean surgery, especially to a woman in labour for many hours and who has received analgesic medications. During the continuous monitoring and recording of the patient's view, it is best practice to re-take the patient's consent again.

In the recent Hong Kong case of *Lai Wing Cheung v Yep Chau Chung & Lin Hin Wu* (Third Party) (2006), the judge said that for the standard of care in medical negligence: "... There is no dispute that the test applied by these courts in cases of medical negligence is that expounded by MacNair J. In the case of *Bolam v Friern Hospital Management Committee* [1957] and later amplified in *Bolitho v City and Hackney Health Authority* [1998] contained in the following words: "(a medical practitioner) is not guilty of negligence if he has acted in accordance with practice accepted as proper by a reasonable body of medical men skilled in that particular art... merely because there was a body of opinion who would take a contrary view."

Applying the *Bolam* test in this case, the judge held that it is clear from the expert opinion that the ordinary medical practitioner would not normally mention that possibility of a dystonic reaction to a patient following

an intra-muscular injection of prochlorperazine because such reactions are so rare.

Voluntariness in Consenting to Obstetric Treatment

If the patient did not give consent freely, then it is not a valid consent in law. The doctor who is obtaining informed consent from the patient should not unduly influence her, which may deny her the freedom to make her own voluntary decision. It is best practice to answer honestly a patient's questions by explaining all the different treatment options and their effects on the foetus and mother, so that she could make an informed choice herself voluntarily.

Competence of Patients to Consent

A patient can only give a 'real' and valid consent in law when she is competent to do so. In obstetric cases, the women may temporarily lack the mental capacity to make decisions for themselves because of pain or exhaustion.

Trespass to Patients

'Consent' by a patient is a defence to legal actions for battery, assault, and false imprisonment. Therefore, doctors should keep good documentation and medical records of patients' consents. Good note keeping ensures a higher quality of care and patient safety, so that when the doctor-in-charge is unable to treat the patient, another new set of doctors can take over anytime because the medical notes are full and up-to-date.

Trespass occurs to a patient when there is a medical mistake which results in the wrong procedure being done. There was a successful action for battery when a doctor carried out a hysterectomy when the patient had given consent to an abortion¹¹.

Refusal of Medical Treatment

A competent patient can refuse treatment, even life-saving or beneficial treatment¹². Therefore, any medical treatment performed despite a refusal of it can expose the doctor to an action for trespass. Failing to give full information to the patient about a treatment vitiates his consent. To refuse treatment, the patient must sufficiently understand the nature, purpose and effects of the proposed treatment. A patient must be given adequate information for him to decide whether to refuse treatment¹³.

Box. Checklist for obtaining an informed consent to obstetric treatment

- Name of operation
- Nature of proposed treatment
- What the operation involves
- Other treatment options or alternatives
- Potential complications
- Risks of operation
- Risks of no treatment
- Special precautions required postoperatively
- Benefits of treatment
- Limitations of treatment
- Success and failure rate of operation
- What happens on admission
- How patient will feel after treatment

particular risks that the patient may be exposed to. The bottom line is good documentation. Write legibly and logically in detail, otherwise there can be big problems to defend oneself in a negligence claim. Be thorough in writing notes, because it is to document patient care so that another doctor can deal with that patient better. A checklist is shown in the Box.

More importantly the written consent form should be written in simple understandable language. Although an oral consent if properly taken is sufficient, it is good practice to obtain a written consent. Further, consent should be taken from the patient herself and not from any other person. If the patient is unable to give an informed consent, the doctor should treat in the best interests of the patient.

Conclusion

In summary, we should re-examine our written consent forms to ensure 'adequate' risks have been disclosed. It is good practice to be specific and detailed on the consent form, which means the doctor must tell the patient about the relevant particular issues. It is important that time is spent to discuss the clinical situations and the

Through the mechanism of the informed consent process, and only by working together with the patient, the doctor can form a 'patient and physician alliance'. This process of sharing can increase rapport with the patient and decrease the shock from an unexpected outcome, thereby providing good medicine in a pleasant environment, rather than blaming and suing the doctor for negligence.

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