

INFORMED CONSENT

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Two and a half thousand years ago, you were lucky and pretty grateful if you managed to find a doctor. If you were fortunate enough to see Hippocrates, he'd have probably given you poppy juice and willow bark, today's morphine and aspirin, but he would not have bothered with informed consent. He knew best, and he would tell you what you were to do.

That attitude prevailed throughout the world until recently. The first changes occurred of course in the United States, in about 1957. A Californian Court added the requirement that it was necessary to disclose information regarding the proposed procedure before obtaining consent. This idea spread to the United Kingdom about 20 years ago and may soon reach Scotland. It has spread throughout Europe, at least on the West side, and even as far South as Italy - well, it is reputed to have done, although I am sure there are still some mastodons who tell the patient what is expected of them.

You yourselves will know this situation best in South Africa, and I want to end this session with a 10 minute discussion on what happens here and where you go from here.

Treating a patient without consent can amount to assault. However, it is extremely unlikely for a doctor to end up in the Criminal Courts over lack of consent, unless you hold someone down and surprise them with an unannounced rectal examination. If, however, as is sometimes the case, the patient has assented to treatment, that is, agreed to it without fully understanding it, the question is not whether you have committed a criminal act, but whether you have fulfilled your duty of care, a duty that includes providing them with sufficient information, in terms that they can understand, to make an informed choice.

Physicians in earlier days had no responsibility for informing patients about a proposed treatment, its risks or benefits or any alternatives. All that was

required was the patient's agreement to undergo the procedure. However, if you don't tell your patient that they might end up blind after an operation on their eye, even if the chance is 1 in 14,000, have they given informed consent?

A Judge in Australia thought not. In *Rogers versus Whitaker* (1992) a Judge found a doctor negligent in not warning of the risk of sympathetic ophthalmia after an eye operation. The Court judged that a risk was material, if a reasonable person in that patient's position, warned of the risk, would be likely to find it "significant".

Consent may be implicit or expressed. Holding out an arm for venisection is implied consent. What about an intravenous anaesthetic? No, that doesn't count, because the patient is going to go to sleep, so you have to discuss the details of the anaesthesia with them. Lying on a couch for examination might be construed as implied consent, but if you are doing a pre-anaesthetic clinic and you want to examine the breasts or abdomen for some reason, you should point this out, because they might not expect that as part of the examination.

Consent is important for all medical interventions, and should be followed by a record, detailing what was discussed, being made in the notes at least. Better still a consent form should be signed. This should be done for any procedure that carries material or significant risks.

Of course, these matters do not apply in exceptional circumstances, such as an emergency, a life-saving procedure or where the patient is too ill to give consent.

Basically, informed consent respects the patient's autonomy. The quality of information given needs to be enough to allow the patient to make their own decision. The General Medical Council announced in

1999 "It is for the patient, not the doctor, to determine what is in the patient's best interests." The information needs to be evidence-based and we need to consider the source of that evidence and specify that; whether it is up to date, and specify the date of the evidence, whether it is relevant, whether it covers the risks and benefits, whether other options are available and what their risks and benefits are.

Thanks very much, I hear you say - but how much do we have to tell them? Must we sit down and go through every rare side-effect of every therapy we recommend? Must we warn of toxic side-effects from local anaesthetics and the chance of a subdural haemorrhage after a spinal anaesthetic?

In the UK, the House of Lords had to decide (Sidaway, 1985) "whether a failure to mention a risk was negligent or not". The decision was that the Bolam principle should apply (Bolam, 1957). The doctor was not negligent for failing to mention the risk, because a reasonably competent doctor in a similar position would not have mentioned it either, and a responsible body of relevant professional opinion would support that decision. You are, however, obliged to warn the patient of significant risks and the Court retains the power, in rare cases, to declare that a view held by a responsible body of professional opinion is not reasonable.

This means you don't have to warn of every conceivable problem, but you should warn of significant risks. You should also address any particular issues that the patient raises. The patient should have time for questions. A risk not generally considered significant might be significant in a particular patient's circumstances. The baseline is that you should give an explanation in accordance with that which would be given by a responsible body of medical professionals working within your field.

Unfortunately, this means that there is not an exhaustive list of information that should be given in every possible therapeutic situation. You have to use your knowledge and judgement. Most obstetric Anaesthetists would warn about dural taps in gaining consent for obstetric epidurals, but recently there was

a discussion in the Medical Defence Union magazine about this. One Senior Consultant felt that this occurred so infrequently in his hands that he no longer warned patients. The MDU's advice was that there were no hard and fast rules in this area! It was suggested that you should warn the patient that the procedure might be uncomfortable, but it did not discuss whether you should warn of the extremely rare chance of neurological damage following an epidural, which, however, could have profound long-term implications. It specified that you don't want to put patients off having treatment by scaring them with risks, but you do need to explain the risks and benefits in a balanced manner, so that the patient can make an informed choice. It mentioned the extremely important point of discussing with the patient alternatives, including the option of not having an epidural.

The Bolam Test

Mr Bolam had a fracture as a result of ECT, during which he was not restrained nor given muscle relaxants. Although it was agreed that many doctors would have used restraint or relaxants, there existed at that time, 50 years ago, a responsible body of practitioners who did not. Thus, Mr Bolam's case was not successful, although there is no doubt that it would be today.

At some time prior to carrying out a procedure, the consent process must be gone through with the patient. This would involve discussing the diagnosis if known, the nature and purpose of the procedure or treatment, the risks, the benefits and the alternatives. These need to be discussed regardless of cost, rationing, health insurance and their risks and benefits also need to be discussed. It is important to discuss the risks and benefits of not receiving the treatment or procedure, and indeed this may be one of the important factors that leads a patient to decide to have the treatment.

The patient should then have a chance to ask questions and to reflect on the information given. So ideally, this process should be gone through in the Out-patient Department and the Consent Form can be

signed then, at the pre-operative visit. This information should not be given for the first time to the patient on the pre-operative visit because that does not give the patient time to reflect on things. Certainly a Consent Form should not be signed in the Anaesthetic Room, although in Great Britain it often is. The Consent Form is now becoming both a legal requirement and an ethical obligation, but does not in itself protect doctors. The more comprehensive the form the more helpful it would be and some doctors have taken to making their own forms up, including all complications that they wish to discuss. However, then a waiver needs to be added, noting something of the nature "The procedure may result in complications, including but not limited to....." Then follows a list of complications. If you don't do this then, if anything occurs which you have not listed, you don't have much hope in Court!

More recently it has become clear that in the States, and indeed in Great Britain, you need to disclose to the patient whether you are experienced enough to carry out the procedure, and if there are other doctors who might be able to do it who have significantly more experience than you. This is obviously going to be a problem for newly-qualified specialists, particularly in the UK and Europe, where the European Rights Directive is stopping doctors from working for more than 56 hours a week, thus restricting their training! Whereas you could probably brag, in the past, that when you became a Consultant you had a significant experience in carrying out procedures, this is becoming less and less the case. So if you want to do brachial plexus blocks, but you haven't had much experience of them, you are going to have to explain this to the patient.

Consent in Children

For those aged 16 or over, this is obtained in the same way. However, in Britain there is the concept of Gillick competence, which means that you can get consent from a minor, if they can understand your advice, if you cannot persuade them to inform their parents or allow you to inform them and if their best interests are served by you carrying out the treatment.

Adults with reduced mental Capacity

Adults with questionable capacity are also dealt with, but may not be quite what is expected. A common misconception is that in people with reduced capacity, a doctor needs the consent of a relative or carer. This is not the case, although you can consult them if attainable. You, the doctor, have to act in what you judge to be your patient's best interests. The relatives' opinions might assist you; for instance, they may say that their elderly relative didn't wish to have life-saving surgery and you can then take that into account.

Conclusion

Consent is a vastly important issue in medical practice. It should not, however, be seen as a legal minefield or simply as an administrative process to be gone through. The requirement to obtain informed consent is bound up with respect for the rights of patients to make their own decisions and the duty of the doctor is to enable them to do so. It is not just a defensive measure to protect ourselves.

References:

- Bolam vs Friern Hospital Management Committee (1957) 1WLR 582
- Bolitho vs City and Hackney HA (1997) 3WLR, 1151
- GMC (1999) Seeking patients' consent: The ethical Considerations London, GMC
- Gillick vs West Norfolk and Wisbech AHA (1985) 3 A11 ER 627
- Mitchell J (1995) A fundamental Problem of Consent Br Med J 1: 43-46
- Rogers vs Whitaker (1992) 67 AWR 47
- Sidaway vs Board of Governors of Bethlem Royal and the Maudsley Hospital (1985) 2 WLR 480

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