PATIENT EDUCATION BRIEFINGS
Winter 2008

Informed consent as an ethical principle

Dr Paul Nisselle
General Manager, Clinical Risk Management
The Avant Mutual Group

"Every human being of adult years and sound mind has a right to determine what shall be done with his own body."

So said Justice Benjamin Cardozo in 1914, translating into law a fundamental ethical principle: the duty to respect a patient's autonomy.[1] But how much information has to be given to a patient to ensure that the patient's right of self-determination has been respected?

Many doctors confuse **valid** consent (sufficient to defeat an accusation of assault or battery, that is, an "unlawful touching"), and **informed** consent (sufficient to defeat an accusation of negligent non-disclosure).

The tests for valid consent are:

1. Has the patient been given information about the nature and purpose of the treatment?
2. Is the patient able to understand that information?
3. Is the patient's consent freely given? Is there any sign of coercion from another person (spouse, parent, etc).

Informed consent requires one further element: provision of information about risks, benefits, alternatives, and so on.

The High Court of Australia[2] has affirmed that the doctor's duty of care is one duty with three components: diagnosis, treatment and provision of information. Whether a doctor breached duty of care in diagnosis and treatment is a matter for expert medical advice. Judges and juries do not have the knowledge to make that assessment. However, they can stand in the patient's shoes and decide whether the information provided to a patient was "enough".

Two tests apply in deciding which information should be given to a patient:

Dr Paul Nisselle

1. Reasonable patient – the "objective test"

This is the information you should provide to every patient about a proposed procedure. A patient education pamphlet would meet this test if:

- the pamphlet is in a language the patient can read
- the patient can understand the information
- you go through it with the patient and explain the content.

2. Particular patient – the "Subjective Test"

In addition to the information you provide to every patient, you need also to show that you have turned your mind to this particular patient. This is a two-step process, as follows.

a) The Reasonable Doctor

Is there other information any reasonable doctor would add, knowing of the circumstances of this particular patient?

b) The Individual Patient

Is there other information the patient wants, having been given the opportunity to seek further information? Ask open questions such as "Is there anything you don't understand?" or "Is there anything else you'd like to know?" or "Do you have any questions?"

You must document the discussions you have with patients. The records do not have to be voluminous. Single words with a " " beside them are enough to show you considered that risk and discussed it. If you use a pamphlet, such as one supplied by your College, you could write, "College info sheet Discussed " as evidence that you addressed the objective reasonable-patient test. The final notation might be "N.O.Q." (shorthand for "no other questions"), which would be reasonable proof that you checked whether the patient wanted further information.

Avant still has a few cases due to pregnancy after tubal sterilisation. Where there has been no surgical error, the assertion is usually that no warning was given of the remote risk of pregnancy. "Warned re risk of pregnancy" written in the notes will usually rebut such a claim.

The key is to provide information structured around the reasonable patient, reasonable doctor and individual patient triad, and to record the information provided.

It's unthinkable to take a patient's blood pressure and not record it in the notes. It's equally unthinkable to have a discussion with a patient without recording a summary of that discussion in the notes.

1. Schloendorff v. The Society of New York Hospital, 211 N.Y. 125 (at 129-130), 105 N.E. 92, 93 (1914).
2. Rogers v Whitaker (1992) 175 CLR 479..

The internet is not a patient education solution

Referring your patients to an internet site is not enough to establish informed consent and could be counterproductive to your risk management.

Dr Calvin Miller
Director
Mi-tec Medical Publishing

In recent years, I have received queries from surgeons, medical practitioners and dentists who want to put patient education online so their patients can access it on the internet. The key objectives are:

- the doctor can save time because patients will access the information in their time on their own computers
- after accessing the online information, the patients can ask questions at subsequent appointments
- the online patient education will assist the informed-consent process and the doctor's risk management.

At first blush, referring a patient to one or several websites would appear to be helpful, and yes, the internet has become a popular source of treatment information for health consumers. However, while the web can act as a repository of treatment information, that does not imply it is assisting the informed-consent process.

Consider these real-world problems.

- The patient is too embarrassed to admit he doesn't have a computer or doesn't know how to use one.
- The patient misplaces the web address that the doctor gave him.
- What if the server is down or some other technical problem prevents downloading of the information?
- Even if the patient successfully downloads the treatment information and reads it, that in itself does not imply that the patient understands the information in isolation of the doctor. That is, the doctor was not involved in the process of communication and explaining the treatment to the patient.
- A black-and-white printout of a colour anatomical illustration is typically a poor reproduction, and the illustration may be crucial to the patient's understanding of the treatment.

Thus, simply referring the patient to a website could well be setting the stage for one very angry patient in the event of a postoperative complication.

To reduce the risk of litigation, effective dialogue between the doctor and patient must be established and recorded in the doctor's notes. Patients' access of treatment information on the net does not assure a process of communication, even if they confine their attention to recommended sites.

High-quality hardcopy pamphlets provided by the doctor have the following compelling advantages.

1. The High Court case of Rogers v Whitaker (1992). The pamphlets can satisfy Rogers v Whitaker considerations by helping to establish a process of communication between the doctor and patient, and assisting the written record. It is the **doctor's** responsibility to implement a process of communication and to determine material risks, not the patient's. Referring a patient to a website would not indicate that a process of communication was underway. In fact, it could indicate quite the opposite, with the inference (by a judge, jury or complaints body) being that the doctor was too busy to provide information and avoided discussions with the patient.

2. Exclusivity. The patient should receive the information specifically from the doctor (or in some cases a designated nurse who undertakes a communication role). Patient education pamphlets should never be distributed independently of the doctor. It would be inimical to the interests of the doctor and the practice's risk management.

It would be better to think of such pamphlets as "Doctors' information for patients". I often get phone calls from lay people who would like to receive a particular surgical pamphlet and are quite happy to pay for it, but I always have to decline on the basis that the pamphlet must be provided by the doctor in an environment of dialogue and communication in order for the best advice to be provided and for questions to be asked.

3. Security of print quality. Pre-printed pamphlets present all text and illustrations with the highest print quality. The excellent print quality and full-colour medical illustrations add credibility, authority and reader acceptance. Conversely, it is easy and common for a page from multi-page laser printouts to go missing and for toner cartridges and ink-jet cartridges to run out of ink, resulting in illegible pages. A missing page (for example, the risks and complications page) would present a serious problem in the event of a complaint. The case would be difficult to defend.

In a patient-education survey conducted last year by Mi-tec, 99% of gynaecologists and obstetricians kept their College's patient education pamphlets in their control and did not provide them ad libidum in waiting rooms. This demonstrates that the doctors are keenly aware of the benefits of personally providing the pamphlets to patients.

In the same survey of 400 Fellows, five percent reported that a formal complaint (to a health services commissioner or state medical board, for example) or legal action against them had been abandoned because the patient pamphlet clearly outlined the risks and limitations of the treatment. Also, the doctors' notes and the piggy-back stickers (on page one of those pamphlets that discuss treatment risks) confirmed that a process of communication was in place between the doctor and patient.

To play devil's advocate, doctors, dentists and other healthcare professionals don't really need the pamphlets at all! There are any number of ways that a process of communication could be implemented and recorded. However, the pamphlets go a long way toward doing the job

Dr Calvin Miller

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quickly, cheaply and easily, and proving it, thus making the doctor's task of informed consent a lot easier and more comprehensive.

In conclusion, a doctor can confirm that a process of communication has been initiated by personally handing to the patient, and discussing, an informative pamphlet that is of the highest standard, both in terms of expertly reviewed content and print quality.

Any substitute of face-to-face discussion and pamphlet quality would not be in the interests of doctors and would contravene the reason for providing patient education: to improve communications between doctors and their patients.

This article is derived from a paper that first appeared in O&G Magazine published by the Royal Australian and New Zealand College of Obstetricians and Gynaecologists: Weaver T, Robertson A, Miller C. Patient education is best when it's a process. O&G 2007 Spring;9(3):62-3.

Dr Paul Nisselle adds this point:

Any standardised communication, whether it be a pamphlet or information on a website, at best can only satisfy the first leg of the Whitaker v Rogers standard, that is, the "objective" (reasonable patient) test. And then, only if the patient has the cognitive and linguistic ability to understand the information provided.

Irrespective of how that information has been "transmitted" to the patient, an interactive process with the doctor is required to ensure it has been "received" as knowledge.