Informed consent

The signed consent form is the physical evidence that consent has been obtained from the patient, but this alone is not enough and it is the addition of the word 'informed' that is open to interpretation and has needed legal definition in the past. The patient’s consent should only be given, or indeed accepted, secure in the knowledge that all aspects, ramifications and possible risks have been adequately disclosed, explained and understood by the patient. This article will focus on the disclosure aspect of informed consent. Patients’ names and identities in clinical practice have been changed to respect their confidentiality and to preserve their anonymity.

Introduction

Beauchamp and Childress (2001) divide informed consent into five components.

- **Competence**: Is the patient competent mentally and physically to grant consent?
- **Disclosure**: Has the surgeon disclosed to the patient all the effects of surgery both probable and possible?
- **Understanding**: Has the patient fully understood the proposed treatment?
- **Voluntariness**: Has the patient agreed to the surgery or treatment voluntarily (without pressure)?
- **Consent**: Has the patient consented to the treatment in light of the above?

The law of informed consent is supposed to protect the principle of patient autonomy. Autonomy comes from the Greek *autos* meaning self, and *nomos* meaning rule, and is a fundamental ethical principle when applied to patients’ choice of medical treatment. If a patient is to be allowed to govern him or herself, then he or she must be in possession of adequate information and be able to deliberate (Gillon 1996). Adequate information should include not only the risks in any proposed surgical or medical treatment, but also a clear explanation of the alternatives (DoH 1995). This is sometimes overlooked in the perioperative setting as staff may feel the decision has already been made and therefore the course of surgery has been set.

But is this always in the patient’s interest? Autonomy can also be linked with self-determination and patients always have the right to refuse a surgical procedure at any point. This choice can be exercised right up to the last minute and can, in the case of local anaesthetic, be exercised halfway through a procedure. In clinical practice, an elderly Miss B came to theatre for an excision of a lesion on her head under a local anaesthetic. She became increasingly agitated and declined treatment both verbally and physically. The surgeon cancelled the treatment as not only would it have been unsafe to continue, but it was obvious that Miss B’s consent had been withdrawn, possibly because she had not...
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understood the procedure when it was explained to her preoperatively. The Department of Health (DH) states that patients are entitled to change their mind after signing the consent form, if they retain the capacity to do so (DoH 2001).

Disclosure

The lack of detailed explanation of risks attached to a surgical operation resulted in the House of Lords ruling for the patient in Chester versus Afshar (House of Lords 2004). Miss Chester had suffered some nerve damage during back surgery. Although the case that the operation was performed negligently was rejected by the trial judge, a ruling was made that the risk of nerve damage was not fully explained prior to the operation, and therefore the Surgeon, Mr Afshar was negligent. Even though Miss Chester could not definitely say that she would not have gone ahead with the operation had all the risks, however small, been explained to her, the surgeon was still held liable (Wheeler 2004).

The DH quantifies the information to be disclosed by requiring doctors to tell patients of serious or frequently occurring risks (DoH 2001). It also urges the healthcare staff to address particular concerns the patient may have, however rare or unlikely they are to occur. Gillon (1996) argues that too much information might not help a patient to make a rational decision in consenting to a procedure. Even though the patient may have asked to know everything, they might not actually want to know the worst case scenario. Clearly some level of responsibility must lie with the healthcare professional as to how much disclosure is appropriate in each individual case. Too little disclosure could be seen as paternalism bordering on patronage and too much disclosure may cause an over-anxious patient to worry unnecessarily.

In the US the position is more clear: the patients have an absolute right to know all of the risks attached to a procedure before they can consent (Gillon 1996). In practice this means surgeons have to include lengthy lists of every conceivable risk (however unlikely) before treatment. Gillon (1996) suggests that detailed technical lists of possible risks are often not understood by the patient and could, in fact, cause more anxiety. The trial judge in Chester versus Afshar (2004) admitted that it was often a very difficult matter for a consultant to advise a patient of minor surgical risks when the patient was already suffering from stress and anxiety. Each circumstance and each patient is highly individual and open to interpretation and discussion both in the workplace and in a court of law.

The perioperative setting

Adams (1990) states that the consent form is an important legal document that acts as a contract between the patient and the

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medical staff, the DH argues that the point of
the form is to record the patient's decision.
However, it is not a legal waiver and a signed
consent form may not be valid if the patient
has not received enough information (DoH
2001).

One of the duties of the healthcare professional
in the perioperative setting is to ensure that the
consent form has been signed and dated and
that the patient has had the procedure
explained but, more importantly, has under-
stood the explanation (Adams 1990). This can
be ascertained by the healthcare professional
asking the patient to repeat his or her
understanding of the procedure in his or her
own words. The DH (2001) suggests asking
open ended questions. This also confirms the
operating site, side and any other details they
have gathered from the medical staff. Any
discrepancy with the patient's own explanation
and the notes or paperwork can be swiftly
addressed (Adams 1990). If the patient arrives
at the operating theatre and does not seem to
understand what is happening to him or her,
then the surgeon or anaesthetist must be
contacted before any medication is given.
Using Beauchamp and Childress' (2001)
definition of informed consent, the components
of understanding and disclosure would not
have been met and if the patient has had
medication administered to them, it could be
argued that the component of competence had
been compromised.

It was observed in clinical practice a Miss A
came to theatre for a split skin graft for a
wound on her hand with her thigh to be the
donor site. It was apparent to the healthcare
staff that on Miss A's arrival at theatre she had
no knowledge of a second operation site
(ie: her thigh). Had the operation gone ahead
at this juncture Miss A would have awoken
surprised and shocked that her thigh was
bandaged and painful. In this scenario it
came the healthcare staff's duty to inform
the medical team so that further explanation
could be given prior to surgery. Had the
scenario unfolded without the medical team's
explanation, Beauchamp and Childress'
components of consent (2001), specifically
disclosure and understanding, would not have
been addressed. The patient's in comprehension
of the procedure was only discovered by the
healthcare staff asking Miss A to describe what
she understood about her operation. Miss A had
no knowledge of the mechanics or procedure
relating to a split skin graft, she clearly expected
her wound would be simply repaired and closed.
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sionals should ensure the patient has had time
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given. In practical terms, Gillon’s (1996) time to deliberate is often unrealistic in cases of non-elective trauma surgery. Then the failure to disclose would be immaterial if the patient was quite clearly not competent (ie: unconscious). In these kinds of extreme cases the Health Professions Council Standards of Conduct, Performance and Ethics (HPC 2004) states that:

- *In emergencies, you may not be able to explain treatment, or get consent.*
  (Standard 9)

This would provide the legal framework for the decision to go ahead and operate providing it was in the patient’s best interests. To delay treatment would negate the healthcare worker’s duty of care to the patient and would over ride any questions about consent. The Association of Operating Department Practitioners’ Code of Conduct (2003) states that the operating department practitioner (ODP) should:

- *‘Carry out all roles and responsibilities in such a way as to promote and protect the rights and health of patients.’*

Delaying treatment on an unconscious patient would not be protecting the health of the patient as delay could be harmful.

**In the dark or blinded by science?**

Hawkins (cited in Gillon 1996) divides patients into two groups: Type A decides to place him/herself and their treatment entirely in the hands of the medical team. Type A patients are often elderly and perhaps not so well informed, they may not want to know the full details. This stance puts the onus on the doctors to volunteer information that they consider relevant for that particular patient. It could be argued that this fosters and encourages the paternalistic approach practised by some doctors. However, this chosen ignorance is to be respected; it is the patient’s right not to know if they so choose and sometimes it is kinder for them not to be in full possession of the facts of the actual process of an operation.

Type B patients however are the more pro-active patient and can be recognised by their pertinent questions and knowledge of their condition and clearly want to retain personal judgement of their treatment (Gillon 1996). This type of patient will be resentful if treated with condescension or paternalism.

Compared to fifteen years ago, today’s patient is generally better informed and has greater access to medical information both on the internet and from publications. It could be argued that more patients nowadays fall into the Type B patient description. Some medical staff may look upon this in a negative way: either because the patient may be misinformed or, on a personal level, that the balance between doctor and patient has somehow been tipped the wrong way. This would be a short-sighted view. In clinical practice it was observed that when a patient asked a question about the statistics relating to their condition, the doctor told the patient they should keep off the internet and that they had obviously been reading too much. Comments like this smack of paternalism and insult the intelligence of the patient.

**Summary**

Disclosure of information prior to consent is a very complex area of medical ethics. On the surface it would seem to be quite clear cut, but on closer inspection the scope for ‘grey areas’ is vast. In practice, however, it could be argued that the number of cases that result in complaint or litigation is comparatively small. However, this does not mean that wrong decisions or unethical scenarios do not occur. It would seem that in clinical practice these ethical grey areas concerning patients’ full knowledge of their condition or treatment are quite common. One of the barometers for
how much disclosure should be given prior to consent could be the feedback obtained from the patients. Are they asking relevant questions pertinent to their condition and do they show a good understanding of the options available? This should be seen as a positive trait and should be welcomed by the healthcare professionals. Ultimately it gives patients greater autonomy and the healthcare professional can expand and build on the patient's knowledge as well as allay fears perhaps based on wrongly held information. Greater communication with the patient would help the healthcare professional pitch their explanations at the right level.

Every case and scenario is different and unique and deserves to be treated as such. Studies have shown that most patients can understand their medical condition and treatment provided communication has been thorough (Gillon 1996). It is in the patients' best interests to feel comfortable with the level of disclosure offered to them. It can only foster greater trust and respect between them and the healthcare profession which has to be mutually beneficial to both parties.

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