INFORMED PATIENT CONSENT - HISTORICAL PERSPECTIVE AND A CLINICIAN'S VIEW

N W Kour, A Rauff

ABSTRACT

Informed patient consent, in this day and age, is usually taken for granted, poorly understood, and inadequately practised. Historically, informed patient consent is relatively new to medical practice, as there was no such consent during the times of the ancient Egyptians, the ancient Greeks or Romans. The culture of individual rights as part of a social trend and evolution of human civilisation with landmarks such as the American Revolution two centuries ago also brought along greater patient awareness of their health and persons as well as their rights in the investigations, treatment and research of their illnesses. The rationale and elements in the practice of informed patient consent is part of this trend. However, there are moral and legal dilemmas involved. Discussion is needed, and though the practice of such consent may sometimes be difficult, the spirit of its application should never be compromised.

Keywords : Informed Consent, Medical Ethics, Medical Philosophy, Medical Practice, Patient Autonomy

SINGAPORE MED J 1992; Vol 33: 44-46

INTRODUCTION

Medical technology has increased in sophistication by leaps and bounds in recent decades and this is likely to accelerate. To keep abreast with this we will also need greater sophistication in the philosophy and ethics of medical treatment. Patient consent is one of these aspects.

Informed patient consent involves the Law but these legal aspects are addressed only superficially in our medical curriculum. We do not propose to discuss the legal aspects of informed consent, as this is best left with the legal profession, but it is a subject which we have to deal with in our everyday practice, in the procedure of obtaining consent for treatment and for investigations.

We propose to elaborate on this subject of informed patient consent in terms of its historical development, the rationale for it, the elements which constitute the practice of informed consent and some situational problems involved in its application.

HISTORICAL DEVELOPMENT OF PATIENT CONSENT

Although a fair amount was known about the ancient Egyptians and their medical practice, there appears little evidence of a definite code regulating the relationship between patients and doctors. This also applies to the Mesopotamians and the other ancient civilisations at that time.

The ancient Greeks as epitomised by Hippocrates defined the need for trust and emphasised the duty of the physician in the privileged position of trust, however there was no hint of a formalised practice of consent for treatment. The Romans too touched on etiquette in the practice of medicine but did not pay much attention to the ethical aspects of medical work.

Division of Urology
University Department of Surgery
National University Hospital
Lower Kent Ridge Road
Singapore 0511

N W Kour, MBChB, FRCS
Senior Lecturer

A Rauff, MBBS, MS, FRCS
Professor and Head

Correspondence to : Dr N W Kour

This lack of a formal treatment consent prevailed through the Middle Ages into modern times and was not formally instituted until the 20th century. The movement towards a more precise code between patients and doctors was part of the general trend of society in its quest for immutable laws of nature, of man and in philosophy which coincided with the scientific revolution. This is reflected by the Bills of Rights; the American Declaration of Independence of 1776 echoed these sentiments and emphasised consent ".....to secure these rights, governments are instituted among men, deriving their just powers from the consent of the governed."

Right up to the end of the First World War the patient-doctor relationship was based on trust and confidence, coupled with a spirit of dedication and *noblesse oblige*. The rapid advancement in knowledge and practice of medical science since then has altered the expectations of the caring profession as well as the public. Whilst in the past cure was taken as a boon, it is now almost automatically taken for granted. Failure to cure is now attributed to ignorance which may amount to negligence.

It is in the background of this ferment of philosophical and political ideas that the concept of patient consent has evolved and matured in medicine. The Nuremberg Code of 1947 which arose from the bitter experience of the indiscriminate human experimentation of the Second World War, and the Helsinki Declaration of 1964 formalised these concepts of patient consent.

WHAT IS INFORMED CONSENT?

The Nuremberg Code, Rule 1 states that:

"The voluntary consent of the human subject is absolutely essential. This means that the person involved should have the legal capacity to give consent; should be so situated as to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, over-reaching or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the subject matter involved as to enable him to make an understanding and enlightened decision. This latter element requires that before the acceptance of an affirmative decision by the experimental subject there should be made known to him the nature, duration and purpose of the experiment, the methods and means by which it is to be conducted, all inconveniences and hazards reasonably to be expected, and the effects upon his health or person which may possibly come from his participation in the experiment."

The American Department of Health, Education and Welfare gives the following criteria:

"Informed Consent means the knowing consent of an individual or his legally authorised representative, so situated as to exercise free power of choice without undue inducement or any element of force, fraud, deceit, duress or other form of constraint or coercion. The basic elements necessary to such consent include:

1. A fair explanation of the procedures to be followed, and their purposes, including identification of any procedures which are experimental;
2. A description of any attendant discomfort and risks reasonably to be expected;
3. A description of any benefits reasonably to be expected;
4. A disclosure of any appropriate alternative procedures that might be advantageous for the subject;
5. An offer to answer any queries concerning the procedures;
6. An instruction that the person is free to withdraw his consent and to discontinue participation in the project or activity at any time without prejudice to the subject."

Informed consent generally applies to two situations, ie research and treatment. The Nuremberg Code was drawn up generally to regulate human experimentation, whilst the US Department of Health Code was relevant to both situations.

RATIONALE AND FUNCTIONS OF INFORMED CONSENT

Professor Alexander Capron of the University of Pennsylvania Law School identified the following functions of informed consent :

1. The promotion of individual autonomy;
2. The protection of patients and subjects;
3. The avoidance of fraud and duress;
4. The encouragement of self-scrutiny by medical professionals;
5. The promotion of rational decisions;
6. The involvement of the public in promoting autonomy as a general social value and in controlling biomedical research.

Apart from these, other authors have cited protection from harm as a reason for informed consent, but this may sometimes be in conflict with the protection of autonomy; eg in someone who refused further steps to prolong his life but was resuscitated nonetheless.

Besides being good medicine, good humanity, good public relations, and good medicolegal defence, informed consent has a therapeutic value of its own - the informed, consenting patient, aware of the risk, is not so shocked should the risk turn up in his case and is much less likely to sue his doctor in the first instance.

ELEMENTS AND PRACTICE OF INFORMED CONSENT

For a valid informed consent, there must be :

a. adequate disclosure of information;
b. adequate comprehension of information;
c. voluntary consent;
d. competence of the subject/patient to consent.

a. Disclosure of information

How much should we disclose to the patient/subject?

Beauchamp and Childress defined three standards of disclosure;

i. the professional practice standard

This refers to the "customary" standard of disclosure as practised by custom and as practised by the medical profession or specialty in general. There is therefore no set limit to what needs to be disclosed as what is customary is not defined. Also it seriously undermines the autonomy of the patient, as the values and goals of the medical profession may not be compatible with the patient's.

ii. the reasonable person standard

The reasonable person is a hypothetical model and is a composite or ideal of reasonable persons in society. This does not therefore apply to the individual patient. There is however greater respect for patient autonomy than the professional practice standard.

iii The subjective standard

Here the disclosure is subjectively tailored to the individual patient. There is also an obligation to disclose information a patient wants or needs to know, so long as there is a reasonable connection between these informational needs and what the physician should know about the patient's position. It is however open to wide interpretation.

There remains the problem of intentional non-disclosure. Some physicians would cite the legal doctrine of "therapeutic privilege" when a physician may intentionally not disclose or underdisclose information based on a "sound medical judgement" that to divulge the information would potentially be harmful to the patient. This is both a moral and a legal problem, with a conflict between protection of the patient's autonomy and protecting from harm.

b. Comprehension of information

Mere acceptance of the information is not equivalent to comprehension of the information. There are different levels of understanding of information disclosed by the physician, just as our understanding of information from a banker or a lawyer may differ.

There may be subjects who may not even want to accept the information. Does forced information in these cases constitute violation of the patient's autonomy?

c. Voluntary consent

Adequate disclosure, adequate comprehension and voluntariness are related; for the consent to be fully voluntary, the options available must be disclosed and understood by the patient. There must be no controlling influences, either social, political, financial or others.

However, patients are often submissive in their relationship with their physicians and are more than willing to go by the wishes and recommendations of their doctors. They may not want to offend their physicians even though this is not solicited by the doctors. Voluntariness in such cases may therefore be compromised.

d. Competence to consent

To be able to consent with competence, there must be comprehension and voluntariness. Competence is subjective, to the individual and to the context of the subject under consideration. It is value laden and thus itself may present a moral dilemma. Sufficient rationality and intelligence are central to competence to consent.

The practice of informed consent does not have to be written. It may be verbal. However for legal documentation the written form is usually recommended. This may be cumbersome as some patients may not be able to read or write. Also the very variable nature of the situation to be explained and to be consented for may make it impractical to carry out to the letter. A compromise is therefore required whereby disclosure and explanation is verbal whilst a less comprehensive written form is used.

SITUATIONAL PROBLEMS IN INFORMED CONSENT

a. Refusal of treatment

The responsibility of informed consent extends to refusal of treatment. Refusal of treatment itself must be competent,

voluntary and informed. Irrationality for religious or personal reasons may present moral and legal problems, eg Jehovah's witness and blood transfusion.

b. **Treatment of incompetents or minors**
There are legal safeguards with regard to these, however there may be value laden judgements. Another situation may arise where the minor who is socially competent may forbid disclosure to parents or their legal guardians.

c. **Emergencies**
In true emergencies this is usually non-controversial. Informed consent is usually deemed unnecessary based on the doctrine of beneficence and non-maleficence. However what constitutes an emergency is not always clearcut and is subjective. The patient may not necessarily see eye to eye with the physician.

d. **Lack of knowledge or expertise of the practitioner**
It is human not to be all knowledgeable. This is both a moral and a legal issue and it is especially relevant for new techniques and new information which may not be known to all. It compromises the requirement for adequate disclosure of information.

e. **Protection against harm vs protection of autonomy**
This may apply to all four basic elements of informed consent, ie disclosure of information, comprehension of information, voluntariness of consent and competence to consent. It remains a moral and a legal dilemma.

f. **Controlling influences, solicited or unsolicited**
There is no ambiguity when it comes to solicited influences. A researcher with a particular interest in an as yet unproven surgical technique may attempt to influence the choice of the patient, thereby controlling the patient's autonomy. Financial gain for the medical practitioner if the patient chooses a certain option is another example. For the unsolicited ones the position is less clear. This may occur when patients take a meek and worshipful attitude towards the doctor, giving consent to a procedure in this position of meekness, thereby subjugating his autonomy unsolicited. Where lies the responsibility for clearing these unsolicited influences, especially when their presence is not even perceived and recognised by the physician?

CONCLUSION

There are sound reasons on ethical, moral and legal grounds to practise informed consent. There are dilemmas involved, and there are also practical difficulties in its practice, however the elements constituting informed consent should remain the bedrock of consent for investigations, treatment as well as research. It may be impractical to carry it out to the letter, but there should not be any compromise in the spirit of its application.

REFERENCES

1. Beauchamp TL, Childress JF. Principles of biomedical ethics. 2nd ed. New York, Oxford: Oxford University Press, 1983: 66-105.
2. Capron AM. A functional approach to informed consent. In: Mappes T, Zembaty J.eds. Biomedical Ethics. New York: McGraw-Hill. 1981: 74-83.
3. Morris RC, Moritz AR. Liability for unauthorised treatment. In: Morris RC, Moritz AR. Doctor and patient and the law. 5th ed. Saint Louis: The C V Mosby Company. 1971: 147-91.
4. Humber JM, Almeder RF.eds. Biomedical ethics and the law. New York: Plenum Press. 1976.
5. Gillon R: Consent - Philosophical medical ethics. Br Med J 1985; 291: 1700-1.
6. Polani PE. The development of the concepts and practice of patient consent. In: Dunstan GR, Seller MJ.eds. Consent in Medicine. London: King Edward's Hospital Fund for London. 1983: 57-88.