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ETHICS ARTICLE

Informed consent

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Introduction

Informed consent is both an ethical and a legal doctrine which is specifically or tacitly applied in all clinical health care and research settings. The ethical component is couched in respect for persons and their right to self-determination while the legal component is enforceable and is entwined within the minimal standards of care.

The origins of informed consent

The historical development of informed consent is a relatively recent event. The American Courts began to set precedents in this area in the early 20th century. In a landmark case in 1914, (*Schloendorf v. Society of New York Hospital*) Justice Cardozo stated, "Every human being of adult years and sound mind has a right to determine what shall be done with his own body; and a surgeon who performs an operation without his patient's consent commits an insult for which he is liable in damages..." He noted that exceptions may be made in true emergencies and in the unconscious patient. Prior to this time, and since the days of Hippocrates, doctors practiced their art under a cloak of benign paternalism. **Paternalism** (or as the more gender-sensitive community would have it: **parentalism**) implies acting for the good of another person without that person's consent, 'as parents do for children'. In Kantian terminology the **end** is benevolent while the **means** are coercive. Paternalism, by its very nature, interferes with individual autonomy. In the medical research arena, the recognition of the rights of subjects to autonomy and informed consent was enshrined in the judgement against Nazi doctors at Nuremberg and has been refined in the Helsinki protocols and other more recent ethical doctrines and policies.

A legal definition of informed consent would include the following: Except in the case of an emergency, a doctor/healthcare worker must obtain a patient's agreement (informed consent) to any course of investigation, treatment or research. Doctors are required to tell the patient anything that would substantially affect the patient's decision. Such information typically includes the nature and purpose of the treatment, its risks and consequences and alternative courses of treatment. In South African law any and all investigation and treatment of patients constitutes assault but this assault is condoned by proper informed consent.

Informed consent is a complex process rather than a signature on a piece of paper. The elements of the consent process must include the following:

Preconditions to consent

Voluntariness

Consent is not valid if the process is adversely influenced by persuasion, manipulation, coercion or reward in any form. The physical state of the patient (such as the presence of pain) or the emotional state (such as fear) may influence the voluntary background. Voluntariness is especially pertinent in consent for research.

Capacity and competence

Capacity and competence are sometimes considered synonymous in discussions regarding consent but it may be useful to consider that we need to assess the mental **capacity** of a person to decide whether they are **competent** to provide informed consent. Certain categories of patients such as young children and patients in coma are obviously incompetent to give meaningful consent although, in the case of children, it is prudent to obtain their **assent** to treatment apart from consent from the parents or guardian.

It is often very difficult to make a decision as to whether an adult patient has the capacity to make a competent decision. In practice, it is usually left to the doctor providing the treatment to decide on competence and this, in itself, is a precarious situation. It is usual that a Yes/No decision for treatment is required for a course of treatment yet patients may have very variable degrees of competence.

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A number of criteria should be considered in the evaluation of the decision-making capacity of the patient. These include:¹

- The recognition of choices and selection of one option. Frequent vacillation may indicate lack of capacity.
- The understanding of relevant information. The patient should be able to paraphrase the benefits and risks of the options.
- The appreciation of the medical situation and the consequences of actions or inactions. Denial is a common cause for impairment.
- The rational manipulation of information regarding options. This looks at the process by which a choice is made. Remember, the competent patient still has the right to make an 'unreasonable choice'.

Informational elements

Disclosure

How much to disclose is always a matter for debate. The doctor should be guided by common practice. Information documents are freely available on the internet, covering most medical and surgical conditions. The information should be in a language and format appropriate to the patient. Although it is permissible to allow a third party to administer the consent process, the contract remains between the patient and the doctor. The information needs to be modified to address the fact that the contract is between an individual specific local physician and a specific individual patient. That is to say, the information should be sufficient for a normal person to make a reasonable decision but should also address the unique needs of the specific individual faced with a given choice. It is essential that doctor's knowledge should be current in the field and that the risks to the patient should relate to skill and experience of the specific, individual doctor.

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Recommendation

The patient is not offered an arbitrary or random choice of treatment options. Rather, the doctor **recommends** a specific course of action. The patient then needs to understand the nature and implications of this recommendation. The model most favoured by patients' is shared decision making. In the past the doctor would exhibit benevolent paternalism on behalf of the patient. On the other side of the scale and in an age of consumerism, there is a tendency to allow the patient free choice of options as if choosing a washing powder from a supermarket shelf. The best decisions are made by informed discussion between patient and doctor arriving at consensus. This takes time and effort.

Understanding

Even the competent adult patient may misunderstand the information presented to them. As mentioned, the language should be understandable to the patient and it should be recognised that there may be linguistic and cognitive limitations. Time spent in this area is well rewarded as many medico legal actions are based on miscommunication rather than negligence. It is necessary that the patient has an understanding of the diagnosis, prognosis, and alternative treatment choices; including no treatment. Recognition should be given that no patient is an island. They come to medical decisions with a history biased by relationships; personal and social, familial and institutional.

Consent elements

Authorisation

This is the part of the consent process where the go-ahead for a course of action is given by the patient; either tacitly or expressly.

Tacit or implied informed consent

Most consent to treatment is implied. When patients consult a physician, they come expecting to be examined, investigated and treated. Uninformed consent has no ethical or legal validity. Under routine conditions, provided that good communication is employed, no 'extra' consideration regarding consent is required. However, each of these components may sometimes require **express** consent. For example, when there is the slightest chance of any non-trivial complication resulting from treatment or from examination or investigation, then express informed consent is advised. These days, there is more litigation resulting from these 'grey areas' than from more obvious lapses in the consent process.

Express consent

Express consent may take the form of verbal (Oral) consent or written (signed) consent.

Verbal consent, *per se*, is ethically correct and legally binding. It is the usual practice for, say, intimate examination. An independent witness is essential. However verbal consent is not always prudent and may be regretted when disputes arise.

Written consent is the 'gold standard' of authorisation. The form should be dated and signed by both parties. If a translator or interpreter is used then they should also sign. The signatures should be verified by an independent witness. It is as important, or perhaps more important, to make notes of the consent process in your clinical records.

Consent for anaesthesia

It was accepted in the past that the consent for anaesthesia was tacitly covered by the surgical consent but this is no longer acceptable. Anaesthesia has its own specific risks and it is now advised that specific consent is obtained by the anaesthesiologist.



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Surrogate consent

It is necessary to obtain consent from a surrogate where the patient is not competent to give their own consent.^{3,4}

In children it is usual for the parents to give consent. One parent, usually the mother, is accepted as sufficient although in the absence of the mother, the father's consent is equally binding. Difficulties might arise if there are conflicts between parents. In emergencies and in the absence of parents, the CEO or Superintendent or the Court may give consent. Where the doctor considers that a parent is withholding consent inadvisably, the doctor must act in the child's best interests. This may require an appeal to the courts. Failure by the doctor to act in the child's best interests may make him or her liable to future litigation. While it is generally accepted that parents are best placed to assess their children's best interests this is not inevitably the case.

The laws governing the age of consent for various situations are complex and confusing. Strode *et al*⁵ have recently commented that 'Parliament has clearly adopted an inconsistent approach in setting consent norms for children. It is difficult to establish any pattern between a child's emerging capacity and the norms for various health interventions.' This subject warrants future discussion at length.

The standard used in the case of an incapacitated adult, who was previously competent, is that of substituted judgement. In this process, the next-of-kin are usually called on to give surrogate consent. They are asked to act in a way that they believe that the patient would have acted had he/she been competent.

Studies³ have shown that the surrogate 'gets it right' about 65% of the time. In each case, the substituted judgement standard requires that the surrogate decision-maker (whether a guardian, a family member, or the court) determine whether the patient, if competent, would have consented to the proposed health care. The surrogate should consider all relevant factors that would influence the patient's medical treatment decisions, including:

- the person's prior statements regarding medical treatment
- the person's express wishes, even if made while the individual is incompetent
- the patient's religious or moral views regarding medical care or the dying process
- the person's prognosis if no treatment is given
- the prognosis if one treatment is chosen over another
- the risk of adverse side effects from the proposed treatment
- the intrusiveness or severity of the proposed treatment
- the ability of the patient to cooperate and assist with post-treatment therapy
- the wishes of family and friends, if those wishes would have influenced the patient.

Consent for medical research

Informed consent in a research setting warrants even greater consideration than in the clinical domain. Apart from consent, major areas of ethical concern in research include; vulnerable research subjects, privacy, confidentiality, best practice, conflicts of interest, publication issues etc. Research ethics will therefore form the basis of a future article.

Conclusion

The process of consent is an important and complex issue with overlapping legal and ethical connotations. In an increasingly litigious society, it seems that practitioners should give more attention to the subject.

References

1. Appelbaum PS. Assessment of Patients' Competence to Consent to Treatment. *NEJM* 2007;357:1834-40.
2. Lee SJ, Back AL, Block SD, Stewart SK. Enhancing Physician-Patient Communication *Hematology* 2002; 464-83.
3. Strode A, Slack C & Essack Z. Child consent in South African law: implications for researchers, service providers and policy-makers. *SAMJ* 2010; 100(4):247-49.
4. Shalowitz DI, Garrett-Mayer E, Wendler D. The accuracy of surrogate decision makers: a systematic review. *Arch Intern Med* 2006; 166(5):493-97.

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Questions True or False

1 According to South African law, all investigation and treatment of patients constitutes assault.

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2 It is never permissible to allow a third party to administer the consent process.

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3 The substituted judgement standard requires that the surrogate decision-maker determine whether the patient, if competent, would have consented to the proposed health care.

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4 Verbal consent is the 'gold standard' of authorisation.

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5 Doctors are required to tell the patient everything that would substantially affect the patient's decision.

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