Article

Informed consent – 2008

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The traditional Hippocratic belief that one could do almost anything on a patient as long as the principles of beneficence (best interests) and non-maleficence (no harm) were upheld has been considerably revolutionised over the last century. Paternalism, the belief that the health care practitioner should protect or advance the interests of the patient even if contrary to the patient's own immediate desires or freedom of choice, no longer has a place in the health care context. Pursuant to the Nuremburg Trials, the Universal Declaration of Human Rights and several other codes and guidelines emanating from international bodies such as the World Medical Association underscore, among other ethical tenets, the value of autonomy and self-determination. Autonomous actions are the outcome of deliberations and choices by rational agents as persons in the moral sense. Rational persons meet the criteria necessary to decide what is in their own best interests. Health care practitioners have a duty to recognise and respect this value in their patients. Not to do so would not only violate their patients' autonomy, but would be synonymous with treating them as less than persons.[1] An autonomous person is someone who has the ability to deliberate about personal goals and to act under the direction of such deliberation. Respecting autonomy denotes valuing the autonomous person's considered opinions and choices and refraining from obstructing their actions unless they are clearly detrimental to others.[2]

While there has been widespread acceptance of patient autonomy, with patients being the ultimate decision-makers in matters that affect themselves, the clinical autonomy and freedom in determining patient management that medical practitioners traditionally enjoyed has been significantly curbed by, *inter alia*, governments, medical insurers and the economic climate. Hence, autonomy or self-determination, one of the foundational principles in medical practice, has changed to a large extent over the years.[3]

In this paper, I will attempt to provide a global overview of informed consent from the perspective of both ethics and the law. Pertinent sections of the law will be discussed in order to provide an update on the current legal status of informed consent in present-day South Africa.

The meaning of informed consent

Founded on basic ethico-legal principles, the doctrine of informed consent entails a process of information sharing and decision making based on mutual respect and participation. It should be considered a procedure and not merely an affirmation, ritual or signature on a piece of paper at a particular point in time. The idea behind informed consent is that it facilitates the performance of professional tasks in a morally defensible way by bringing the patient's informed preferences into the health care practitioner's plans. Being well informed on entering the decision-making process protects the patient's dignity in the health care environment. The fundamental belief behind informed consent is that trust between the health care practitioner and the patient will be fostered and engendered.[4] An obvious requirement for ensuring that consent is truly informed is a health care practitioner with communication, listening and interpretative skills. In addition, it is an ethical imperative that the health care practitioner recognises and respects the patient's choice of decision, which may be that of informed refusal rather than consent.

In law, the health care practitioner-patient relationship is usually a contractual one with the contract taking the form of an implied agreement that the health care practitioner will make a diagnosis and treat the patient in accordance with generally accepted standards.[4] All forms of management must be discussed with the patient first. A related legal concept is the idea of a fiduciary relationship, whereby the patient places a special trust or confidence in the health care practitioner. Hence the health care practitioner violates his or her legal duty if information that is necessary for a patient to make a rational decision regarding care is withheld.[4]

Consent to treatment can be expressed either orally or in writing (signed), or can be implied (tacit) by conduct. In law, there is no difference between written or oral consent, except that written consent is easier to prove should a dispute ensue.[5] Usually when a patient undergoes surgery or complex procedures, written consent is required. It is the duty of the health care practitioner to ensure that consent has been obtained from the patient. The health care practitioner cannot rely on a nurse or other health care professional to ensure that consent has been obtained. Treatment without proper consent could result in the health care practitioner being guilty of the crime of assault or invasion of privacy if, for example, blood is tested without consent.[5]

Validity of consent

The ethical and legal elements of a valid consent process are:[5]

- Disclosure
- Understanding
- Capacity
- Voluntariness.

Disclosure

The patient should not only be given information on the proposed management but be informed of the risks and complications associated with the treatment. In addition, the patient should be given information on possible alternatives to the proposed management, the range of diagnostic procedures and treatment options generally available and information on how she or he would fare should no treatment be implemented. The consent, once obtained, would be comprehensive, i.e. would include consent to risks and complications.[5] Section 6 of the National Health Act[6] further states that patients should be informed of their rights to refuse the health service, i.e. diagnostic and/or therapeutic procedures. They should also be informed of the implications, risks and obligations of such refusal.

The exact information to be disclosed to the patient has been the subject of much debate. In the past, the accepted standard of disclosure was that of the 'professional community standard'. How much information to be imparted was largely a matter of health care practitioner discretion. This professional community standard has in most jurisdictions been replaced by the 'reasonable patient' standard, which entails a patient-centred approach to informed consent.[7] The health care practitioner does not have to painstakingly point out all the conceivable complications that may arise.[8] She/he is obliged to warn the patient of any 'material' risks inherent in the proposed treatment.[5] A risk would be material if a reasonable person in the position of the patient when warned of the risk would attach significance to it. Moreover, the health care practitioner should reasonably be aware that the patient, if warned of the risk, would attach significance to it.[9] In determining the standard for disclosure, it would be important to take into consideration the patient's background and the relative advantages and disadvantages of each decision for the patient's well-being. The health care practitioner providing the pertinent information must personalise the amount and the type of information provided despite the difficulty in doing so.[4] Furthermore, the National Health Act makes provision for the therapeutic privilege by allowing for the withholding of information in circumstances where there is substantial evidence that the disclosure would be contrary to the interests of the patient.[6]

Understanding

A requisite for the health care practitioner is the obligation to ascertain the level of a patient's ability to grasp the information given, i.e the mental competence or capacitation.[4] One of the greatest challenges to the doctrine of informed consent is the difficulty in ascertaining whether or not the patient truly understands and grasps the nature of his/her illness and the basis for consenting or refusing the management proposed. Of assistance are the four levels of competence that have been proposed by Appelbaum and Grisso.[10] Ideally, the patient should have all four levels for optimal competence.

1. The ability to communicate choices.
2. The ability to understand relevant information upon which the choice is made.
3. The ability to appreciate the situation according to one's own values.
4. The ability to weigh various values to arrive at a decision.

Information sharing should be in simple, understandable language, preferably in a language that the patient understands, and in a manner that takes into consideration the patient's level of literacy.[6] Differences of language and culture are two major obstacles to good practitioner-patient communication, with differences in cultural understanding of the nature and cause of illness at times impeding the understanding of the diagnosis and treatment options provided by the practitioner.[3]

Capacity

Capacity refers to mental and legal capacity to consent. The patient should be in the appropriate frame of mind to make an informed decision. When this is not possible, a legally appointed proxy may provide the consent. Section 7 of the National Health Act[6] stipulates:

> … a health service may not be provided to a user without the user's informed consent, unless –
>
> (a) the user is unable to give consent and such consent is given by a person –
>
> (i) mandated by the user in writing to grant consent on his or her behalf; or
>
> (ii) authorized to give such consent in terms of any law or court order;
>
> (b) the user is unable to give informed consent and no person is mandated or authorized to give such consent, and the consent is given by the spouse or partner of the user, or, in the absence of such spouse or partner, a parent, grandparent, an adult child, or a brother or sister of the user in the specific order as listed;
>
> (c) the provision of a health service without informed consent is authorized in terms of any law or a court order;
>
> (d) failure to treat the user, or group of people which includes the user, will result in a serious risk to public health; or
>
> (e) any delay in the provision of the health service to the user might result in his or her death or irreversible damage to his or her health and the user has not expressly, impliedly or by conduct refused that service.

According to the Mental Health Care Act,[11] a health care provider or health establishment may provide care, treatment or rehabilitation services to, or admit, a patient if the patient consents, or where a court order or Review Board authorises such treatment or admission or where, owing to mental illness, any delay may result in death or irreversible harm to the patient, infliction of serious harm on the patient or others, or damage or loss of property belonging to the patient or others.

Legal capacity refers to age of consent. According to section 28 of the Bill of Rights, a child is any person less than 18 years of age.[12] In addition, the Children's Act[13] places the age of majority at 18. At the time of writing, some sections of the Child Care Act[14] are still in force while selected sections of the Children's Act have already been promulgated. Section 39(4) of the Child Care Act (still in force) provides that children of 14 years or over may consent to medical treatment and persons of 18 years or over may consent to surgical operations. This will change when the pertinent sections of the Children's Act are promulgated. Children aged 12 years and older would be able to consent to medical treatments provided they are of sufficient maturity to do so. Children aged 12 years and older would be able to consent to surgical treatment provided they are of sufficient maturity and duly assisted by the parent or guardian. The challenge here is how maturity is determined, in particular where the child is a first-time patient and there has not been sufficient time to establish a medical practitioner-family relationship. Furthermore, the Choice on Termination of Pregnancy Act[15] provides for termination on request up to 12 weeks of pregnancy for females of any age with no stipulations with regard to 'maturity'.

For children less than 12, parental, guardian or caregiver consent will be requisite for medical management. Regarding surgical procedures for children under 12, the Act stipulates the need for parental or guardian consent, and is silent on the issue of caregiver consent. The law, while differentiating between medical and surgical treatments on the issue of age of consent, makes no mention of level of risk and invasiveness of treatment. It would make more sense if risk determined the age of consent rather than simply medical or surgical management. The Act also states that no parent, guardian or caregiver of a child may refuse to assist a child or withhold consent because of religious or other beliefs, unless they can show that

there is a medically accepted alternative choice to the medical treatment or surgical operation concerned. Hence, in this situation, it would have to be the parent, guardian or caregiver that applies for a Court Order to prevent treatment. So far, it has been the obligation of the practitioner to make an application to institute management in the best interests of the child when consent has been withheld.

Section 130(2) of the Children's Act (in force) provides that where it is in their best interests children may consent to an HIV test if they are aged 12 years or over, or if they are under 12 years of age and are sufficiently mature to understand the benefits, risks and social implications of such a test. Where it is in their best interests and children under 12 years of age are not sufficiently mature to consent, consent may be given by a parent or caregiver, the provincial head of social development, or a designated child protection organisation. Caregiver is widely defined in the Act, and could include anyone who cares for the child. Where it is in the child's best interests and consent is unreasonably withheld, application may be made to a Children's Court to authorise the HIV test. A court application may also be made if it is in the child's best interests and the child, parent or caregiver is incapable of giving consent.

Also in force is Section 134(1) of the Children's Act which states that no person may refuse to sell condoms to children over the age of 12 years or to provide condoms to children over the age of 12 years on request where condoms are provided or distributed free of charge. Section 134(2) of the Act provides that contraceptives other than condoms may be provided on request by a child without the consent of a parent or caregiver if the child is at least 12 years of age, proper medical advice is given to the child, and the child is medically examined for contraindications.

Both the Child Care Act and the Children's Act are similar to section 28 of the Bill of Rights of the Constitution[12] in stipulating that in all activities involving a child, the child's best interests are of paramount importance. Parental refusal to treat the child may be overridden where it is unreasonable and such lack of treatment could impact negatively on the child. The Acts makes provision to apply for a Court Order to reverse parental refusal. This would apply in the semi-elective and elective situations. In an emergency, the health care practitioner should proceed with immediate management.

Voluntariness

For informed consent to be genuinely valid, there should be no coercion or manipulation compelling the patient to consent or refuse against her or his own best interests and wishes. Special safeguards are recommended to protect those patients considered to be vulnerable and in dependant positions, e.g. the elderly, as there is a tendency for the voluntariness element of informed consent to be eroded in these situations.

The South African Constitution and consent[12]

Section 12 of the Bill of Rights of the Constitution on freedom and security of the person affirms in subsection 2 that everyone has the right to bodily and psychological integrity, which includes the right to security and control over their body. Accordingly all patients in South Africa have the right to free choice and informed consent and refusal in the health care context. However, section 36 limits all rights in the Bill of Rights on condition that the limitation can be demonstrated to be reasonable and justifiable in an open and democratic society. Hence, autonomy is not absolute. Where patients request non-therapeutic procedures or procedures not accommodated for in public policy, while their ability to make free choices is respected, it would be acceptable not to accede to their requests. In addition, recent involuntary admissions of patients with extremely drug-resistant tuberculosis in South Africa could be justified by invoking section 36. Moreover, every right has a corresponding responsibility. An important aspect of the informed consent process would be the need to highlight the importance of patients honouring their obligatory responsibilities as part of the health care practitioner-patient relationship. The rights and limitations to informed consent, informed refusal and the corresponding responsibilities are also detailed in the Patients' Rights Charter.[16]

Research and consent

Respect for persons entails that participants enter research voluntarily and with adequate information that they have understood. In terms of section 71 of the National Health Act,[6] consent in research must be written. Where minors are involved in therapeutic research, consents of the parent/guardian and minor (if in a position to understand) must be obtained before their participation. In the case of non-therapeutic research involving minors, in addition to the respective consents, permission should also be obtained from the Minister of Health. There was clearly a lack of insight into the therapeutic/non-therapeutic distinctions when this aspect of the law was formulated.

With regard to research involving retrospective record reviews and data collection, there is no need for the patient's consent where the data are anonymised in terms of section 16 of the Act.

Conclusion

While the informed consent process is quite challenging in many respects, it is ethically, legally and at a human level imperative that patients are accorded their rights to self-determination. Effective communication and trust are central to a healthy practitioner-patient relationship. A practitioner who respects a patient's autonomy in turn gains the trust and respect of the patient. Informed consent and respect for persons is now standard of care in health care practice and must be integrated into South African health care practice if the needs and desires of our patients are to be respected. Informed consent is not merely a legalistic exercise, but must be seen as a process that empowers our patients to exercise their capacity to plan and execute their decisions regarding their health, taking into consideration their own values and beliefs.

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