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Informed consent

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Introduction

Obtaining valid informed consent is central to the ethical and legal duties of a doctor. In South Africa obtaining informed consent for all medical and surgical procedures has been a legal requirement since 1923 (Stoffberg v Elliot).[1] Failing to obtain informed consent breaches a patient's constitutional right and can lead to a complaint at the Health Professions Council of South Africa (HPCSA), a civil case or even criminal proceedings for assault or battery.

Ethical medical practice is based on four principles: beneficence, non-maleficence, distributive justice and autonomy. Informed consent falls under the last mentioned principle. It is important to note that informed consent for all procedures not only protects the rights of the patient, but the rights of the doctor as well, since both parties have an obligation to protect the integrity of the doctor-patient relationship.

Definition of informed consent

Informed consent is not the signature of a patient on a form. The signature is just a symbol that acts as proof that a process has taken place whereby the patient and the health care practitioner engage in a dialogue about a proposed medical treatment's nature, consequences, harms, benefits, risks, and alternatives.[2]

Elements of valid informed consent

For an individual to give valid informed consent, three components must be present: disclosure, capacity and voluntariness.[3,4]

Disclosure

Disclosure entails providing the patient with the information necessary to make an autonomous decision. The National Health Act states: "that every health care provider must inform the user of the user's health status except in circumstances where there is substantial evidence that the disclosure of the user's health status would be contrary to the best interests of the user; the range of diagnostic procedures and treatment options generally available to the user; the benefits, risks and consequences and costs generally associated with each option; and the user's right to refuse health services and explain the implications, risks and obligations of such refusal".[5] It is important that such information be given in a language that the patient understands and medical terminology should be avoided. Many patients have English as a second or third language and an interpreter should be available if needed, especially when translating technical terms into the patient's first language.

Capacity

Capacity is determined by two different aspects, namely decisional capacity and age. Decisional capacity refers to the ability of a patient to understand the information, to make a reasonable judgement based on the potential consequences of the decision and to reason about the treatment. Decisional capacity is not an all or nothing concept. For example, a patient with mild mental impairment might be able to have the capacity to understand the consequences of a simple procedure like draining a Bartholin's abscess, but unable to understand the life altering implications associated with exenterative surgery. Therefore, capacity to make a decision must take into account both the reasoning ability of the patient and the complexity of the procedure.

The age aspect of capacity is determined by legislation. The age of full legal capacity in South Africa is 18 years.[6] Therefore, it can be accepted that an individual of 18 years or older has the capacity to give informed consent for all medical procedures, unless it is proven that such an individual has a mental impairment which would hinder decision making. If a child of older than 12 has the maturity to understand the implications of a treatment, they may consent on their own. If a surgical procedure is to be undertaken, a child of 12 years and older may give consent, but this consent must be accompanied by the legal guardian assent.[6]

Voluntariness

Voluntariness means that every patient must make the decisions without outside influence or coercion. As medical professionals, we may fall into the trap of trying to convince the patients to follow a specific treatment plan, because in our opinion this will be the best for the patient. Our interpretation of beneficence should however not interfere with the patient's autonomous decision-making process.

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Forms of consent

Consent can be either expressed or implied. Express consent is recorded either orally or in writing. For each proposed intervention, the healthcare professional must assess how well the patient has understood the implications of the intervention, and not simply rely on the form in which their consent has been expressed or recorded.[7] It is prudent that in procedures and investigations in which risk is involved, written record of the patient's consent (or refusal) is available. It is advisable to be wary of implied consent. If a patient is compliant with a procedure, this does not automatically imply consent. A good example is a pelvic examination. This is an invasive investigation and the fact that a patient presents herself for gynaecological assessment does not imply she is willing to undergo an internal examination. Therefore, explain carefully what you are going to do, make sure she understands the nature of the examination and obtain her verbal (or written) expressed consent.

The scope of Informed consent

As stated above, one of the key elements of valid informed consent is information. Patients have a right to information regarding their condition and treatment options available to them. The amount of information that must be given to the patient is specific to each case. The nature of the condition, the complexity of the treatment and the risks associated with the treatment will determine the detail required for the informed consent. The National Health Act[5] requires patients to be given information about:

- Their health status, except where there is substantial evidence that disclosure of a patient's health status would be contrary to the best interest of the patient. It is important to note that this is not a decision the family members can make on behalf of the patient – no family member can decide to withhold a diagnosis from a patient and order the doctor to not disclose it to the patient. It is the patient's right to have their diagnosis disclosed to them and only them and denying this would be against the constitutional rights of the patient.
- The range of diagnostic procedures and treatment options generally available to the patient.
- The benefits, risks, costs and implications generally associated with each option. It is evident that the information a doctor will have available with regard to the costs involved would be limited to the cost of their specific involvement with the case, for example the cost of the surgery. It is therefore important to advise the patient to contact the hospital in which the treatment is to be rendered as well as other specialists involved in the case to calculate the full cost. The primary treating doctor can act in co-ordinating this process.
- The right to refuse health services and explain the implications, risks and obligations of such refusal.

Generally, the complication list section of informed consent is insufficient.[8] All complications and risks are not revealed equally. This especially applies to the more undesirable risks. These undesirable risks should be emphasised, because in 42% of malpractice cases, the complication section of informed consent was an issue.[9] Patients tend to initiate legal action when outcomes do not meet expectations. In order to align expectations, especially regarding complications better with outcomes, full disclosure is paramount in the informed consent process.

Explaining the risk of a given complication can be quite challenging and should be presented in a way a patient can comprehend. This explanation of risk may in some cases require the use of numerical tables.[10]

In high risk procedures, there is a of lot information to understand and to come to terms with. If it is not an emergency situation, give the patient some time to process all the information and talk to his or her family and friends about the decision. Promoting realistic expectations in riskier procedures is a pro-active ethical practice because it instils the proper caution for the patient to consider in her decision-making process.[9] Deciding in an instant which risks are acceptable or not is rarely possible, for example the consequence of a stoma after surgery sounds very daunting, but once a patient has done research on the subject it might become an acceptable risk.

Table 1: Presenting information on risk[11]

Term	Equivalent numerical ratio	Colloquial equivalent
Very common	1/1 to 1/10	A person in a family
Common	1/10 to1/100	A person in a street
Uncommon	1/100 to 1/1000	A person in a village
Rare	1/1000 to 1/10000	A person in a small town
Very rare	1/10000 to 1/100000	A person in a large town

Informed consent and the nature and procedures pertaining to the Obstetrician and Gynaecologist

Gynaecological examination

Patients will often describe a gynaecological examination as an invasive event and rightly so. This examination must be undertaken with the necessary understanding of and respect for the dignity of a patient. Before starting a pelvic or breast examination explain the reason for the examination and obtain verbal consent. The Royal College of Obstetricians and Gynaecologists regard the presence of a chaperone during these examinations essential.[11] The presence of a chaperone protects both the doctor and the patient and where possible a chaperone should be present.

Outpatient procedures

Several procedures that were traditionally performed in theatre are being performed in an outpatient setting, for example office hysteroscopy and management of premalignant lesions of the cervix. It is important that written informed consent be obtained and the complications be discussed in the same manner as would have been done had the patient gone to theatre. It must also be emphasised that in case of a complication, for example a perforated uterus after a hysteroscopic procedure, there may still be a need to go to theatre to manage the complication and the patient should preferably agree to this at the time of the outpatient procedure.

The obstetric patient and a birth plan

In an obstetric patient, a birth plan must be devised in the ante-natal period. This should include (but not be limited to) the timing and route of delivery, pain management during labour and future contraceptive choice. The necessity to deviate from the plan and possible interventions in case of an emergency, for example cutting an episiotomy, an assisted delivery and an emergency caesarean section should be discussed before labour. In devising the birth plan the doctor-patient relationship must be respected by both parties. The doctor must abide by evidence based principles when advising the patient. The patient however cannot force the doctor to follow a birth plan the doctor feels uncomfortable with, or regards as being risky practice. The ante-natal period is an ideal time to decide on the above-mentioned matters. If there are differences that cannot be settled, the doctor has the full right to refer the patient to another healthcare worker or to advise to the patient to continue their ante-natal care with another healthcare worker – providing that the patient is not experiencing an emergency.

During labour or when a patient is experiencing severe pain, it is not an ideal time to obtain informed consent. If a woman is receiving opioid analgesia or sedation, her decisional capacity might be impaired, thus consent might not be considered as valid. This emphasises the need for providing summarised information in the ante-natal period. If consent needs to be obtained in labour, information must be given to the patient in between contractions, so that she can process and understand the information better. In an emergency situation, it might not be possible to obtain written consent for operative procedures. It is sufficient to obtain verbal consent in these instances, but always in front of a witness. As soon as the emergency situation is stabilised, this verbal consent must be recorded in writing and the reasons for proceeding to an emergency delivery without written consent must be documented.[12]

The obstetric patient and refusal of intervention

Almost everyone who has practiced in obstetrics has been faced with the difficult situation of a woman in labour with fetal distress refusing intervention. If the woman is deemed to have full decisional capacity, regardless of her age, her refusal of the intervention must be respected. The law of persons in South Africa regulates the birth, private-law status and death of a natural person.[12] It determines the requirements and qualifications for legal personhood and subjectivity in South Africa and the right and responsibilities attached to it. Legal subjectivity begins at birth.[13] Before birth the fetus is generally not regarded as a legal person, but merely part of the mother, with no rights, duties or capacities. The woman's autonomy and decision not to intervene must be respected.

Consent in special situations

Minors

After much controversy and amendments to the Act, the new Children's Act was promulgated on 1 April 2010 by the then Deputy President, Kgalema Motlanthe, after the regulations of the Act were finalised by both the Department of Social Development and the Department of Justice and Constitutional Development and is now referred to as the Children's Act 38 of 2005 as amended. This Act therefore is the primary statute that guides and regulates the provision of all services, including medical services to children in the Republic of South Africa. As stated earlier on in this article, if a child is considered as mature enough, he or she can consent to medical treatment from the age of 12. When it comes to surgical treatment, a child from the age of 12 years can consent to this treatment, if this consent is accompanied by the legal guardian's assent. The onus is thus on the treating medical doctor to assess the maturity and decisional capacity of the child involved. This is sometimes a daunting task if the doctor has had minimal prior contact with the child. The South African Constitution provides that "a child's best interests are paramount in every matter concerning a child." This law and the inner ethical compass must often guide the doctor involved to assist in making the correct judgement. Fortunately, we do not practice in isolation. If in doubt discuss with a colleague and involve members of the multi-

disciplinary team, for example a family doctor who knows the child, a social worker or a child psychologist. If the legal guardian's wishes are in conflict with what is considered to be the best interest of the child, it might be necessary to seek legal advice and apply to the High Court for a ruling. The High Court is the upper guardian of all minor children.

Mentally incapacitated adults

There are two Acts to take cognisance of when dealing with mentally incapacitated adults; the National Health Act[5] and the Mental Health Care Act.[14] As stated previously, to determine the capacity for decision making, the ability of the individual and the complexity of the procedure must be considered. The National Health Act makes provision for certain persons to give consent on behalf of mentally incompetent patients for medical interventions. The Act also sets out a priority list of persons who may consent for interventions. They are as follows (in descending order of priority): a person authorised by the court (curator), patient's spouse, partner, parent, grandparent, major child or brother or sister.[5]

Incapacitated individuals

This refers to individuals who had prior capacity to make a decision with regard to medical intervention, but have for some reason, which may or may not be linked to the current disease state, lost the capacity to make a decision. The National Health Act[5] also makes provision for the proxy decision maker in this event: the patient's spouse, partner, parent, grandparent, major child or brother or sister. If none of the above mentioned can be reached, it is the onus of the most senior specialist involved in the case, after reviewing all aspects of the case to act as proxy for the patient. There is no legal support for the current practice of obtaining informed consent in these instances from the medical superintendent. If the medical superintendent is the most senior team member involved, then it is obvious that he or she will be the primary decision maker – this however is rarely the case. The Head of Department or most senior consultant on call of the involved discipline would be the correct person in most instances to act as proxy.

Advance directives and Living wills

The purpose of a Living will is to assist family members and doctors in the decision-making process in a patient who was previously regarded as having full decisional capacity, but who has become an incapacitated individual due to illness or injury. The jurisprudential basis for a living will is that of informed consent, which as stated above is a constitutional right. It is however interesting to note that Living wills do not fall under the Wills Act[15], which only covers testamentary dispositions, nor are they recognised explicitly by any other statute[16], therefore it is not a legally enforceable instruction. However, it is not possible to assign a temporal limitation to informed consent, therefore an autonomous decision cannot have an expiry date and it can be argued thus that the National Health Act[5] makes allowance for this in sections 7 and 8 even though it is not explicitly stated.

Termination of pregnancy

According to the Choice on Termination of Pregnancy Act[17] a woman of any age can give consent to a termination of pregnancy. Again the provision is that the healthcare provider must be of the opinion that the patient involved has the capacity to make the decision. The request for termination of pregnancy must be in accordance to the parameters set out by the above-mentioned law when it comes to gestational age of the fetus, also who can perform the termination of pregnancy and sites for termination of pregnancy. The only person who needs to consent for the termination of pregnancy is the pregnant women herself.

Emergency situations

In an emergency, where consent cannot be obtained, health care practitioners may provide medical treatment to anyone who needs it, provided the treatment is limited to what is immediately necessary to avoid mortality or severe morbidity.[7] Once the patient has gained the capacity to make decisions, they will take over the decision-making process again. It is also important that after the emergency full disclosure of events and interventions be given to the patient and that an explanation is given for the course of action taken.

Informed consent for high risk procedures

By nature of the practice of Obstetrics and Gynaecology, many procedures are considered high risk in this field. If the amount of legal action that is currently been taken against obstetricians and gynaecologists be considered, as well as the medical indemnity amount associated with private obstetrical practice, it can be said that nearly all procedures and every delivery should be regarded as high risk!

Certain procedures are however associated with a higher risk of complications and failure, for example radical oncological surgery, fetal surgery, and invitro fertilisation (IVF). Albert Einstein said, "In the middle of difficulty lies opportunity" – and this saying applies directly to these procedures. The risk associated with them is very high, but if these procedures are successful, the gain is also tremendous – and this must be considered in a risk benefit discussion with the patient. Often this intervention proposed will be the only opportunity for cure, a live fetus or a pregnancy, but in the intervention, lies a great deal of difficulty and risk.

Surgical therapy and high-risk procedures occur as a specific event, usually requiring entering a patient's body, the therapeutic event can be timed exactly (assigning culpability), the emotional stress on the

patient is greater, and this patient plays a more passive role than patients of other medical specialities once anaesthesia is induced.[18] Since these high-risk procedures are often carried out by a team of healthcare professionals, it is important to ensure that the person taking consent is suitably educated, trained and qualified and has sufficient knowledge of proposed investigation or treatment and understands the risks involved to explain it clearly to the patient. For high risk procedures, a patient's decisional capacity should be assessed and steps be taken to enable in depth understanding of what is proposed. The doctor should be attentive to internal or external controlling influences and, if necessary address such influences so that the patient's decision process is voluntary.[19]

Informed refusal and withdrawal of consent

If the patient has adequate capacity and information with regard to the treatment options proposed, he or she has the right to refuse all forms of treatment, even if this refusal may lead to disability or death. It however is prudent that all information about the disease, treatment options and consequences of refusal of treatment be clearly explained to the patient. The reason for refusal must also be sought and attempts must be made to address hidden fears and anxieties, without falling into the trap of coercion.

This will be an expressed refusal in most instances and documentation of this must be kept.

Patients with decisional capacity may also withdraw consent for continuing treatment. Stopping or interrupting medical treatment is usually straightforward, but it is more complicated with surgical procedures. If during such a procedure a patient indicates that he or she would like to stop the procedure and the patient has full decisional capacity (this becomes an even more difficult call to make if the patient underwent sedation), the healthcare workers should do so as soon as it is safe to do so after explaining the consequences of not completing the procedure. The wishes of patients who lack decisional capacity and who indicate that they want to terminate a procedure due to pain and discomfort must also be respected.

ICD 10 coding and informed consent

Patients are often unaware that their diagnosis and treatment plan will be given to the medical aid schemes in ICD 10 coding form for reimbursement purposes. If the patient chooses not to divulge the diagnosis to the medial aid scheme, this is the patient's right, but the implication would be that the patient needs to settle all the providers' accounts directly. The patient must also take cognisance of the fact that the practitioner does not have control over the management and utilisation of this information once divulged to the medical aid scheme and that the medical aid scheme takes responsibility for any further disclosure or utilisation of such information for whatever purpose.[7]

Conclusion

Informed consent is an essential component of good clinical practice. It is important for patients to understand that certain procedures can have adverse outcomes, that may lead to severe morbidity or even mortality. Informed consent is thus not only a process, but a place where the doctor-patient relationship enters a realm of acceptance by the patient who authorises the doctor to risk harm to the patient in order to help. This great honour and responsibility must be treated with gravity by the doctor and both partners in this relationship must understand that in life, variability can lead to adversity, even though both partners have been exemplary in terms of their intentions, integrity and actions.

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