

MEDICAL PROTECTION SOCIETY
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Consent to Medical Treatment in South Africa

An MPS Guide

www.mps-group.org

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Important – please note

Due to the dynamic nature of medical law we suggest that you access our website at www.mps.group.org for the most up-to-date information. August 2012.

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This booklet was produced as a resource for MPS members in South Africa. It is intended as general guidance only. For more specific practical advice and support with medicolegal issues that may arise please contact MPS.

The Medical Protection Society is the leading provider of comprehensive professional indemnity and expert advice to doctors, dentists and health professionals around the world.

We are a mutual, not-for-profit organisation offering more than 270,000 members help with legal and ethical problems that arise from their professional practice. This includes clinical negligence claims, complaints, medical council inquiries, legal and ethical dilemmas, disciplinary procedures, inquests and fatal accident inquiries.

Fairness is at the heart of how we conduct our business. We actively protect and promote the interests of members and the wider profession. Equally, we believe that patients who have suffered harm from negligent treatment should receive fair compensation. We promote safer practice by running risk management and education programmes to reduce avoidable harm.

MPS is not an insurance company. The benefits of membership are discretionary – this allows us the flexibility to provide help and support even in unusual circumstances.

Introduction

In most situations, obtaining a patient's valid consent to a procedure or treatment is a simple matter of following straightforward guidelines, but circumstances can occasionally develop in which conflicting principles must be resolved and this can pose a dilemma for clinicians. This booklet has been written as a guide to the ethical and legal principles that should be applied, both in straightforward and more challenging circumstances.

To treat competent patients without their valid consent is a violation of their constitutional rights and transgresses a fundamental principle of medical law. The basic rule is simple: no-one has the right to touch anyone else without lawful justification and if doctors do so it may well undermine patients' trust as well as violate their rights to physical integrity. The only exception to this rule is when the patient lacks the capacity (by virtue of his or her lack of maturity or a mental impairment) to give valid consent, in which case someone else has to make decisions on the patient's behalf.

Failure to respect a patient's rights to bodily integrity may lead to a complaint to the HPCSA, civil or criminal proceedings for assault, or to a claim. It is important to remember that a well-taken consent is not based on a one-off event, but is an outcome of an ongoing communication process (see Figure 1 on page 4).

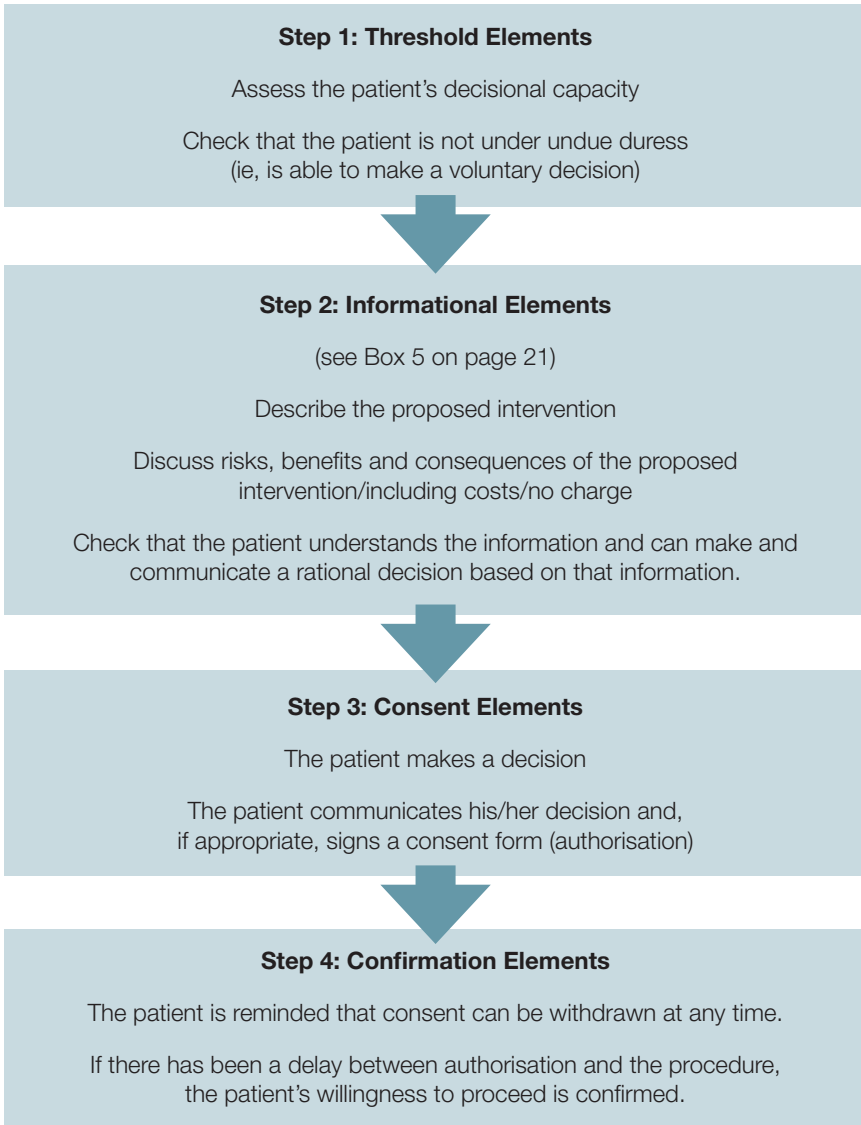
There are three components to valid consent:

- Capacity
- Information
- Voluntariness



Figure 1: Steps in the consent process

Obtaining a patient's consent to treatment is not just a matter of asking for a signature on a consent form; it is a communication process, as the flowchart below shows.





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Capacity

Legal capacity has two components – age and decisional capacity.

Age

The age component of legal capacity is determined by legislation – ie, the age at which the law confers certain rights and obligations on individuals at different stages in their lives.

The age of full legal capacity in South Africa is 18.¹ In terms of consent to clinical treatment, this means that people of 18 and older should be assumed to have the decisional capacity to make choices on their own behalf, unless there is good reason to believe that they have a mental impairment that compromises their ability to make specific decisions. Children of 12 or older who have the maturity to understand the implications of a proposed treatment may consent on their own behalf. If a surgical procedure is being proposed, the child's consent must be accompanied by a parent or guardian's written assent. (See page 11 for more about children and consent.²)

There are other circumscribed situations (for example, HIV testing or termination of pregnancy) in which the law sets out who may give consent, depending on the circumstances. These are covered later in this booklet.

Decisional capacity

There are two overriding principles to bear in mind regarding a person's capacity to consent to treatment:

- Adults are presumed to be competent to make decisions. You must therefore be satisfied that they lack the capacity to make a particular decision before intervening without their consent.
- Minors are generally presumed to lack decisional capacity. You must therefore be satisfied that they have the capacity (maturity) to make a particular decision before intervening with their consent.

Decisional capacity (also referred to as “mental capacity”) is variously defined as the capacity to make decisions in light of information about the relevant risks, benefits and consequences of the proposed intervention, specifically being able to:

- Understand relevant information
- Appreciate the consequences of the situation
- Reason about treatment.³

Decisional capacity is not an “all or nothing” concept. A patient might, for example, be perfectly capable of grasping the implications of minor surgery to remove a sebaceous cyst, but be unable to comprehend all the risks and benefits associated with a bowel resection. The capacity to consent to treatment is, therefore, decision-specific.

A patient's decisional capacity might also fluctuate over time – even in the course of a day – so the time at which consent is sought may be crucial.

Assessing decisional capacity

A person's decisional capacity, or lack thereof, should not be judged simply on the basis of age, appearance, condition or any aspect of his/her behaviour. If a patient's decisional capacity is in doubt, an assessment should be carried out. In general, this means conveying information to the patient, discussing it to gauge his/her understanding and then asking questions about the salient points to see if the patient has grasped them. The focus should be on the reasoning the patient employs to arrive at a decision, rather than on the choice the patient makes – ie, not what the patient decides, but how he or she decides.

There is limited advice available in the medical literature on how to make such an assessment, and it is difficult to find agreed standards and criteria to apply – a problem that a few authors (eg, Applebaum⁴) have tried to address.

Patients with cognitive impairment should be supported and encouraged as much as possible to exercise their decisional capacity. This means delivering information in a form that they can understand and using visual and other aids to assist them

if necessary. A speech and language therapist, a translator, or other professionals with special skills or knowledge might be needed to help with communication.

Avoid asking questions inviting “Yes” or “No” answers – for example, “Do you understand?” Instead, frame your questions in such a way that the patient will need to give a fuller response – for example, the above question could be re-phrased as “Tell me what you understand by...” Words like “What”, “How”, “Why”, and “Tell me” are good for framing open-ended questions.

Box 1: Defining incapacity

The following extract is from a proposed Bill. It has not been tabled in Parliament yet, and is unlikely to be in the near future, but the principles it contains can nevertheless be followed as a matter of good practice.

Adult with incapacity

4. (1) An adult is an adult with incapacity if at the time a decision needs to be made he or she is unable, temporarily or permanently and irrespective of the cause –
 - a. to make the decision for him- or herself on the matter in question; or
 - b. to communicate his or her decision on that matter.
4. (2) An adult is unable to make a decision for him- or herself as contemplated in subsection (1) (a) if he or she is unable
 - a. to understand or retain the information relevant to the decision; or
 - b. to make an informed, rational decision based on that information.
4. (3) An adult must not be regarded as unable to understand the information referred to in subsection (2)(a) if he or she is able to understand an explanation of the information in broad terms and in simple language.
4. (4) An adult must not be regarded as unable to make a decision referred to in subsection (2) (b) merely because he or she makes a decision which would not be made by a person of ordinary prudence.
4. (5) An adult must not be regarded as unable to communicate his or her decision referred to in subsection (1)(b) unless all practicable steps to enable communication of the decision has been taken without success.

South African Law Reform Commission, Discussion Paper 105, *Assisted Decision-making: Adults with Impaired Decision-making Capacity* (January 2004). www.doj.gov.za/salrc/dpapers.htm

Other aspects to consider are the timing and location of an assessment. A patient's mental state may fluctuate in the course of a day, so choosing the best time to assess someone is important. It is also important to be aware of the possible impact of the environment – if it is strange or intimidating, it may inhibit the patient or make him/her tense and agitated.

Even if a patient lacks decisional capacity, they should still be involved, as far as possible, in decisions that affect their lives. Patients who lack the decisional capacity to consent to treatment may still be able to assent (ie, indicate their willingness to go along with the proposed treatment).

The process of assessing a patient's decisional capacity should be carefully documented, including all the evidence gathered to inform the judgment about the patient's decision-making abilities – eg, past decisions made by the patient, the views of family and carers, and the results of formal functional tests.

Compromised decisional capacity

When patients lack decisional capacity, in the absence of an advance directive someone else has to make decisions about medical interventions on their behalf. This may be a person previously mandated by the patient to act as his or her proxy, a person authorised by law or a court order, a member of the patient's family (see Box 2), or a healthcare professional.⁴



Box 2: When an adult patient lacks decisional capacity⁴

An advance directive must be honoured if the instructions and expressed preferences it contains are appropriate to the circumstances and there is no good reason to believe that the patient had subsequently changed his or her mind.

If there is no advance directive, or an advance directive is not relevant to the current clinical situation, one of the following surrogates (in the order of precedence listed below) may make decisions on the patient's behalf:

1. A proxy mandated in writing by the patient to make decisions on his or her behalf.
2. A person authorised by law or a court order.
3. The patient's spouse or partner
4. Parent.
5. Grandparent.
6. Adult child.
7. Brother or sister.

If none of the above surrogates exists, or can be contacted, the healthcare professionals responsible for the patient's care must decide how best to proceed using the "best interests" principle (see Box 3). If the patient has never been mentally competent, or if his or her beliefs, values and preferences are unknown, the best interests principle should be applied by choosing the option a reasonable person would be most likely to prefer.

Any treatment that is authorised by law or a court order or is necessary to protect public health may lawfully be carried out under the terms of the National Health Act. The NHA also allows for emergency treatment to prevent either death or irreversible damage to the patient's health, provided the patient had not previously "expressly, impliedly or by conduct" refused such treatment.

Even if a patient is found to lack the decisional capacity to make an informed choice about the proposed treatment, he or she should still be included as far as possible in the decision-making process.

If the patient's compromised state is temporary, it may be possible to wait until the patient has regained decisional capacity, but if this is not an option, medical intervention may proceed with the consent of someone the law recognises as an acceptable proxy. If no such proxy is available, intervention to prevent the patient's death or "irreversible damage to his or her health" may be given, provided the patient has not previously refused such treatment or implied that he or she would refuse it.⁵

Box 3: The "best interests" principle

- 1 "In deciding what options may be reasonably considered as being in the best interests of a patient who lacks capacity to decide, health care practitioners should take into account:
 - 1.1 The options for investigation or treatment which are clinically indicated;
 - 1.2 Any evidence of the patient's previously expressed preferences, including an advance statement;
 - 1.3 Their own and the health care team's knowledge of the patient's background, such as cultural, religious or employment considerations;
 - 1.4 Views about the patient's preferences given by a third party who may have other knowledge of the patient, for example, the patient's partner, family, carer, or a person with parental responsibility;
 - 1.5 Which option least restricts the patient's future choices, where more than one option (including non-treatment) seems reasonable in the patient's best interests.
- 2 The South African Constitution and the HPCSA provides that 'a child's best interests are paramount in every matter concerning a child'."

HPCSA, *Seeking Patients' Informed Consent: The Ethical Considerations* (2008), para 10.

If there is conflict between clinicians' and a proxy's opinions about what is in a patient's best interests (see Box 3), the HPCSA recommends seeking legal advice, with a view to applying for a court order.⁶ If the situation is an emergency, and there is no time to apply for a court order, intervention to prevent death or irreversible damage to the health of the patient as described above is permissible under the terms of the National Health Act.

Circumstances may arise where it is not easy to determine whether a patient is incapacitated or not. A woman in labour, for example, or a patient on strong analgesia is arguably not in the best position to think through their immediate options in a clear-headed manner. Consider the scenario of a woman with a post-partum haemorrhage who needs an emergency blood transfusion. She refuses, and cannot be persuaded to change her mind. Although her decision may seem irrational (ie, it is putting her life at risk), this in itself cannot be taken as evidence of a compromised decisional capacity (see Box 1, paragraph 4). In cases like this, it would be helpful to consult with the patient's family to find out whether the patient's current expressed wishes are consistent with her character and previously stated preferences and beliefs. You should also discuss your options with senior colleagues and seek legal advice, if necessary. Ideally, a decision like this should be resolved by the courts, but if this is not possible, and it falls to the doctor to decide, it is extremely important to document the reasons for deciding one way or the other, together with details of discussions with the patient, family and colleagues.

When patients being seen over a period of time might conceivably end up in a life-threatening situation requiring a blood transfusion or emergency surgery, it is advisable to explore – and document – beforehand their views about what treatment they will and will not accept. In the above scenario, for example, such a discussion could take place during an antenatal consultation.

Children and young people

Current law

The law governing minors and consent to medical treatment is contained in several pieces of legislation, one of which is not yet fully in force (see The Children's Act on page 15). Table 1 (overleaf) sets out the legal situation as it stands at the time of writing.

Even with the guidance of specific legislation, there will be grey areas in the matter of consent to treatment of minors. The maturity of the child concerned, the wishes and opinions of the parents or guardian, as well as the clinical circumstances, all have to be taken into consideration and some of these may conflict. The principle to bear in mind in such circumstances is that the child's best interests are paramount.⁷

In law, the consent of the parent or legal guardian is required if a child is under the age of 12. In practice, however, it is reasonable to seek the consent of a minor with the capacity to understand the nature and implications of the proposed treatment or procedure. This should not present a problem if the child and parents are in accord about a decision to consent to treatment. If there are two people with parental responsibility (see Box 4), it is usually sufficient for one of them to give consent, but where decisions may have profound, irreversible consequences, both of them should be consulted where practicable.

Table 1: The current legal situation regarding clinical treatment of minors

Circumstance	Age at which patient can consent	Relevant Act	Comments
Medical treatment	12	Section 129 of the Children's Act 2005	A child of 12 or older may consent to medical treatment.
Surgical treatment	12	Section 129 of the Children's Act 2005	A child of 12 or older may consent with a parent's or guardian's assent
HIV test	12	Section 130 of the Children's Act 2005	Consent for an HIV test may be given by a child of 12 or older, or by a younger child with sufficient maturity to understand the implications of the test.
Termination of pregnancy	No lower age limit.	Section 5 of the Choice on Termination of Pregnancy Act 92 of 1996	5(2) "no consent other than that of the pregnant woman shall be required for the termination of a pregnancy." For the purposes of this Act, "woman" means any female person of any age.
Request for contraception	12	Section 134 of the Children's Act 2005	Came into force in July 2007.
Virginity test	16	Section 12 of the Children's Act 2005	It is illegal to carry out a virginity test on someone under the age of 16. If they are 16 or older, a test may be carried out only with their written consent.
Circumcision	16 (males only)	Section 12 of the Children's Act 2005	Female circumcision is illegal at any age. Male circumcision is permissible under specific circumstances (see page 16)
Sexual intercourse	16	Sections 1, 15, 16 & 57 of the Criminal Law (Sexual Offences and Related Matters) Amendment Act 32 of 2007	Section 54 of the Act places an obligation on anyone with knowledge (or a reasonable suspicion) of a sexual offence against a child to report it to the police. There are harsh penalties for failure to report.
Minor with parental responsibility for a child	12	Section 129 of the Children's Act 2005.	A child-parent of sufficient maturity may consent to medical or surgical treatment on her child's behalf.
Sterilisation	18	The Sterilisation Act 44 of 1998 and the Sterilisation Amendment Act 3 of 2005.	

Table 1: continued across**Conditions that have to be met**

The patient must be mature enough to understand the implications of undertaking the proposed treatment, but if he/she lacks capacity, a person with parental responsibility or a care-giver can consent on his/her behalf. Failing that, the head clinician of a hospital can give consent.

Patients may consent to surgery if they are mature enough, but a parent or guardian must also agree to the operation. The patient's consent and parent's assent must be in writing and signed using Form 34.

The child must have proper pre- and post- test counselling. The clinical and social implications must be explained.

A girl of any age can request a TOP, but if she is a minor, she should be advised to consult with her parents/guardian, though she should not be denied a TOP if she fails to do so.

It is illegal to refuse to sell (or supply freely available) condoms to children aged 12 or over. Other forms of contraception can also be supplied if the child is mature enough to understand the implications and it is clinically appropriate.

If a minor seeks contraceptive advice without parental consent, his/her confidentiality should be respected, unless there are reasonable grounds for suspecting the child is being exploited or abused.

Consent for a virginity test must be given in writing on the specified form (Form 1) and signed by both the subject of the test with the signed assent of a parent or guardian.

Male circumcision may only be carried out on a boy under 16 if it conforms to religious practices or is medically necessary. Consent must be in writing on Form 2. Circumcision for social or cultural reasons must only be carried out if the boy is aged 16 or older and with his written consent (using Form 3) and the signed assent of a parent or guardian.

Children are considered incapable of consenting to sex until the age of 12. Between 12 and 16, they are considered capable, but not mature enough to consent to sex. At 16, the law considers them both capable and mature enough for consensual sex.

If the consent is for surgical treatment, the assent of the parent or guardian of the child-parent's should also be obtained. The consent must be in writing on Form 35.

Minors may only be sterilised if their life would be jeopardised or their health seriously impaired by a failure to do so. In such cases, a sterilisation can be carried out if the parents/guardian have consented and an independent medical practitioner, after consulting with the child concerned, makes a written statement that the sterilisation would be in the best interests of the child.



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If surgery is being proposed and the child is aged 12 or over and has the maturity to understand the implications, the child may consent on his/her own behalf with a parent or guardian's written assent.

In an emergency, where a person with parental responsibility is not available to give consent, required treatment may proceed with the consent of the superintendent of a hospital, or the person in charge if the superintendent is unavailable. If neither is available, HPCSA guidance states that a healthcare practitioner may treat the child, provided it is in the child's best interests and that the treatment given is "limited to treatment which is reasonably required in [the] emergency". In state hospitals, the decision to give emergency treatment should be taken by the clinical manager.⁸ In non-urgent situations, an application should be made to the Minister, who is empowered to give consent in lieu of the child's parent or guardian.⁹

Occasionally, parents make decisions that are likely to affect a child adversely; they may disagree with the orthodox management of certain conditions, for example, and although this may not be life-threatening, the child may suffer by not having access to conventional treatment. If there is reason to believe that a parent's refusal to consent to a child's medical treatment is placing that child at risk, the matter should be referred to the hospital's legal department, who may either petition the court for a ruling or apply to the Minister of Health for consent.¹⁰

If a minor with decisional capacity refuses life-saving treatment, any decision to overrule the patient's withholding of consent should be made by the courts, rather than the treating clinicians, except in an emergency where immediate action must be taken to preserve the child's life or prevent serious harm.

Even when children lack the decisional capacity to give consent, they should still be involved in the decision-making process – for example, in terms of who goes to theatre with them or what toys they take.

The Children's Act 2005

The most significant provision of this Act is the setting of the age of consent to medical and surgical treatment at 12 years. It also includes important provisions covering HIV testing, virginity tests and circumcision.

Implementation of the Act is governed by the General Regulations Regarding Children (Regulation 261).

Section 129

This section lowers the age at which the law considers a child should be able to consent to treatment.

Specifically, it makes the following provisions:

Children aged 12 or more

Provided they have the maturity “to understand the benefits, risks, social and other implications of the treatment”, children of this age may consent to medical treatment on their own behalf.

If the proposed treatment involves a surgical procedure, a sufficiently mature child may still consent, if he or she is “duly assisted by his or her parent or guardian”.

Minors of 12 or over who are themselves parents (“child parents”) may also, if they possess the maturity to do so, consent to medical examinations and treatment for their child.

They may also consent to surgical treatment for their child, but only with the assistance of someone who has parental responsibility for them.

Children under 12 or over 12 but lacking the maturity to make an informed decision

A parent, guardian or care-giver* of the child may consent on behalf of the child to medical treatment.

A parent or guardian may consent to surgical treatment on the child's behalf. (See Box 4 on page 16.)

Box 4: Parental responsibility?

Mothers – The biological mother of a child automatically has full parental responsibilities and rights, regardless of her marital status. If she herself is a minor (a child parent) and neither she nor the child's biological father has guardianship of the child, her own guardian is also considered a guardian of her child.

Fathers – A child's biological father has full parental responsibilities and rights if any of the following apply:

- He is married to the child's mother.
- He was married to her when the child was conceived or born.
- He was married to her at any time between the child's conception and birth.
- He was living with the mother in a permanent life partnership when the child was born.
- He has consented to be identified as the child's father and contributes to its upkeep.
- He has had full parental responsibilities conferred on him by a court order.

Guardians – A child's legal guardian has full parental rights and responsibilities.

Parental rights and responsibilities agreement – A person with full rights and responsibilities for a child can enter into an agreement with another person who has an interest in the child's care, wellbeing and development to confer parental rights and responsibilities on that person. The agreement must be made formally and registered with a family advocate.

Caregivers – Section 32 of the Children's Act* allows a person who cares for a child on a voluntary basis without formal parental responsibilities, to consent to medical (but not surgical) examination and treatment on that child's behalf.

* The Act gives a broad definition of "care-giver". Section 31 describes such a person as "A person who has no parental responsibilities and rights in respect of a child but who voluntarily cares for the child either indefinitely, temporarily or partially". This section expands slightly on the provision in section 129 by stating that a care-giver has the right "to consent to any medical examination or treatment of the child *if such consent cannot reasonably be obtained from the parent or guardian*" (emphasis added).

Section 130: HIV tests

Consent for an HIV test may be given by a child of 12 or older without parental consent. A child under the age of 12 may also consent to an HIV test if he or she is mature enough to understand its benefits, risks and social implications. If a child under the age of 12 lacks the maturity to consent, a parent, the provincial head of social development, a designated child protection organisation, or the superintendent of a hospital may consent on the child's behalf.

If an HIV test is considered necessary and the child lacks capacity or unreasonably withholds consent, application can be made to a children's court.

Furthermore, the Act empowers the superintendent of a hospital (in the absence of a parent, guardian or care-giver) to consent, in an emergency, to a child's medical or surgical treatment if it is necessary to preserve the child's life or "to save the child from serious or lasting physical injury or disability".

In the event of either a legally competent child or a child's parent or guardian "unreasonably refusing to consent" to treatment, either the Minister or the High Court may overrule the refusal. The Minister may also be applied to for consent to treat a child when the person with parental responsibility cannot be traced, is deceased, or lacks the decisional capacity to give consent.

Written consent for surgery

The Regulations specify that consent for surgery must be given in writing on Form 34.

The consent form must be completed in writing either by the person performing the operation or by the hospital/clinic and it must be signed by the child.

The person with parental responsibility assisting the child must assent to the operation in writing.

If the parent consenting to surgical treatment for a child is a child parent, the consent form must include written assent by the child parent's parent or guardian. The appropriate form is Form 35.

Section 12

Section 12 of the Children's Act deals mostly with virginity tests and circumcision, but the first paragraph has wider implications.

It states that "Every child has the right not to be subjected to social, cultural and religious practices which are detrimental to his or her well-being".¹¹ This would, therefore, include the issue of blood transfusions for children of Jehovah's Witnesses, for example.

Virginity tests

Virginity testing of children under the age of 16 is prohibited, and may only be performed on children over 16 with their consent, obtained after proper counselling. Moreover, the results of a virginity test may not be disclosed without the child's consent. The signed consent of the child and assent of a parent or guardian must be made on Form 1.

Circumcision

Female circumcision of children is prohibited.

Male circumcision is prohibited under the age of 16, unless it conforms to prescribed religious practices or is medically necessary. Circumcision of boys of 16 and over must be carried out in a prescribed manner and only with the boy's consent, given after appropriate counselling. The Act further states that "Taking into consideration the child's age, maturity and stage of development, every male child has the right to refuse circumcision".¹²

Circumcision for religious or medical purposes must only be carried out after Form 2 has been signed by a parent or guardian. Circumcision on a boy aged 16 or over for social and cultural reasons requires both the boy and his parents to sign Form 3.

Information

The National Health Act 2003 makes it an offence to provide a health service to a user without the user's informed consent. (see Appendix 3)**/13

Moreover, the National Patients Health Charter (2008) states: "Everyone has a right to be given full and accurate information about:

- the nature of one's illnesses
- diagnostic procedures
- the proposed treatment, and
- the costs involved

for one to make a decision that affects any one of these elements."



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** The exceptions to this rule are: (a) an emergency where delay would result in the death or serious harm to the patient, (b) when mandated by law or a court order, or (c) where failure to treat the patient would result in a serious risk to public health. If the patient lacks capacity, and a proxy or family member is consenting on the patient's behalf, that person must be given all the necessary information to give informed consent.



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The HPCSA offers this guidance regarding the context in which the information should be presented:

“When providing information, health care practitioners must do their best to find out about patients’ individual needs and priorities.

“For example, patients’ beliefs, culture, occupation or other factors may have a bearing on the information they need in order to reach a decision.

“Health care practitioners should not make assumptions about patients’ views, but discuss these matters with them and ask them whether they have any concerns about the treatment or the risks it may involve.”¹⁴

These are important considerations as each patient will take a different view on the implications of the risks and benefits, depending on his or her personal priorities.

A patient who earns his living repairing watches, for example, is likely to place great significance on a risk of brachial nerve damage, no matter how slight that risk might be.

Box 5 lists the minimum information that the HPCSA considers patients should have before they are in a position to give informed consent.

It should be presented in a form and language that the patient can understand, bearing in mind his or her level of literacy.

Box 5: Information the patient should be given during the consent process

- “Details of the diagnosis, and prognosis, and the likely prognosis if the condition is left untreated.
- Uncertainties about the diagnosis, including options for further investigation prior to treatment.
- Options for treatment or management of the condition, including the option not to treat.
- The purpose of a proposed investigation or treatment; details of the procedures or therapies involved, including subsidiary treatment such as methods of pain relief; how the patient should prepare for the procedure; and details of what the patient might experience during or after the procedure, including common and serious side effects.
- For each option, explanations of the likely benefits and the probabilities of success; and discussion of any serious or frequently occurring risks, and of any lifestyle changes which may be caused or necessitated by the treatment.
- Advice about whether a proposed treatment is experimental.
- How and when the patient’s condition and any side effects will be monitored or re-assessed.
- The name of the doctor who will have overall responsibility for the treatment and, where appropriate, names of the senior members of his or her team.
- Whether students will be involved, and the extent to which students may be involved in an investigation or treatment.
- A reminder that patients can change their minds about a decision at any time.
- A reminder that patients have a right to seek a second opinion.
- Where applicable, details of costs or charges which the patient may have to meet.”

HPCSA, *Seeking Patients’ Informed Consent: The Ethical Considerations* (2008), para 3.1.3.

Voluntariness

Patients overtly coerced into undergoing treatment they plainly do not want may rightly claim that their “consent” was not given freely and is therefore not valid. Cases of overt coercion are rare, but there are many circumstances in which patients may feel that they have been covertly pushed into accepting treatment they would prefer not to have had.

For example, patients may sometimes find it very difficult to say “No” to the proposed treatment, or to challenge the doctor’s assumption that they would have no objections to going ahead, so it is best to check that they have no misgivings before proceeding.

Patients who are detained by the police, immigration services, or prison authorities may be particularly vulnerable, and under these circumstances you should try to ensure that they are aware that they may refuse treatment if they so wish.

Involuntary mental health patients

Under the Mental Health Care Act 2002, involuntary and assisted mental health care users do not lose their right to consent to treatment for illnesses other than mental illnesses, except where “a mental health care practitioner deems a user to be incapable of consenting to treatment or an operation due to mental illness or intellectual disability”. In such cases, a court-appointed curator or a family member may consent on the patient’s behalf.¹⁵ (See Box 3 on page 10 for the order in which family members may consent.) If none of these people are available, the head of the institution may grant consent.

Treatment for mental illnesses may only be given without the patient’s consent within the terms of the Mental Health Care Act 2002 – ie, if authorised by a court or a Review Board or in an emergency where failure to treat would result in “death or irreversible harm to the user” or in the user “inflicting serious harm to himself or others” or to property.¹⁶ Under no circumstances may psychosurgery be performed on a mental health patient without the patient’s consent.¹⁷

Other aspects of consent

HIV/AIDS tests

The Department of Health's National Policy on Testing for HIV ("the Policy") sets out the conditions that must be met for informed consent to HIV tests to be considered valid. Both pre- and post-test counselling is advisable. The aforementioned policy provides that the Medicare Benefits Schedule (MBS) advises that the requesting practitioner should ensure that the patient has given informed consent, appropriate pre-test discussion should be provided to the patient and that further discussion may be necessary upon receipt of the test results. (See Box 6).

While the issue of consent to disclosure of confidential information lies outside the scope of this booklet, it should be touched upon here because the health and wellbeing of the sexual partners of HIV-positive patients raises ethical concerns that are not easy to address if the patient refuses to disclose his or her HIV status. In this situation, the HPCSA offers the following guidance:

"If the patient refuses consent, the health care practitioner should use his or her discretion when deciding whether or not to divulge the information to the patient's sexual partner, taking into account the possible risk of HIV infection to the sexual partner and the risks to the patient (eg, through violence) that may follow such disclosure. The decision must be made with great care, and consideration must be given to the rights of all the parties concerned. If the health care practitioner decides to make the disclosure against the patient's wishes, the practitioner must do so after explaining the situation to the patient and accepting full responsibility at all times."¹⁸

The Policy provides the following in relation to the confidentiality of information obtained during HIV testing:

"Confidentiality and privacy issues are a major concern for people undergoing HIV testing. Therefore, confidentiality and privacy issues should be explained in detail, and it may be necessary to give examples to make sure the meaning of confidentiality and privacy is understood."

If you are faced with this scenario, we recommend reading the whole of the HPCSA's guidance in its booklet, *Ethical Guidelines for Good Practice with Regard to HIV*.

HIV tests without informed consent

Aside from anonymised testing of existing blood and tissue samples, the only circumstances in which HIV testing may be conducted without informed consent are:

- Where existing blood or tissue samples are used for epidemiological research. The samples must be anonymised and unlinked and the research must comply with national, legal and ethical guidelines.
- In an emergency situation (eg, a healthcare worker has been accidentally exposed to a patient's blood) where an existing blood sample is available and the patient has declined to consent to testing, or is unable to consent. The patient should, however, be informed – if possible – that the test is being carried out and that the health care worker concerned will be told the results, but that the results will otherwise remain confidential.
- Where testing without consent is authorised by law. The relevant legislation here is the Criminal Law (Sexual Offences and Related Matters) Amendment Act 2007. This makes provisions for victims of sexual offences or an officer investigating such a crime to apply for a magistrate's order for the compulsory testing of the alleged offender.¹⁹

Communicable diseases

Occasionally, the principle of respecting a person's right to autonomy comes into conflict with the rights of the larger society. The National Health Act 2003 addresses this situation by stating that health services should not be provided to users without their informed consent, unless "failure to treat the user, or group of people which includes the user, will result in a serious risk to public health".²⁰

The most common circumstance where this would apply is when an individual refuses to be examined or treated for a dangerous communicable disease. Regulations published under the National Health Act in 2008²¹ make provisions for mandatory medical examination, isolation and quarantine of carriers, contacts and sufferers of specified communicable diseases. In such circumstances, individuals have to comply with medical examination and may be forcibly admitted to a health facility and put into quarantine even if they refuse to consent to any of these measures.

The regulations do not go so far as to make treatment mandatory, but an infected person who "wilfully refuses treatment" may be put into quarantine by order of the High Court. Similarly, the High Court may order carriers or susceptible contacts to be quarantined if they pose a threat to public health.

The regulations also make it mandatory for carriers, contacts and infected individuals to comply with instructions from health care providers regarding "precautionary measures to prevent or restrict the spread of an infection".

Box 6: HIV tests: pre- and post-test counselling

- Information on how HIV is transmitted (where appropriate)
- Risk assessment and discussion of the reason for testing
- Timing of the risk event and options for PEP
- Possible desirability of other STI testing
- Information about confidentiality and privacy
- Information about the testing process including how results are to be provided, the window period, and the difference between HIV and AIDS
- Information about what happens to test results
- Seeking informed consent for the test to be conducted
- Assessment of the person's preparedness to be tested and assurance that the person wishes to proceed with the test
- Information about what a negative or positive results means
- Assessment of support mechanisms while waiting for the test result and/or if the result is positive.

Post-test counselling involves one or more sessions (ideally at least two) and should include discussions on:

- Feedback and understanding of results:

If the result is negative:

- Strategies for risk reduction
- Possibility of infection in the “window period”

If the result is positive:

- Immediate needs and support
- Safe behaviours – education, information and support
- Whom the person should tell and how, including information around the person's rights regarding disclosure
- Managing or understanding strong emotions, feelings, reactions and changes, including ways to deal with loss and grief, depression, anger and anxiety
- Options in drug treatments and medical management
- Ongoing counselling or therapy if required
- Complementary/alternative management options
- Strategies for managing HIV that are flexible and appropriate to the person's needs
- Legislative requirements (notification, contact tracing, storage and coding).

Department of Health, *National Policy for Health Act 116 of 1990: National Policy on Testing for HIV* (2006).

End of life decisions

When patients are seriously ill and lack decisional capacity, others are obliged to make treatment decisions on their behalf; in the absence of an appropriate proxy decision-maker (see page 8), this responsibility may fall to the patient's doctor. The decision might include choosing not to intervene if a treatment or procedure would be burdensome and with little benefit to the patient (see HPCSA statement in Box 7).

Not all terminally ill patients lose their decisional capacity, and in this case the same principle applies as with treatment for all competent adults – healthcare professionals should respect and – as far as possible – comply with the patient's wishes.

There are, however, limits to this obligation. Firstly, healthcare professionals are expressly forbidden – by medical ethics and the law – from honouring a patient's or family's request to intentionally hasten the patient's death. Conversely, the HPCSA states that healthcare professionals are not obliged to comply with requests to continue treatment that they consider futile. In this situation, it advises giving the patient or family the choice of transferring to another institution where the treatment is available. If they refuse, and the futility of the treatment is confirmed by an independent healthcare practitioner, the health team may withhold or withdraw the treatment.²²

Box 7: Terminally ill patients who lack decisional capacity

“The willful act by a healthcare professional to cause the death of a patient is unacceptable, notwithstanding whether or not such an act is performed at the request of the patient or his or her closest relatives or of any other person.”

HPCSA, *Guidelines for the Withholding and Withdrawing of Treatment* (2008), para 1.3

Do Not Resuscitate (DNR) orders

The decision not to institute CPR if it is likely to be successful should not be taken lightly, or in isolation. If the patient is competent, he or she should be involved in the decision making, as should the family (with the patient's consent). Ideally, the whole healthcare team should also be consulted. Ultimately, though, the decision rests with the senior clinician in charge of the patient's care.²³

Such decisions should not be made on the basis of assumptions about the patient's age, condition or perceived quality of life, but on a clinical assessment of the potential benefits and burdens of resuscitation on the individual, taking into account what is known about the patient's views, beliefs and wishes and those of his or her close relatives (see Box 8).

If a DNR order is made, this should be clearly documented in the patient's notes, together with the reasons for the decision and the process of decision making.²⁴

Advance directives

An advance directive is a statement made by a competent adult in anticipation of a time in the future when he or she may lack the capacity to make healthcare decisions. Such statements usually take the form of advance refusal of specified treatments, but may also contain information about the patient's values and beliefs.

Box 8: DNR decisions

“A decision that CPR will not be attempted, on best interests grounds, because the burdens outweigh the benefits should be made only after careful consideration of all relevant factors, discussion with the patient, or those close to patients who lack capacity, and these include:

- the likely clinical outcome, including the likelihood of successfully re-starting the patient's heart and breathing for a sustained period, and the level of recovery that can realistically be expected after successful CPR
- the patient's known or ascertainable wishes, including information about previously expressed views, feelings, beliefs and values
- the patient's human rights, including the right to life and the right to be free from degrading treatment
- the likelihood of the patient experiencing severe unmanageable pain or suffering
- the level of awareness the patient has of their existence and surroundings.”

British Medical Association, the Resuscitation Council (UK) and the Royal College of Nursing, *Decisions Relating to Cardiopulmonary Resuscitation: A Joint Statement* (2007), p. 11.

The HPCSA states: “Where a patient lacks the capacity to decide, health care practitioners must respect any valid advance refusal of treatment.”²⁵

It further recommends encouraging patients with terminal conditions to appoint a proxy to make decisions on their behalf in the event of their losing decisional capacity. Moreover, patients should be given the opportunity to write a directive setting out their wishes regarding their future care to guide those who will be tasked with deciding what is in their best interests.²⁶

If there is any doubt about the validity or applicability of an advance decision (eg, there is reason to believe that the patient might have had a change of mind since drawing up the directive, or the current circumstances do not correspond to those specified in the directive), the patient should be provided with care to secure his/her best interests while the issue is resolved, if necessary by reference to the courts.

Documentation

All decisions to withdraw or withhold treatment, either with or without the patient's consent, should be fully and clearly documented in the patient's medical record and accessible by all those involved in the patient's care. Such documentation should include:

- The relevant clinical findings
- Discussions with the patient and others
- Details of "treatment or other significant factors which may affect future care".²⁷

Clinical trials and research

"Everyone has the right to bodily and psychological integrity, which includes the right (a) to make decisions concerning reproduction; (b) to security in and control over their body; and (c) not to be subjected to medical or scientific experiments without their informed consent."

(Constitution of the Republic of South Africa 1996, section 12(2))

The Department of Health specifies that participants' verbal and written consent must be obtained before research may begin.²⁸ To be valid, such consent must be given freely, without coercion and it must be based on comprehensive information about the nature of the proposed research. The Medical Research Council (MRC) stipulates that all the information listed in Box 9 must be disclosed – and presented in a form the individual concerned can understand, giving due regard to his or her culture and language.

A patient's care should not be compromised in any way by his or her refusal to participate in research (see Box 10).

Adults lacking decisional capacity

If a patient is not capable of giving consent, written consent must be obtained from an appropriate proxy or family member (see Box 2 on page 9). Special care should be taken to ensure that incapacitated individuals' rights, dignity and welfare are not being compromised by their participation in research, particularly if the research

Box 9: What patients should know before agreeing to participate in clinical trials

All clinical research must be approved by an accredited research ethics committee. The Medical Research Council's guidelines regarding participants' consent is set out below.

- i. "the precise nature, scope, purpose and duration of the proposed research project. That is, whether it is therapeutic, non-therapeutic, invasive, observational, a pilot study, controlled, randomised, single blind, double blind, triple blind or quadruple blind, and whether or not placebos are involved;
- ii. the nature, scope and consequences of the proposed research intervention;
- iii. the anticipated benefits and disadvantages compared to those expected from available standard therapy;
- iv. the foreseeable prognosis and all foreseeable and additional risks, dangers and complications, as well as the possibility of unforeseen risks, dangers and complications, irrespective of whether the proposed research is therapeutic or nontherapeutic;
- v. personal benefits, including financial benefits, that may accrue from the research to participants, investigators and anyone giving proxy consent. Moreover, the research participant, or the participant's proxy, should be informed that participation is voluntary and that he or she is:
 1. under no obligation to consent to the research procedure and that a refusal will not adversely affect future treatment;
 2. free to withdraw consent at any time without adverse consequences and without having to state a reason."

MRC, *Guidelines on Ethics for Medical Research: General Principles* (2006), para 5.3.2.3

Box 10: Recruiting dependent patients for research

"When seeking informed consent for participation in a research study the physician should be particularly cautious if the potential subject is in a dependent relationship with the physician or may consent under duress. In such situations the informed consent should be sought by an appropriately qualified individual who is completely independent of this relationship."

WMA, *Declaration of Helsinki* (2008), para 28.

is of no direct benefit to them. If the patient is unconscious, Department of Health guidance stipulates that consent “must be given by others, including relevant statutory authorities” and that they “should be excluded from all but minimally invasive observational research”.²⁹

Minors

Consent for minors should be obtained from a parent or guardian and (if the child is mature enough) the child concerned. If the research entails minimal risk or the likelihood of direct benefit for the child, the consent of one parent is sufficient. If there is a greater than minimal risk and is of no direct benefit to the child, the consent of both parents is required. If possible, assent of a child lacking the maturity to consent should also be obtained.

Only parents, legal guardians or a person authorised by law may consent to research on a child’s behalf. No other caregiver may legitimately act on a child’s behalf in this context.

Lastly, “A minor’s refusal to participate in research must be respected, ie such refusal settles the matter.”³⁰

Who should take consent?

As consent is a process centred on discussing the benefits, side effects and potential complications of proposed treatments and procedures, the person who



takes consent must also be able to provide all necessary information to the patient and so, ideally, the person taking consent should be the same person providing that aspect of the patient's care. As that is not always practicable, obtaining consent may be delegated to others providing that they are suitably trained and qualified, have sufficient knowledge of the proposed investigation or treatment, understand the risks involved and comply with the HPCSA's guidance on consent.³¹

Doctors who delegate responsibility for obtaining consent remain responsible for ensuring that their patients have been given sufficient time and information to make an informed decision before embarking on treatment, and that their consent to proceed is valid.

When should consent be taken?

For many elective procedures, consent is taken in the outpatient department weeks or sometimes months prior to admission for surgery. There is no specific time limit on consent taken in advance, but further questions may occur to patients, or doubts about the wisdom of their decision may creep in during the interim.

Patients' conditions may also change during the intervening period, or new information about the procedure may have become available. It is good practice, therefore, to confirm consent prior to the procedure, using this as an opportunity to find out if there have been any material changes since consent was first taken, and to ask the patient if there are any further questions.

The fact that consent has been confirmed should be documented, either in the patient's medical record or as a (signed and dated) supplementary note on the original consent form.

As a general principle of good practice, if the treatment is not urgent, patients should be given plenty of time to think about their options before they consent to treatment and be encouraged to ask further questions.

Implied and express consent

Patients undergoing invasive procedures will normally give express consent – either by signing a consent form or stating that they agree to go ahead with treatment.

Written consent should be taken where:

- “The treatment or procedure is complex or involves significant risks and/or side effects;
- Providing clinical care is not the primary purpose of the investigation or examination;
- There may be significant consequences for the patient's employment, social or personal life;

- The treatment is part of a research programme.”³²

However, consent is often implied by the patient’s compliance, an obvious example being when a patient rolls up a sleeve so that a blood sample can be taken. Nevertheless, patients should be told about the nature and purpose of any examination, investigation or procedure beforehand.

Any discussions with patients about the risks and benefits of a proposed procedure or treatment should be documented in the medical record.

Recording consent and consent forms

The presence of a signed consent form does not in itself prove valid consent to treatment – the important factors will always be the quality, extent and accuracy of the information given beforehand. Being able to demonstrate this afterwards depends on contemporaneous notes recording the key points discussed and relevant warnings given to the patient.

There are statutory forms of written consent required for certain procedures, interventions and circumstances – eg, sterilisation and termination of pregnancy. The Regulations deriving from the Children’s Act also specify the form that minors’ written consent to various interventions should take.

Patient information leaflets

Numerous studies have shown that patients retain comparatively little information given to them during a consultation, particularly if they are anxious or in pain. Many patients find it helpful if they are given written information as a reminder of the key points discussed. However, written information is not a substitute for detailed discussion with patients and must be seen as an adjunct to, not a replacement for, that discussion. If information leaflets are used to augment discussion with a patient, this should be documented in the patient’s notes.

Refusing consent

“Although the term ‘consent’ implies acceptance of treatment, the concept of informed consent applies equally to refusal of treatment or to choice among alternative treatments. Competent patients have the right to refuse treatment, even when the refusal will result in disability or death.”³³

Consent law would be completely pointless if it did not protect a patient’s right to refuse treatment. Doctors may not override a patient’s refusal of treatment simply because they think it is a foolish or illogical decision. And they may not disregard patients who choose not to take their advice.

If the patient is not giving clear reasons for refusing the proposed treatment, it may be worth probing a little further to find out whether she/he is harbouring hidden fears and anxieties that could be assuaged with further information and discussion. Any such discussion, however, must be conducted sensitively and respectfully, otherwise it could be construed as coercion.

Occasionally, it may be appropriate to assess the patient's decisional capacity, but the patient's refusal should never, in itself, be taken as evidence of lack of decisional capacity. If the patient is capable, she/he should be given all material information to ensure that the refusal is truly informed. Available alternatives should then be offered, with a reminder that the patient may change his/her mind.

Withdrawing consent

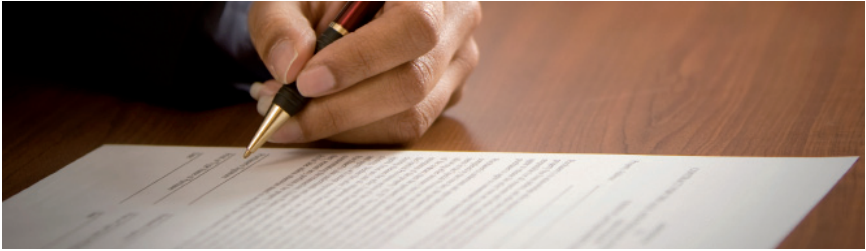
Patients with decisional capacity may also withdraw consent for continuing treatment. If, during a procedure, a patient indicates that she/he wants you to stop, you should stop the procedure as soon as it is safe to do so and then explain the consequences of not proceeding further, without implying coercion. It is important to let patients know that stopping a procedure will not compromise their care.

The rights of patients who lack decisional capacity should also be respected in this regard. If they indicate that they want a procedure to stop because they are in pain or discomfort, their wishes should be complied with, as above.

Summary

- Consent is not a signature on a form, but a communication process.
- Competent adult patients can refuse to consent to treatment or withdraw their consent once given.
- To be valid, consent must be obtained from a competent informed person free from undue duress.
- All adults are assumed to be competent to consent to treatment unless there is reason to believe their decisional capacity has been impaired.
- Decisional capacity is not an “all or nothing” concept – a person’s capacity to make a decision depends on the nature of the decision.
- Consent can be given by specified surrogates if a patient’s decisional capacity is impaired.
- If they have the maturity to do so, children aged 12 or over may consent to medical treatment on their own behalf and to surgical treatment with the assistance/assent of a parent or guardian.
- For consent to be valid, the person giving consent must be given all relevant information, including the material risks and consequences of each option, including no treatment.
- HIV testing without a patient’s consent is illegal, except in circumscribed situations authorised by law.
- When a patient loses decisional capacity, an advance directive made when he or she was still competent must be honoured unless there are good reasons for believing that the patient changed his or her mind.

Case studies



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Case 1

Mrs M is 82 and usually very lively and alert. However, she has recently become very confused, probably due to a urinary tract infection. She is admitted to hospital where it is noted that she has an irreducible femoral hernia. The surgeons who are called to see her suggest immediate repair to avoid the risk of strangulation, but as Mrs M is unable to consent and there is no imminent danger (the hernia is not strangulated), it is decided to wait, in the expectation that she will regain capacity, and then seek consent to surgical repair.

Case 2

Mrs N is 86 years old and has had a stroke. Her speech is unintelligible and she dozes much of the time. She suffers a fractured neck of femur in a fall. The staff on the ward explain what has happened and that she needs an operation. Because she is unable to speak, the staff watch her body language intently to gauge her understanding and give her a picture board to help her communicate. Mrs N is able, through these means, to convince the staff that she understands what has happened and that she wants them to carry out the operation.

Case 3

Dr T is a newly qualified doctor working in gynaecology. Mrs V is admitted prior to a Uterine Artery Embolisation (UAE) and Dr T is asked to confirm her consent to the procedure, which she gave three weeks earlier in the outpatients' department. Further questions and some concerns have occurred to Mrs V in the intervening weeks, and she particularly wants to know how the UAE will affect her chances of conceiving and carrying a baby to term. Dr T has only a sketchy, theoretical, understanding of the procedure, which he has never seen performed. He is therefore not competent to obtain Mrs V's consent and must refer her questions to the radiologist who will be carrying out the procedure.

Case 4

Mrs D is 42 and has recently discovered a lump in her breast. She is told that malignancy cannot be excluded and an urgent referral to a specialist is required. She asks the GP to defer the referral, however, explaining that her daughter is currently preparing for important exams in five weeks' time and she does not want to cause her any anxiety. Dr F, her GP, cannot understand how she can take such a risk but it is clear on talking to her that she fully understands the implications of her decision.

Dr F records his findings along with Mrs D's reasons for not agreeing to an immediate referral.

Case 5

Mr H is a plasterer in his late 40s. He has been experiencing pain in his left knee, on and off, for several years, but this has been adequately managed with a combination of physiotherapy and NSAIDs. One day, he comes to see his GP, Dr J, complaining of intense pain and limited movement in his knee. Dr J, noting Mr H's history and finding, on examination, that the knee is slightly swollen, recommends an intra-articular injection of Kenalog. As he is aware that Mr H is self-employed and needs to be able to return to work as soon as possible, he suggests that he administer the injection there and then.

Mr H is doubtful about having an injection straight into the joint, but Dr J brushes aside his doubts, saying that it will get him "up and running in no time". He points out that it is unlikely he will get another appointment at the practice until the following week, which will only delay his recovery. Mr H reluctantly acquiesces, and allows Dr J to administer the injection. Unfortunately, he subsequently develops septic arthritis in the joint. Although this is successfully treated with antibiotics, he loses several more weeks' work and decides to sue Dr J for compensation. His claim alleges invalid consent, not only because he had not been warned about the small risk of infection, but because he had felt coerced into making a hasty decision.

Case 6

Mr D has been admitted as a day case for colonoscopy for investigation of rectal bleeding. He finds the colonoscopy extremely uncomfortable and insists that the procedure be stopped. This happens just as the surgeon identifies a suspicious-looking lesion in the transverse colon.

The surgeon stops the procedure and then explains the situation to Mr D, who agrees to further sedation being administered so the colonoscopy can be continued and the lesion biopsied.

Appendix 1

Key legislation referred to in the text

Constitution of the Republic of South Africa no. 108 of 1996

The Bill of Rights in the Constitution enshrines the rights of citizens to human dignity and to freedom and security of the person. In the case of children, their interests must be of paramount importance in any matter pertaining to them.

National Health Act no. 61 of 2003

Section 7 protects the rights of competent health service users to consent to treatment and places a duty of health service providers to “take all reasonable steps to obtain the user’s informed consent”.

Section 8 stipulates that health care users have the right to participate in decisions affecting their health and treatment. Furthermore, it requires health service providers to share relevant information with users who lack the capacity to make decisions “unless the disclosure of such information would be contrary to the user’s best interests”.

Child Care Act no. 74 of 1983

This Act will be repealed when the Children’s Act comes fully into force. It sets the age at which a minor may consent to medical treatment without parental consent at 14. The consent of parents is required for surgical treatment of a minor.

Children’s Act no. 38 of 2005

This Act sets the age of majority at 18 and the age at which a child may consent to medical and surgical treatment at 12. It confers on children of 12 or older the right to consent to HIV tests and to purchase condoms without their parents’ consent.

The Act also introduced important rights protecting children from undergoing virginity tests and circumcision against their will.

The General Regulations Regarding Children (Regulation 261) set out how the provisions of the legislation should be implemented. They can be downloaded (including relevant consent forms) from www.polity.org.za/article/childrens-act-382005-general-regulations-regarding-children-gazette-no-33076-regulation-261-2010-04-15

Choice on Termination of Pregnancy Act no. 92 of 1996

This legislation allows a girl of any age to have a termination of pregnancy. There is no age or maturity test.

Criminal Law (Sexual Offences and Related Matters) Amendment Act no 32 of 2007

Alleged sexual offenders may be subjected to mandatory HIV tests under this legislation.

Appendix 2

Links to relevant information

World Medical Association

Medical Ethics Manual (2005)

www.wma.net/e/ethicsunit/resources.htm

Health Professions Council of South Africa

Ethics and professional conduct guidance booklets

www.hpcs.co.za/hpcs/default.aspx?id=152

South African Medical Research Council

Ethics booklets

www.mrc.ac.za/ethics/ethics.htm

South African Medical Association

www.samedical.org

Department of Health

Legislation and guidance

www.doh.gov.za/docs/index.html

South African Journal of Bioethics and Law

www.sajbl.org.za/index.php/sajbl

National Health Act 2003

www.acts.co.za/national_health/index.html

Patients Charter

www.doh.gov.za/docs/legislation/patientsright/chartere.html

Appendix 3

National Health Act, 2003, Chapter 2: Sections 6, 7 and 8 Rights and Duties of Users and Health Care Personnel

6. User to have full knowledge

- 1 Every health care provider must inform a user of:
 - a) 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;
 - b) the range of diagnostic procedures and treatment options generally available to the user;
 - c) the benefits, risks, costs and consequences generally associated with each option; and
 - d) the user's right to refuse health services and explain the implications, risks, obligations of such refusal.
- 2 The health care provider concerned must, where possible, inform the user as contemplated in subsection (1) in a language that the user understands and in a manner which takes into account the user's level of literacy.

7. Consent of user

- 1 Subject to section 8, a health service may not be provided to a user without the user's informed consent, unless:
 - a) the user is unable to give informed 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) authorised 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 authorised 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 a sister of the user, in the specific order as listed;
 - c) the provision of a health service without informed consent is authorised 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.
- 2 A health care provider must take all reasonable steps to obtain the user's informed consent.
 - 3 For the purposes of this section "informed consent" means consent for the provision of a specified health service given by a person with legal capacity to do so and who has been informed as contemplated in section 6.

8. Participation in decisions

- 1 A user has the right to participate in any decision affecting his or her personal health and treatment.
- 2
 - a) If the informed consent required by section 7 is given by a person other than the user: such person must, if possible, consult the user before giving the required consent.
 - b) A user who is capable of understanding must be informed as contemplated in section 6 even if he or she lacks the legal capacity to give the informed consent required by section 7.
- 3 If a user is unable to participate in a decision affecting his or her personal health and treatment, he or she must be informed as contemplated in section 6 after the provision of the health service in question unless the disclosure of such information would be contrary to the user's best interest.

Appendix 4

Children’s Act (38/2005): General regulations regarding children (Gazette No. 33076 – Regulation 261)

Children’s consent forms

The forms specified in the Children’s Act (38/2005): General regulations regarding children, can be found at: www.polity.org.za/article/childrens-act-382005-general-regulations-regarding-children-gazette-no-33076-regulation-261-2010-04-15

References

1. Children's Act 38 of 2005, section 17. Came into force in July 2007.
2. Child Care Act 74 of 1983, section 39(4)
3. National Health Act 61 of 2003, section 7(1)(a, b,e).
4. Applebaum, PS, Assessment of Patients' Competence to Consent to Treatment, *N Engl J Med* 357(18):1835 (2007).
5. National Health Act 61 of 2003, section 7(1)(e).
6. HPCSA, *Seeking Patients' Informed Consent: The Ethical Considerations*, second edition (May 2007), para 11.
7. 28(2) of the Bill of Rights.
8. HPCSA, *Seeking Patients' Informed Consent: The Ethical Considerations*, second edition (May 2007), para 9.5.6
9. Child Care Act 74 of 1983, section 39(1).
10. HPCSA. *Seeking Patients' Informed Consent: The Ethical Considerations*, second edition (May 2007), para 9.9.5–6; Child Care Act 74 of 1983, section 39(2).
11. Children's Act 38 of 2005, section 12(1).
12. Children's Act 38 of 2005, section 12(10).
13. National Health Act 61 of 2003, section 7(1).
14. HPCSA, *Seeking Patients' Informed Consent: The Ethical Considerations*, second edition (May 2007), para 3.1.4.
15. Mental Health Care Act no. 17 of 2002: General Regulations (Gazetted December 2004 – no. R1467), section 34(2).
16. Mental Health Care Act no. 17 of 2002, section 9(1).
17. Mental Health Care Act no. 17 of 2002: General Regulations (Gazetted December 2004 – no. R1467), section 32(1).
18. HPCSA, *Ethical Guidelines For Good Practice with Regard To HIV* (2008), para 9.2.
19. Criminal Law (Sexual Offences and Related Matters) Amendment Act 32 of 2007, parts 2 and 3.

20. National Health Act no. 61 of 2003, section 7(1)d.
21. Prevention and Control of Communicable Diseases by Health Authorities and Heads of Institutions, *Government Gazette* no. 30681 (January 2008).
22. HPCSA, *Guidelines for the Withholding and Withdrawing of Treatment*, second edition (2007), para 2.6.
23. HPCSA, *Guidelines for the Withholding and Withdrawing of Treatment*, second edition (2007), para 3.
24. HPCSA, *Guidelines for the Withholding and Withdrawing of Treatment*, second edition (2007), para 2.7.
25. HPCSA, *Guidelines for the Withholding and Withdrawing of Treatment*, second edition (2007), para 8.2.1.
26. HPCSA, *Guidelines for the Withholding and Withdrawing of Treatment*, second edition (2007), paras 2.1 and 2.3.
27. HPCSA, *Guidelines for the Withholding and Withdrawing of Treatment*, second edition (2007), para 11.1.
28. Department of Health, *Ethics in Health Research: Principles, Structures and Processes* (2004), para 2.6.
29. Department of Health, *Ethics in Health Research: Principles, Structures and Processes* (2004), para 5.2. [emphasis added]
30. Department of Health, *Ethics in Health Research: Principles, Structures and Processes* (2004), para 5.2.
31. HPCSA, *Seeking Patients' Informed Consent: The Ethical Considerations*, second edition (2007), para 5.
32. HPCSA, *Seeking Patients' Informed Consent: The Ethical Considerations*, second edition (2007), paras 13.3.1–13.3.4.
33. WMA, *Medical Ethics Manual* (2005), page 43.

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South Africa membership enquiries

Ian Middleton

T 0800 118 771 (toll-free within SA)

E mps@global.co.za

Alika Maharaj

T 083 277 9208 (cell phone)

E mps@iburst.co.za

South African Medical Association

T 0800 225 677 (toll-free within SA)

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