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PART 1 is approved for **TWO (2) Ethics** Continuing Education Units (CEU's)

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**THE HEALTHCARE PROFESSIONS COUNCIL OF SOUTH
AFRICA**

**GUIDELINES FOR GOOD PRACTICE
IN THE HEALTHCARE PROFESSIONS**

**SEEKING PATIENTS' INFORMED CONSENT:
THE ETHICAL CONSIDERATIONS**

BOOKLET 4

REVISED: DECEMBER 2021

THE SPIRIT OF PROFESSIONAL GUIDELINES

Good clinical practice is based on a trust relationship between patients and healthcare professionals. Being a good healthcare practitioner requires a life-long commitment to sound professional and ethical practice and an overriding dedication to the interests and wellbeing of one's fellow human beings and society. This makes the practice in the healthcare profession a moral enterprise. It is in this spirit that the HPCSA presents the following ethical guidelines to guide and direct practice by healthcare practitioners. These guidelines are an integral part of the standards of professional conduct against which professional conduct is evaluated.

[Note: The terms "healthcare practitioner" and "healthcare professional" in these guidelines refer to persons registered with the HPCSA].

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1. GUIDANCE TO HEALTHCARE PRACTITIONERS

Being registered under the Health Professions Act No. 56 of 1974 (as amended) gives healthcare practitioners certain authority and privileges. In return, practitioners must meet the standards of competence, care and conduct set by the Health Professions Council of South Africa (HPCSA).

This booklet sets out the principles of good practice which all healthcare practitioners are expected to follow when seeking patients' informed consent to investigations, treatment, screening or research.

2. INTRODUCTION

- 2.1 Successful professional relationships between healthcare practitioner and patients depend upon mutual trust. To establish that trust, practitioner must respect patient's autonomy - their right to decide whether or not to undergo any medical intervention - even where a refusal may result in harm to themselves or in their own death. Patient must be given sufficient information in a manner that they can understand, to enable them to exercise their right to make informed decisions about their care. This is what is meant by an informed consent
- 2.2 The right to an informed consent flows from the South African Constitution, the National Health Act, various other statutes, the common law and the HPCSA's ethical rules and guidelines. Healthcare practitioner is expected to be aware of the laws in this regard. The laws prescribe the minimum requirements when seeking informed consent from patient.
- 2.3 Effective communication is key to enabling patients to make informed decisions. Healthcare practitioner must take appropriate steps to ensure that patient is provided with information about their condition and its treatment. Such dialogue with patient leads to clarity of objectives and understanding and strengthens the quality of the relationship between healthcare practitioner and patient. It provides an agreed framework within which healthcare practitioner can respond effectively to the individual needs of patient. Patient who makes properly informed decisions about their healthcare is more likely to co-operate fully with the agreed management of their conditions.

3. CONSENT TO INVESTIGATION AND TREATMENT

3.1 PROVIDING SUFFICIENT INFORMATION

- 3.1.1 Patient is entitled to information about his/her condition and the treatment options available to them. The amount of information that must be given to each patient will vary according to factors such as the nature of the condition, the complexity of the treatment, the risks associated with the treatment or procedure, and the patient's own wishes. For example, patient may need more information to make an informed decision about a procedure which carries a high risk of failure or adverse side effects, or about an investigation for a condition which, if present, could have serious implications for the patient's employment, social or personal life.
- 3.1.2 The National Health Act requires patients to be given information about:
 - 3.1.2.1 Their patient's health status except in circumstances where there is substantial evidence that the disclosure of the patient's health status would be contrary to the best interests of the patient;

- 3.1.2.2 The range of diagnostic procedures and treatment options generally available to the patient;
 - 3.1.2.3 The benefits, risks costs and consequences generally associated with each option; and
 - 3.1.2.4 The patient's right to refuse health services and explain the implications, risks and obligations of such refusal.
- 3.1.3 Patient has a right to information about any condition or disease from which they are suffering. This information should be presented in a language that the patient understands. The information which patient want or ought to know, before deciding whether to consent to treatment or an investigation, include:
- 3.1.3.1 Details of the diagnosis and prognosis (and the likely prognosis if the condition is left untreated);
 - 3.1.3.2 Uncertainties about the diagnosis, including options for further investigation prior to treatment;
 - 3.1.3.3 Options for treatment or management of the condition, including the option not to treat;
 - 3.1.3.4 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;
 - 3.1.3.5 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;
 - 3.1.3.6 Advice about whether a proposed treatment is experimental;
 - 3.1.3.7 How and when the patient's condition and any side effects will be monitored or re-assessed;
 - 3.1.3.8 The name of the practitioner who will have overall responsibility for the treatment and, where appropriate, names of the senior members of his or her team;
 - 3.1.3.9. Whether students will be involved, and the extent to which students may be involved in an investigation or treatment (patients should be informed of their right to refuse the involvement of students);
 - 3.1.3.10 A reminder that patient can change his/her mind about a decision at any time;
 - 3.1.3.11 A reminder that patient have a right to seek a second opinion;
 - 3.1.3.12 Details of costs or charges which the patient may have to meet.
- 3.1.4 When providing information, healthcare practitioner 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. Healthcare practitioner should not make assumptions about patients' views but should discuss these matters with them and ask them whether they have any concerns

about the treatment or the risks it may involve. Healthcare practitioner should provide patient with appropriate information, which should include an explanation of any risks to which they may attach particular significance. Patient should be asked whether they have understood the information and whether they would like more before making a decision.

- 3.1.5 Healthcare practitioner must not exceed the scope of the authority given by a patient, except in an emergency. Therefore, healthcare practitioner providing treatment or undertaking investigations must give the patient a clear explanation of the scope of consent being sought. This will apply particularly where:
 - 3.1.5.1 Treatment will be provided in stages with the possibility of later adjustments;
 - 3.1.5.2 Different healthcare practitioners provide particular elements of an investigation or treatment (for example anaesthesia during surgery) and where such situation arise, it is incumbent for each practitioner to engage the patient separately and fully for the consent to be completely informed;
 - 3.1.5.3 A number of different investigations or treatments are involved;
 - 3.1.5.4 Uncertainty about the diagnosis or about the appropriate range of options for treatment may be resolved only in the light of findings once an investigation or treatment is underway, and when the patient may be unable to participate in decision making.
- 3.1.6 In the cases referred to in para 3.1.5 above, healthcare practitioner should explain how decisions will be made about whether or when to move from one stage or one form of treatment to another. There should be a clear agreement about whether the patient consent to all or only parts of the proposed plan of investigation or treatment, and whether further consent will have to be sought at a later stage.
- 3.1.7 Healthcare practitioner should raise with patient the possibility of additional problems emerging during a procedure when the patient is unconscious or otherwise unable to make a decision. They should seek consent to treat any problems which they think may arise and ascertain whether there are any procedures to which the patient would object, or prefer to give further thought to before they proceed. Healthcare practitioner must abide by patients' decisions on these issues. If in exceptional circumstances healthcare practitioners decide, while the patient is unconscious, to treat a condition which falls outside the scope of the patient's consent, their decision may be challenged in the courts, or be the subject of a complaint to their employers or the HPCSA. Healthcare practitioner should therefore seek the views of an experienced colleague, wherever possible, before providing the treatment. They must be prepared to explain and justify their decisions based on such consideration as preservation of life. Healthcare practitioner must tell the patient what they have done and why, as soon as the patient is sufficiently recovered to understand.

3.2 RESPONDING TO QUESTIONS

Healthcare practitioner must respond honestly to any questions the patient raises and, as far as possible, answer as fully as the patient wishes. In some cases, a patient may ask about other treatments that are unproven or ineffective. Some patients may want to know whether any of the risks or benefits of treatment are affected by the choice of institution or practitioner providing the care. In any given situation where there's limitation in their competence/experience to provide the fullest possible answer, they should commit to seek the additional information from credible sources and provide same to the patient. Healthcare practitioner must answer such questions as fully, accurately and objectively as possible.

3.3 WITHHOLDING INFORMATION

- 3.3.1 Healthcare practitioner should not withhold information necessary for decision making, unless they judge that disclosure of some information could cause the patient serious harm. In this context, serious harm does not mean the patient would become upset or decide to refuse treatment.
- 3.3.2 The South African courts have held that patients must be informed of all “material risks” in order to give a proper informed consent. A risk is “material” if:
 - 3.3.2.1 A reasonable person in the position of the patient, if warned of the risk, would attach significance to it; and
 - 3.3.2.2 The healthcare practitioner should reasonably be aware that the patient, if warned of the risk, would attach significance to it.
- 3.3.3 No-one may make decisions on behalf of a mentally competent adult. If patients ask healthcare practitioner to withhold information and make decisions on their behalf or nominate a relative or third party to make decisions for them, the healthcare practitioner should explain the importance of patient knowing the options open to them, and what the treatment they may receive will involve. If patient insist that they do not want to know in detail about their condition and its treatment, the healthcare practitioner should still provide basic information about the treatment. If a relative asks a healthcare practitioner to withhold information, the latter must seek the views of the patient. Again, healthcare practitioner should not withhold relevant information unless they consider that it would cause the patient serious harm.
- 3.3.4 The National Health Act provides that healthcare practitioner must provide patient with information about their health status, unless “there is substantial evidence that the disclosure of the patient’s health status would be contrary to the best interests of the patients”.
- 3.3.5 In any case where healthcare practitioner withholds relevant information from the patient, they must record this, and the reason for doing so, in the patient's health records and they must be prepared to explain and justify their decision.

3.4 PRESENTING INFORMATION TO PATIENTS

- 3.4.1 Obtaining informed consent cannot be an isolated event. It involves a continuing dialogue between healthcare practitioner and their patient or their next of kin which keeps them abreast of changes in the condition of patients and the treatment or investigation the practitioners propose. Whenever possible, healthcare practitioner should discuss treatment options at a time when the patient is best able to understand and retain the information.
- 3.4.2 To be sure that their patient understand, healthcare practitioner should give clear explanations and give the patient time to ask questions. In particular, healthcare practitioner should:
 - 3.4.2.1 Use up-to-date written material, visual and other aids to explain complex aspects of the investigation, diagnosis or treatment where appropriate and practicable;
 - 3.4.2.2 Make arrangements, wherever possible, to meet particular language and communication needs, for example through translations, independent interpreters, people who sign on behalf of patients, or the patient's representative;

- 3.4.2.3 Where appropriate, discuss with patients the possibility of being accompanied by a relative or friend, as appointed by patient;
- 3.4.2.4 Explain the probabilities of success, prognosis, the risk of failure of, or harm associated with options for treatment, using accurate data;
- 3.4.2.5 Ensure that information which patients may find distressing is given to them in a considerate way. Provide patients with information about counseling services and support groups, where appropriate;
- 3.4.2.6 Allow patient sufficient time to reflect, before and after making a decision, especially where the information is complex or the severity of the risks is great. Where patients have difficulty understanding information, or there is a lot of information to absorb, it may be appropriate to provide it in manageable amounts, with appropriate written or other back-up material, over a period of time, or to repeat it;
- 3.4.2.7 Involve nursing or other members of the healthcare team in discussions with the patient, where appropriate. They may have valuable knowledge of the patient's background or particular concerns, for example in identifying what risks the patient should be told about);
- 3.4.2.8 Obtaining of informed consent belongs exclusively with the primary practitioner and should not be delegated.
- 3.4.2.9 Ensure that, where treatment is not to start until sometime after informed consent has been obtained, patients are given clear instructions on how to review their decision with the healthcare practitioner providing the treatment.
- 3.4.2.10 Consent will not be informed if it was given as a result of duress, coercion, manipulation, misrepresentation or mental impairment (e.g. under the influence of alcohol, drugs, including premedication in the theatre).

4. WHO OBTAINS CONSENT?

- 4.1 A healthcare practitioner providing treatment or undertaking an investigation has the responsibility to discuss it with the patient and obtain informed consent, as the practitioner will have a comprehensive understanding of the procedure or treatment, how it is to be carried out, and the risks attached to it. Where this is not practicable, healthcare practitioner may delegate these tasks provided they ensure that the person to whom they delegate:
 - 4.1.1 Is suitably educated, trained and qualified;
 - 4.1.2 Has sufficient knowledge of the proposed investigation or treatment and understands the risks involved; and
 - 4.1.3 Acts in accordance with the guidance in this Booklet.
- 4.2 A healthcare practitioner will remain responsible for ensuring that before he or she starts any treatment, the patient has been given sufficient time and information to make an informed decision and has given consent to the investigation or procedure.

5. THE RIGHT OF PATIENTS TO INFORMATION

- 5.1 Patients have a right to information about the healthcare services available to them, presented in a way that is easy to follow and use.
- 5.2 The National Health Act provides that healthcare providers (this includes healthcare practitioners) must inform users (patients) of the following:
 - 5.2.1 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;
 - 5.2.2 The range of diagnostic procedures and treatment options generally available to the user;
 - 5.2.3 The benefits, risks costs and consequences generally associated with each option; and
 - 5.2.4 The user's right to refuse health services and explain the implications, risks and obligations of such refusal.

6. ENSURING VOLUNTARY DECISION MAKING

- 6.1 It is for the patient, not the healthcare practitioner, to determine what is in the patient's own best interests. Nonetheless, practitioners may wish to recommend a treatment or a course of action to patient, but they must not put pressure on patient to accept their advice. In discussions with patients, healthcare practitioners should:
 - 6.1.1 Give a balanced view of the options;
 - 6.1.2 Explain the need for informed consent.
- 6.2 Healthcare practitioner must declare any potential conflicts of interest, for example where they or their organisation benefit financially from the use of a particular drug or treatment, or treatment at a particular institution if permitted by the HPCSA.
- 6.3 Pressure may be put on patients by employers, insurance companies or others to undergo particular tests or accept treatment. Healthcare practitioner should do their best to ensure that patient has considered the options and reached their own decision. Healthcare practitioner should take appropriate action if they believe patient is being offered inappropriate or unlawful financial or other rewards.
- 6.4 Patients who are detained by the police or immigration authorities, or are in prison, and those detained under the provisions of any mental health legislation may be particularly vulnerable. Where such patients have a right to decline treatment, healthcare practitioners should do their best to ensure that they know this and are able to exercise this right.

7 EMERGENCIES

- 7.1 In an emergency, where consent cannot be obtained, healthcare practitioner may provide medical treatment to anyone who needs it, provided the treatment is limited to what is immediately necessary to save life or avoid significant deterioration in the patient's health.
- 7.2 However, healthcare practitioner must respect the terms of any valid advance refusal by the patient which they know about, or which is drawn to their attention.

- 7.3 After the emergency healthcare practitioner should tell the patient what has been done and why, as soon as the patient is sufficiently recovered to understand.

8 ESTABLISHING CAPACITY TO MAKE DECISIONS

8.1 ASSESSING MENTAL CAPACITY

- 8.1.1 Healthcare practitioner must work on the presumption that every adult has the capacity to decide whether to consent to, or refuse, proposed medical intervention, unless it is shown that they cannot understand information presented in a clear way.
- 8.1.2 If a patient's choice appears irrational, or does not accord with the healthcare practitioner's view of what is in the patient's best interests, this is not evidence in itself that the patient lacks competence. In such circumstances it may be appropriate to review with the patient whether all reasonable steps have been taken to identify and meet their information needs.
- 8.1.3 Where healthcare practitioner need to assess a patient's capacity to make a decision, they should consult the guidance issued by the relevant professional bodies.
- 8.1.4 In the case of children who have legal capacity to give consent in terms of the Child Care Act (Act No. 35 of 2005) or the Choice on Termination of Pregnancy Act (Act No.92 of 1996), health care practitioners should make sure that the children have sufficiently mental maturity to understand the nature and effect of the treatment or procedure to which they are consenting (see below para 8.5).

8.2 FLUCTUATING CAPACITY

- 8.2.1 Where patient has difficulty retaining information or are only intermittently competent to make a decision, healthcare practitioner should provide any assistance they might need to reach an informed decision.
- 8.2.2 Healthcare practitioner should record any decision made while the patient was competent, including the key elements of the consultation.
- 8.2.3 Healthcare practitioner should review any decision made whilst the patient was competent, at appropriate intervals before treatment starts, to establish that their views are consistently held and can be relied on.

8.3 MENTALLY INCAPACITATED PATIENTS

- 8.3.1 The National Health Act makes provision for certain persons to consent on behalf of mentally incompetent patients to an operation or medical treatment where such patients are unable to give the necessary consent and have not mandated - while still mentally competent- somebody else in writing to give consent on their behalf.
- 8.3.2 The Act sets out a priority list of persons who may consent in such circumstances:
- 8.3.2.1 A person authorized by the court (e.g. a curator); or
 - 8.3.2.2 In order of priority, the patient's spouse, partner, parent, grandparent, major child or brother or sister.
- 8.3.3 Healthcare practitioners should also consult the provisions of the Mental Health Care Act (Act No.17 of 2002) when dealing with mentally ill patients.

8.4 THIRD PARTY NOMINATIONS IN REGARD TO CONSENT

- 8.4.1 The National Health Act allows patient – while still mentally competent - to mandate another person in writing to give consent on their behalf
- 8.4.2 If healthcare practitioner is treating a patient who has lost the capacity to consent to or refuse treatment, for example through the onset or progress of a mental disorder or other disabilities, they should try to find out whether:
 - 8.4.2.1 The patient has previously mandated someone else in writing to make decisions on their behalf; or
 - 8.4.2.2 Have indicated preferences in an advance statement (e.g. an “advance directive” or “living will”).
- 8.4.3 Healthcare practitioner must respect any refusal of treatment given when the patient was competent, provided the decision in the advance statement is clearly applicable to the present circumstances, and there is no reason to believe that the patient has changed his or her mind. Where an advance statement of this kind is not available, the patient's known wishes should be taken into account

8.5 CHILDREN

The ages as stipulated in this document are a reflection of the Children's Act, 2005 (Act No. 38 of 2005).

- 8.5.1 Healthcare practitioner must assess a child's capacity to decide whether to consent to or refuse a proposed investigation or treatment before they provide it.
- 8.5.2 In general, a competent child will be able to understand the nature, purpose and possible consequences of the proposed investigation or treatment, as well as the risks and consequences of non-treatment.
- 8.5.3 A healthcare practitioner's assessment must take account of the following:
 - 8.5.3.1 A person over the age of 18 years is an adult and is legally competent to decide on all forms of treatment and medical procedures (Children's Act, 2005).
 - 8.5.3.2 A child who is 12 years of age is legally competent to consent to medical treatment if the child is of sufficient maturity and has the mental capacity to understand the benefits, risks, social and other implications of the treatment (Children's Act, 2005 (Act No. 38 of 2005) section 129(2)).
 - 8.5.3.3 Where a child is under 12 years of age or not of sufficient maturity and does not have the necessary mental capacity his or her parent, guardian or care-giver may give consent to medical treatment (Children's Act, 2005 section 129(4)).
 - 8.5.3.4 A child who is 12 years of age is legally competent to consent to a surgical operation if the child is of sufficient maturity, has the mental capacity to understand the benefits, risks, social and other implications of the surgical operation, and is duly assisted by his or her parent or guardian (Children's Act, 2005 section 129(3)).

- 8.5.3.5 Where a child is under 12 years of age or not of sufficient maturity and does not have the necessary mental capacity his or her parent or guardian may give consent to a surgical procedure (Children's Act, 2005 section 129(5)).
- 8.5.3.6 The superintendent of a hospital or the person in charge of a hospital in the absence of the superintendent may consent to the medical treatment of or a surgical operation on a child if the treatment or operation is necessary to preserve the life of the child or to save the child from serious or lasting physical injury or disability; and the need for the treatment or operation is ~~so~~ urgent that it cannot be deferred for the purpose of obtaining consent that would otherwise have been required (Children's Act, 2005 section 129(6)).
- 8.5.3.7 The Minister of Health may consent to the medical treatment of, or surgical operation on a child if the parent or guardian of the child unreasonably refuses to give consent or to assist the child in giving consent, is incapable of giving consent or of assisting the child in giving consent, cannot readily be traced, or is deceased (Children's Act, 2005 section 129(7)).
- 8.5.3.8 The Minister may consent to the medical treatment of or surgical operation on a child if the child unreasonably refuses to give consent (Children's Act, 2005 section 129(8)).
- 8.5.3.9 A High Court or children's court may consent to the medical treatment of or a surgical operation on a child in all instances where another person that may give consent refuses or is unable to give such consent (Children's Act, 2005 section 129(9)).
- 8.5.3.10 No parent, guardian or care-giver of a child may refuse to assist a child or withhold consent by reason only of religious or other beliefs, unless that parent or guardian can show that there is a medically accepted alternative choice to the medical treatment or surgical operation concerned (Children's Act, 2005 section 129(10)).
- 8.5.3.11 A female of any age is legally competent to consent to a termination of pregnancy (Choice on Termination of Pregnancy Act, 1996 (Act No. 92 of 1996)) provided she has the necessary mental capacity to give an informed consent by understanding and appreciating the benefits, risks, social and other implications of the termination of pregnancy.

9. THE "BEST INTERESTS" PRINCIPLE

- 9.1 In deciding what options may be reasonably considered as being in the best interests of a patient who lacks capacity to decide, healthcare practitioner should take into account:
 - 9.1.1 The options for investigation or treatment which are clinically indicated;
 - 9.1.2 Any evidence of the patient's previously expressed preferences, including an advance statement;
 - 9.1.3 Their own and the healthcare team's knowledge of the patient's background, such as cultural, religious or employment considerations;

- 9.1.4 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;
- 9.1.5 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.
- 9.2 The South African Constitution provides that “a child’s best interests are paramount in every matter concerning a child”.

10. APPLYING TO THE COURT

- 10.1 Where a patient's capacity to consent is in doubt, or where differences of opinion about his or her best interests cannot be resolved satisfactorily, or third party is not nominated, healthcare practitioner should consult more experienced colleagues and, where appropriate, seek legal advice on whether it is necessary to apply to the court for a ruling.
- 10.2 Healthcare practitioner should seek the court where a patient lacks capacity to consent to a medical intervention and the situation is contentious for example, parent withholding consent to life-saving treatment for children under the age of 12 years, in other words, in any situation where the interest of the patient is protected by a constitutional right.
- 10.3 Where healthcare practitioner decides to apply to a court they should, as soon as possible, inform the patient, or his or her representative of their decision and of his or her right to be represented at the hearing.

11. FORMS OF CONSENT

To determine whether patients have given informed consent to any proposed investigation or treatment, healthcare practitioners must check how well the patients have understood the details and implications of what is proposed, and not simply rely on the form in which their consent has been expressed or recorded – especially where the initial consent was obtained by a third party.

12 EXPRESS CONSENT

- 12.1 Patients can indicate their informed consent either recorded or in writing.
- 12.2 In some cases, the nature of the risks to which the patient might be exposed makes it important that a written record is available of the patient's consent and other wishes in relation to the proposed investigation and treatment. This helps to ensure later understanding between healthcare practitioner, the patient and anyone else involved in carrying out the procedure or providing care.
- 12.3 Except in an emergency, where the patient has the capacity to give consent, healthcare practitioners should obtain written consent in the following cases, although this list is not exhaustive:
 - 12.3.1 The treatment or procedure is complex or involves significant risks and/or side effects;
 - 12.3.2 Providing clinical care is not the primary purpose of the investigation or examination;

12.3.3 There may be significant consequences for the patient's employment, social or personal life;

12.3.4 The treatment is part of a research programme.

12.4 Healthcare practitioner must use the patient's formal health records or the consent form to detail the key elements of the discussion with the patient, including the nature of information provided, specific requests by the patient, and details of the scope of the consent given.

13. STATUTORY REQUIREMENTS

Some statutes require particular forms of consent to be obtained for specific procedures (for example, sterilizations (Sterilization Act (Act No. 44 of 1998), terminations of pregnancy (Choice on Termination of Pregnancy Act (No.92 of 1996) and removal of organs from deceased people (National Health Act, 2003). Healthcare practitioners need to consult the law in this regard when carrying out such procedures.

14. IMPLIED CONSENT

Healthcare practitioner should be careful about relying on a patient's apparent compliance with a procedure as a form of consent. Submission in itself may not necessarily indicate consent. For example, the fact that a patient lies down on an examination couch does not indicate that the patient has understood what the health care practitioner proposes to do and why. Consent must at all times be expressed and not implied.

15. REVIEWING CONSENT

15.1 A signed consent form is not sufficient evidence that a patient has given, or still gives, informed consent to the proposed treatment in all its aspects. Healthcare practitioners must review the patient's decision close to the time of treatment, and especially where:

16.1.1 Significant time has elapsed between when the consent was obtained and the start of treatment;

16.1.2 There have been material changes in the patient's condition, or in any aspects of the proposed treatment plan, which might invalidate the patient's existing consent;

16.1.3 New, potentially relevant information has become available, for example about the risks of the treatment or about other treatment options.

16. CONSENT TO SCREENING AND TESTING

16.1 Screening or testing of healthy or asymptomatic people to detect genetic predispositions or early signs of debilitating or life threatening conditions can be an important tool in providing effective care. However, the uncertainties involved in screening or testing may be great, for example the risk of false positive or false negative results. Some findings may potentially have serious medical, social or financial consequences not only for the individuals, but for their relatives. In some cases the fact of having been screened or tested may itself have serious implications.

16.2 Healthcare practitioner must ensure that anyone considering whether to consent to screening or testing can make a properly informed decision. As far as possible, practitioners should ensure that screening or testing is not contrary to the individual's interests. Healthcare practitioner must pay particular attention to ensuring that the information the person wants or ought to have is identified and provided. Practitioner should be careful to explain clearly:

- 16.2.1 The purpose of the screening or test;
- 16.2.2 The likelihood of positive or negative findings and the possibility of false positive or negative results;
- 16.2.3 The uncertainties and risks attached to the screening or testing process;
- 16.2.4 Any significant medical, social or financial implications of screening or testing for the particular condition or predisposition;
- 16.2.5 Follow up plans, including the availability of counseling and support services.

17. ICD10 CODING AND INFORMED CONSENT

Informed consent is an exercise of an **informed choice** by a patient who **has the capacity** to give consent:-

- a) in instances where there are multiple options or alternatives to treatment; or
- b) in making a decision whether to withhold or disclose information or allow someone else to disclose information on their medical condition to a defined third party; or
- c) in making a decision for purposes of reimbursement by a Medical Scheme,

based on adequate information and a detailed analysis or unpacking of each of the options or alternatives as well as the legislative requirements for disclosure of such information.

This means there must be a full and frank disclosure of all the material facts to enable the patient to decide from an informed basis. With regards to ICD 10, for instance, the patient should be given information as to who will access their information, for what purpose and what would be the implications of the utilization of such information etc.

17.1 PROVIDER RESPONSIBILITIES: ICD-10

Healthcare provider have the following obligations, the list not being exhaustive as any other ethical obligation in handling and dealing with patient information and respecting their confidentiality will be required:-

- a) to provide information to the patients about the legislative requirement of supplying ICD-10 codes to the medical schemes for purposes of reimbursements and the inevitable consequences of the medical scheme becoming aware of the diagnosis of the patient/member;
- b) to procure patient's consent to release ICD-10 coding to the medical scheme and/or (where required) to the other health professional (within the healthcare team);
- c) to advise the patient of their choice not to have their ICD-10 coding divulged to the medical scheme which would mean the patient has to settle the provider's account directly; and

- d) to indicate that the practitioner does not have control over the management and utilization of this information once divulged over to the medical scheme and that the medical scheme takes responsibility for any further disclosure or utilization of such information for whatever purpose.

It is strongly suggested that written consent be procured from the patient by the provider in order to safeguard the interests of both parties. Consent by a patient may be once-off in relation to the treatment of a similar condition provided there is a verbal reminder to the patient about their initial commitment to confirm if they are still comfortable with the disclosure. It would be advisable for a provider to note the verbal reminder on that patient's file. Where a patient presents with a new or different condition, a fresh consent should be obtained from the patient and appropriately documented.

Provider without a direct patient contact like Pathologists and Radiologists act on referrals from other providers. Their responsibility would be to ensure that the referring provider has procured consent for that other provider (in this case a pathologist or radiologist) to access and also disclose the information to the medical scheme for reimbursement purposes.

17.2 INFORMED CONSENT FOR INTER-COUNCIL INTERACTION OF HEALTH PROFESSIONALS AS MEMBERS OF A HEALTHCARE TEAM
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Sharing of information with members of a healthcare team providing a health service to a patient would be permissible to the extent that it is necessary to enhance the quality of care to be provided to that patient and the patient has given consent to treatment and disclosure of such information to another healthcare practitioner. This would include members beyond the HPCSA.

Ethical guidelines for good practice in the health care professions

The following Booklets are separately available:

- Booklet 1: General ethical guidelines for healthcare professions***
- Booklet 2: Ethical and professional rules of the health professions council of South Africa as promulgated in government gazette R717/2006***
- Booklet 3: National Patients' Rights Charter***
- Booklet 4: Seeking patients' informed consent: The ethical considerations***
- Booklet 5: Confidentiality: Protecting and providing information***
- Booklet 6: Guidelines for the management of patients with HIV infection or AIDS***
- Booklet 7: Guidelines withholding and withdrawing treatment***
- Booklet 8: Guidelines on Reproductive Health management***
- Booklet 9: Guidelines on Patient Records***
- Booklet 10: Guidelines for the practice of Telehealth***
- Booklet 11: Guidelines on over servicing, perverse incentives and related matters***
- Booklet 12: Guidelines for the management of healthcare waste***
- Booklet 13: General ethical guidelines for health researchers***
- Booklet 14: Ethical Guidelines for Biotechnology Research in South Africa***
- Booklet 15: Research, development and the use of the chemical, biological and nuclear weapons***
- Booklet 16: Ethical Guidelines on Social Media***
- Booklet 17: Ethical Guidelines of Palliative Care***

QUESTIONNAIRE PE8(25) Part 1 of 2

Seeking patients' informed consent: the ethical considerations - Booklet 4

INSTRUCTIONS

- Read through the article and answer the multiple-choice questions provided below.
- Some questions may have more than one correct answer; in which case you must mark **all** the correct answers.

Introduction

Question 1: Is it **TRUE** that successful professional relationships between healthcare practitioners and patients depend upon mutual trust?

- A: YES
- B: NO

Question 2: Healthcare practitioners must take appropriate steps to ensure that patients are provided with information about their condition and its treatment. Which one of the following best describes how this can influence patient behaviour?

- A: Leads to clarity of objectives and understanding
- B: Strengthens the quality of the relationship between healthcare practitioner and patient
- C: Provides an agreed framework within which the healthcare practitioner can respond effectively to the individual needs of his / her patient
- D: Most likely leads to full co-operation with the agreed management of their conditions

Consent to investigation and treatment

Providing sufficient information

Question 3: A patient is entitled to information about his/her condition and the treatment options available to them. Which of the following impacts on the amount of information given to make an informed decision?

- A: The nature of the condition
- B: The complexity of the treatment
- C: The risks associated with the treatment or procedure
- D: An investigation for a condition which, if present, could have serious implications for the patient's employment, social or personal life
- E: The patient's ability to understand medical information

Question 4: The information that a patient wants or ought to have before deciding whether to consent to treatment or an investigation, includes which of the following information?

- A: Purpose of a proposed investigation or treatment
- B: Details of the procedures or therapies involved
- C: Methods of pain relief
- D: How the patient should prepare for the procedure
- E: Details of what the patient might experience during or after the procedure, including common and serious side effects

Question 5: A practitioner providing treatment or undertaking investigations must give the patient a clear explanation of the scope of consent being sought, except in which **ONE** of the following circumstances?

- A: When treatment will be provided in stages with the possibility of later adjustments
- B: If different healthcare practitioners provide particular elements of an investigation or treatment
- C: A number of different investigations or treatments are involved
- D: In an emergency

Question 6: In exceptional circumstances, such as when the patient is unconscious and a healthcare practitioner decides to treat a condition which falls outside the scope of the patient's consent, the practitioner should refrain from which of the following?

- A: Seeking the views of an experienced colleague wherever possible, before providing the treatment as this could endanger the patient's life
- B: Acting solely on his / her own understanding of the situation at hand
- C: Being prepared to explain and justify their decisions based on such consideration as preservation of life
- D: Telling the patient what they have done and why, when the patient is sufficiently recovered to understand

Withholding information

Question 7: Is it **TRUE** or **FALSE** that healthcare practitioners should not withhold information necessary for decision making, even if they judge that disclosure of some information could cause the patient serious harm.

- A:** TRUE
- B:** FALSE

Presenting information to patients

Question 8: To be sure that their patients understand, healthcare practitioners should avoid which **ONE** of the following actions?

- A:** Giving overly clear explanations as the patient may feel “intellectually” judged
- B:** Giving the patient time to ask questions as this complicates the issue at hand
- C:** Using up-to-date written material, visual and other aids to explain complex aspects of the investigation, diagnosis or treatment where appropriate and practicable
- D:** Expecting a patient to make decisions in a restricted period of time
- E:** Giving information, which patients may find distressing, in a considerate way

Question 9: Consent will not be informed if it was given as a result of which of the following?

- A:** Duress
- B:** Coercion
- C:** Manipulation
- D:** Mental impairment

Who obtains consent?

Question 10: Which of the following entities will remain responsible to ensure that before any treatment is started, the patient was given sufficient time and information to make an informed decision and consented to the investigation or procedure?

- A:** A delegate appointed by the practitioner, who can be a nurse, practice manager or properly trained medical receptionist
- B:** The healthcare practitioner providing treatment or undertaking an investigation

THE END

QUESTIONNAIRE PE8(25) Part 2 of 2

Seeking patients' informed consent: the ethical considerations - Booklet 4

INSTRUCTIONS

- Read through the article and answer the multiple-choice questions provided below.
- **Some questions may have more than one correct answer;** in which case you must mark **all** the correct answers.

The right of patients to information

Question 1: Which **ONE** of the following is **NOT** a true reflection of the provisions of the National Health Act that healthcare providers and healthcare practitioners must inform patients of.....?

- A:** The user's health status irrespective of the fact that there is substantial evidence that such disclosure would be contrary to the best interests of the patient
- 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
- D:** The user's right to refuse health services
- E:** The implications, risks and obligations of such refusal of health service

Ensuring voluntary decision making

Question 2: Practitioners may wish to recommend a treatment or a course of action to a patient, but they must not put pressure on a patient to accept their advice. In discussions with patients, doing which of the following can be regarded as unethical?

- A:** Giving a balanced view of the options
- B:** Explaining the need for informed consent
- C:** Concealing any potential conflicts of interest to prevent harm to the patient
- D:** Doing their best to ensure the patient has considered the options and reached their own decision

Establishing capacity to make decisions

Mentally incapacitated patients

Question 3: Is it **TRUE** that the National Health Act makes provision for certain persons to consent to an operation or medical treatment on behalf of mentally incompetent patients, who are unable to give the necessary consent and have not mandated somebody else in writing to give consent on their behalf?

- A:** YES
- B:** NO

Children

Question 4: Which **ONE** of the following is **NOT** seen as legally competent to decide on all forms of treatment and medical procedures?

- A:** A person over the age of 18 years, but not yet 21 years of age
- B:** A child who is 12 years of age and of sufficient maturity and who has the mental capacity to understand the benefits, risks, social, and other implications of the treatment
- C:** A child under 12 years of age, or not of sufficient maturity and who does not have the necessary mental capacity
- D:** A child who is 12 years of age of sufficient maturity, has the mental capacity to understand the benefits, risks, social and other implications of the surgical operation, and is duly assisted by his or her parent or guardian

Question 5: Is it **TRUE** or **FALSE** that a female of any age is legally competent to consent to a termination of pregnancy provided she has the necessary mental capacity to give informed consent by understanding and appreciating the benefits, risks, social and other implications of the termination of pregnancy?

- A:** TRUE
- B:** FALSE

The "best interests" principle

Question 6: In deciding what options may be reasonably considered as being in the best interests of a patient who lacks capacity to decide, healthcare practitioners should **NOT** take which of the following into account?

- A:** The options for investigation or treatment which are clinically indicated
- B:** Any evidence of the patient's previously expressed preferences, including an advance directive
- C:** Their own and the healthcare team's knowledge of the patient's background
- D:** Their own and the healthcare team's preferences
- E:** The option that least restricts the patient's future choices

Applying to the court

Question 7: When should it be UNNECESSARY for a healthcare practitioner to apply to a court?

- A: Where a patient's capacity to consent is in doubt or lacking
- B: Where differences of opinion about a patient's best interests can be resolved satisfactorily
- C: A third party is not nominated
- D: Where the situation is contentious
- E: Any situation where the interest of the patient is protected by a constitutional right

Express consent

Question 8: In which of the following cases is it NOT important to obtain written consent?

- A: When the treatment or procedure is complex or involves significant risks and/or side effects
- B: When providing clinical care is the primary purpose of the investigation or examination
- C: There may be significant consequences for the patient's employment, social or personal life
- D: The treatment is part of a research program

Implied consent

Question 9: Healthcare practitioners should be careful about relying on a patient's apparent compliance with a procedure as a form of consent. If a patient lies down on an examination couch, does it indicate that the patient has understood what the health care practitioner proposes to do and why?

- A: Definitely
- B: Not necessarily

Consent to screening and testing

Question 10: When a patient is considering whether to consent to screening or testing, which aspect of the process should receive particular attention?

- A: Ensuring that anyone considering to consent to screening or testing can make a properly informed decision
- B: Ensuring that screening or testing is not contrary to the individual's interests
- C: Ensuring that the information the person wants, or ought to have, is identified and provided

THE END



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*HPCSA number

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Personal detail changes

I hereby declare that the completion of this document is my own effort without any assistance.

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DATE:

This activity is accredited for **FOUR (4) ETHICS** CEU'S. You have to achieve **70%** to pass this activity.





ANSWER SHEET

PE8(25)

Seeking Patients informed consent: The ethical considerations - Booklet 4

*Time spent on activity												hour min											
PART 1												PART 2											
	A	B	C	D	E		A	B	C	D	E		A	B	C	D	E		A	B	C	D	E
1						6						1						6					
2						7						2						7					
3						8						3						8					
4						9						4						9					
5						10						5						10					

How relevant was the content of this activity to your scope of practice?

			
Not at all	Somewhat	Mostly	Extremely

RETURN ANSWER SHEET TO

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