



GUIDELINES FOR GOOD PRACTICE IN THE HEALTH CARE PROFESSION

OBTAINING PATIENTS' INFORMED CONSENT: Ethical Considerations

*"Promoting Quality Healthcare and Safeguarding
the Public is our Prime Concern"*

1st Edition, March 2016

TABLE OF CONTENTS

The Spirit of Professional Guidelines.....	1
Definition of terms.....	1
1.0 Guidance to Health Practitioners.....	1
2.0 Introduction.....	1
3.0 Consent to Investigation and Treatment.....	1
3.1 Providing Sufficient Information.....	1
3.2 Responding To Questions.....	4
3.3 Withholding Information.....	4
3.4 Presenting Clear Information To Patients.....	4
4.0 MeaningOfInformedConsent.....	5
5.0 Who Obtains Consent?.....	5
6.0 The Right Of Patients To Information.....	6
7.0 Promoting Voluntary Decision Making.....	6
8.0 Emergencies.....	7
9.0 EstablishingCapacityToMakeDecisions.....	7
9.1 Assessing Mental Capacity.....	7
9.2 Fluctuating Capacity.....	7
9.3 Mentally Incapacitated Patients.....	7
9.4 Third Party Nominations In Regard To Consent.....	8
9.5Children.....	8
10. The “Best Interests” Principle.....	9
11. Applying to the Court.....	9
12. FORMS OF CONSENT.....	9
13. ExpressConsent.....	9
14. ImpliedConsent.....	10
15. Reviewing Consent.....	10
16. Consent To Screening And Testing.....	10
17. Informed Consent among members of the Health Care Team.....	11
18. Accountability.....	11
References.....	11

THE SPIRIT OF PROFESSIONAL GUIDELINES

The Guidelines on seeking patient consent amplify the patients' rights as enshrined in the National Health Care Standards. The provisions are enshrined to uphold the patients right to consent and address unethical behavior of patient coercion and situations which disregard the choice of patients when providing health services.

The guidelines provide unwavering guidance in elective situations, emergencies as well as recognizing the validity of advance consent directive.

Practice as a health Practitioner is based upon a relationship of mutual trust between patients and health practitioners. To be a good health practitioner, requires a life-long commitment to sound professional and ethical practices and an overriding dedication to the interest of patients.

In essence, health care practice is a moral and societal obligation. In this spirit, the Health Professions Council of Zambia presents the following ethical guidelines to guide and direct the practice of health practitioners. These guidelines outline one of the integral part of the standards of professional practice against which a complaint of professional misconduct may be evaluated.

DEFINITION OF TERMS

PATIENTS' INFORMED CONSENT:

1. Guidance To Health Practitioners

Being registered under the Health Professions Act , gives health practitioners certain rights and privileges. In return, you must meet the standards of competence, care and conduct set by the Health Professions Council of Zambia. This booklet expounds the principles of good practice which all health practitioners are expected to follow when seeking patients' informed consent to investigations, treatment, screening or research in respect to patients rights.

2. Introduction

- 2.1 Successful relationships between health practitioners and patients depend upon mutual trust. To establish that trust practitioners must respect patients' 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. Patients must be given sufficient information in a way 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 National Health Care Standards which every health practitioners is expected to be aware of .
- 2.3 Effective communication is the key to enabling patients to make informed decisions. Health practitioners must take appropriate steps to find out what patients want to know and ought to know about their condition and its treatment. Such dialogue with patients leads to clarity of objectives and understanding, and strengthens the quality of the relationship between health practitioners and patients. It provides an agreed framework within which health practitioners can respond effectively to the individual needs of patients. Patients who make properly informed decisions about their health care are more likely to co-operate fully with the agreed management plan of their conditions.

3. CONSENT TO INVESTIGATION AND TREATMENT

3.1 Providing Sufficient Information

- 3.1.1 Patients have a right to information about their condition and the treatment options

available to them, 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;

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, patients 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 patient should be availed sufficient information on the range of diagnostic procedures and treatment options, benefits, risks, costs and consequences associated with each option.
- 3.1.4 Patient's have the right to refuse health services and are entitled to information regarding the Implications, risks and obligations of such refusal.
- 3.1.5 Patients have 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 patients want or ought to know, before deciding whether to consent to treatment or an investigation, includes:
 - 3.1.5.1 Details of the diagnosis and prognosis, and the likely prognosis if the condition is left untreated;
 - 3.1.5.2 Uncertainties about the diagnosis, including options for further investigation prior to treatment;
 - 3.1.5.3 Options for treatment or management of the condition, including the option not to treat;
 - 3.1.5.4 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;
 - 3.1.5.5 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;
 - 3.1.5.6 Advice about whether a proposed treatment is experimental;
 - 3.1.5.7 How and when the patient's condition and any side effects will be monitored or re-assessed;
 - 3.1.5.8 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;
 - 3.1.5.9 Whether students will be involved, and the extent to which students may be involved in an investigation or treatment;
 - 3.1.5.10 A reminder that patients can change their minds about a decision at any time;

- 3.1.5.11 A reminder that patients have a right to seek a second opinion;
- 3.1.5.12 Where applicable, details of costs or charges which the patient may have to meet.
- 3.1.6 When providing information, health 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 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. Health practitioners should provide patients with appropriate information, which should include an explanation of any risks to which they may attach particular significance. Patients should be asked whether they have understood the information and whether they would like more before making a decision.
- 3.1.7 Health practitioners must not exceed the scope of the authority given by a patient, except in an emergency. Therefore, health practitioners providing treatment or undertaking investigations must give the patient a clear explanation of the scope of consent being sought. This will apply particularly where:
- 3.1.7.1 Treatment will be provided in stages with the possibility of later adjustments;
 - 3.1.7.2 Different health practitioners provide particular elements of an investigation or treatment (for example anaesthesia during surgery);
 - 3.1.7.3 A number of different investigations or treatments are involved;
 - 3.1.7.4 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.
 - 3.1.7.5 Health practitioners 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 consents 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.
- 3.1.8 Health practitioners should liaise with patients 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. Health practitioners must abide by patients' decisions on these issues. If in exceptional circumstances health care 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 HPCZ.

Health practitioners 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. Health practitioners 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

Health practitioners 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 doctor providing the care. Health practitioners must answer such questions as fully, accurately and objectively as possible.

3.3 WITHHOLDING INFORMATION

3.3.1 Health practitioners should not withhold information necessary for decision making unless they judge that disclosure of some relevant information would 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 Health Professions Council of Zambia holds 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 health care 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 health practitioners to withhold information and make decisions on their behalf, or nominate a relative or third party to make decisions for them, the health practitioner should explain the importance of patients knowing the options open to them, and what the treatment they may receive will involve. If patients insist they do not want to know in detail about their condition and its treatment, the health practitioner should still provide basic information about the treatment. If a relative asks a health practitioner to withhold information, the latter must seek the views of the patient. Again, health practitioners should not withhold relevant information unless they judge that it would cause the patient serious harm.

3.3.4 These guidelines demands that patients must be informed 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 health practitioners withhold relevant information from the patient they must record this, and the reason for doing so, in the patient’s medical records and they must be prepared to explain and justify their decision.

3.4 PRESENTING CLEAR INFORMATION TO PATIENTS

3.4.1 Obtaining informed consent cannot be an isolated event. It involves a continuing dialogue between health practitioners and their patients which keeps them abreast of changes in the condition of patients and the treatment or investigation the practitioners proposes. Whenever possible, health practitioners 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 patients understand, health practitioners should give clear explanations and give the patients time to ask questions. In particular, health care practitioners 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, sign language, independent interpreters, , or the patient’s representative;
 - 3.4.2.3 Where appropriate, discuss with patients the possibility of being accompanied by a relative or friend, or making a tape recording of the consultation;
 - 3.4.2.4 Explain the probabilities of success, or 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 patient support groups, where appropriate;
 - 3.4.2.6 Allow patients 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 information 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 health care 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 informed of);
 - 3.4.2.8 Ensure that, where treatment is not to start until sometime after consent has been obtained, patients are given clear instructions on how to review their decision with the health practitioner providing the treatment.

4. MEANING OF INFORMED CONSENT

The Health Professions Council of Zambia holds that for a proper informed consent the patient must have:

- 4.1. Knowledge of the nature or extent of the procedure or treatment
- 4.2 Appreciated and understood the nature of the possible harm or risk;
- 4.3 Comprehensively consented to the procedure in writing with full knowledge, (i.e. extended to the entire transaction, inclusive of its consequences) and conscious of the benefits and risk.

5. WHO OBTAINS CONSENT?

- 5.1 A health practitioner providing treatment or undertaking an investigation has the

responsibility to discuss it with the patient and obtain 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, health practitioners may delegate these tasks provided they ensure that the person to whom they delegate:

- 5.1.1 Is suitably qualified with a valid licence
 - 5.1.2 Has sufficient knowledge of the proposed investigation or treatment and understands the risks involved; and
 - 5.1.3 Able to communicate in the language appropriate to the patient
 - 5.1.4 Convey's back the outcome to the attendant practitioner in its entirety
 - 5.1.5 Acts in accordance with the guidance in this Booklet.
- 5.2 A health 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.

6. THE RIGHT OF PATIENTS TO INFORMATION

- 6.1 Patients have a right to information about the health care services available to them, presented in a way that is easy to understand .
- 6.2 The health practitioners should inform the patient;
- 6.2.1 His/her 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;
 - 6.2.2 The range of diagnostic procedures and treatment options generally available to the user;
 - 6.2.3 The benefits, risks costs and consequences generally associated with each option; and
 - 6.2.4 The right to refuse health services and explain the implications, risks and obligations of such refusal.

7. PROMOTING VOLUNTARY DECISION MAKING

- 7.1 In discussions with patients, health practitioners should:
- 7.1.1 Give a balanced view of the options, devoid of personal biases
 - 7.1.2 Explain the need for informed consent.
- 7.2 Health care practitioners must declare any potential conflicts of interest, for example where they or their organization benefit financially from the use of a particular drug or treatment, or treatment at a particular institution.
- 7.3 Do their best to ensure that patients have considered the options and reached their own decision. Health practitioners should take appropriate action if they believe patients are being offered inappropriate or unlawful financial or other rewards.

- 7.4 Patients who are detained by state authorities, or 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, health practitioners should do their best to ensure that they know this and are able to exercise this right.

8.0 EMERGENCIES

- 8.1 In an emergency, where consent cannot be obtained, health practitioners should 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.
- 8.2 However, health practitioners must respect the terms of any valid advance refusal by the patient which they know about, or which is drawn to their attention.
- 8.3 After the emergency health practitioners should tell the patient what has been done and why, as soon as the patient is sufficiently recovered to understand.

9.0 ESTABLISHING CAPACITY TO MAKE DECISIONS

9.1 Assessing Mental Capacity

- 9.1.1 Health practitioners 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.
- 9.1.2 If a patient's choice appears irrational, or does not accord with the health 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.
- 9.1.3 Where health practitioners need to assess a patient's capacity to make a decision, they should consult the guidance issued by the relevant authorities.

9.2 FLUCTUATING CAPACITY

- 9.2.1 Where patients have difficulty retaining information, or are only intermittently competent to make a decision health practitioners should provide any assistance they might need to reach an informed decision.
- 9.2.2 Health practitioners should record any decision made while the patients were competent, including the key elements of the consultation.
- 9.2.3 Health practitioners should review any decision made whilst the patients were competent, at appropriate intervals before treatment starts, to establish that their views are consistently held and are reliable.

9.3 MENTALLY INCAPACITATED PATIENTS

- 9.3.1 The Mental 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.
- 9.3.2 The priority list of persons who may consent in such circumstances: include the patient's spouse, partner, parent, grandparent, major child or brother or sister.

9.3.2.1 or A person authorized by the court (e.g. a curator);

9.3.3 Health practitioners should comply with the provisions of the Mental Health Act when dealing with mentally ill patients.

9.4 THIRD PARTY NOMINATIONS IN REGARD TO CONSENT

9.4.1 The Mental Health Act allows patients – while still mentally competent - to mandate another person in writing to give consent on their behalf

9.4.2 If health care practitioners are 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 disability, they should try to find out whether:

9.4.2.1 The patient has previously mandated someone else in writing to make decisions on their behalf; or

9.4.2.2 Have indicated preferences in an advance statement (e.g. an “advance directive” or “living will”).

9.4.3 Health practitioners 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

9.5 CHILDREN

9.5.1 Health practitioners must assess a child’s capacity to decide whether to consent to or refuse a proposed investigation or treatment before they provide it.

9.5.2 In general, a competent child at the age of 18 and above will be able to understand the nature, purpose and possible consequences of the proposed investigation or treatment, as well as the consequences of non-treatment.

9.5.3 A health practitioner’s assessment must take account of the following:

9.5.3.1 A child with sufficient maturity at the age of 18 years or above can be treated as an adult and is legally competent to decide on all forms of treatment, and medical and surgical procedures.

9.5.4 Where a legally competent child above the age of 18 years refuses life-saving treatment, application may be made to the Court for it to authorize treatment which is in the child’s best interests. Legal advice may be helpful on how to deal with such cases.

9.5.5 Where a child is not legally competent to give or withhold informed consent, the parent or guardian may authorise investigations or treatment which are in the child’s best interests. Such parent or guardian may also refuse any intervention, where they consider that refusal is in the child’s best interests, but health practitioners are not bound by such a refusal and may seek a ruling from the court.

9.5.6 In an emergency where there is no time to contact the parent or guardian and the

health practitioners consider that it is in the child's best interests to proceed, they may treat the child, provided it is limited to treatment which is reasonably required in that emergency. In such circumstances consent must be given by the Supervisor of the health facility registered by the Health Professions Council of Zambia.

10. THE "BEST INTERESTS" PRINCIPLE

- 10.1 In deciding what options may be reasonably considered as being in the best interest of a patient who lacks capacity to decide, health practitioners should take into account:
 - 10.1.1 The options for investigation or treatment which are clinically indicated;
 - 10.1.2 Any evidence of the patient's previously expressed preferences, including an advance statement;
 - 10.1.3 Their own and the health care team's knowledge of the patient's background, such as cultural, religious or employment considerations;
 - 10.1.4 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, career, or a person with parental responsibility;
 - 10.1.5 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.

11. APPLYING TO THE COURT

- 11.1 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, health practitioners should consult more experienced colleagues and, where appropriate, seek legal advice on whether it is necessary to apply to the court for a ruling.
- 11.2 Health practitioners should seek the court's approval where a patient lacks capacity to consent to a medical intervention and the situation is controversial, for example, parents withholding consent to life-saving treatment for children.
- 11.3 Where health practitioners decide 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.

12. FORMS OF CONSENT

To determine whether patients have given informed consent to any proposed investigation or treatment, health care practitioners must check how well the patients has 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.

13. EXPRESS CONSENT

- 13.1 Patients can indicate their informed consent either orally or in writing.
- 13.2 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 health practitioner, the patient and anyone else involved in carrying out the procedure or providing care.

- 13.3 Except in an emergency, where the patient has the capacity to give consent, health practitioners should obtain written consent in the following cases, although this list is not exhaustive:

13.3.1 The treatment or procedure is complex or involves significant risks and/or side effects;

13.3.2 Providing clinical care is not the primary purpose of the investigation or examination;

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

13.3.4 The treatment is part of a research programme.

- 13.4 Health practitioners must use the patient's case notes 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.

14. IMPLIED CONSENT

Health practitioners 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 practitioner proposes to do and why.

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. Health practitioners must review the patient's decision close to the time of treatment, and especially where:

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

15.1.2 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;

15.1.3 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 Health practitioners must ensure that anyone considering whether to consent to screening or testing makes a properly informed decision. As far as possible, practitioners should ensure that screening or testing is not contrary to the individual's interests. Health practitioners must pay particular attention to ensuring that the information the person wants or ought to have is identified and provided. Practitioners 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. Informed Consent among members of the Health Care Team

Sharing of information with members of a health care 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 that the patient has given consent to treatment and disclosure of such information to other health practitioner.

18. ACCOUNTABILITY

Health practitioners are accountable and are required to comply to the ethical tenets of informed patient consent. We urge all professionals to uphold ethical considerations with regard to rights of patients in accordance with the National Health Care Standards.

References

- *Health Professions Council of South Africa (2007) Seeking Patients Informed Consent, Pretoria. SA. <http://www.hpcs.co.za>*
- *Health Professions Council of Zambia(2011), National Health Care Standards, Lusaka, Zambia.*
- *General Medical Council (2008) Consent Guidance: patients and doctors making decisions together, United Kingdom.*



Published by:
Health Professions Council of Zambia,
P.O Box 32554,
Dental Training School Premises, Wamulwa Road,
Thornpark, Lusaka.
Tel: (260-1) 236241,
Fax: (260-1) 239317
Email: hpcz@iconnect.zm
Website: www.hpcz.org