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1. BASIC RIGHTS AND ETHICAL DUTIES

1.1 Ethics and law – two concurrent sets of principles

Two sets of rules form the basis of this document: human rights, as entrenched in Chapter 2 of the Bill of Rights of the Constitution of the Republic of South Africa, 1996 ("the South African Constitution") and the ethical rules found in the Health Professions Council of South Africa’s ("HPCSA") Regulations. Some of these rules have been crystallized in the National Health Act 61 of 2003 and in specific national and international ethical guidelines developed in response to, inter alia, the challenges posed by HIV/AIDS.

Medical practitioners should bear in mind that action may be taken against them for breaches of ethical rules, which may be quite different and apart from breaches in terms of the law. This means that the HPCSA may find a medical practitioner not guilty on disciplinary charges relating to his/her ethical conduct, but the complainant may still have a legal claim against the specific practitioner based on an infringement of a right.

1.2 The Constitution of the Republic of South Africa, 1996

The South African Constitution grants to every person-

- the right of access to health care services,
• the right to **equality** and to be free from unfair discrimination,
• the right to **freedom and security** of the person (bodily integrity and autonomy)
• the right to **privacy** (confidentiality) and
• the right to an **environment that is not harmful** to their health or well-being.

These rights accrue to patients, medical practitioners and the public alike. Central to an understanding of these rights and a fundamental right in itself is human dignity. A respect for human dignity should guide any health care worker’s actions, as it also underpins the ethos of good patient care.

Rights are not absolute and may be limited only as set out in section 36 of the South African Constitution. However such limitations must be shown to be as a result of a law of general application (that is, the limitation is permitted by law) that is reasonable and justifiable in the context, based on human dignity, equality and freedom. It is good practice to consider, when there is a possibility that one could be breaching or limiting the right to privacy or the right to autonomy, the section 36 criteria. For example, is there a law that authorises this limitation? One such law may be the Employment Equity Act, but it stipulates that the Labour Court has to authorise such tests.

The Constitution also forms the basis of subsequent legislation that gives further details as to the application of these rights in the health care sector. In the field of HIV/AIDS, these laws include, amongst others, the National Health Act and the Medical Schemes Act. Some laws may authorise limitations to the rights pertinent to HIV/AIDS.

**1.3 Ethical Rules**

Ethical rules bind medical practitioners and health professionals, registered with the HPCSA. The HPCSA may (and in some circumstances must) take appropriate steps against practitioners in breach of these ethical rules. A variety of penalties may be imposed on practitioners found guilty of breaches of ethical duties.
The most important rules are found in the following documents:

- The Ethical Rules of the Health Professions Council –
  - Professional confidentiality (Ethical Rule 12): It affirms that, except as required by statute, court order or justified in the public interest, information may only be divulged with the patient’s express (and preferably written) consent, and if a child is under 14 years of age, with the parent or guardian’s consent. If a patient is deceased, the written consent of the next-of-kin or the executor has to be obtained.
  - Certificates and Reports (Ethical Rule 15): Requires that a diagnosis may only be written on a certificate of illness if the patient provides informed consent.

- The HPCSA Guideline “Core ethical values and standards for good practice” reiterates the principles of best interest or well-being of the patient. It finds expression in two principles:
  - Non-maleficence: do not harm or act against the best interests of patients, even when they conflict with your own self-interest” and
  - Beneficence: act in the best interests of patients even when there are conflicts with your own personal self-interest”.

- Impairment in another student, intern or practitioner has to be reported, including impairment by a medical practitioner about him/herself. Practitioners living with HIV could be regarded as impaired and should modify their practice in order to ensure that patients are not placed at risk. This rule is affirmed in the HPCSA Guidelines for the Management of Patients with HIV Infection or AIDS.

- The HPCSA Guidelines on HIV also sets out the general duties of the medical fraternity as-
  - Supporting all efforts to keep the spread of HIV infection in the community as low as possible.
  - Such measures include appropriate education regarding the infection, alteration of lifestyle, improved management of predisposing and aggravating factors, including other sexually transmitted diseases, mobilising support from the community and disseminating information regarding preventive measures.

There is no specific ethical rule referring to the protection of third parties. However, it is generally accepted that any professional with knowledge that another person may be harmed by a client or patient, may take steps to protect such known third
party. In law, society expects of persons not to be negligent and to take steps to prevent imminent harm. This issue is discussed in greater detail below.

1.4 World Medical Association (WMA)

The World Medical Association (WMA) also provides useful guidance on what ethical behaviour means:

- The International Code of Medical Ethics states that a physician shall protect the rights of patients, of colleagues, and of other health professionals, and shall safeguard patient confidences.
- The Statement on Patient Advocacy and Confidentiality affirms that medical practitioners have an ethical duty and a professional responsibility to act in the best interests of their patients at all times.
- As early as 1987 the WMA recommended that National Medical Associations participate fully in the development of AIDS public awareness campaigns, and that all physicians should be trained to be effective counsellors.
- The 1988 Statement on the Professional Responsibility of Physicians in Treating AIDS Patients deals with professional responsibilities, as well as those of the seropositive medical practitioner, stating that patients are entitled to expect that their doctors will not increase their exposure to the risk of contracting an infectious disease.

1.5 Patient and provider rights and responsibilities in terms of the National Health Act 61 of 2003 (“National Health Act”)

Patient have rights and responsibilities. Section 19 of the National Health Act stipulates that patients should:

- Adhere to the rules of the health establishment when receiving treatment or using health services at the health establishment;
- Subject to section 14 on confidentiality, provide the health care provider with accurate information pertaining to his or her health status and co-operate with health care providers when using health services;
- Treat health care providers and health workers with dignity and respect; and
- Sign a discharge certificate or release of liability if he or she refuses to accept recommended treatment.
Providers have rights not to be discriminated against, and to be protected against damage to their person or property, including disease transmission (section 20). This is dealt with in more detail elsewhere in these guidelines.

2. TESTING FOR HIV

2.1. Informed consent as a precondition for HIV testing

Any medical test, including a test for HIV is potentially an infringement of a person’s right to privacy and bodily and psychological integrity (which includes the right to security in and control over their body). For these reasons a number of aspects have to be considered in various situations where testing is requested or required.

In principle, a person may only be tested after s/he, personally, has given the necessary informed consent for such test. However, as part of the overall good patient care package the South African Medical Association ("SAMA") encourages medical practitioners to strongly advise all their patients to undergo HIV testing and also provide an explanation of why this test is recommended.

A person may otherwise only be tested without consent if it is authorised by legislation or a court order that satisfies the test set out in section 36 of the Constitution. SAMA recommends that medical practitioners request exact details if it is alleged that a person is being tested pursuant to a specific law or in terms of a court order. Medical practitioners should, in principle, not test any person without their informed consent or, otherwise, without ascertaining the extent of their legal obligations and possible legal ramifications.

The National Health Act is such a law that stipulates situations under which consent other than that of the patient can be lawfully used, or when the patient can be tested without consent. Section 7 sets out the following situations:

- If the user is unable to give informed consent, a person mandated by the patient can consent on his or her behalf (for example, if needle-stick injuries occur when the patient is unconscious such mandated person can consent on behalf of the patient).
• If no person is mandated or authorised to give consent, the consent can be given by the spouse or partner, a parent, grandparent, an adult child or a brother or a sister of the user, in the specific order as listed.

• If another law authorises testing without consent. For example, the regulations to the Mental Health Care Act of 2002 states consent for treatment (other than for a mental illness) of a mental health care user can be provided by a curator (if there is one), a spouse, next of kin, a parent or guardian, a child over the age of 18, a brother or sister, or a partner or associate, or if they are untraceable, the head of the establishment, on a declaration by a medical practitioner that the treatment is necessary. This would obviously also apply to HIV testing and treatment.

• If the Court so orders or a law authorises treatment / testing without consent.

• If failure to treat the user, or group of people which includes the user, will result in a serious risk to public health. However, this provision is unlikely to relate to the HIV context, or any other Sexually Transmitted Disease ("STD"), for that matter.

• If 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 explicitly, by implication or by conduct refused that service.

It is also of particular importance to note that the National Health Act stipulates that all patients are to participate in decisions affecting them, to the level of their understanding and irrespective of their legal capacity to consent. It also requires that patients, where possible, be informed in a language that s/he understand, taking into account the patient’s level of literacy. This is of particular importance in the HIV setting, where understanding of testing, treatment and the disease itself, is paramount.

All health services (including tests and treatment) undertaken without informed consent has to be reported to the provincial health authorities in terms of the National Health Act (Section 9). This serves as an additional prompt for medical practitioners to rather obtain informed consent.
The following aspects have to be considered if an HIV test is to be performed:

- Check for legislative provisions that may prohibit or regulate HIV testing, for example in schools, prisons, in the workplace, for medical scheme purposes, insurance policies, etc. These instances are discussed in detail below.
- Are the tests required for medical reasons / clinically indicated? Has this been explained to the patient as part of his/her pre-test counselling (see above)? In this regard practitioners should be consistent in testing and should be wary not only to test for HIV where there could/should have been similar grounds for other tests to be performed as well. Practitioners should also ensure that the same tests are recommended for all patients in similar situations.
- Remember to ensure that the patient consents to all tests that are to be performed.
- Has pre-test counselling been done, including informing the patient about HIV, the test itself, the window-period, etc.?
- Have all of the principles of informed consent been addressed?
- Have all the aspects that now constitute informed consent been noted?
- Has the patient consented in writing to the test?
- Is the confidentiality of the test and the results guaranteed?

2.2 Practical situations and informed consent

Testing as a pre-operative measure may only be done if clinically indicated and if the patient consents to such testing. Emphasis should be placed on the need to provide the best possible care for the patient and that testing is required in that light. It should be stressed that HIV testing should always be voluntary.

In emergencies, however, treatment may not be refused on the basis of lack of informed consent, nor can it be made a standard agreement for emergency treatment. In the South African Constitution the right to emergency treatment is formulated in absolute terms. The National Health Act and the regulations to the Medical Schemes Act also recognise the right to emergency treatment. Universal precautions provide the best protection in all emergencies. The HPCSA HIV Guidelines set out the exact measures that constitute “universal precautions”. The HPCSA Guidelines on the Management of Patients with HIV Infection or AIDS state
that where certain well-defined high risk or exposure-prone procedures are contemplated, the patient should be informed and asked to consent to a test. Following universal precautions, but especially if a patient declines, s/he should be managed as if s/he were HIV positive.

Medical practitioners may not perform HIV tests simply at the request of employers wishing to know the status of their employees or prospective employees. This is in terms of the Employment Equity Act 1998 and is in keeping with the ethical and legal requirements of informed consent to testing. This aspect is discussed later in more detail.

The HPCSA HIV Guidelines states that requirements of routine or universal testing of patients in the health care setting are unjustifiable and undesirable. Routine testing refers to testing that is done periodically, sometimes as part of standard procedures, such as pre-employment assessments or periodic health assessments. Universal testing is where all people in a group, such as all employees, or all patients, are tested in certain situation. In these situations the “ordinary” legal or ethical requirements have to be adhered to.

Testing as part of research is permitted, but only with the participant’s informed consent and in terms of an approved research protocol. The laws, principles and guidelines relating to medical research, such as the National Health Act, the Department of Health’s Research Ethics Guidelines and the Declaration of Helsinki, have to be adhered to. See “HIV and Research” below.

Where testing was done as a result of a miscommunication or a laboratory fault, and the medical practitioner is informed of such result, the medical practitioner should discuss this with the patient and obtain the patient’s consent before divulging the information. Furthermore, principles relating to pre- and post-test counselling must be complied with. SAMA recommends that the importance of knowing one’s HIV status, as well as the effects of non-disclosure should be discussed with the patient.

Testing an existing blood sample is only permitted if the patient (or a mandated or other person as indicated in the National Health Act if the patient is unable to) consents. It may be required to test a patient or patients in an emergency situation
in order to protect the patient or other persons. In such cases, in order to pass the tests of reasonability and justifiability, consideration should be had for the nature of the injury/injuries and the source patient(s) has to be evaluated to determine the likelihood of HIV. However, the patient must be informed afterwards that the sample was tested and if s/he, after pre-test counselling wishes to know the results, the principles of post-test counselling etc. have to be adhered to.

2.3. Unlinked and anonymous testing

Unlinked and anonymous testing is permitted for epidemiological purposes if undertaken by the national, provincial or local health authority or an agency authorised by any of these bodies, provided that HIV testing for epidemiological purposes is carried out in accordance with national legal and ethical provisions regarding such testing. SAMA endorses the World Medical Association’s Statement on Health Databases which requires patients to consent to their information been stored on any database. The Draft Protection of Personal Information Bill proposed by the SA Law Reform Commission in 2005 may also apply to situations where patient data is stored with personal identifiers. It is suggested that even where data is stored unlinked, patients have to consent to their data being included in such database.

2.4 Home/rapid testing

There are home-test HIV kits available. A medical practitioner who is told by his/her patient that they have used such a test must inform the patient of the advantages and disadvantages of the test. S/he should encourage the patient to undergo a second HIV test (bearing in mind the pre-test counselling principles) and adhere to all other principles of good patient care. It is likely that the duty to provide post-test counselling may fall on a practitioner even where s/he did not ask for the test to be performed on the patient. In this regard, see the Department of Health Booklet “Rapid HIV testing” (August 2000). In occupational injuries, the Department states that an approved rapid HIV test could be performed and later confirmed by a routine HIV test.

There are also numerous other tests being developed and for these, and issues of accuracy medical practitioners should consult the relevant clinical guidelines and
keep abreast of new developments. Practitioners should inform patients of the different types of tests available and the advantages and disadvantages of each test.

The HPCSA Guidelines recommend that the attention of patients should be drawn to the potential abuse of HIV test kits that are available on the market. Patients who wishes to use such kits should ascertain from his or her doctor or another credible source whether such kits are reliable and safe. New forms of HIV testing should only be adopted if they conform with the guidelines set out in this policy document.

2.5 Unwillingness to undergo a test

It is often difficult to deal with an unwillingness to even discuss the possibility of a HIV test. Two situations may arise, i.e. needle-stick injuries or general refusal where a test is clinically indicated or where a test is advisable due to the particular patient history, profile or situation.

Patients may be unwilling to undergo HIV testing due to fear of stigmatisation, disbelief, ignorance or an attitude of “I am going to die anyway” or “I do not even want to know”. Various strategies may be used to allay these fears. Fear of victimisation and discrimination could be countered by an assurance of privacy and protection offered by the various laws. Attitude and life-style problems may be countered with reference to the need for good patient care and better control over and treatment of secondary diseases. It is important to think about the various reactions that health care workers have, and may encounter, and to discuss these as well as appropriate strategies with colleagues. Although criminal or civil action by others who may be affected by a person who may be living with HIV is a reality, this may not be the most effective strategy to use to persuade a patient to undergo an HIV test. Patients who fail to undergo a test, in spite of being advised to do so and subsequently infect others, may be found to have acted negligently.

Where a health practitioner is exposed to the possibility of HIV infection during the course of his/her work, such as a needle-stick injury, the general rule is that informed consent has to be obtained, even where an existing blood sample is available. The HPCSA Guidelines state that an existing sample may be tested even if the patient refuses consent. In terms of the National Health Act, informed consent
may only be disposed of as a pre-condition for medical testing if a law or a court order authorises this. There is currently no such law that explicitly authorises testing under such conditions. However, it could be argued that, in order to prevent the unnecessary administration of post-exposure prophylaxis ("PEP") and the risk of increased resistance against PEP by health care staff, a violation of the rights of patients under such circumstances may be justified.

The HPCSA Guidelines on HIV states that a needle-stick injury may be determined to be an emergency situation (emphasis provided). However, as we have no law currently expressly governing this situation, medical practitioners are advised to proceed with caution in these cases. SAMA strongly advises that national policy be developed to address the inconsistencies and legal uncertainty in this regard.

### 2.6 Paying for a test

If an HIV test is undertaken with the consent of the patient but for insurance purposes or where a court has authorised an employer to do so, the insurance company or employer must pay for the tests. However, an offer of payment for the tests by an employer or insurance company is not enough to permit a test without the patient’s consent and should not be used to influence a patient to consent. Payment for tests does not automatically entitle the payer to the results of the test.

Tests done in public and private health care facilities are charged according to their policies. Patients should be informed about these costs and made aware of possible exclusions in payments by medical aid funds. Payment for tests done on medical practitioners as a result of occupational injury and the post-exposure prophylaxis, are ordinarily undertaken by the employer. However, where there is any variation required in, for example, the type of test or treatment, the employer may not be required to pay. SAMA is of the view that employers and employees should reach agreement as to the nature and extent to which it will cover HIV tests and PEP, including situations where the health care staff member may be experiencing serious side effects and require alternative medication.
2.7 Testing the Newborn Baby and Young Infant

The testing of newborn babies for HIV infection poses a special set of practical problems. Testing is often performed for diagnostic confirmation of clinically suspected AIDS, in cases where prophylaxis against other infections is being considered (e.g. TB, PCP). The usually useful antibody based tests such as the ELISA or RAPID Tests are not diagnostic of HIV infection in the newborn as they reflect maternal antibody levels. As such, babies with positive antibody tests in the first 18 months of age should be considered as HIV exposed but not necessarily infected. An accurate and reliable method of confirming true HIV infection in infants is the Polymerase Chain Reaction technology (PCR).

The newborn may only be tested with the consent of the mother or parents. Pre-test counselling in such settings is of critical importance, especially where treatment may be clinically indicated and may possibly increase the chances of saving the life of the child. If the mother or parents refuse or cannot be found, the provisions of the Child Care Act states that the Minister of Social Development may consent on behalf of the parent (section 39(1)). Furthermore, where the medical superintendent, or medical practitioner acting on his/her behalf, is of the opinion that medical treatment (or testing) is “necessary to save him or her (the child) from serious and lasting physical injury or disability and consent cannot be deferred for the purpose of consulting the person who is legally competent to consent” (section 39(2)), such medical superintendent, or medical practitioner acting on his/her behalf, may give the necessary consent. It will therefore be a clinical question whether testing and/or treatment in a particular situation falls with the context of section 39(2) or section 39(1) of the Child Care Act.

3. INFORMED CONSENT FOR HIV TESTS AND FOR TREATMENT

3.1 Basic legal and ethical criteria

Informed consent relates to a person’s right to human dignity and autonomy. It has long been part of South African law that a patient must give informed consent for all medical treatment (diagnostic or therapeutic) performed on him/her (Stoffberg v Elliot, 1912). Informed consent means that sufficient information is provided to the
patient to enable him/her to make a decision based on an understanding of the information and the implications of all the available options.

Section 7 of the National Health Act requires of health practitioners to “take all reasonable steps to obtain informed consent”.

The following are elements of informed consent:

- Consent must be voluntary and without constraint;
- In the case of an HIV test, consent should preferably be written, although consent may be verbal (although difficult to prove);
- Consent must not conflict with the rules of ethics or the South African Constitution;
- The patient must be capable of consenting, that is s/he must not be a minor or be mentally impaired;
- The patient must give the consent personally, unless proxy consent is applicable (see below);
- The patient should know why the medical practitioner needs the results of the test;
- There should be sufficient information made available to the patient on the diagnosis, proposed treatment, alternative treatment, probable results, expected benefits, risks, costs and consequences associated with each option, etc.;
- The patient must actually understand, i.e. there is likely to be a need for an interpreter or at least sensitivity that the patient may not actually understand everything and arrangements should be made to assist the process of understanding.

Part of the understanding that a patient should have of his or her situation and options has now been codified in section 6 of the National Health Act. It requires every health care provider to inform a patient (even a patient who does not have the legal capacity to consent on his or her own) 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.

The issue of informed consent becomes pertinent in the multi-cultural setting. Language and cultural barriers may prevent patients from expressing their concerns or from asking questions on HIV tests. The National Health Act requires of health care providers to, where possible, inform the patient of the section 6-issues in a language that the user understands and in a manner which takes into account the user’s level of literacy. Failure to have proper regard for a patient’s language and literacy may result in the patient not actually providing consent freely and voluntarily. As the South African Constitution provides for equality of languages, SAMA believes that there is a duty on the state to make adequate arrangements for interpreters to be provided or at least to provide proper training for staff acting as interpreters.

In view of the above, it is clear that a general poster in a ward or consultation room that “all patients will be tested for HIV” does not constitute informed consent. It is also not recommended that a patient be merely provided with a leaflet or just referred to another institution to explain to him/her what the HIV test is about.

One of the laws that could give effect to the provisions of section 7 of the National Health Act, which states that a law may authorise treatment or testing without consent, is the Compulsory HIV Testing of Alleged Sexual Offenders Bill of 2003 (which is not in force as it has not been passed by Parliament to date). This Bill proposes that rape suspects be tested for HIV without their consent. The objective would be to provide the rape survivor with peace of mind, and not to provide him or her with evidence to take further steps against the alleged perpetrator. Should this law be passed in future, this duty is likely to be performed by the District Health Officers or medical staff servicing prisons or places of detention. They will be under pressure to verify that the detainee is in fact a rape suspect and to deal with the issue within the strict confines of the empowering law.
3.2 Substitute consent and treatment without consent

In terms of section 7, a patient may not receive any health service (i.e. test or treatment), without his or her informed consent. But patients may not always be able to consent. The National Health Act now provides that patients may mandate in writing, another person to grant consent on his or her behalf. If the user is unable to give informed consent and no person is mandated or authorised to give such consent, consent may be 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. This “substitute” consent apply to cases where patients are incapacitated (such as during an operation when a needle-stick injury takes place) or when they do not have the legal capacity to consent. Section 8, however requires the person who can consent on behalf of another to consult that person, where possible. That would mean, for example, where a patient prior to an operation, has stated certain requirements or preferences in terms of issues that could be consented to, the person consenting on the patient’s behalf should respect the patient’s wishes.

The circumstances under which testing or treatment may be undertaken without consent has been discussed above (authorised by law, court order, emergency treatment for the patient, or threat to public health).

Even 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.

3.3 Persons incapable of consenting

In a number of cases a patient may not be able or capable of giving informed consent, such as where s/he is unconscious or mentally incapable due to illness or disability.

In the case of mentally impaired persons, the curator, spouse, parent, major child, brother or sister, or the medical superintendent must consent on the person’s behalf.
If a person is temporarily incapable of providing consent, the general principle is that such a person should first be restored to a state where s/he can consent.

People who are mentally ill, but capable of consenting, may be tested and/or treated for HIV in terms of the regulations to the Mental Health Care Act of 2002 with their informed consent. A curator, if a court has appointed one, a spouse, next of kin, a parent or guardian, a child over the age of 18, a brother or sister, or a partner or associate may consent to the treatment or operation for persons who are incapable of consenting due to mental illness or mental disability. Notwithstanding the above, the head of the health establishment where the mental health care user resides or the head of the facility licensed in terms of regulations 42(1) of the Mental Health Care Act, may grant consent to treatment or an operation, and document all relevant information in a clinical record before treatment or operation, if :-

(a) none of the persons referred to above are available and unsuccessful attempts have been made to locate them and this has been confirmed in writing,

(b) the relevant alternatives have been discussed with the head of the health establishment or the head of the licensed facility concerned and that head is satisfied that the most important intervention is to be performed; and

(c) the medical practitioner who is going to perform that operation recommends the treatment or operation.

Although consent may be dispensed with in cases where the patient’s life or limb is under threat or where public health is at stake, the HPCSA recommends that even in situations of emergency, every effort should be made to obtain vicarious or proxy consent from the patient’s closest available relative. The National Health Act stipulates the order of such proxy consent (set out above). If there is a needle-stick injury and the patient is not willing or not capable of consenting, it is possible to test an existing blood sample. This should however not be the general policy or first line of reaction. Refer to the section below on occupational injuries for more information on needle-stick injuries.

Persons who are arrested, detained or awaiting trial, as well as sentenced prisoners, like all other people, have to consent to HIV tests and should be given pre- and post-
test counselling (*C v Minister of Correctional Services*, 1996). Prisoners are discussed in more detail below.

### 3.4 Children

In terms of the Child Care Act of 1983 a child who is older than 14 years may consent to medical treatment independently. This means that such a child can consent independently to a HIV test without the knowledge of his/her parents/guardian. A person who is older than 18 years may consent independently to any operation.

The National Health Act states that all health care users have the right to participate in any decision affecting his or her personal health and treatment. This includes children. Section 8 makes it clear that even where a patient lacks the legal capacity to consent, s/he should participate in the decision-making and should be informed of his or her health status, and the issues required by section 7. This means that even though a parent would have the legal decision-making power for children under 14 as far as HIV testing and treatment is concerned, the section 7-information may not be withheld and the child should at least be consulted in the informed consent process.

Guidelines suggest that where research involving children is undertaken, for example, the testing of HIV drugs for use in children, the consent of both parents and assent of children should be obtained.

**Example of a consent form:**

I, ........................ (full name), an adult male/female from ........................................ (address) hereby confirm that I have been informed by Dr ......................... about the nature, conduct, benefits, risks and implications involved in undertaking an HIV test (or treatment). I have also received and understood all the relevant information concerning the proposed test (or treatment). I have had sufficient opportunity to ask questions and to consider whether I want to proceed with the test (or treatment).
I therefore freely and voluntarily agree to the HIV test being performed, which includes the drawing of a blood sample and a test on that sample. I agree that Dr ........ will inform me of the results of the test in person. I hereby agree that the results of the test (or treatment) may be anonymously used for purposes of research and/or data-collection purposes, provided that such information is de-identified with sufficient safeguards. I know that I am, at any stage, free to withdraw my consent to undergo this test (or treatment).

Signed:

…………………………………………..                        ……

Patient (full name, signature and date)                        Witness 1

…………………………………………..                        …………………………

Medical practitioner (full name, signature and date)                       Witness 2

A proxy consent form should include references to the capacity of the person who is consenting on behalf of the patient, the reason why s/he is consenting on behalf of the patient (e.g. in terms of Mental Health Act or Child Care Act), etc.

4. PRE- & POST-TEST COUNSELLING

4.1 Importance of pre-test counselling

The World Medical Association (WMA) recommended in its 1987 Statement on AIDS, for medical practitioners to be trained to be effective AIDS counsellors. Pre-test counselling is an important element of such effective counselling skills. Pre-test counselling is highly effective in pre-emptively addressing some of the practical challenges facing practitioners, such as refusal by a patient to be informed of the result of an HIV test, or the difficulty some patients have in disclosing their status to others.

The Courts have decided that pre-test counselling forms an integral part of the concept of informed consent (C v Minister of Correctional Services, 1996).
4.2 National Health Act

The 2003 National Health Act requires informed consent for any test or treatment. Part of this informed consent includes an explanation of the range of diagnostic options (tests) generally available, as well as the benefits, risks, costs and consequences generally associated with each option. As the health practitioner also has to inform the person of his or her health status, the recommendation to undertake an HIV test may often be based on the health status as observed by the practitioner. Coupled with the important psychological aspects of HIV/AIDS and its link to sexual behaviour, pre-test counselling is a critical element of the process of informed consent.

4.3 What forms part of pre-test counselling?

The SA Medical Association believes that having a person merely sign a form or reading a leaflet before an HIV test does not constitute appropriate and valid pre-test counselling.

Pre-test counselling should include the following aspects:
- What an HIV test is and the purpose of the test;
- How long a test takes and what is actually done (drawing blood, etc.)
- The need for a test in the particular circumstances, for example in the pre-operative setting, the effect the results may have on treatment and the patient’s future health care, etc;
- The advantages and disadvantages of taking the test and of knowing one’s HIV status;
- The meaning of a positive result and all practical implications, including impact on behaviour, capacity to work, family life, possible pregnancy, children, etc;
- The meaning of a negative result and the need for/possibility of a second test to confirm the result;
- An explanation of the window period and the need for a second test in order to confirm results;
- The necessity of- and coping with life-style changes;
- Assessment of personal risk of HIV infection;
- Strategies to reduce risk of infection;
- Coping with a positive result, including divulging one’s status;
- Where support services are and how to access those; and
- Sufficient space and opportunity to make an informed decision about taking the test.

4.4 Post-test counselling

The South African Medical Association supports the principles of good health care management, which should be one of the guiding rules in post-test counselling. Patients should know that they have rights and responsibilities in relation to their HIV status.

The duty to do post-test counselling falls on the practitioner who commissions or performs the test. This duty cannot be disposed of by referring a patient to counselling services, although these and other support services may be helpful for the patient after the post-test counselling takes place. Post-test counseling should address issues of managing HIV/AIDS and should facilitate the patient’s decision-making process, both socially and clinically, including:

- Why is it necessary to disclose, who to tell, when and how;
- What health care follow-ups are necessary;
- Which types of treatments are available and at what cost, i.e. the section 6 – issues in the National Health Act;
- Health care insurance/medical scheme issues;
- Planning for the future and assessing the current situation, e.g. employment, children, insurance, pension/provident fund issues, etc;
- Palliative care and living wills may also be discussed, if the situation could call for consideration of these issues.

As part of good health care management, a patient should be informed of the difference between Post-exposure prophylaxis (PEP) (in the cases of needle-stick injuries, accidental exposure, or sexual assault), Anti-retroviral drugs, Combination Therapy and Prophylactic treatment for opportunistic infections, as well as the relative costs, side-effects, etc.
Many of the aspects dealt with under pre-test counselling should again be addressed at this stage, especially where the patient has tested positive. In this context, post-test counselling is an ongoing process whereby the patient is provided with information relating to his/her health care, and informed decisions are continuously made based on the new assessment and treatment options as discussed with the medical practitioner.

Post-test counselling should also take place where a patient has tested negative. Important aspects such as the window-period, the need for a second test a few days or months later (the period will depend on the type of test done initially), life-style changes and how to stay negative, should form an integral part of post-test counseling in this context.

In the case of occupational injuries, any health care worker who has been exposed and who has access to PEP should receive counselling on the benefits and risks of PEP treatments, duration, etc.

5. CONFIDENTIALITY

5.1 Trust and confidentiality
Patient confidentiality is one of the cornerstones of the medical profession. It underpins trust and hence ensures that a patient divulges all the information relevant to his/her health care to the practitioner, thereby assuring the best appropriate health care. Apart from the ethical rule to confidentiality, the South African Constitution protects the right to privacy and confidentiality. Even before the constitutional dispensation the Appellate Division of the Supreme Court (now the Supreme Court of Appeal) recognised the right to confidentiality in relation to HIV in the well-known case of *Jansen van Vuuren v Kruger*, 1993.

5.2 The National Health Act
The National Health Act now confirms the right to privacy and confidentiality and sets out its scope in greater detail. Sections 14, 15 and 16 deal with issues of confidentiality:
• Section 14 states that all information concerning a patient, including information relating to his or her health status, treatment or stay in a health establishment, is confidential.

• According to section 14 confidentiality may only be breached if -
  o the patient consents to that disclosure *in writing*;
  o a court order or any law requires that disclosure; or
  o non-disclosure of the information represents a serious threat to public health.

• Section 15 deals with the handling of health records and disclosure to others, including other health care providers or establishments. This may only take place –
  o As is necessary
  o For any legitimate purpose
  o Within the ordinary course and scope of the other person’s duties.

• Section 16 permits health care providers to examine a user’s health records for the purposes of treatment, study, teaching or research, but only with the authorisation of the patient, the head of the health establishment concerned and the relevant health research ethics committee.

Section 14 details the types of health information that is protected and confidential – it includes not only diagnostic, health status- and treatment information, but also the fact that a person has been to or stayed in a health facility. For health care practitioners this means that written consent not only needs to be obtained for health information, but also to cover situations where others ask whether the patient has indeed been there or is indeed a patient of the particular practitioner.

Prevailing attitudes of stereotyping and stigmatisation continue to impact on the confidentiality debate as it relates to HIV. SAMA supports initiatives aimed at voluntary disclosure by people living with HIV. However, SAMA simultaneously and strongly condemns all forms of discrimination based on a person’s (perceived or real) HIV status from any source. It recommends that patients who find themselves unfairly discriminated against should pursue all avenues created by relevant
legislation, such as the Promotion of Equality and Prevention of Unfair Discrimination Act and the Employment Equity Act, to remedy such instances. SAMA is also of the view that there is nothing unethical in a medical practitioner advising a patient to obtain relevant assistance in such matters.

5.3 Disclosures to other health care providers and establishments

Section 15 could potentially allow for disclosures of the HIV status of a patient amongst health care practitioners, - workers and others working in health establishments. However, it is important to note that the disclosure has to be necessary for any legitimate purpose within the ordinary course and scope of such a person’s job. Disclosure to potentially protect another health care professional may not withstand the strictness of the “necessary” criterium, or may not be regarded as a legitimate purpose in all contexts.

SAMA recommends that the general rule of obtaining a patient’s written consent should prevail in all cases before any disclosure is made. However, the patient may stipulate the extent and nature of the disclosure, for example he/she may only consent to his/her status being disclosed to particular people such as a specific team of health care practitioners involved in a surgical intervention. Although all health care workers are bound to adhere by the principle of confidentiality, a patient may refuse that his/her status be made known to other health care workers or to a medical practitioner that s/he is referred to, unless such knowledge-sharing can be defended in terms of the provisions of section 15, as set out above.

However, disclosure on an account in order to ensure that a valid account is rendered to a medical scheme for purposes of processing payment, could constitute such a necessary disclosure. SAMA recommends that patients’ written consent be obtained to all disclosures needed to secure payment from a funder.

The HPCSA recommends the formulation of policies in health care facilities that regulates the conduct of health care workers to ensure good conduct and the maintenance of confidentiality in relation to HIV. Such a policy should make specific reference to appropriate conduct in pathology laboratories, wards and medical practitioners’ reception areas vis-à-vis confidentiality.
The HPCSA notes in its 2001-Guidelines that there is no persuasive evidence that knowledge of a patient’s HIV status diminishes the possibility of exposure. The South African Medical Association believes that knowledge of a patient’s HIV status may be extremely relevant in order to provide the patient with the best possible health care, but that this has to take place within the guidelines in this document. SAMA recommends that where disclosure is necessary for the effective treatment of the patient, that it should be explained to patients that not disclosing their HIV status to those under whose direct care they are, may compromise their treatment and access to good health care.

5.4 Requests for information

The rule of thumb when a health care practitioner or facility is faced with a request for access to health information by a third party, is to ask the requester for either a certified copy of the patient’s written, informed consent to such disclosure, or for an exact reference to the specific section in a specific law that authorises the third party for access to particular information.

The following is an example of a standard reply to requests for health-related information:

"Patient confidentiality is protected by legislation and ethical rules binding medical practitioners. Unless the patient (or in the case of a deceased person, his/her next of kin) consents, no medical information may be provided to third parties. If you are relying on any existing legislation, contract or agreement binding on yourself and the patient, please provide me with a copy thereof so as to facilitate a proper evaluation as to the possibility of disclosure."

Confidentiality also includes the right to know information about oneself and what information is kept on oneself, including health information. Section 6(a) allows for therapeutic privilege, i.e. withholding information on the patient’s health status where there is “substantial evidence that the disclosure of the user’s health status would be contrary to the best interests of the user”. However, especially in the HIV context, extreme caution has to be exercised about withholding his or her HIV status from a patient. SAMA advises that practitioners consult an ethics committee before
exercising this option. This option applies in the context of obtaining informed consent, as the first step in deciding on an appropriate course of action for a person’s health.

In terms of section 61 of the Promotion of Access to Information Act, information that is directly requested by a person/patient about his or her health (or on the direct mandate of such a person/patient), may not be withheld. However, if the head of an establishment is of the opinion that the disclosure of the record to the relevant person might cause serious harm to the patient’s physical or mental health or well-being, the head may consult with a health practitioner who has been nominated by the patient. The head of an establishment then discloses this information to the nominated health care practitioner. If such practitioner is of the view that the disclosure of the record would be likely to cause serious harm to his or her physical or mental health, or well-being, disclosure may only take place if adequate provision is made for counselling before, during or after the disclosure of the record to limit, alleviate or avoid such harm to the patient. The person responsible for counselling must be given access to the record. The parents or guardians of patients who are younger than 16, or patients who are incapable of managing their own affairs, have to make this nomination on their behalf.

The Promotion of Access to Information Act also states that access to information or records can be refused if it amounts to an unreasonable disclosure of third party personal information. This means that where another person or institution requests health information in general, or HIV-related information in particular, such information may be withheld lawfully. Situations that would be covered by this include requests by family members of a person’s HIV status or health information, requests by lawyers, insurers or any other third party. The only way in which information may be made known under the Promotion of Access to Information Act will be if the person whose information it is, consents to its disclosure in writing as per the National Health Act.

5.5 New Draft Protection of Personal Information Bill

A 2005 Draft Protection of Personal Information Bill is being proposed by the SA Law Reform Commission to protect data on persons held by institutions. All personal data
gathered, in whichever way and under whatever circumstances has to be dealt with in terms of the following nationally and internationally-accepted standards of data protection, i.e.:

- openness in respect of policies in relation to personal data;
- purpose specification and use (data may only be collected and used for the purposes that it was provided for);
- limitation of collection (data must be collected lawfully and fairly, with the consent of the person(s) concerned);
- data quality (correctness, regular updates, etc.);
- individual participation (the right of an individual to know if and what information/data is held on him/her);
- security safeguards should be in existence and data controller should be accountable in terms of these.

This means that, for example, data gathered by data-warehouses in the medical scheme industry, may only be used for the purposes for which it has been collected, which purpose has to be lawful. It would also allow patients to enquire as to what data about them is kept by whom. The same would apply for data gathered in clinical trials, or even the data held by medical practitioners on patients.

5.6 Sexual partners

Informing sexual partners of a patient’s HIV positive status is an extremely complicated issue, and depends on whether a legal- or an ethical view is taken of the issue. Medical practitioners should be aware of the fact that their decisions in this regard may be measured against the South African Constitution and/or the relevant ethical guidelines. These rights and ethical duties exist in all cases, not only in relation to HIV. Alleged unjustifiable disclosures may result in huge claims for damages or compensation from the medical practitioner concerned.

Medical practitioners are under an ethical duty to preserve life and to preserve confidentiality. Both these duties also exist in law, placing a duty on them to act reasonably in the circumstances. These duties have to be balanced where the disclosure of a patient’s HIV status to his/her sex partner(s) is concerned. This is, at best, a difficult and contentious decision not to be taken lightly and, in the absence
of case law in this regard, no guarantees can be provided on how the courts and/or the HPCSA will view such disclosures.

The HPCSA’s HIV Guidelines sets out the following course of action:

- If the patient’s consent cannot be obtained, ethical guidelines recommend that the health care worker should use his or her discretion whether or not to divulge the information to other parties involved who are at clear risk or danger. However, in reaching a decision the greatest care is to be taken.
- The first step is to counsel the patient on the importance of disclosing to his or her sexual partner(s) and to take other measures to prevent HIV transmission. When informing the patient about the importance of disclosure, the attention of the patient should be drawn to the possibility of violence and other adverse consequences that such disclosure may hold in store for the patient concerned, which should inform the decision of the practitioner to disclose or not.
- Secondly, the practitioner should provide support to the patient to make this disclosure.
- Where the patient still refuses to disclose his or her HIV status or refuses to consider other measures to prevent infection, it is necessary to counsel the patient on the health care worker’s ethical obligation to disclose such information and requesting consent to do so.
- Disclosing such information.

SAMA has, in its 2001-HIV Guidelines, recommended that if the patient is still unwilling to disclose after counselling, the medical practitioner may disclose the patient’s HIV status to his/her sexual partner/s only if all the following conditions are met:

(a) The sexual partner/s should be known and identified person/s. A general suspicion that people may be at risk is not sufficient.

(b) The sexual partner should be at real risk of being infected. This means that the patient has refused to disclose or take the necessary precautions and the medical practitioner has reason to believe that the patient is posing a risk to the sexual partner. The medical practitioner may be required in court to show that s/he was acting on substantial information and not on mere suspicion. There should not be any other way to protect the partner/spouse.
(c) The patient should be informed beforehand that the medical practitioner is intending to breach his/her duty to maintain confidentiality. It may be wise to tell the patient of this intention and allow the patient a specified period of time to tell the partner him/herself.

(d) Only after the above steps have been followed may the medical practitioner disclose the HIV status to the partner. Pre-test counselling and/or referral of the person to a counselling, support and/or treatment facility should be offered.

Where the patient firmly believes that there is a risk of harm if their HIV status is made known to the partner, the medical practitioner’s primary duty is to protect the life of the patient and act in his/her best interest. In some communities people living with HIV are persecuted. This factor should also be considered, according to the HPCSA HIV Guidelines. The South African Medical Association recommends that the HIV status is not disclosed to the partner in these circumstances.

5.7 Family members and third parties

A family does not have the right to know the patient’s HIV status. However, the advantages of telling one’s family should be pointed out during counselling. Patients should also be made aware of the fact that their next of kin (in the ordinary hierarchy of spouse/partner, parent, major child/children, parents, brother/sister, etc.) may obtain access to their medical records after their death.

In medical schemes, the principal member of a medical scheme, although paying for the services, has no automatic right to obtain the medical information of his/her dependants. The codes that are being used in terms of the Medical Schemes Regulations and the emphasis on treatment should preserve patient confidentiality.

6. ACCESS TO TREATMENT AND CLINICAL INDEPENDENCE

Everyone has the right of access to health care services as stipulated in the South African Constitution. No medical practitioner may refuse to treat a patient who is HIV positive solely on that person’s HIV status. A medical practitioner may also not refuse normal standards of treatment to a patient based on the patient’s HIV status. A medical practitioner may also not, by failing to fill out required forms for, e.g.
social assistance grants etc., hinder a patient’s right of access to treatment. Where a patient refuses to follow the advice and treatment of the medical practitioner, the medical practitioner may advise that the patient see a different medical practitioner. A medical practitioner should ensure that this does not prevent the patient from access to health care, i.e. there should be other health care facilities and/or medical practitioners available.

In terms of the South African Constitution no patient may be refused emergency treatment. This rule binds public health facilities and private health facilities. In the latter case, a patient has to be stabilised at least before being transferred to a state facility.

It must be remembered that the duty of the state is to ensure that the right of access to health care services in South Africa is progressively realised, within the availability of resources. This means that there might be circumstances when health care facilities are not able to treat all patients needing particular types of care, due to resource constraints. The state has the duty to ensure that there are progressive improvements in the health care facilities. The cases of Soobramoney v Minister of Health (KZN) and Grootboom v Oostenberg Municipality have set out the nature of these duties in more detail. For example, plans to give effect to health care rights have to be reasonable, have to allocate clear responsibilities and have to show that it makes an impact.

However, it is not only the state sector that limits access to health care for reasons relating to scarcity of resources. In medical schemes, formularies, treatment protocols and pre-authorisation may place de facto limitations of the types of treatment, and even facilities and health care providers, which patients/members may access.

The South African Medical Association has during July 2001 adopted the following resolution in this regard:

*The Committee affirms its strong support for the rights of medical practitioners to clinical independence and autonomy. This includes the right to treat patients without undue influence, pressure or victimisation from employers or government institutions. Medical practitioners are under an ethical duty to act in the best interest*
of their patients, who form an exceptionally vulnerable group in South African society. The Committee also supports the rights of patients to receive necessary treatment, always with their informed consent.
7. ACCESS TO POST-EXPOSURE PROPHYLAXIS

7.1 Occupational Injuries in the Health Care Settings

As a general rule, universal precautions should be taken by all health care professionals and workers with all patients under all circumstances. However, where an occupational injury does occur, testing the source patient is a complex issue. In principle, it should be done with the informed consent of the patient. If that consent cannot be obtained, for example where the patient is unconscious or legally incapable of consenting, and testing has to be done as a matter of urgency, an existing blood sample may be used or vicarious consent (from a mandated person, partner/spouse, etc) must be obtained. If the patient is unwilling to consent or refuses to consent, forcefully drawing blood or drawing blood under false pretences may result in legal action against the health care workers involved. Therefore the South African Medical Association does not recommend this last option, but rather recommends that rapid HIV testing on the health care worker be done. However, this area becomes more complex and SAMA urges the development of a policy and regulatory framework that caters for these difficulties.

There are two potential reasons why a medical practitioner might want to know a source patient's HIV status:

Firstly, to make a decision on whether or not to take PEP. As recent research has shown that HIV is most infectious during the window period, it is not medically advisable to use the source patient's status to make a decision on PEP. The decision should be based on the risk associated with the type of injury (eg a deep injury with a hollow instrument that has been inserted in the vein or artery of a patient is high risk but a blood splash on the skin is very low risk). It is also important to note that the risk of contracting HIV from a "needle-stick" injury, even if the patient is known to be HIV positive, is 0.3%. SAMA recommends that individual practitioners weigh up the risk to the medical practitioner, the benefit of knowing the patient's status,
and the extent of violation to the patient's rights, before deciding to make any provisions for testing a patient against their will.

Secondly, if a medical practitioner does contract HIV from a workplace injury, they may want to use the patient's HIV status as a further motivation for a claim in terms of Compensation for Occupational Injuries and Diseases Act (COIDA). If the injury has been properly recorded, and the practitioner has undergone the appropriate base-line HIV test, followed by HIV testing at 3 weeks, two months and six months, this should be sufficient to show that the HIV was contracted as result of the workplace injury. If the patient's HIV status is known, this information can be added to the claim, but if the patient's HIV status is not available (for any reason), the Compensation Commission should not refuse the claim on this basis, as long as the procedures set out above have been complied with, and usually it is sufficient to show that an attempt to ascertain the patient's status was made.

The above issue is complicated due to the possibility of resistance by medical practitioners and healthcare workers to take PEP in cases of occupational exposure, especially where patient or proxy consent cannot be obtained or where the patient’s HIV status is uncertain. SAMA recommends that this factor should be considered in further national policy-development, which is urgently needed.

The Department of Health applies two criteria in cases of occupational injuries, before PEP may be accessed:
(a) The risk of infection (nature of the occupational injury) and
(b) The status of the exposure source.

The Department of Health’s document “Management of Occupational Exposure to HIV”, 1999 contains further clinical guidelines. Where there are discrepancies in the application of the departmental policy, or where practitioners find it difficult to access the policy or PEP, the Medical Association should be contacted for assistance immediately.

The South African Medical Association believes that a supply of PEP should always be available at health care facilities. These supplies should not be unnecessarily restricted. It also recommends that decisions of access should not be left to a single
individual person (e.g. the Infection Control Medical Officer) who may not always be present in the workplace at the appropriate times. There should also be a mechanism in place at all facilities, such as an Ethics Committee, to which appeals could be lodged on an urgent basis in cases of dispute.

Medical practitioners should also be aware of the following policies:

- The Department of Health’s National Antiretroviral Treatment Guidelines (2004)
- The HPCSA’s HIV Policy contains an addendum on the Basic Elements of Practically Applicable Universal Precautions.
- All provinces have their own occupational exposure policies that should be available in- and apply to all state facilities in that province.
- If the injury takes place during the course of one’s duties as an employee, a claim can be made in terms of the Compensation for Occupational Injuries and Diseases Act (COIDA).
- The issue of payment for PEP has been the subject of negotiations in the Public Sector Co-ordinating Bargaining Council (PBCSC) and agreement has been concluded that is now binding on all state facilities.
- Private employers (private hospitals, practitioners in private practice) are also bound by the COIDA and there should be policies within the company that deal with occupational exposure and the accessibility of- and payment for PEP.
- Employers have duties in terms of the law, for example, the Employment Equity Act in relation to implementing HIV programmes for employees.

7.2 Post-Exposure Prophylaxis for Survivors of Sexual Assault

It has now become policy that public facilities provide PEP to survivors of sexual violence. Medical schemes also must fund, as part of the prescribed minimum benefits, in full the medical management (including PEP) as well as psychotherapy/counselling in sexual abuse cases (regulation 8 and Annexure A to the Medical Schemes Regulations).

At a facility or contact-point level, health care professionals should adhere to the Department of Health’s Uniform National Health Guidelines for Dealing with Survivors of Rape and Other Sexual Offences. This forms part of the National Policy Guidelines.
for Victims of Sexual Offences, which aims to co-ordinate responses and roles of the Departments of Social Development, Health, Police Services and Justice. The Policy stipulates, inter alia that:

- The medical examination should get priority over the survivor’s statement. The attending officer at the scene has to inform the survivor that if he/she wishes to continue with the case, a medical examination will be necessary.
- The medical examination must be carried out as soon as possible and will be done by the accredited health care practitioner. The investigating officer will make the necessary arrangements. However, the docket has to be “registered” before the healthcare practitioner can examine the patient.
- It must be explained to the victim that the purpose of the examination is to collect medico-legal evidence. Any medical treatment that may be required will be provided by or arranged at the health care institution.
- It must be explained to the victim that bathing, showering or washing before the medical examination will destroy any evidence that may be collected and for this reason he or she must patiently wait until the end of the medical examination. Once the examination has been completed, the victim will be allowed to bath. If possible, victims should be requested to take clean underwear with them.

If it has been established that the victim has been indecently assaulted in his or her mouth, liquid must not be offered to the victim, as evidence may be lost by this. This restriction is applicable only if the victim has not already rinsed his or her mouth because an oral swab can be taken only within six hours after the incident. If the victim needs to urinate, he or she must be advised to retain any sanitary material used.

Apart from the “ordinary” elements of informed consent, the following also has to be addressed as part of the process of informed consent and pre-test counselling:
- The purpose of this particular medical examination, what it entails and the taking of various samples for testing has to be explained to the patient carefully.
- The treatment options in the cases of injury has to be explained and in particular what PEP is, why it may be advisable, whether there may be any side-effects, etc.
• The need for a blood sample or samples to be taken, whether it will be used for an HIV test, where and when testing will be done and why it is important to obtain a result.
• Reproductive issues, including treatment for STDs and dealing with possible pregnancy, have to be addressed as well.
• Referral to appropriate counselling services.

The Policy contains all the details as to the required samples to be taken from both a victim and an alleged perpetrator. However, the Policy is silent on the issue of consent. In the absence of any legislative framework allowing the taking of samples and testing without informed consent, medical practitioners should require without a court order.

The investigating officer is responsible for the samples taken. The following protocol is detailed by the Uniform Health Guidelines:
1. Introduce yourself - name and qualification.
2. Take a detailed medical history on patient record card and a verbal history of the alleged incident. While it is desirable to elicit what allegedly happened to the victim so that the medical examination is appropriately focussed, it cannot be expected of the medical practitioner to take and record a detailed statement, such as would be taken by an investigating officer. If any note is kept of what is said by the victim in that connection and questions arise concerning those notes at the trial, it should be made clear that the notes do not purport to be a full account of what occurred. For example, there could be a suggestion that an allegation made by the victim in court is a recent fabrication because no mention was made of that particular allegation in the notes.
3. Explain nature and purpose of examination:
   • to collect evidence for court purposes
   • full body medical examination including genital and anal areas
   • need for possible samples/tests
   • need for detailed medical information to be recorded
4. Obtain written consent
   • on own consent form or SAP 308
   • for medical evidence to be collected and disclosed in a court of law
5. Full medical examination
6. Take necessary samples (see Crime Kit protocol)
7. Record detailed findings –
   • on the examination on J88 (in duplicate) and addendum (if space is limited on J88). A copy of the J88 should be kept for a period of three years so that if the original is mislaid evidence of the medical notes made at the time is still available.
   • patient record card - include sketches as it is easier to recall in court - years later.

After examination at least the following procedures should be followed:
1. Emergency medical treatment at primary health centre (PHC) or referral to appropriate centre. The appropriate procedure to follow in any area will have to be decided locally.
2. Prophylactic treatment against sexually transmitted diseases (PHC) should be given (with the consent of the victim). The syndromic management of STDs should be used.
3. Post-coital contraception should be given (with consent of victim).
4. The victim should also be given a letter to attend her nearest family planning centre following her next normal menstruation.
5. Information on follow-up services available should be given to the victim. In dealing with literate victims a booklet should be designed of all accessible services.
6. Referral to an appropriate counselling service should be given. Whilst ideally crisis counselling should be available on the premises, this is not always possible. Referral could for example be to an appropriate NGO (eg Rape Crisis, POWA) or to a local social worker.
7. Survivors should be counselled regarding the possibilities of HIV infection and referred for HIV counselling and testing.
8. Referral channels to provincial hospitals should be opened.
9. Medical certificates for school or work should be provided.
10. The victim should be informed of complaints mechanisms and how to use them.
11. If the victim arrived without referral by the SAPS but now indicates that she wishes to lay charges, the police should be called to the health centre.
12. Supply patient with information (preferably in a booklet form) regarding:
13. Do not hand J88/patient record card to patient.
14. Until a trial takes place, access to the privileged confidential information contained in the J88 is restricted legally to the investigating officer and Justice Department. The J88 and crime kit are to be given only to the investigating officer who must sign a register and the J88 to acknowledge receipt.
15. The health worker should report any information which occurs in the consultation that could be useful to the case. This should include information on the physical condition and emotional and psychological state of the victim, the state of their clothes, evidence of rape as well as information provided verbally (and agreed by the victim to be used as evidence).

8. MEDICAL CERTIFICATES

Both the HPCSA and the South African Medical Association have guidelines on sick certificates. The Ethical Rules contain details as to what should be put on a medical certificate. It includes “a description of the illness, disorder or malady in lay person’s language”. The South African Medical Association believes that it is possible to harmonize the patient’s need to protect confidential information, such as his/her HIV status and the rights of employers to an employee’s presence at work. Where the “illness, disorder or malady” is of a sensitive nature, the medical practitioner should ask the patient if s/he may write that on the certificate or not.

The Health Professions Council and the SAMA Human Rights, Law and Ethics Committee agree that the nature of the illness should not be disclosed. Both the Ethical Guidelines and the Basic Conditions of Employment Act make provision for a practitioner to state that the employee is, in his/her opinion, not capable to work due to injury or illness for a certain period of time, without disclosing the diagnosis or nature of the illness (Refer to the SAMA recommendations in relation to medical certificates and its pro forma certificate as well).

Employers should be made aware of the fact that a medical practitioner only recommends sick leave for a certain period of time. The actual absence from work is an issue to be dealt with between the employer and the employee. In this, the
medical practitioner may, on the request of the employer and only with the written informed consent of the employee-patient, write a report for the employer or affirm that the illness is of such a nature that the employee could not attend work. The employer may also require of the employee to obtain a second opinion of the employee’s choice, for which the employer pays. In these circumstances the patient’s confidentiality must still be preserved and the medical practitioner may only write a sick certificate to the extent indicated above. Employees who want to claim reasonable accommodation of their illness or disability in terms of the Employment Equity Act should be informed of their duty to disclose all relevant information to the employer, so that the employer can evaluate the type of accommodation that is necessary.

Employers who suspect fraud or abuse of medical certificates should report this to the nearest South African Medical Association Branch Ethical Committee or report the incident to the HPCSA. The National Council of SAMA resolved in December 2000 that the issuing of fraudulent sick certificates and prescriptions was unethical and illegal and that medical practitioners involved in such activities would be open to charges of unprofessional conduct. Medical practitioners whose certificate stationery have been stolen or whose certificates have been unlawfully reproduced could lay criminal charges against the suspected individuals.

9. DEATH NOTIFICATION FORMS AND DEATH CERTIFICATES

New regulations on death notification forms have been passed in 1998. The new death notification form has two pages, which are detachable. The first page is used so that the burial can be authorised by Home Affairs, or to give an indication as to whether further investigations into the death is required by the SAPS and the Prosecuting Authority. On this page the cause of death is only indicated as “natural” or “unnatural”. This is the page on which the Death Certificate is issued by the Department of Home Affairs as proof of death. This is the Certificate that insurers will require in order to look into a claim relating to a life insurance policy, etc.

The two pages must be detached. The second page is confidential and is used by the state (Home Affairs) to collect data. On this the medical cause of death, which may include reference to HIV status as the cause of, for example, an infection that led to...
death. The deceased person is not named on this page, and the information found on it is used for purely statistical purposes. This second page may not be used by any other party and may not be given, even on request, to any third party, insurer, etc. The second page is meant to be sent to (or in many cases collected from the hospital by) the Department of Home Affairs. However, the practical recommendation is for the second page to be sealed in an envelope and stapled to the first page, to accompany the body to the undertaker. The Department of Home Affairs has indicated that it cannot deal with the notification from being separated from the first page.

10. HIV/AIDS AND EMPLOYMENT

Medical practitioners are often employees, and often employers. They have to deal with employers requesting HIV tests for (prospective) employees, as well. For these reasons they have to be familiar with the relevant provisions of labour law in this regard.

10.1 Unfair discrimination on HIV/AIDS

In the case of Hoffman v South African Airways, 2000, the South African Constitutional Court found the discrimination against a HIV positive (prospective) employee to be unfair. The Court took notice of the employee’s CD-4 count, his actual capability to conduct the work and whether he would be able to undergo the yellow-fever vaccination for flights to African countries. This indicates the importance of a scientifically justifiable approach to HIV. The Court also rejected arguments that passengers would feel uncomfortable with an HIV positive flight attendant. It also rejected arguments that many other airlines have similar discriminatory policies, stating that discrimination elsewhere in the world cannot be used as a justification for unconstitutional behaviour in South Africa. This case also implies that refusal to retain an HIV positive employee will also be unlawful. Dismissal based on a person’s HIV status will constitute a prima facie unfair dismissal in terms of the Labour Relations Act of 1995. The Employment Equity Act of 1998 expressly prohibits unfair discrimination against any employee based on their HIV status.
10.2 Testing (prospective) employees for HIV

Section 7 of the Employment Equity Act prohibits the medical testing of employees and job applicants. This may only be done if the consent of the Labour Court has been obtained in this regard. This has mostly been used by employers requiring data on prevalence in their workplace, and to plan for the healthcare needs and other implications of HIV prevalence. That means that no individual employee’s results are made known and data is collected and reported on as overall company-data. The Department of Labour’s Code of Good Practice in HIV states that section 7-Labour Court consent has to be obtained in the following situations, if HIV is:

- deemed relevant during an application for employment;
- set as a condition of employment;
- regarded as relevant during procedures related to termination of employment (such as extended sick leave where reasonable accommodation of the employee is no longer possible);
- an eligibility requirement for training or staff development programmes; and
- an access requirement to obtain employee benefits.

However, there is conflicting case law on what section 7 means in practice in terms of informed consent. Some jurisdictions stating that testing at the request of an employer may only be conducted with the informed consent of each and every employee individually, others finding that the consent of the court substitutes those of the employees. However, SAMA recommends that, in the interest of ethics and certainty, individual employees should still be required to provide informed consent and should be encouraged to obtain their individual results. This means that no employer may force an employee or job applicant to undergo an HIV test. If a medical practitioner is requested to perform an HIV test by an employer, he/she should request to see the order from the Labour Court.

Medical practitioners should ensure that where an employee has been referred for an HIV test by an employer, the employee understands his/her rights with regard to informed consent and confidentiality. In such circumstances, the medical practitioner should take particular care to ensure that an employee has consented to an HIV test of his/her own free will, and is not under duress or compulsion from the employer. If, after appropriate pre-test counselling, the employee consents to an
HIV test, the medical practitioner should advise the employee that he/she will not disclose the results of the test to the employer.

Where an employer refers an employee for an HIV test or medical examination to the employer’s practitioners, the medical practitioner should ensure that he/she is not placed in a situation of conflict between his/her responsibilities to the employer and employee as patients. If the potential for such conflict of interests should arise, the medical practitioner should rather refer the employee to another medical practitioner.

If the employee provides their informed consent that their status may be disclosed to the employer, the employer must keep that information confidential, unless the employee consents to that information being made known to co-employees. These disclosures should take place with the necessary counseling and training exercises.

The current labour legislation applies to all employees (including farm workers and domestic workers), except for employees of the South African National Defence Force (SANDF), the National Intelligence Agency and the Secret Service. However, the Constitutional Court has ruled in 1998 that they have a constitutional right to fair labour practices, which should include those in relation to HIV. They also have a right to equality and protection against unfair discrimination. At present, the specific rights of prospective SANDF members with regard to HIV-related discrimination have not been tested in court, and the SANDF continues to require pre-employment testing for HIV.

Employers who are not covered by the Employment Equity Act will be bound by the Promotion of Equality and Prevention of Unfair Discrimination Act of 2000. This Act also bind employers towards "any person", i.e. not only employees and claims may be lodged at any Magistrates’ Court.

10.3 Medical practitioners living with HIV

The HPCSA guidelines state that no medical practitioner is obliged to disclose their HIV status to an employer or co-employee. Infected medical practitioners may continue to practise, but have to seek counselling and advice so as to adjust their
professional activities to protect their patients. In general, only scientifically justifiable restrictions will be permissible. Medical schools and facilities are currently attempting to address this issue so as to balance the rights of people to choose a profession with the rights of patients. The HPCSA suggested that medical academic institution should designate an appropriate and professional counselling service.

10.4 Workplace policies

All employers should have HIV policies for the workplace and conduct educational and training activities. Medical practitioners can play a constructive role in imparting scientific and clinical knowledge on this matter. The Code of Good Practice on HIV and AIDS in Employment, issued by the Department of Labour, provides more details on the duties that rest on employers in terms of HIV:

- Preventing unfair discrimination and stigmatisation of people living with HIV or AIDS through the development of HIV/AIDS policies and programmes for the workplace;
- Conducting awareness, education and training on the rights of all persons with regard to HIV and AIDS;
- Establishing mechanisms to promote acceptance and openness around HIV/AIDS in the workplace;
- Providing support for all employees infected or affected by HIV and AIDS; and
- Grievance procedures and disciplinary measures to deal with HIV-related complaints in the workplace;
- Ensuring confidentiality protection;
- Ensuring compliance with all relevant legislative requirements, such as those relating to employment testing and occupational safety;
- Ensuring that there is no discrimination in any employment policy or practice, including those relating to pensions, medical scheme membership, etc.
- Ensuring that there is a workplace policy containing the following elements:
  - the organisation’s position on HIV/AIDS;
  - an outline of the HIV/AIDS programme;
  - details on employment policies (e.g. position regarding HIV testing, employee benefits, performance management and procedures to be followed to determine medical incapacity and dismissal);
express standards of behaviour expected of employers and employees and appropriate measures to deal with deviations from these standards;

grievance procedures in line with item 12 of the Code of Good Practice;

set out the means of communication within the organisation on HIV/AIDS issues;

details of employee assistance available to persons affected by HIV/AIDS;

details of implementation and coordination responsibilities; and

monitoring and evaluation mechanisms.

10.5 Occupational Health

The National Health Act (NHA), section 20, requires of all health facilities to implement measures to minimise injury or damage to the person and property of health care personnel working at that establishment; and disease transmission. This is an important duty in the context of HIV. It applies to medical practices, hospitals (public and private), clinics and all other health facilities. This means that such facilities should have a policy and protocol detailing the specific measures to be taken in terms of the prevention and risk minimisation of HIV transmission and the protection of staff against occupational injuries, as well as the procedure should transmission or injury occur. This duty is similar to that in section 8(1) of the Occupational Health and Safety Act - an employer is obliged to provide, as far as is reasonably practicable, a safe workplace. The Mine Health and Safety Act contains the same provision. The Occupational Health and Safety Act also place this duty on “all employers”, who have to adopt measures at work to reduce the risk of HIV transmission at work. These measures have to be rational and therefore based on the relevant scientific and legal facts.

The Basic Conditions of Employment Act of 1997 stipulate the rights of employees to sick leave. HIV-positive employees may require reasonable accommodation in this regard and in the allocation of duties, etc. as prescribed by the Employment Equity Act and the Labour Relations Act. An employee who is infected with HIV as a result of an occupational exposure to infected blood or bodily fluids, may apply for benefits
in terms of Section 22(1) of the Compensation for Occupational Injuries and Diseases Act, No. 130 of 1993.

If an employer provides benefits such as medical aid and provident fund membership, such benefits must be available to all employees on an equitable basis, regardless of their HIV status. Discrimination on the basis of HIV in these contexts could also render the employer and the specific funds or schemes liable for complaints of discrimination in terms of the Promotion of Equality and Prevention of Unfair Discrimination Act.

11. HIV/AIDS, INSURANCE AND SOCIAL SECURITY MECHANISMS

There are three types of mechanisms to assist people when some risk materialises, such as ill health, death, or disability:

- Private insurance, based on the individual’s risk profile (e.g. whether the person smokes or has a disease that could influence life-expectancy);
- Social insurance, based on a community risk rating (e.g. what is the prevalence of a particular disease in a specific population);
- Social assistance, based on the need of a person who does not have to means to contribute to any insurance scheme (e.g. disability grants or childcare grants).

Medical practitioners are often approached to fill out forms in relation to the patient’s HIV status or whether the person has undergone an HIV test. The same ethical principle applies, that is that patient information is confidential. However, the above mechanisms often include legal provisions that qualify this confidentiality.

SAMA recommends that counselling of people living with HIV addresses issues of insurance and assistance.

11.1 Social insurance – medical schemes, pensions and provident funds

In terms of section 24(2)(e) of the Medical Schemes Act, No 131 of 1998, a registered medical scheme may not unfairly discriminate directly or indirectly against its members on the basis of their "health status".

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Section 67(1)(9) regulations may be drafted stipulating that all schemes must offer a minimum level of benefits to their members. The regulations stipulate that all medical schemes must now provide prescribed minimum benefits (PMBs) to all members and beneficiaries, including people living with HIV/AIDS, including treatment for all opportunistic infections and anti-retroviral treatment and schemes have to fund the treatment of these conditions “in full and without co-payment” (regulation 8). However, in order to manage cost, schemes may appoint designated service providers (DSPs) and may have formularies, protocols and pre-authorisation requirements. The utilisation of these strategies is subject to the provisions of the law. Especially in the context of HIV management, some schemes utilize the services of managed care groups to manage patients living with HIV. However, these strategies have to be based on evidence-based medicine and may take into account cost-effectiveness and affordability.

SAMA condemns any utilisation of DSP mechanisms (hence implying in change in service providers and even transfer from one health facility to another) only when it becomes apparent to the scheme that the patient is living with HIV.

ICD coding provides a particular challenge. SAMA opposes the depth of coding that could lead to possible data utilisation in contravention with internally accepted data-principles and that could reveal information not required for the funding decisions to be made by medical schemes, e.g. whether a condition is indeed a PMB or not.

Pension- and Provident Funds operate in terms of the general provisions of the applicable laws dealing with these subjects, but are also often subject to specific fund rules. These fund rules sometimes create exceptions and exclusions, for example that disability related to HIV/AIDS are not covered by the fund’s temporary or permanent disability benefits. As the trustees of these funds are also representative of employees, patients living with HIV should be encouraged to determine the entitlements of persons living with HIV, in order to establish, and possibly challenge, their relative vulnerability, and the financial vulnerability of their family should they become disabled or die as a result of HIV/AIDS.

Patients could challenge the above exclusions or limitations on the basis of the Promotion of Equality and Prevention of Unfair Discrimination Act.
11.2 Private insurance – the Long-term Insurance Act

Life insurance, burial policies, etc. often contain HIV exclusion clauses which allow the insurer to repudiate the claim if the death was directly or indirectly caused by HIV. Other insurers may wish to access a client’s medical information because they suspect that the death may have been caused by a pre-existing condition which was not disclosed to the insurer when the policy was taken out.

Case law has affirmed the duty placed on an insured to disclose “material facts”, based on section 59 of the Long-term Insurance Act of 1998. The question then will be whether the (mis)representation would have materially affected the assessment of risk at the time of issue of the policy, objectively spoken (Joubert v ABSA Life, 2001).

The primary contract is between the policy-holder and the insurance company. The medical practitioner may only disclose medical details if the insurance company can provide the medical practitioner with a copy of a document where the patient has provided informed consent that his/her medical details may be released to the insurer. Failing that, the medical practitioner should only write “confidential information” in the spaces provided and/or use the example above in relation to third party requests as a response to the requesting company. Where the insured has passed away, the next-of-kin may consent to the disclosure of the medical information. Where the policy-holder and the insured person is not the same person, the insured person should provide informed consent before medical details are disclosed.

Medical practitioners should note that if they do not provide the medical information where a person has given consent for the insurer to access their medical records, the insurer will not process the claim.

Most insurance products do not provide cover if a person tests positive. Insurance companies should adhere to all the principles of HIV testing, i.e. pre-test counselling, informed consent, post-test counselling and confidentiality. This becomes the duty of the medical practitioners involved in testing for insurance purposes. The South
African Medical Association believes that blanket consent provided for insurance purposes does not conform to the principles of informed consent. SAMA recommends that the outcome of HIV testing for insurance purposes be dealt with as any other HIV test, i.e. the patient has to undergo pre- and post-test counselling and should be informed of the necessity to obtain the result of the test, irrespective of the insurance application outcome.

The Promotion of Equality and Prevention of Unfair Discrimination Act of 2000 contains, *inter alia*, in the illustrative list of unfair practices in certain sectors the practice of “unfairly disadvantaging a person or persons, including unfairly and unreasonably refusing to grant services, to persons solely on the basis of HIV/AIDS status. Although this section of the Act has not yet been tested with regard to the practices of insurance companies, patients may approach any Equality Court with complaints by insurers relating to their HIV status.

11.3 Social Assistance – the Social Assistance Act

The 2004-Social Assistance Act has replaced the 1992-Act. It creates the following grants, of which people living with HIV, has to be aware:

- Child support grant – of importance for parents concerned about the welfare of their children after their death. This grant could be claimed by, for example, a family member who will be looking after the children.
- Care dependency grant – for caregivers of children suffering mental or physical disability, including children living with HIV/AIDS.
- Foster child grant – in cases where parent(s) living with HIV is not able to care for their children anymore.
- Disability grant – for persons of physical or mental disability, unfit to obtain by virtue of any service, employment or profession the means needed to enable him or her to provide for his or her maintenance.

All the above is accompanied by eligibility criteria that are set for each type of grant, such as SA residency or citizenship, income thresholds; means testing; age limits, disabilities (such as the stage of HIV and CD4) and care dependency; proof of and measures to establish or verify identity, gender, age, citizenship, family relationships, care dependency, disabilities, foster child and war veterans’ status;
forms, procedures and processes for applications and payments; and measures to prevent fraud and abuse.

12. HIV/AIDS AND RESEARCH

12.1 General requirements

The basic ethical guidelines that underlie medical research are found in the following principles:

- Beneficence and non-maleficence which mean that medical practitioners/researchers are required to act for the good of their patients/research participants, and concomitantly should do no harm to their patients/research participants.

- Autonomy which means that the researcher must respect the patient/participant. This would entail ensuring that the patient/participant is given adequate information about the research being done, so that he/she makes informed decisions about participation. Should the patient/participant choose not to take part, this decision should be respected.

- Justice requires that considerations of fairness pervade all decisions concerning the research agenda. This includes fairness in the choice of research participants as well as fairness in respect of the risks and benefits of the research.

Particular care has to be taken in the choice of a patient population for HIV-related research. Vulnerable groups and communities should not be exploited and such choice has to be scientifically justifiable. Such populations have the same rights to autonomy and respect as any other, whilst their relative vulnerability has to be duly considered in all communications and processes relating to the envisaged research and during such research.

The World Medical Association’s Declaration of Helsinki is the most important ethics document for medical practitioners world-wide:

- It is the duty of the physician to promote and safeguard the health of the people.
- Considerations related to the well-being of human subjects should take precedence over the interests of society and science.
• The research protocol should always contain a statement of the ethical considerations involved.
• The importance of the objective should outweigh the inherent risks and burdens to the subject.
• The subjects must be volunteers and fully informed participants.
• Privacy and confidentiality of subjects must be guaranteed.

12.2 The Constitution and the National Health Act

Section 12 of the SA Constitution states that no person may be subjected to medical experiments without his or her consent.

Section 11 of the National Health Act (NHA) now also requires of health facilities to inform the patient, in the prescribed manner by the Minister, that the health service is for experimental or research purposes or part of an experimental or research project. The patient, the health care provider primarily responsible for the user’s treatment, the head of the health establishment in question, as well as the relevant health research ethics committee all have to give prior written authorisation for the provision of the health service (research in this case) in question. Section 71 reiterates that written consent is required and that the patient has to be informed of the objects of the research or experimentation and any possible positive or negative consequences on his or her health.

Informed consent may not be given freely and voluntarily if incentives sway a participant’s decision. Such consent will be unlawful. According to the Department of Health (2004), incentives should not be so excessive as to unfairly influence patients to submit themselves to the trial. Payment relating to transport should be fair and reasonable without ‘making the patient an offer they cannot refuse’ and thereby influence the patient to overlook other important considerations.

The NHA also establishes a National Research Committee with the mandate to determine the health research to be carried out by public health authorities ensure that health research agendas and research resources focus on priority health problems. The Department of Health (2004) recommends that consultation on
research should include people living with HIV/AIDS (PLWA’s) in the processes of ethics approval.

12.3 Children

Where children are concerned, section 71 states that research or experimentation for a therapeutic purpose, the research or experimentation may only be conducted—

- if it is in the best interests of the minor;
- in such manner and on such conditions as may be prescribed;
- with the consent of the parent or guardian of the child; and
- if the minor is capable of understanding, with the consent of the minor.

Research or experimentation for a non-therapeutic purpose, may only be conducted—

- in such manner and on such conditions as may be prescribed;
- with the consent of the Minister;
- with the consent of the parent or guardian of the minor; and
- if the minor is capable of understanding, the consent of the minor.

The NHA states that the Minister may not give consent in circumstances where the objects of the research or experimentation can also be achieved if it is conducted on an adult; where the research or experimentation is not likely to significantly improve scientific understanding of the minor’s condition, disease or disorder to such an extent that it will result in significant benefit to the minor or other minors; where the reasons for the consent to the research or experimentation by the parent or guardian and, if applicable, the minor is contrary to public policy; where the research or experimentation poses a significant risk to the health of the minor; or where there is some risk to the health or well-being of the minor and the potential benefit of the research or experimentation does not significantly outweigh that risk.

12.4 Department of Health Policy documents and guidelines

The Department of Health’s “Ethics in Health Research – Principles, Structures and Processes” of 2004 contains a special Appendix entitled “Ethical considerations for HIV/AIDS clinical and epidemiological research”. It sets the following criteria:
• Research should be appropriate to South Africa (i.e. take into account the various settings and applied to communities in different social and economic circumstances and address South African health priorities).
• Drug trials should not be conducted solely because they facilitate access to drugs for some patients. The rationale for drug trials should be independently assessed and evaluated on its merits.
• Researchers must ensure that patients in drug trials provide informed consent and understand the implications of the trial. This includes the advantages and disadvantages of all drug regimens, and the potential limitations in taking medications only for the period of the drug trial.
• A special case involves the use of placebo after an intervention has already been shown to be effective. The general principle is that the use of placebo in these circumstances is unethical. However with increasing disparities in health care between wealthy and poor countries, therapy that has been shown to be effective is often unaffordable in resource-poor settings. However, placebos may only be used when the anticipated benefits will outweigh the risks to participants, and participants will not be harmed, and full justification must be provided for use of placebo.
• The patient information section of the informed consent document should specify the action to be taken if the study drug or drugs are withdrawn because of side effects. In such a situation, appropriate therapy to manage the adverse drug effects should be made available within the study framework at no cost to the patient, by referral to the local health service, or through the patient’s medical insurance, unless exceptions have been agreed upon by all parties.
• Where patients withdraw from a study for any reason, or where a study is completed, the patients should be advised about the ongoing management of their condition. Except in cases where therapeutic efficacy is demonstrated, ongoing therapy should be administered according to the local standard of care. Costs of this care should be borne by the local health service, the patient’s medical insurance or the patient.
• Where a patient shows a therapeutic response to a study drug, that patient should be offered ongoing treatment. In designing studies, consideration should be given to the costs of long-term provision of study drugs and of clinical monitoring, including the costs of medical staff. The duration of drug therapy in a
study should also be clearly stated in the patient information section of the
informed consent document.

The MRC (2003) requires that the research protocol describes the nature of medical
treatment to be provided for injuries, as well as compensation for harm due to
research-related activities, and the process by which it is to be decided whether an
injury will be compensated. This must also be fully explained in the informed consent
process.

12.5 Informed consent in context of research and surveillance (Department
of Health, 2004)

Written informed consent is of particular importance in the following contexts:
• Epidemiological studies, such as sentinel surveillance on pregnant women;
• Observational studies, such as the effect of long-acting progestins on the risk of
  HIV transmission in women;
• Drug trials, to establish efficacy and safety;
• Vaccine trials.

The MRC (2003) recommends that community representatives, investigators,
research ethics committees, regulatory bodies, and sponsor(s) be undertaken to
design an effective informed consent strategy.

If HIV testing is done for surveillance purposes, It is considered ethically acceptable
to conduct unlinked anonymous testing without individual consent if the following
criteria are met:
• Blood is routinely collected for a reason other than HIV testing;
• After routine testing, personal identifiers are removed;
• Leftover blood or blood products are used for HIV testing;
• No other non-routine interventions, including the completion of questionnaires, are
carried out.

In linked anonymous testing the HIV result is linked to a patient’s other clinical data,
but the patient remains anonymous. This form of testing is best suited to research
where HIV infection is a major confounder and not where HIV infection is the endpoint. Patients should provide informed consent to linked anonymous testing and be offered confidential HIV testing.

Informed consent is of particular importance in the context of HIV vaccine trials. The MRC (2003) states that every effort must be made to provide participants with optimal risk reduction counselling and interventions to prevent HIV infection. Informed consent in this context should be “meaningful, independent, ongoing informed consent of vulnerable persons, should respect their rights, foster their well-being, and protect them from harm. Extra efforts that should be taken to ensure this include:

- Counselling to facilitate decision-making and to explore the impact of participation on such persons;
- Evaluation of consent processes by an independent advocate, ombudsperson or group, or trial monitor;
- Ongoing evaluation of potentially negative consequences related to trial participation; and
- Access to supportive counselling and psychological and legal support services for trial-related harmful consequences, where necessary.”

12.6 Researchers and clinical trials

12.6.1 General provisions

Clinical trials have to be registered at the Medicines Control Council. Regulation 34 to the Medicines and Related Substances Act of 1965, as amended, deals with the manner of applying for such registration.

Such trial application should include a trial protocol (containing specific information); an investigator’s brochure containing relevant chemical, pharmaceutical, pre-clinical pharmacological and toxicological data and where applicable, human pharmacological and clinical data with the substance concerned; curricula vitae of all investigators; a signed declaration by the applicant and all investigators that they are familiar with and understand the protocol and will comply with Good Clinical Practice as determined by the Council in the conduct of the trial; and informed consent document and endorsement by any ethics committee recognised by the Council. The
The medicine used in such clinical trial has to be properly labelled and the package must sufficiently identify the clinical trial to be carried out; the medicine to be used; the person to whom the medicine is to be administered; and the name and address of the premises where the clinical trial is to be carried out.

SAMA is of the view that all medicinal treatments, irrespective of whether allopathic, traditional or complementary, in which claims are made in terms of the efficacy of treating HIV/AIDS or associated illnesses, should undergo clinical trials before being sold as such treatments.

Medical practitioners who participate as investigators or researchers in clinical trials or other research, have to ensure that any incentives provided by a sponsor not unduly influence the direction of the study or any ethical issue. The MRC Guidelines on HIV Vaccine Trials recommend that care should be taken to minimise the potential for conflicts of interest, when assistance in capacity building for scientific and ethical review, is provided.

As far as research results are concerned, the Department of Health (2004) warns that premature release may result in the broadcast of sensational, inaccurate, misleading and irresponsible information on HIV and AIDS.

### 12.6.2 Vaccine trials

According to the Department of Health (2004), some of the important ethical considerations in vaccine trials include:

- The impact of local HIV prevention initiatives on research outcomes;
- The possible influence of receiving a vaccine candidate on reducing incentives for participants to take necessary precautions to prevent HIV transmission;
- The implications of ‘false positive’ HIV tests in patients who agree to vaccine trials;
- The appropriateness of the vaccine clade to the local population.
- Vaccine research should be done in consultation with national and international initiatives.

The MRC (Guidelines on Ethics for Medical Research - HIV Preventive Vaccine Research, 2003) states that HIV preventive vaccine trials should be carried out in
South Africa only if the capacity exists to conduct appropriate, competent and independent scientific and ethical review. It also recommends that careful scientific and ethical consideration should be given to whether phase I and II trials that have been performed in a sponsor country should be repeated in the South African community in which phase III trials are to be conducted.

13. HIV/AIDS TESTING IN SCHOOLS

According to the National Policy on HIV/AIDS drafted by the Department of Education, there is no medical justification for routine testing of learners, students or educators for evidence of HIV infection. The testing of learners or students for HIV/AIDS as a prerequisite for admission to, or continued attendance at school or institution, to determine the incidence of HIV/AIDS at schools or institutions, is prohibited. The testing of educators for HIV/AIDS as a prerequisite for appointment or continued service is also prohibited. The policy further discourages the compulsory disclosure of a learner’s or educator’s HIV status.

Some have argued that HIV tests (and therefore a subsequent disclosure) serve to “protect teachers” and “co-learners” from possible infection, but it is doubtful whether this approach would serve any useful purpose, and would rather have the opposite effect of stigmatising the HIV positive learner. Instead, universal precautions should be used by all learners and educators. Should a medical practitioner participate in any activity that makes such testing mandatory, it would constitute a breach of the ethical duties of the medical practitioner.

Schools, whether they are public or private, may not test learners without the appropriate consent (either from the parent/guardian or the child) as required by the Child Care Act. A teacher will not be able to provide consent on behalf of a learner. Even if consent is obtained in the school setting, such tests may be found to violate the human rights of the learners concerned, especially where there is pressure to consent. The court will take into account factors similar to those considered in the Hoffmann-case and section 36 of the Constitution:

- The objective of the testing, which must be constitutionally defensible.
There has to be a rational connection between the objective and the testing, if the testing is to protect learners, such testing should indeed lead to the achievement of the objective of protecting learners.

There has to be no less intrusive measures to achieve the objective (e.g. to protect all learners).

However learners and educators should be educated about the disease, universal precautions, safe sexual practices, and available treatment options. They should be encouraged to be tested. Should some learners be interested in testing, the schools could facilitate the process by making available the information of testing sites. For medical practitioners who test learners, the same principles apply as with any patient:

- There must be informed consent. Children above the age of 14 may consent independently and should then be the bona fide patients of that practitioner. If the child is under the age of 14, his/her parent or guardian must consent. Where parental consent is required, is the child has the maturity to appreciate the risks and benefits associated with the test and the results, then consent must be sought from him/her as well. Note however, that a new Children’s Bill may change consent requirements where HIV/AIDS and reproductive health is concerned.

- Confidentiality must be guaranteed. Medical practitioners requested by- or in the employ of public educational institutions should familiarise themselves with the provisions of National Policy on HIV/AIDS.

Practitioners should note that peer pressure may influence the consent given by a learner. If there is any evidence that consent has not been freely given, the subsequent test could amount to a violation of the child’s rights to privacy and freedom and security of the person. Practitioners should therefore make all reasonable attempts to ensure that learner’s who choose to be tested do so freely and voluntarily. This could be done during the pre-test counselling. If informed consent is given and the test is done, the results may only be made known to the patient, i.e. the learner. Pre- and post-test counselling is imperative and should be conducted in a manner appropriate to the child’s level of development.
14. HIV/AIDS AND PRISONS

The Constitution, apart from the ordinary rights such as human dignity and physical integrity, contain a set of rights applicable to arrested, accused and detained persons. One of the crucial elements is the right to adequate medical treatment. Medical treatment includes voluntary HIV testing and counselling. At present, prison hospitals are not accredited to provide ARV treatment, but prisoners who require ARV drugs should receive ARV treatment on an out-patient basis at the nearest accredited public health care facility. All provincial Department of Correctional Services are required to enter into agreements with their counterparts in the provincial Departments of Health, to ensure that prisoners are able to access ARV treatment through state hospitals and clinics.

In the case of C v Minister of Correctional Services, 1996, the absence of counselling indicated that there was no informed consent. In the case of W v Minister of Correctional Services, 1996 the right to confidentiality, informed consent, counselling, access to condoms, non-discrimination, etc. in the prison setting were affirmed in the Cape Town High Court.

Medical practitioners working in correctional facilities should also be aware of the fact that segregation of prisoners based on their HIV status is likely to be unconstitutional (unless they suffer from an infectious disease such as TB which would ordinarily require quarantine or isolation from the general prison population). The Department of Correctional Services has a Management Strategy on HIV and AIDS in Prisons, which includes information on high-risk practices, the use of universal precautions, etc.

Prisoners who are terminally ill and who are not expected to recover can apply for medical parole in order to spend their last days in dignity with their families. Medical parole must be recommended by two medical practitioners employed by the Department of Correctional Services. Medical practitioners in correctional facilities should pro-actively identify prisoners who require medical parole, and make the appropriate recommendations.
Prisoners on ARV treatment should not be referred for medical parole, unless all possible treatment regimes have failed and there is no chance that the patient will recover.

Special attention should be given to pregnant female prisoners, such as education on pre-natal care, the need to know one’s HIV status, access to treatment, etc. Youth facilities should also embark on special programmes on HIV awareness, testing, treatment and prevention. Prison authorities should do as much as possible to prevent rape and/or other forms of sexual assault" in prisons and to educate prisoners on procedures to be followed after a rape has been committed, particularly with regard to accessing PEP for HIV and other STI’s.

15. HIV/AIDS AND POPULAR EDUCATION/COMMUNICATION

The South African Medical Association believes that medical practitioners individually and collectively can play an important role in the fight against HIV by getting involved in popular educational and training activities in their own communities. Practitioners should apply these guidelines as part of good health care management and good patient care. In the past, some medical practitioners have been placed in the unfortunate position of having to choose between their professional ethics and certain policies and practices in health care facilities. The South African Medical Association recognises those practitioners who have taken a public stand in favour of patient’s rights and medical ethics and those who are already involved in the more controversial aspects of the fight against the epidemic, but realises that all practitioners can contribute to the fight against HIV/AIDS in a number of different ways even if on a smaller scale.

WHERE TO GO OR REFER PATIENTS FOR ASSISTANCE

Complaints of unprofessional or unethical conduct of medical practitioners could be forwarded to:

- The Ethics Committee of the specific SAMA branch
  (Branch details available from the SAMA Head Office – Tel: (012) 481 2000)

- The Registrar of the Health Professions Council of SA
  P.O Box 205
Complaints in connection with Medical Schemes should be directed to:

- The Registrar of Medical Schemes
  Private Bag X34
  Hatfield 0020
  Tel 012 430 7652; Fax 012 430 7644
  http://www.medicalschemes.com (log your complaint online)

Employment issues may fall within the jurisdiction of:

- the Commission for Conciliation, Mediation and Arbitration (CCMA) that has branches in all nine provinces (see your telephone directory in this regard, call 011 3376600 or go to their website at http://www.ccma.org.za)

Human Rights violations may be reported to:

- The South African Human Rights Commission
  Private Bag 2700
  Houghton 2041
  Tel 011 484 8300; Fax 011 484 1360
  http://www.sahrc.org.za (log your complaint online)

- The Treatment Action Campaign
  34 Main Rd Rd
  Muizenberg, Cape Town
  Tel 021 788 3507; Fax 021 788 3726

- The AIDS Law Project
  University of the Witwatersrand
  Private Bag 3, Wits 2050
  Tel 011 7178600; Fax 011 4032341

Complaints in relation to short- and long-term insurance can be directed to:

- The Short-term Insurance Ombudsperson
  P O Box 30619
  Braamfontein 2017
  Tel 011 726-8900; Fax 011 726 5501

- The Long-term Insurance Ombudsperson
  P O Box 45007
  Claremont 7735
  Tel 021 674 0330; Fax 021 674 0951
Violations in prison:

- Office of the Inspecting Judge
  Private Bag X9177
  Cape Town 8000

USEFUL SOURCES & LINKS

- **HPCSA:** Ethical Rules; Management of Patients with HIV Infection or AIDS (updated 2005): [http://www.hpcsa.co.za](http://www.hpcsa.co.za)

- **WMA Statements:** - on Issues raised by the HIV Epidemic (Sept 1992); - on Patient Advocacy and Confidentiality (Oct 1993); - on Aids (Oct 1987); - on the Professional Responsibility of Physicians in Treating Aids Patients (Sept 1988); - on Health Databases (2001): [http://www.wma.net](http://www.wma.net)

- **South African legislation & all government departments:** The Constitution Act of 1996; Employment Equity Act of 1998 (see the textbook by Pretorius, Klinck and Ngwena where pertinent aspects, such as reasonable accommodation, etc. are discussed in detail); National Health Act of 2003; Medical Schemes Act of 1998 and Regulations; Promotion of Equality and Prevention of Unfair Discrimination Act of 2000; etc.: [http://www.polity.gov.za/gnuindex.html](http://www.polity.gov.za/gnuindex.html)

- **South African Law Reform Commission:** Reports and discussions papers on Aspects Relating to HIV/AIDS; etc: [http://www.law.wits.ac.za/salc/salc.html](http://www.law.wits.ac.za/salc/salc.html)


- **Life Offices Association**: HIV/AIDS policies, procedures, etc. in relation to Long Term Insurance: [http://www.loa.co.za](http://www.loa.co.za)


**USEFUL DOCUMENTS**
The documents below will be accessible from the SAMA website on the following link:

**HPCSA:**
Booklet 8 : Guidelines for the Management of Patients with HIV Infection or AIDS

**Department of Health:**
Occupational Exposure (2000)

**Department of Education:**
National Policy on HIV/AIDS for Learners and Educators in Public Schools (1999)

**Department of Labour:**
Code of Good Practice on Key Aspects of HIV/AIDS and Employment (2001)

**World Medical Association:**
Helsinki Declaration (2001)
Statement on Patient Advocacy and Confidentiality (1993)
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