# Ethical principles becoming statutory requirements

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### Abstract

Medical practitioners in the past mainly relied on ethical guidelines of the Health Professions Council of South Africa, international codes, declarations and common ethical principles as guidance to practice. In the past twelve years several pieces of legislation have been promulgated which totally changed this situation. Important issues in medicine such as the way in which medical treatment and or services are rendered, the privacy of a patient, the confidentiality of patients' information, the patient's right to self-determination and the informed consent of a patient are now all influenced and regulated by statutes. It is thus very important that the training programmes of medical schools and the further training of medical practitioners makes provision for the inclusion of the study of human rights issues, medical law and bio-ethics.

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### Introduction

Ethical principles and ethical guidelines were previously the only form of guidance for medical practitioners. The promulgation of new legislation has changed things dramatically in this regard over the past few years. As a result of these changes, the need to train healthcare workers in medical law and ethics is becoming more and more important in developing countries, especially in the development of third world countries like South Africa. When one talks about healthcare workers, it includes not only medical practitioners, but also professional nurses and all the other health care related professions. Educating and training these professionals does not only mean that they must be familiar with the contents and the functioning of their relevant fields of speciality, but that they must also be well-educated in the ethical principles/aspects as well as the legal requirements involved. Medical law and medical ethics/bio-ethics must therefore play a very important role in training, education and continued development programmes of healthcare practitioners.

In the past the medical profession mainly relied on the relevant ethical guidelines set out by the Health Professions Council of South Africa, international codes, declarations and common ethical principles, ignorance of which could lead to legal as well as ethical accountability and conviction of unprofessional and unethical conduct. Over the past few years several pieces of legislation have been promulgated with the effect that statutory recognition was given to most of these ethical principles. In this discussion focus will be placed on the most important ethical principles which are currently supplemented by legislative requirements.

### **Current training programmes**

At the moment there is no uniform curriculum for the education and training of medical students in human rights, ethics and medical law

at medical schools in South Africa. In certain instances trainers are not adequately qualified to teach on issues of moral philosophy, moral theology or even the law. Human rights and ethics have not been regarded as an integral part of the practice of medicine. There is also no clear consensus as to which ethics should be taught, how it should be taught and who should teach it. South Africa is currently not keeping pace with the prominence and academic rigour given to bio-ethics as a global discipline. Ethical issues in the healthcare contexts frequently arise. Questions with regard to how a practitioner should behave in certain situations and how to deal with difficult decisions are some of the problem areas. The objectives of teaching bio-ethics would be to combine the development of medical practitioners' skills and knowledge of bio-ethics and health law with patient care as well as with research participant protection.

Human rights play a fundamental and integral part in the training of practitioners. Factors affecting human rights practice, such as knowledge, skills, attitudes, and ethical research practices are of importance. Knowledge of and competence and proficiency in the field of national and international standards to which the practitioner will be held accountable should be a requirement for qualification and also for registration. The neglect and failure of human rights and ethics in the medical profession has resulted in an ad-hoc nature of teaching, a lack of examinability of ethics, inconsistency of teaching and the failure to integrate human rights into curricula.

Medical law also plays an important role. There is legislative and judicial control over the practice of medicine. The doctor must be aware of the legal and ethical debates around issues like the doctor-patient relationship, the legal framework in which all these issues take place, and the role that the doctor plays in broader issues of bio-ethics.

The incorporation of medical law into the curricula will assist with issues such as: the contractual relationship between doctor and patient; confidentiality in the doctor-patient relationship; procedural matters in the practice of medicine; medical negligence; regulation of medicines; right to privacy; access to information; the ethical and legal basis for informed consent; standards of disclosure; legal issues in reproduction; legal issues in mental health; and the right to beginning and ending of life.

### Ethical principles in medicine and legislation

The five most important issues in medicine which play a major role in ethical health care, especially in the doctor-patient relationship, are the following:

- the way in which medical treatment and or services are rendered;
- the privacy of a patient;
- the confidentiality of patients' information;
- the patient's right to self-determination; and
- informed consent by the patient.

The past decade saw several changes in legislation regulating or influencing medical treatment and the provision of medical care to users. The following pieces of legislation are of importance in this regard:

- Constitution of the Republic of South Africa of 1996;
- National Health Act 61 of 2003;
- Mental Health Care Act 17 of 2002;
- Promotion of Access to Information Act 2 of 2000.

The influence of the different statutes on the said five ethical issues will be discussed below.

### Constitution of the Republic of South Africa of 1996

The Constitution of the Republic of South Africa of 1996 had a dramatic effect on medical law and the healthcare system of our country and will, in future play an even more important role.<sup>1</sup> The Bill of Rights, contains rights such as the right to equality, the right to life, the right to privacy, the right to confidentiality, the right to self-determination, the right to health care, the right to access to information and the right to just administrative action which all form part of health care and health services.

### National Health Act 61 of 2003

The National Health Act 61 of 2003 came into effect on the  $2^{nd}$  May 2005. This Act regulates health issues and will do even more so when all the sections have come into effect in future. Chapter 8 of the Act is not in force yet.

### Mental Health Care Act 17 of 2002

The Mental Health Care Act 17 of 2002 came into effect in 2003. The Act regulates all the issues regarding mental health care users. The Act especially provides for certain rights for mental health care users.

### Promotion of Access to Information Act 2 of 2000

The Constitution in section 32 stipulates that legislation must be promulgated to regulate access to information, which especially influences access to medical records. The Promotion of Access to Information Act 2 of 2000 was promulgated to this effect and provides for the procedures to be followed to gain access to information.

## Ethical principles' transformation to statutory requirements/ obligations

The discussion will now deal with the relevant issues that in the past were only ethical principles/considerations guiding medical

practitioners but that now have been transformed by legislation into statutory obligations/requirements that medical practitioners and healthcare providers should comply with. Non-compliance is a statutory offence.

### The principle to treat and cure

One could ask the question whether there is an obligation on a medical practitioner to cure?<sup>2</sup> The general principle is that a doctor is not legally liable if he or she neglects to give assistance to a sick or injured person where his or her presence could ward off death, for example where a practitioner does not give assistance at a scene of an accident. This general principle contradicted the Geneva Declaration of 1948 whereby the doctor solemnly declares:

I will treat human life with the highest esteem ... even if I am threatened I will not exercise my knowledge of medicine contradictory to the norms of humanity.

Strauss<sup>3</sup> is of the opinion that international codes of ethics have repeatedly underlined the duty of the doctor to respect and protect human life.

The next question to be asked is whether there is a so-called professional right to cure? Can a medical practitioner just treat a patient because he is a medical doctor?<sup>3</sup> The question as to the ground of justification for medical intervention is of great importance where it deals with interventions against the will of the patient or where the patient is unable to express his will. It has been submitted that, except for consent, state recognition of the healing motive, customary law or "professional competence" can be argued as grounds for justification of the intervention. These points of view are not supported because it grants the doctor a license to arbitrarily intervene against the will of the patient. South African law recognises consent and emergency as grounds for justification.<sup>3</sup>

Interference without the will of the patient is not necessarily unlawful, but interference against the will of the patient is unlawful.<sup>4</sup> The former may in certain circumstances be justified by way of *negotiorum gestio* (acting in the interest of another in his absence).<sup>5</sup> Consent as ground for justification is based on the maxim *volenti non fit iniuria* (to him who consents no injury can occur).<sup>5</sup>

Although from a medical point of view a medical intervention is usually to the benefit of the patient, an intervention against the will of the patient, from a juridical point of view, constitutes a violation of his right to self-determination and privacy and is thus a wrong or injury. The law therefore refers to "consent by the patient to prejudice".<sup>5</sup>

Medical practitioners all over the world, on completion of their studies, solemnly pledge that they will treat their patients in an ethically sound way and that they will respect the privacy and dignity of their patients.

Section 9 of the Constitution deals with equality and prohibits unfair discrimination. This principle is also applicable to health care and everybody should be treated equally in the provision of health care. The Promotion of Equality and Prevention of Unfair Discrimination Act 4 of 2000 gives effect to section 9 of the Bill of Rights. The Schedule to the Act contains a few examples of unfair practices in health care:

- subjecting persons to medical experimentation without their informed consent;
- unfairly denying or refusing any person access to health-care facilities or failing to make health-care facilities accessible;

- refusing to provide emergency medical treatment to persons or particular groups of persons; and
- refusing to provide reasonable health services to the elderly.

Furthermore, in terms of section 27 of the Constitution, everybody has the right to healthcare services<sup>1</sup> and section 28 protects the rights of children. It provides that every child has the right to basic health-care services. Children under the age of 6 years as well as pregnant women are currently receiving free health care.

The Constitution also provides in section 27 that no one may be refused emergency medical treatment.<sup>1</sup> This is further emphasised by the National Health Act which stipulates in section 5 that nobody may be refused emergency treatment. Emergency treatment is thus both a Constitutional right as well as a statutory requirement.

The National Health Act also stipulates in section 7 that health services may not be provided to a user without his informed consent. This stipulation thus clearly illustrates the transformation of an ethical principle into a statutory requirement.

### The principle of self-determination

A patient's consent to the performance of any form of medical treatment be it therapeutic, non-therapeutic or diagnostic, is currently generally accepted as a necessary prerequisite. Society places a high premium on the individual's right to physical integrity and to self-determination.<sup>2</sup> After the Nazi atrocities of World War II this right to self-determination is recognised worldwide.<sup>4</sup>

South Africa does not lag behind in this regard. As early as 1923 our courts confirmed this principle. In the case of *Stoffberg v Elliot* 1923 CPD 148 recognition was given to the protection of the individual's personality and free will, where the judge stated as follows: *In the eyes of the law every person has certain absolute rights which the law protects. They are not dependent on statute or on contract, but they are rights to be respected, and one of these rights is absolute security to the person ... Any bodily interference with or restraint of a man's person which is not justified in law, or excused in law or consented to, is a wrong ...* 

The World Medical Association's Declaration on the Rights of the Patient<sup>6</sup> includes the following rights which may be applicable here:

- right to medical care of good quality;
- right to freedom of choice;
- right to self-determination, especially with respect to:
  - the unconscious patient;
  - o the legally incompetent patient;
  - o procedures against the patient's will;
- right to information;
- right to confidentiality;
- right to health education;
- right to dignity;
- right to religious assistance.

See the World Medical Association's website for a more comprehensive layout of these rights.<sup>6</sup>

It is clear that a health care user has the right to receive or refuse treatment. Section 12 of the Constitution deals with freedom and security of the person. Section 12(2) provides that every person has the right to bodily and psychological integrity which includes the right:

- to make decisions concerning reproduction;
- to security in and control over their body; and
- not to be subjected to medical scientific experimentation without their informed consent.

Carstens and Pearmain<sup>1</sup> are of the view that although there is an express right of access to health services, including reproductive health care, a right to health, being broader than a right to medical treatment, must also protect and respect a person's physical and mental well-being which includes bodily and psychological integrity. They are further of the opinion that this right is a part of the larger right of freedom and security of the person.

Again the National Health Act also provides in section 7 that a person cannot be treated without his or her co-operation and consent. Both the Constitution and the National Health Act make this a statutory requirement to be complied with.

We must not forget that the common law also recognises the right to self-determination. Dada and McQuiod-Mason<sup>7</sup> are of the opinion that a patient has an absolute common law and constitutional right to his or her bodily integrity and security.

### The principles of privacy and confidentiality

It is incredible to think that one of the founders of medical ethics, namely Hippocrates who lived in 460-377 BC was one of the first ethicists to compile guidelines for doctors. Several authors are of the opinion that the so-called Hippocratic Oath is widely regarded as the basis of the constitution of the medical profession.<sup>8,9</sup> The Oath contains the following phrase:

Whatever, in connection with my professional practice, or not in connection with it, I may see or hear in the lives of men which ought not to be spoken abroad I will not divulge, as reckoning that all such be kept secret.

Although the Hippocratic Oath requires a medical practitioner to preserve confidentiality of patient information, the law may demand that the doctor breaches such confidence.<sup>7</sup>

The Declaration of Geneva of 1948<sup>10</sup> made by the World Medical Association involves the following phrase: *I will respect the secrets that are confided in me, even after the patient has died.* 

The International Code of Medical Ethics of 1949<sup>10</sup> contains the following statement:

A physician shall respect the rights and preferences of patients, colleagues and other health professionals. And furthermore:

A physician shall respect a patient's right to confidentiality.

The World Medical Association also states in the Declaration of Helsinki<sup>11</sup> that doctors must protect the patient's privacy when medical research is done.

The South African Medical Association to which the majority of South African doctors belong has its own Member's Credo<sup>12</sup> part of which reads as follows:

...to foster a good relationship with my patients based on mutual respect, communication and trust. And also: Respect the confidentiality of information entrusted to them, unless law or ethical duty prevents this.

The Health Professions Council of South Africa has established ethical rules which also contain certain stipulations regarding the relationship of trust between a doctor and patient. The Ethical Rules are contained in *Booklet 2 – Ethical and Professional Rules of the Health Professions Council of South Africa as promulgated in Government Gazette R717 of 2006.* Rule 13 of the Ethical Rules reads as follows:

- 13. Professional Confidentiality
- A practitioner shall divulge verbally or in writing information regarding a patient which he or she ought to divulge only –
  - (a) in terms of a statutory provision
  - (b) at the instruction of a court of law, or
  - (c) where justified in the public interest.
- (2) Any information other than the information referred to in subrule
  (1) shall be divulged by a practitioner only
  - (a) with the express consent of the patient;
  - (b) in the case of a minor under the age of 14 years, with the written consent of his or her parent or guardian, or;
  - (c) in the case of a deceased patient, with the written consent of his or her next-of-kin or the executor of such deceased patient's estate.

The various medical schools in South Africa each make use of their own modernised and adjusted versions of the Hippocratic Oath taken by students on completion of their studies. Graduates at the School for Medicine at the University of the Free State for example solemnly pledge that:

...all confidential information about my patient will be diligently kept.'

Our Constitution also protects the right to privacy in section 14. As a result thereof medical records and information of a patient are private and confidential. A healthcare worker is not allowed to give any information regarding a patient to a third person without his or his guardian's or his curator's consent.

On top of that the National Health Act stipulates in section 14 that all information of a user is confidential. The privacy of mental health care users is also protected by the Mental Health Care Act. Section 13 stipulates that all the information of a mental health user is confidential.

Carstens and Pearmain<sup>1</sup> are of the opinion that also in terms of sections 34 and 64 of the Promotion of Access to Information Act the unreasonable disclosure of personal information about a patient to a third party is prohibited.

There are thus four pieces of legislation which protect the privacy of patients.

Again we must not forget that the right to privacy is also protected by the common law.

### The principle of information

Section 32 of the Constitution provides that everyone has the right of access to:

- any information held by the state; and
- any information that is held by another person and that is required for the exercise or protection of any right.

Patients thus have the right of access to their own medical records

held by state hospitals, state clinics, private hospitals or private medical practitioners.

Section 32 of the Constitution provides that legislation must be promulgated to give recognition to this right. As stated before, this resulted in the enactment of The Promotion of Access to Information Act 2 of 2000.

The National Health Act provides in section 15 for access to health records. The Mental Health Care Act furthermore stipulates in section 17 that a mental health care user must be informed regarding his or her rights and this may include the right of access to medical records.

The Promotion of Access to Information Act came into operation as from the beginning of 2002. The Act gives effect to the constitutional right of access to any information held by the State and any information held by another person that is required for the exercise or protection of any rights. The constitutional right of access is, however, subject to justifiable limitations, including limitations aimed at the reasonable protection of privacy. The Act applies to records held by both public and private institutions, including medical records, regardless of when those records came into existence.

### The principle of consent

Informed consent is a prerequisite for any form of medical treatment, be it diagnostic or therapeutic.

Ethically, for valid consent, a patient must be informed about:

- The nature and consequences of the treatment.
- The risk associated with the intervention.
- The diagnosis.

These ethical requirements are now statutorily laid down in the National Health Act which stipulates in section 6(1) that the provider of health care must inform the user of:

- the user's health status;
- the general diagnostic procedures and treatment options available;
- the general associated advantages, risks, costs and consequences of the options; and
- the user's right to refuse healthcare services and an explanation of the implications, risks and obligations of such refusal.

Section 6(2) of the National Health Act further stipulates that the provider of healthcare services must inform a user in a language that he understands and in a way that takes his level of literacy into consideration regarding the aspects mentioned in section 6(1). Section 7 provides that health services may not be provided to a user without his informed consent.

In terms of section 8 of the National Health Act a user has the right to participate in the decisions. Section 8(1) stipulates that a user has the right to participate in any decision affecting his or her personal health and treatment. Section 8(2)(a) stipulates that if the informed consent required by section 7 is given by a person other than the user, such person must, if possible, consult the user before giving the required consent. Section 8(2)(b) provides that if a user is capable of understanding, he or she must be informed as contemplated in section 6 even if he or she lacks the legal capacity to give the informed consent required by section 7. If a user is unable to participate in a decision affecting his or her personal health and treatment, section

8(3) provides that 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.

The Mental Health Care Act also provides in section 9 for the giving of consent to care, treatment and rehabilitation services and admission to health establishments depending on the mental health status of the user.

It is thus clear from the above examples that there is a definite interrelationship between the ethical principles and legislative prescriptions. Ethical principles therefore cannot stand on their own anymore because of the statutory requirements/obligations.

### Conclusion

Medical law, medical ethics and human rights are so interwoven that in the practising of medicine today it forms an important part of the arsenal of every competent practitioner. Older practitioners practice medicine only according to ethical principles. The new generation of practitioners must also apply the legislative requirements. It is therefore of paramount importance that every practitioner is well-trained in both ethical principles of medicine as well as all the legislative requirements.  $\P$ 

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### MASTERS DEGREE IN CLINICAL PHARMACOLOGY

Since 1974 the Department of Pharmacology at the Faculty of Health Sciences, University of Pretoria, has been delivering a very necessary and highly sought after service in the medical field in that they provide a singular opportunity for doctors in all spheres of medicine to follow a formal course in Clinical Pharmacology. This course, which is unique in South Africa, leads to a master's degree in Clinical Pharmacology (M.Pharm.Med) after successful completion of the course. The aim of the course is to guide the study to the acquirement of a critical, analytical approach to Clinical Pharmacology in general, resulting in better therapeutic reasoning and decision-making.

During the three years of part time study all aspects of the field, i.e. pharmacokinetics, pharmacodynamics, toxicology and medical biostatistics are covered. This also includes topics such as evidence-based medicine, pharmaco-economics and the critical appraisal of literature. Elective modules such as Bio-ethics, Pharmaceutical medicine and Epidemiology have also been incorporated in the course. A student must also successfully complete an approved research project in his specific working environment in order to qualify. The popularity of this degree has grown over the years emphasising the importance of clinical pharmacology in modern medicine.

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### NOTE: Full registration with the HPCSA is a requirement.