



**THE ALLIED HEALTH PROFESSIONS COUNCIL OF  
SOUTH AFRICA**

**THE DOCTRINE OF INFORMED CONSENT IN SOUTH  
AFRICAN LAW**

**PRESENTED BY  
DR LOUIS MULLINDER, REGISTRAR  
2015**

# MEDICAL LAW

- ❑ Body of rules that relate directly to the care of health and -
  - ❑ is the concern of a complex group of professions dealing not only with patients and diseases, but
  - ❑ also with healthy people and public health

# MEDICAL LAW

- Body of rules relating to:
  - The **medical profession**
  - The relationship between -
    - **Doctor/patient/hospital**
    - **Medical profession and other health care workers**
  - The **doctor and health care legislation**

# STATUTES AFFECTING HEALTH CARE

- 1) National Health Act
- 2) Mental Health Care Act
- 3) Health Professions Act [HPCSA]
- 4) Allied Health Professions Act [AHPCSA]
- 5) Nursing Act
- 6) Pharmacy Act
- 7) Traditional Health Practitioners Act
- 8) Human Tissue Act
- 9) Choice on Termination of Pregnancy Act
- 10) Sterilisation Act
- 11) Births and Deaths Registration Act
- 12) Children's Act, the Older Persons Act
- 13) Medical Schemes Act

# STATUTES AFFECTING HEALTH CARE: OTHER

- 1) Boxing and Wrestling Act.
- 2) Inquests Act.
- 3) Medicines and Related Substances Act.
- 4) Criminal Procedure Act.
- 5) SA Research Council Act.
- 6) Prevention and Treatment of Drug Dependency Act.
- 7) Academic Health Centres Act.
- 8) Compensation for Occupational Injuries and Diseases Act.
- 9) Occupational Health and Safety Act.
- 10) National Road Traffic Act.
- 11) Institute for Drug-Free Sport Act.
- 12) Correctional Services Act.
- 13) Domestic Violence Act.
- 14) Promotion of Access to Information Act.
- 15) Promotion of Administrative Justice Act.
- 16) Promotion of Equality and Prevention of Unfair Discrimination Act.
- 17) Council for Medical Schemes Levies Act .....

# ETHICS AND BIOETHICS

- ❑ **Ethics** – a division of ‘moral philosophy’ and is concerned with the moral choices people make and includes the study of right and wrong actions – thus the study of morality.
- ❑ **Bioethics** – reflection on a wide array of moral issues concerning all living things which arise from the application of biomedical science to human affairs and the whole biosphere - **the practice of ethics in health care falls under this umbrella.**

# ETHICS AND BIOETHICS

- ❑ **Various bioethical models:**
  - Utilitarianism
  - Deontological absolutism
  - Universalism
  - Practical ethics
  - Hermeneutics
  - Casuistry
  - Consequentialism
  - Kantian deontology
  - Virtue ethics
  - Social contract theory
  - Principlism

# DUTY AND OBLIGATION

- ❑ A duty is an obligation to act or withhold action and may be ethical, legal, or both.
- ❑ Duties are inherent to the personal, social, professional and political spheres of our lives.

# PRINCIPLISM

- ☐ Respect for autonomy

(no right to impose treatment on a patient, including informed consent)

- ☐ Beneficence

(do good for patients)

- ☐ Non-maleficence

(do not cause harm – *primum non nocere*)

- ☐ Justice

(fair treatment, equitable and reasonable)

# PRINCIPLISM: AUTONOMY

- Tell the truth
- Respect the privacy of others
- Protect confidential information
- Obtain consent for interventions
- Help others make important decisions

# PRINCIPLISM: BENEFICENCE

- Active promoting of goodness, kindness and charity
- Protect and defend the rights of others
- Prevent harm from occurring to others
- Remove conditions that will cause harm to others
- Help persons with disabilities
- Rescue persons in danger
- Translates into clinical competence, risk-benefit analysis and avoidance of paternalism
- Patient autonomy ousts medical paternalism [Hay v B 2003 (Moodley 60 FF0

# PRINCIPLISM: NON-MALEFICENCE

- First do no harm: Primum non nocere
- Do not kill
- Do not cause pain or suffering to others
- Do not incapacitate others
- Do not cause offence to others
- Do not deprive others of the goods of life

# PRINCIPLISM: JUSTICE

- Refers to fairness - thus fair treatment of patients
- Translates into:
  - Respect for morally accepted laws: legal justice
  - Respect for human rights: rights-based justice
  - Fair distribution of limited resources: distributive-justice
- Constitution: Section 9 [Right to Equality], Section 11 [Right to Life], Section 27 [Right to Access to Healthcare], also Promotion of Equality and Prevention of Unfair Discrimination Act 4 of 2000

# INFORMED CONSENT

- Ethical and legal considerations of a valid consent process are:
  - **Disclosure**
  - **Understanding**
  - **Capacity**
  - **Voluntariness**

Bioethics, Human Rights and Health Law, Dhai A and McQuoid-Mason D, Juta 2011

# INFORMED CONSENT: CAPACITY

- Capacity is a pre-requisite for informed consent
- Competence: the functional ability to meet demands of any specific decision-making situation weighed in light of its potential consequences

# DUTY TO THE PATIENT

## **INFORMED CONSENT**

- Section 12(2)(b) of the Constitution of the RSA
- **Section 12 Freedom and Security of the Person**

.....

(2) Everyone has the right to bodily and psychological integrity, which includes the right –

- (a) to make decisions concerning reproduction;
- (b) to security in and control over their body; and
- (c) not to be subjected to medical or scientific experiments without their informed consent

# DUTY TO THE PATIENT

## **INFORMED CONSENT**

- Also from Section 10 of the Constitution: Right to Dignity  
and
- Section 14 of the Constitution: Right to Privacy
- All rights in the Bill of Rights to be read against the context of Section 36 [Limitation of Rights] and Section 39 [Interpretation of the Bill of Rights]

# THE NATURE OF THE CONSTITUTION

- In *S v Makwanyane* 1995 (3) SA 391 (CC) paragraph 62 Mahomed CJ referred to the new constitutional dispensation: "the South African constitution is different: it retains from the past only what is defensible and represents a decisive break from, and a ringing rejection of, that part of the past which is disgracefully racist, authoritarian, insular, and repressive and vigorous identification of and commitment to a democratic, universalistic, caring and aspirationally egalitarian ethos, expressly articulated in the Constitution"

# DUTY TO THE PATIENT

## **INFORMED CONSENT**

- The National Health Act stipulates that health services **may not be provided to a patient without his/her informed consent.**
- Informed consent to the treatment must be **obtained before a treatment commences** and **the principle of informed consent during the treatment must also be applied.**
- The patient must be **informed in a language that is reasonably understandable** to the patient of:
  - the description and of the treatment and procedures;
  - the number and frequency of treatments;
  - the possible reactions after the treatment and
  - the fee which will be charged for the treatment.

# **NATIONAL HEALTH ACT: INFORMED CONSENT**

## **ACT 61 OF 2003**

### **Section 5**

#### **Emergency treatment**

5. A healthcare provider, health worker or health establishment may not refuse a person emergency medical treatment.

# NATIONAL HEALTH ACT: INFORMED CONSENT

## Section 6

### User to have full knowledge

6. (1) Every healthcare provider must inform a user of-

(a) the user's health status except in circumstances when there is substantial evidence that the disclosure of the user's health status would be contrary to the best interests of the user;

(b) the range of diagnostic procedures and treatment options generally available to the user;

(c) the benefits, risks, costs and consequences generally associated with each option;  
and

(d) the user's right to refuse health services and explain the implications, risks, obligations of such refusal.

(2) The healthcare provider concerned must, where possible, inform the user as contemplated in subsection (1) in a language that the user understands and in a manner which takes into account the user's level of literacy.

# NATIONAL HEALTH ACT: INFORMED CONSENT

## Section 7

### Consent of user

7. (1) Subject to section 8, the health service may not be provided to a user without the user's informed consent, unless-

(a) the user is unable to give informed consent and such consent is given by a person-

(i) mandated by the user in writing to grant consent on his or her behalf; or

(ii) authorised to give such consent in terms of any law or court order;

(b) the user is unable to give informed consent and no person is mandated or authorised to give such consent, and the consent is given by the spouse or partner of the user or, in absence of such spouse or partner, a parent, grandparent an adult child or a brother or sister of the user, in the specific order as listed;

# NATIONAL HEALTH ACT: INFORMED CONSENT

## Section 7 cont

(c) the provision of health service without informed consent is authorised in terms of any law or court order;

(d) failure to treat the user, or a group of people which includes the user, will result in a serious risk to public health; or

(e) any delay in the provision of the health service to the user might result in his or her death or irreversible damage to his or her health and the user has not expressly, impliedly or by conduct refused that service.

# NATIONAL HEALTH ACT: INFORMED CONSENT

## Section 7 cont

(2) A health care provider must take all reasonable steps to obtain the user's informed consent.

(3) for the purposes of this section "informed consent" means consent for the provision of a specified health service given by a person with legal capacity to do so and who has been informed as contemplated in section 6.

# NATIONAL HEALTH ACT: INFORMED CONSENT

## Section 8

### Participation in decisions

8. (1) A user has the right to participate in any decision affecting his or her personal health and treatment.

(2)(a) If the informed consent required by section 7 is given by a person other than the user, such person must, if possible, consult the user before giving the required consent.

(b) A user who is capable of understanding must be informed as contemplated in section 6 even if he or she lacks the legal capacity to give informed consent required by section 7.

(3) If a user is unable to participate in a decision affecting his or her personal health and treatment, he or she must be informed as contemplated in section 6 after the provision of the health service in question unless the disclosure of such information would be contrary to the user's best interest.

# NATIONAL HEALTH ACT: INFORMED CONSENT

## Section 9

### Health service without consent

9. (1) Subject to any applicable law, where a user is admitted to a health establishment without his or her consent, the health establishment must notify the head of the provincial department in the province in which that health establishment is situated within 48 hours after the user was admitted of the user's admission and must submit such other information as may be prescribed.

(2) If the 48-hour-period contemplated in subsection (1) expires on a Saturday, Sunday or public holiday, the health establishment must notify the head of the provincial department of the user's admission and must submit the other information contemplated in subsection (1) at any time before noon of the next day that is not a Saturday, Sunday or public holiday.

(3) Subsection (1) does not apply the user consents to the provision of any health service in that health establishment within 24 hours of admission.

# CASTELL V DE GREEFF

[1994 (4) SA 408 (C)]: Staphylococcus infection in wounds after mastectomy; misalignment of areolae

Impact in South African medical law:

- Importing and accepting informed consent in South African medical law (as per USA, European continent and Australia [contra the United Kingdom: real consent])
- Ousting medical paternalism in favour of patient autonomy;
- Treating the lack of informed consent as an issue of **wrongfulness** (in the context of assault) and not **negligence**
- Establishing the yardstick of the "reasonable patient" as the test for informed consent and not that of the "reasonable doctor"

# DUTY TO THE PATIENT

## INFORMED CONSENT: SUMMARY

- Consent is a communication process
- Competent adult patients may refuse to consent to treatment or may withdraw their consent once given
- To be valid, consent must be obtained from a competent informed person free from undue duress
- All adults are assumed to be competent to consent to treatment unless there is reason to believe the decisional capacity has been impaired decisional capacity is not an "all or nothing" concept-a person's capacity to make a decision depends on the nature of the decision
- Consent can be given by specified surrogates if patients decisional capacity is impaired

# DUTY TO THE PATIENT

## INFORMED CONSENT: SUMMARY

- If they have the maturity to do so, children aged 12 or above may consent to medical treatment on their own behalf and to surgical treatment with the assistance/assent of a parent or guardian
- For consent to be valid, the person giving the consent must be given all relevant information, including the material risks and consequences of each option, including no treatment
- HIV testing without the patient's consent is illegal, except in circumscribed situations authorised by law
- When a patient loses decisional capacity, an advance directive made when he or she was still competent must be honoured, unless there are good reasons for believing that the patient has changed his or her mind

# PROFESSIONAL CONFIDENTIALITY

## HEALTH PROFESSIONS COUNCIL OF SOUTH AFRICA: RULE 13

### 13. Professional Confidentiality -

(1) A practitioner shall divulge verbally (sic) 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 information referred to in sub-rule (1) shall be divulged by a practitioner only-

(a) with the express consent of the patient.

# PROFESSIONAL CONFIDENTIALITY

## HEALTH PROFESSIONS COUNCIL OF SOUTH AFRICA: RULE 13 CONT

(b) In the case of a minor under the age of 12 years, with 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 executor of such deceased patients estate

# DIAGNOSIS DISCLOSURE

- Is diagnosis disclosure obligatory?
- Moot point in law, but is indicated where:
  - It may affect patients decision to submit intervention or not;
  - It is an express or implied term of the contract between the doctor and the patient;
  - Or it is essential for therapy

# LEGAL BASIS OF DOCTOR AND PATIENT RELATIONSHIP

THE LAW OF OBLIGATIONS: EITHER THE LAW OF CONTRACT AND/OR THE LAW OF DELICT

- Relationship essentially a private law matter
- In the ordinary course of events the relationship is a contractual one, but the breach of duty of care and negligence may underlie both - the same act or omission by the doctor/hospital may result in liability for both
- If there is no contract between the parties the relationship is then covered by the Law of Delict

# LEGAL BASIS OF DOCTOR AND PATIENT RELATIONSHIP

## THE LAW OF CONTRACT

### Nature of the agreement

- Conclusion of the agreement required
- No legal formalities required
- Contract may be express or tacit
- Written or oral
- Normally into tacit agreement when patient consults and Dr attends
- Agreement marks its commencement
- Written contract with informed consent should however be a priority - always indicated in certain cases

# LEGAL BASIS OF DOCTOR AND PATIENT RELATIONSHIP

## TERMS OF AGREEMENT

- The doctor undertakes to examine/diagnose/treat with professional skills/care/judgement ordinarily expected
- In return, the patient undertakes the payment of the profession the which may also be payable by a 3rd party
- Examination of the patient does not obliged the doctor to personally diagnose or treat
- A duty to refer exists if outside the sphere of specialisation
- A warranty of cure/guarantee of success should not be included in the agreement

# **LEGAL BASIS OF DOCTOR AND PATIENT RELATIONSHIP**

## **BREACH OF CONTRACT: LEGAL CONSEQUENCES**

**Non-performance/departure from express/implied terms may result that:**

- **Dr will be held liable for the breach of contract resulting in liability for patrimonial loss, but not for non-pecuniary damages or being unable to recover a fee for services rendered**
- **Patient will be liable for the breach of contract for failure to pay the professional fees or for failure to keep an appointment**

# LEGAL BASIS OF DOCTOR AND PATIENT RELATIONSHIP

## TERMINATION OF CONTRACT

- Once the doctor completes the treatment/operations/fulfils obligations, the contract comes to an end
- Series of separate/continuous treatments?
- Mutual agreement regarding the impossibility of performance will also terminate the agreement

# LEGAL BASIS OF DOCTOR AND PATIENT RELATIONSHIP

## FREEDOM OF CONTRACT

- Both doctors and patients are free agents
- Doctors in private practice have the right to refuse/accept patients and the same applies to patients-the choice to undergo or/refuse medical treatment
- Doctors have no professional right or legal duty to intervene

# LEGAL BASIS OF DOCTOR AND PATIENT RELATIONSHIP

## THE LAW OF DELICT

- Similar to the Law of Contract - the Law of Delict imposes the duty of reasonable care
- Failure to do so, causing damage, will result in liability in negligence
- The intentional violation of privacy or physical integrity is equivalent to assault in law
- Both patrimonial and non-pecuniary damages are recoverable

# LEGAL BASIS OF DOCTOR AND PATIENT RELATIONSHIP

## CRIMINAL LAW: LIABILITY FOR OMISSIONS

“The liability for omissions is more restricted than the liability for commissions due to the fact that the courts are reluctant to make individuals within society responsible for the welfare of others to whom they have no relationship.

.....

In the context of health care, the Constitution has to some extent introduced an exception to this rule in the form of the right in Section 27 (3) not to be refused emergency medical treatment.” (Carstens, 2007, pp 507-508)

# LEGAL BASIS OF DOCTOR AND PATIENT RELATIONSHIP

## CRIMINAL LAW: LIABILITY FOR OMISSIONS

Liability for omissions is a failure to act positively when there is a legal duty to do so

- In the following instances:
  - Control over a potentially dangerous situation or object
  - Statutory duty
  - Contractual duty
  - Emergency situations
  - Duty to complete treatment and
  - Boni mores/constitution

# LEGAL BASIS OF DOCTOR AND PATIENT RELATIONSHIP

## STATUTORY OBLIGATIONS

- Duty of the medical practitioner to report cases of dangerous mental illness
- Failure to report child abuse - Section 54 the Sexual Offences Act 32 of 2007 and Section 110 of the Children's Act 38 of 2005
- Notifiable diseases

# GROUNDS FOR JUSTIFICATION

- Consent
- Therapeutic privilege
- Emergencies
- Statutory authority
- Court authorisation/court order
- Boni mores
- Not a closed menu

# GROUNDS FOR JUSTIFICATION: THERAPEUTIC PRIVILEGE

- “(i) full disclosure could be life-threatening to the patient or could detrimentally affect his physical or psychological welfare;
- (ii) full disclosure might influence the patient’s decision-making to such a degree that it may prevent him from coming to a rational decision;
- (iii) full disclosure would possibly cause such anxiety and distress that it may jeopardise the final outcome of the proposed medical intervention;
- (iv) the patient is moribund and full disclosure would be insensitive or inhuman;
- (v) disclosure could seriously prejudice third parties; or
- (vi) the risks of full disclosure equal or exceed the dangers of the proposed intervention or treatment.”

Strauss SA, Van Osten FFW. The so-called therapeutic privilege or contra-indication: its nature and role in non-disclosure cases. *Medicine and Law* 1991; 11: 32.

# GROUNDS FOR JUSTIFICATION: THERAPEUTIC PRIVILEGE

To comply with the ethical guidelines with regard to clinical note keeping and to record the fact that the doctor applied therapeutic privilege, the following should be contemporaneously and carefully documented in the clinical notes:

- (i) details of the patient's history, psychological profile and clinical assessment;
- (ii) the nature of the diagnosis or disease, its course and prognosis;
- (iii) the material risks and/or complications associated with the treatment envisaged and the risks that will remain undisclosed;
- (iv) the extent and reasons for the nondisclosure; and
- (v) the nature of the harm and the detrimental effect that the medical practitioner recognised and sought to avoid.

[Van den Heever P. Pleading the defence of therapeutic privilege. SAMJ; 2005; 95:6]

# REFERENCES

- Legislation as cited
- Bioethics, Human Rights and Health Law, Dhali A and McQuoid-Mason D, Juta 2011
- Foundational Principles of South African Law, Carstens P and Permain D, LexisNexis 2007
- Strauss SA, Van Osten FFW. The so-called therapeutic privilege or contra-indication: its nature and role in non-disclosure cases. *Medicine and Law* 1991; **11**: 32.
- M Phil (Medical Law and Ethics) Lecture Notes, Carstens P, University of Pretoria 2015
- Van den Heever P. Pleading the defence of therapeutic privilege. *SAMJ*; 2005; **95**:6



**KEEP CALM  
AND  
DO IT THE  
REGISTRAR'S WAY**

THANK YOU