



**HEALTH CARE NEEDS
ASSESSMENT EXTERNAL
FACTORS: Legal Framework
in South Africa**

**Professor Marylyn Christianson
School of Law, Wits University, Johannesburg
December 2009
Trolleholm, Sweden**

A FEW INTERNATIONAL CONVENTIONS & DIRECTIVES

- **Convention on Human Rights and Biomedicine of the Council of Europe 1997**
 - **Article 11: Prohibition of any form of discrimination on the ground of genetic heritage**
 - **Article 12: Predictive genetic testing ONLY for health purposes and subject to appropriate genetic counselling**
- **Data Protection Directive in the EU**
- **Fundamental rights to confidentiality and Privacy**

THE EFFECT OF THE CONVENTIONS AND DIRECTIVES

- This resulted in an acknowledgment that there were basic human rights of equality, dignity and privacy for patients with genetic conditions
- Everyone was entitled to basic health care
- Predictive testing and the laboratories that do the tests should be regulated or at least have guidelines in place to protect the patients and the health care professionals

What about Developing Countries?

- **If a Health Care Needs Assessment is to be carried out in Developing countries it will also be necessary to conduct an audit of what legislation is in place to protect patient rights in the following circumstances:**
 - **The right to have access to general health care including access to genetic testing**
 - **The right to confidentiality and privacy**
 - **The right to have data protection including protection against discrimination in all areas including insurance and employment**
 - **The right to have protection of information as well as access to information**

How does South African legislation fit in with international norms?

South African Laws

- The Constitution
- National Legislation
- Regulations
- Medical Research Guidelines
- Policy documents

OVERVIEW OF THE LEGAL FRAMEWORK SOUTH AFRICA

- **The South African Constitution 1996**
- **The National Health Act 2003**
- **The Protection of Personal Information Bill 2008**
- **The Protection of Access to Information Act (PAIA) 2000**
- **The Termination of Pregnancy Act 1996**

The Constitution of South Africa 1996: Fundamental Rights

- **Sec 9: The right to Equality**
 - 'Everyone is equal before the law and has the right to equal protection and benefit of the law'
- **Sec 10: The right to Dignity**
 - 'Everyone has inherent dignity and the right to have their dignity respected'
- **Sec 11: The right to Life**
 - 'Everyone has the right to life'

The Constitution of South Africa: Socio-economic rights in Sec 27

- **Sec 27(1): Health Care and Social Security rights**
 - Everyone has the right to access to health care services, including reproductive health care
 - sufficient food and water and
 - social security including if they are unable to support themselves and their dependants, appropriate social assistance
- **Sec 27(2): The State must take reasonable legislative and other measures, within its available resources, to achieve the progressive realisation of each of these rights**

The Constitution of South Africa: The right not to be refused emergency medical treatment

- **Sec 27(3): No one may be refused emergency medical treatment**
 - In the Constitutional Court case of *Soobramoney v Minister of Health (KZN)* 1998 (1) SA 765 (CC) it was held that emergency medical treatment refers to treatment that is necessary because of 'a sudden catastrophe which calls for immediate medical attention'.
 - A person (such as Mr Soobramoney) suffering from a treatable but incurable condition such as renal failure does not fall within the protection of section 27(3) but rather within section 27(2) which requires the State to take all reasonable measures to ensure the progressive realisation of access to health care

The Constitution of South Africa: The right not to be refused emergency medical treatment

- **Constitutional Court can rule on socio-economic rights such as the right to have access to health care:**
 - **In the Constitutional Court case of *Grootboom v Government of SA and the Premier of the Province of the Western Cape* (CC) it was held that the right of everyone to have access to adequate housing was a justiciable right and the Constitutional Court ordered the Provincial Government (with others) to provide adequate housing for Mrs Irene Grootboom**

Legislative measures to realise the section 27 rights

The Constitution further provides in Section 27 that the State must pass legislation and take other reasonable measures within its available resources to achieve the progressive realisation of each of the socio-economic rights to health care and social security

THE LEGAL FRAMEWORK IN SA:

The National Health Act 2003

- **The National Health Act of 2003 (NHA) is 'arguably the most important Act giving effect to the right to everyone to have access to health care services as guaranteed by section 27 of the Constitution'**
- **Based on the original ANC Health Plan of 1994 and the White paper on Health Transformation in 1997 the NHA includes the decentralisation of the health care services through a district health system, the need for good human resources planning and development and increasing access to health care services for everyone**
- **The NHA gets its authority and limitations from the Constitution but it cannot alter constitutional promise of a right to have access to health care services**

THE SOUTH AFRICAN NHA: Getting access to health care

- **Free Health Care Services (Section 4)**
 - **Pregnant and lactating women**
 - **Children below six years of age who do not belong to a medical aid**
 - **All persons who do not belong to a Medical Aid are entitled to free primary health care services**
 - **Pregnant women are entitled to termination of pregnancy in terms of the Choice of Termination of Pregnancy Act of 1996**
- **Emergency Treatment**
- **Consent to Medical Treatment**

THE SOUTH AFRICAN NHA: Emergency Treatment in Section 5

■ **Emergency Treatment**

- **A health care provider, health care worker or health establishment may not refuse a person emergency medical treatment**
- **This includes public and private facilities**
- **BUT no further regulations have been implemented for this section and some private hospitals insist on payment for treatment**
- **The definition of what is an emergency is also not entirely clear**

SOUTH AFRICAN National Health Act: Access to information (sec 6)

■ User to have full knowledge

- A health care provider must inform a user of the following:**
 - Health status – except when it is against the best interests of the user**
 - The range of diagnostic procedures and treatment options**
 - The benefits, risks, costs and consequences associated with each option**
 - The user's right to refuse health services**
- The patient should be informed in a language she understands - taking literacy level into account**

South African National Health Act: Informed consent (sec 7)

■ Consent

- A health service may not be provided without **informed consent** UNLESS
 - The user is unable to give consent
 - Another is mandated by the user or by any law to give consent for the user
 - Failure to treat will result in serious risk to public health
- **All reasonable steps** should be taken to obtain informed consent
- **'Informed consent' means** consent given by a person with legal capacity and who has been

South African National Health Act: Participation in decision making (sec 8) and other relevant provisions

- A user has the right to **participate** in any decision affecting his or her personal health and treatment
- Provision is made in section 9 for health services **without consent** in limited circumstances
- A user must be informed if a **health service is for experimental of research purposes**

The National Health Act: Right to Information and confidentiality (Secs 12-14)

- **All National and Provincial Departments of Health must disseminate information on all health services and procedures for accessing services**
- **All information concerning a user and his or her health status must remain confidential**
- **No information may be disclosed without consent**
UNLESS:
 - **The user consents in writing**
 - **A court order requires disclosure**
 - **Non-disclosure will result in a serious threat to public health**

The National Health Act: Right to access to information (Sections 15-17)

- Personal information may only be disclosed as is necessary in the ordinary course and scope of the duties of a health care worker where it is in the best interests of the user
- **The Promotion of Access to Information Act (PAIA) 2000** should be read with these sections
- Unauthorised access to health records should be prevented and careful checks and balances should be in place to ensure this
- **The Protection of Information Bill** is currently a work in progress in South Africa

CARE of people with a Birth Defect: Other relevant legislation

- **The Health Professions Act 1974**
- **The Nursing Act 2005**
- **Medical Schemes Act 1998** covers medical insurance for those who can afford to pay the premiums for private health care
- **The Medicines and Related Substances Act 1965**

A National Health Insurance System?

- **Currently there is a commission looking into the possibility of a new National Health Insurance system for all**
- **In South Africa we have both a public and a private health care system**
- **The NHI scheme if introduced will cover everyone but allow those who can afford it to top up with private medical insurance**
- **The current proposals are controversial and are still a work in progress**

PREVENTION: The Choice of Termination of Pregnancy Act 1996

- **This Act was introduced soon after our new democracy in 1994**
- **The Act is liberal and provides the conditions and procedures to be followed for a woman to obtain a termination of pregnancy:**
 - **Upon request during the first 12 weeks**
 - **From 13-20 weeks if the medical practitioner in consultation with the pregnant woman is of the opinion that:**
 - **there exists a substantial risk that the fetus would suffer from a severe physical or mental abnormality**
 - **After the 20th week if continued pregnancy would result in a severe malformation of the fetus**

PREVENTION: Control of the use of blood products, tissue and gametes in humans (The National Health Act)

- **Chapter 8 of the NHA deals with the control of the use of gametes and zygotes in humans and prevents the production of reproductive cloning of human beings**
- **A person may not in terms of this chapter manipulate any genetic material including genetic material of human gametes, zygotes or embryos**
- **The Minister may permit, on written application, research on stem cells and zygotes that are not more than 14 days old**
- **Some regulations re Ch 8 have been published for comment but most sections of this chapter have not yet been promulgated**

GUIDELINES AND POLICIES

- **Policy guidelines for the Management and Prevention of Genetic Disorders and Prevention of Genetic Disorders, Birth Defects and Disabilities**
- **Medical Research Council Guidelines:**
 - **For ethical research**
 - **Regarding confidentiality and privacy**
 - **Testing for fetal sex selection**

WHAT THEN IS NEEDED FOR DEVELOPING COUNTRIES?

- **The Protection of basic human rights to equality, dignity and the right to life**
- **The right to have equitable access to health care, emergency treatment and social security benefits**
- **The right to data protection of personal information**
- **The right to have access to information**
- **The right to privacy of information**
- **The freedom of choice regarding prevention of having a baby born with a birth defect-this goes hand in hand with autonomy for the person making the decision and the right to religious and cultural freedom**
- **The purpose of Human Genetic Services is to 'help people with a genetic disadvantage to live and reproduce as normally and responsibly as possible' (the WHO 1985)**