



Electronic Health Records: Ethico-legal issues

Selaelo Mametja
selaelom@samedical.org





Ethical Principles

- **Autonomy**: Rights of privacy. Requirements to keep information confidential, provisions of disclosure of information, Consent and valid consent processes.
- **Benefits**: Electronic Health Records must clearly benefit the patients. This benefits must BE clearly outlined, tangible, measurable and there must be accountability.
- **Non-maleficence**: First do no harm: Unauthorised access, security breaches. . Derailment from clinical functions. Disclosures not in best interest of patients, lack of Quality improvement strategies, erosion of patient doctor relationship
- **Justice**: Unfairness, Digital divide, Social Sorting, Discrimination, stigmatisation, Ownership of data, secondary analysis of data to inform business intelligence, sales of data.





Confidentiality



**IF ONLY LIBERTY HAD
THIS...**



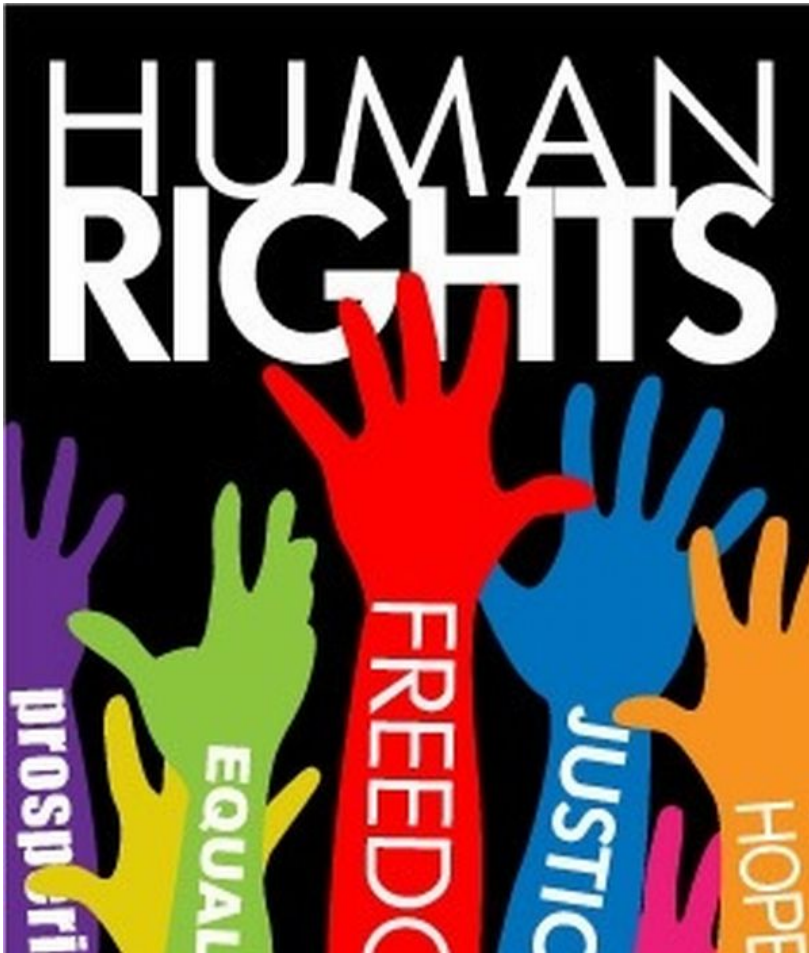


OF RULE LAW





Constitution of SA



- S (10): Everyone has inherent dignity and the right to have dignity respected and protected
- S (14): Everyone has the right to privacy
- S (27): recognises that access to health care is itself a basic human right





National Health Act

- S (13) obliges for health establishment to keep records in accordance with National Archives Act 43 of 1996 and Promotion of Access to Information Act 2 of 2000
- S (14) makes provision for confidentiality and conditions for disclosure.

(Informed) Consent has been provided by the user

There is a court order

Threat to public health





NATIONAL HEALTH ACT

- S (15) Disclosure of information only *in the interest of the user*. Allows for sharing of the information between health care workers and Health establishment.
- S (16) makes provision for access to health records for health care workers for treatment, research and training.
- S (17) makes provision for the protection of health records and places the onus on the person responsible for the health establishment (i.e. Medical Managers, specialists and GPs) to prevent unauthorised access to records and storage of such. The section also outlines offences related to unauthorised access, damage and amendments of health records





Promotion of Access to Information Act, Act 2 of 2000

- S9 provides for the constitutional right of access to information held by the state, or by another person, which is required to exercise or protect any rights. This provision is subject to justifiable limitations, including, but not limited to, reasonable protection of privacy and commercial confidentiality.
- S34 and S64) makes provision for the mandatory protection of personal privacy, mental- or physical health, or well-being of a third party unless that third party has consented to the disclosure.





POPI Act

Condition 1: Accountability

The responsible party must ensure that the conditions set out in this Chapter and all measures that give effect to the conditions are complied with

Who is the responsible party?

Accountability is that the responsible party remains responsible for the processing of information regardless of it having passed that personal information to a third party





Condition 2: Condition of Minimality

Processing Limitations:

Personal information may only be processed if, given the purpose for which it is processed, it is adequate, relevant and not excessive.

Therefore Information collected primarily for diagnosis and treatment must be used exactly for that.





POPIA

- Consent is defined as any **voluntary**, specific and **informed expression of will** in terms of which permission is given for the processing of personal information
- **Ethical Rules for consent**
 - Voluntary,
 - Capacity to give consent
 - Sufficient disclosure of information (informed)

S11 (2) (a) The responsible party bears the burden of proof for the data subject's or competent person's consent as referred to in subsection (1) (a)





Consent in Minors

Consent vs. ASSENT

Protection of access vs. disclosures

Minors are not different from adults

No clear guidelines for information sharing

Rules differ based on circumstances





Condition 4

Further processing of personal information must be in accordance or compatible with the purpose for which it was collected

Clinical Information used for diagnosis and treatment should not be used for any purpose other than for diagnosis and treatment.

For purposes of payment ICD10 codes and treatment codes must be provided





- S9 Personal information must be processed— a) lawfully; and b) in a reasonable manner that does **not infringe the privacy** of the data subject
- S10: Personal information may only be processed if, **given the purpose for which it is processed, it is adequate, relevant and not excessive**
 - **Inputs, Process and outcome indicators vs. entire clinical information**





Condition 6 : openness outlines requirements

- a) the information being collected and where the information is not collected from the data subject, the source from which it is
- b) the purpose for which the information is being collected
- c) the consequences of failure to provide the information
- d) existence of the right to object to the processing of personal information





HPCSA rules: Confidentiality

- Patients 'Rights to expect practitioners to keep their information confidential
- Doctors have ethical obligations to keep patient's information confidential
- Disclosure of information: Informed consent, de-identifying the data, keep disclosure minimum
- For claiming purposes: ICD code and treatment codes.
- Capacity to give consent: it is the doctors responsibility to assess capacity to give consent:





Choice of termination of Pregnancy ACT

- *According to Section 7 (5) of the Choice of Termination of Pregnancy Act the identity of a woman who has requested or obtained a termination of pregnancy shall remain, confidential at all times unless she herself chooses to disclose that information.*





Points for discussion

- POPIA: responsible party vs. Operator
- Principles of protection of medical information

