

HIV Testing Services (HTS) – a bioethical perspective

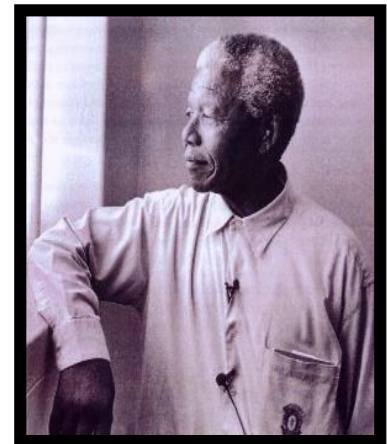
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Introduction

- “...HIV is not just a virus. It is also a disease of society and human relationships. It brings out both the best and the worst in how people treat each other. Tragically up to now, it has been more of the latter than the former.
- HIV has become an epidemic of stigma, unfair discrimination and even extreme violence against people known or suspected to have HIV.
- Our history is becoming full of untold stories of people who have had to face the cruelty of others simply because of the fact that they live with the virus that is now treatable and manageable.”

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Current Status

- South Africa has a generalised and maturing HIV epidemic,
- highest number of people (6.4 million) living with HIV in the world.
- The prevalence of HIV in South Africa remains high. This can be attributed to the rapid scale-up and success of the antiretroviral treatment (ART) programme.
- It is estimated that approximately three million people are on ART, making it the largest programme in the world.
- NATIONAL HIV TESTING SERVICES: POLICY 2016 accessed at <http://www.hst.org.za/sites/default/files/HTS%20Policy%2028%20July%20final%20copy.pdf>

- Awareness of HIV status is the first step in accessing care, and has been strongly advocated not only as a potential prevention tool but also as a way to normalise and destigmatise HIV
- De Cock KM, Bunnell R, Mermin J. Unfinished business--expanding HIV testing in developing countries. N Engl J Med. 2006;354(5):440–2. [[PubMed](#)]

HIV 'Test and Treat policy- 1st Sept 2016

- New policy in line with WHO guidelines
- Urgent commencement of treatment for people who are HIV +ve – regardless of CD 4 count- is extremely beneficial

- Those that are currently eligible to be initiated at CD4 count less than 500 can now be treated **regardless of their CD4 count.**
- Based on research evidence, NDOH has already removed CD4 as an eligibility criterion for HIV +ve pregnant women, children under 5years of age as well as HIV and TB co-infected patients over the past few years.
- This new policy extends this to all PLWH

Problem identification:

- New policy will result in more HIV +ve people accessing ART services, which may lead to congestion and increased waiting times at health facilities.
- “In order to decrease the burden on both patients and health facilities, the Dept. has initiated a process of decanting stable patients, those that do not need to see a nurse or doctor more than once a year, into support groups and into the chronic medicine dispensing and distribution system closer to their homes.”

MEC Dhlomo- Sept 2016

Rationale for 'Test and Treat'

- Unless the incidence of new HIV infections can be reduced, there will be a continuous increase in the number of HIV-positive individuals who will require ART in future.
- Achieving high coverage of ART will therefore become increasingly challenging in the absence of substantial reductions in HIV incidence.
- Given the limited array of proven prevention tools, universal testing and treatment (UTT) has been proposed as a potential new HIV prevention strategy that may be highly effective in high prevalence settings
- Mathematical modelling has shown that UTT could lead to steep reductions in HIV incidence and might potentially eliminate HIV as a public health problem over a period of 15-20 years, as well as reducing HIV-related morbidity and mortality

Hayes, S. D., Gaddist, B. W., & Rawls, A. W. (2011). Universal access and human rights: for women and girls, too. *GPSolo*, 28(2), 32-33.

- A trial that was recently halted early, due to unequivocal evidence of a protective effect of early ART, currently provides the most persuasive data to support universal treatment to prevent transmission - *HIV Prevention Trials Network (HPTN) 052*-
- 1700 sero-discordant couples- immediate ART given to uninfected partner- representing a 96% reduction in HIV transmission to the uninfected partner.

Hayes, S. D., Gaddist, B. W., & Rawls, A. W. (2011). Universal access and human rights: for women and girls, too. *GPSolo*, 28(2), 32-33.

- HIV counselling and testing (HCT) is now referred to as HIV testing services (HTS) to embrace the full range of services that should be provided together with HIV testing.
- These services include:
 - counselling (pre-test information and post-test counselling)
 - linkage to appropriate HIV prevention, treatment and care services and other clinical and support services
 - coordination with laboratory services to support quality assurance and the delivery of correct results.
- NATIONAL HIV TESTING SERVICES: POLICY 2016 accessed at <http://www.hst.org.za/sites/default/files/HTS%20Policy%2028%20July%20final%20copy.pdf>

HIV/AIDS- Ethical and Legal issues South Africa

- In SA, HIV/AIDS notification is NOT compulsory.
 - Issues of Informed consent
 - Issues of confidentiality vs disclosure
 - Treatment access and treatment adherence
 - Reproductive rights
 - Stigma
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- *Moodley K. Medical Ethics, Law and Human Rights-A South African Perspective South Africa: Van Schaik Publishers, 2011.*

Patient Autonomy

Informed Consent and Confidentiality

- HCW need to ensure that patients have sufficient information- nature, effect and consequences of an HIV test.
- NHA No 61 of 2003-Ch 2, every healthcare provider must inform a patient of “ the range of diagnostic procedures and treatment options generally available” and the “ benefits , risks, costs, and consequences generally associated with each option”.
- The right to confidentiality must be assured.
- Constitution of Republic of SA Act 108 of 1996- rights to dignity(s10), life(s11), bodily integrity (s12) and privacy (s14).
- National Health Act 61 of 2003- consent(s7); confidentiality (s 14)
- HPCSA- Guidance for Good Practice in Health Professions: Seeking Patients Consent: Ethical Considerations Booklet 15. Pretoria: HPCSA, 2002
- HPCSA- Guidance for Good Practice in Health Professions: Confidentiality: Protecting and Providing Information Booklet 14. Pretoria: HPCSA 2002.
- Common Law: *Castell v De Greef* 1994(4) SA 408 (C) (Informed Consent); *Jansen van Vuuren v Kruger* 1993 (4) SA 842 (A) (confidentiality)

Right to dignity and non discrimination

- Every person has inherent dignity and the right to have their dignity respected and protected.
- No actions should be taken against any individuals solely on the basis of their HIV status, as this will constitute stigma and discrimination.

Right to privacy and confidentiality

- All personal information concerning a client, his or her health status, treatment or stay in a health establishment must be kept confidential, unless ordered by the court of law or done so for the advancement of the client's care and treatment after following the necessary procedure.

Right to refuse HIV testing

- Clients have the right to refuse HIV testing, without compromising their access to standard healthcare.
- There shall be no mandatory HIV testing and all testing shall remain voluntary with informed consent, even when the services are initiated by the service provider.
- The only exception is in cases of sexual assault where the survivor requests the status of the perpetrator (Criminal Law; Sexual Offences and Related Matters) Amendment Act No. 32 of 2007 (Government gazette 31957, 6 March 2009).

Informed consent

- Informed consent refers to a person being given relevant and appropriate information about an HIV test, and based on that information, given an opportunity to either accept or refuse to do the HIV test.
- Informed consent should always be in writing and signed by the client or proxy and the healthcare provider to avoid unintended disclosure of results.

Requirements of informed consent

- The information that clients and patients require in order to give their informed consent may vary based on the service delivery approach and setting, but should generally include information about:
- benefits and implications of knowing one's status and reasons for recommending HTS
- client's right to withdraw consent at any stage of the process
- availability of follow-up treatment; care and support; and prevention services
- importance of disclosure and partner/family testing and availability of couple HTS
- HTS process and procedures

Capacity to consent

- Any person aged 12 years and older, and/or with sufficient maturity and mental capacity to understand the benefits, risks, social and other implications of HIV testing, may give consent for HTS in South Africa.
- Potential clients or patients should:
- understand why they are being tested
- understand and report on the consequences of a negative or positive test result
- report how they are likely to respond to either result

Capacity to consent

- If the patient/client is assessed as being incapable of giving informed voluntary consent, then proxy consent may be sought.
- This is consent given by someone else who is acting in the best interests of the patient/client (e.g., a senior clinician in charge of the case).
- If the patient regains capacity results must be disclosed.
- If the patient/client has irreversible neurocognitive impairment, results can be shared with the carer.

Capacity to consent

- HIV testing must always be voluntary and free from coercion.
- In some cases HIV testing can be prescribed by a court of law.
- Consent shall be conducted in a language understood by the client, and in child-friendly versions, as applicable. Consent shall be verbal but preferably written.

Inability to make a decision:

- According to the *National Health Act*, if a client is unable to give informed consent, for example, in the case of unconsciousness/incapacitation or cognitive disability, and if the test is clinically indicated, such consent can be given by a person authorised to give such consent, in terms of any law or court order.
- In the case of adults, the spouse, next-of-kin (parent, grandparent, an adult child or a sibling of the person), clinician or clinical manager, in the specific order listed, can give informed consent.

- Any client or patient who does not give consent for HTS should still be provided with the best possible care and should not be denied other health services.
- Client(s) or patient(s) declining an HIV test should be offered assistance to access HTS in the future, and their decision to decline should be noted in their medical record so that a discussion of HTS can be reinitiated at subsequent visits to the health facility.

The Children's Act

- The *Children's Act*, Section 130, stipulates when and how a child may be tested for HIV. The Act has clearly distinguished HIV testing from other forms of medical treatment and has enforced conditions for HTS among children.

Children may only be tested for HIV in two circumstances:

- if testing is in their best interest and lawful consent has been given for the test
- if the test is needed to establish the child's HIV status in cases where a healthcare worker, caregiver, parent or another person may have contracted HIV from the child's body fluids.
- This provision protects children against discriminatory or arbitrary HIV testing.

Consent for HIV testing for children may be given:

- by a child if he or she is older than 12 years
- by a child younger than 12 years if he or she has “sufficient maturity”
- by a parent, caregiver or the provincial head of the Department of Social Development if the child is younger than 12 years and is not sufficiently mature.
- This section of the Act ensures that a wide range of people may assist a child by consenting for HIV testing on the child’s behalf. It facilitates HTS for orphans and vulnerable children.

No person may disclose a child's HIV status without consent

- Consent for the disclosure of HIV status can be given by the child if he or she is older than 12 years, or is sufficiently mature.
- If the child does not have the capacity to give consent to the disclosure, consent can be given by a range of people, including a parent or caregiver.
- This provision aims to ensure that a child's right to confidentiality is protected.

CONFIDENTIALITY

EXCEPTIONS TO ETHICAL AND LEGAL RULE

- A court of law orders them to make a disclosure
- An Act of Parliament requires them to make a disclosure;
- There is a moral or legal obligation on them to make a disclosure to a person or agency that has a reciprocal moral or legal obligation to receive the information;
- Patient consents to the disclosure.
- Outside these exceptions a breach of confidentiality may result in an action for invasion of privacy or defamation.
- *Jansen van Vuuren v Kruger* 1993(4)SA 842 (A)

Disclosure

HPCSA Guidelines for Good Practice in respect of HIV

- *use discretion*
- *decision must be made with great care*
- *if decide to disclose against patient's wishes, explain to patient first*
- *follow steps:*
 - counsel patient on importance of disclosure*
 - advise on possible adverse consequences of disclosure*
 - support patient to make disclosure*
 - if patient still refuses, inform of ethical obligation to disclose and request consent*
 - disclose information*
- *be prepared to justify and defend decision*
- *accept full responsibility*

DISCLOSURE (cont)

Legal consequences of unlawful disclosure

Breach of contract

Delictual claim

Disciplinary action by HPCSA

Beneficence

- Adoption of HTS- would benefit patient-
enable patients testing HIV positive to access
care, treatment and support programs
timeously.
- Constitution- everyone has right of access to health care services s 27(1)(a)
- NHA- s 3(2)requires state-funded health depts. to ' provide health services 'within the limits of available
resources'.

Non-maleficence

- HTS - w.r.t. rape survivors- PEP, and other patients at risk of being HIV positive.

- Constitution- nobody may be refused emergency medical treatment s 27(3);
- Everyone has a right to ' an environment that is not harmful to their health or well-being' s 24(a)

Practical Implications- workplace

Workplace

Employer cannot

Force applicant to have an HIV test

Refuse to employ person because of HIV status

Automatically make an HIV test part of medical examination

Force employees to undergo HIV testing

Demand to know the diagnosis by a HCP

Dismiss an employee because of HIV status

Disclose HIV status of an employee without consent

Discriminate against an employee because of HIV status

HCP may not disclose HIV status / diagnosis to an employer without consent

Justice

- Requires that all patients are treated equally and fairly.
- The Constitution, s9, provides that nobody may be unfairly discriminated against on 'one or more grounds, including race, gender, sex, pregnancy, marital status, ethnic or social origin, colour, sexual orientation, age, disability, religion, conscience, belief, culture, language and birth'.

Justice

- An approach to HIV testing, would encourage greater access to HIV testing by making it easier (less onerous counselling procedures) and less stigmatising.
- The CC held that HIV status may also be a ground for discrimination. *Hoffman v SA Airways* 2001(1) SA 1 (CC)
- The Employment Equity Act 55 of 1998 specifically mentions HIV status as a prohibited ground of discrimination.

- HIV-positive people would be treated like any other patients suffering from a potentially life-threatening disease who are subjected to routine testing for their own protection.

Conclusion

- Routine HTS with ‘opt-out’ is consistent with ethical principles.
- Such testing is in line with the Constitution and other laws.
- However, HIV education and adherence counselling remain an priority.
- It could be argued that large scale ART initiation would:
 - - need significant and sustainable financial resources and efficient supply chain delivery of ART to many a remote site to sustain its impact ,
- The incidence of ART toxicities would increase, as well as admissions to hospital to to manage these toxicities,
- The potential for large scale drug resistance, esp. among large cohorts of PLWH who default treatment , either due to S/E’s or relative feelings of wellness.

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