INTENSIVISTS' PERCEPTIONS OF UNCONSENTED HIV TESTING IN SOUTH AFRICAN ACADEMIC INTENSIVE CARE UNITS (ICUs).

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DECLARATION

I, Dhivendra Singh, declare that this research report titled: *Intensivists' perceptions of unconsented HIV testing in South African academic intensive care units*, submitted for assessment for the MSc Med (Bioethics & Health Law) at the University of Witwatersrand, Johannesburg, is my own unaided work except where I have explicitly indicated otherwise. I have followed the required conventions in referencing the thoughts and ideas of others.

This thesis has not previously been submitted for any degree or examination at this or any other university.

ABSTRACT

Introduction

The National Health Act of 2003 and guidelines from the Health Professions Council of South Africa (HPCSA) and the South African Medical Association (SAMA) require consent for Human Immunodeficiency Virus (HIV) testing. However, critically ill patients in the intensive care unit (ICU) are often unable to provide informed consent. Currently there is little guidance for South African intensivists when HIV testing is necessary and informed consent cannot be obtained.

Aims

To ascertain the views of intensivists with respect to unconsented HIV testing of patients in South African ICUs and to investigate the factors that influence their current practice in that regard.

Objectives

The objectives of the study were (1) to determine the availability of protocols to guide unconsented HIV testing in different South African ICUs; (2) to assess the views of South African intensivists on (i) the importance of HIV testing in their ICU; (ii) the ethics of unconsented HIV testing; (3) to describe the current practice of intensivists when they consider HIV testing is necessary, but are unable to obtain informed consent from the patient; and (4) to provide some practical recommendations with regard to HIV testing in the ICU.

Methods

The study was a descriptive, cross-sectional survey of academic hospital staff intensivists.

Results

The response rate was 51% and most respondents had more than 5 years of experience in critical care. The majority (79%) did not have protocols or policies for HIV testing in their ICUs. Unconsented HIV testing was considered to be ethical by 83% of respondents and 87% were comfortable with ordering HIV tests in critically ill patients. Opinions were relatively evenly split in terms of wanting to know the HIV status of all patients. Most respondents considered current guidelines inadequate and felt that they were not in the best interests of the patient.

The majority did not believe that surrogate consent was either reliable or acceptable and felt that HIV testing should be at the discretion of the physician.

If the patient recovered, most respondents felt that the results should not be available to the family or spouse, but should be available to the patient. If the patient demised, most respondents agreed that the result should be recorded on the death certificate and made available to the spouse or partner, but not be available to the patient's family.

Conclusion

Intensivists may view testing for HIV without consent in selected cases as ethical and in the patient's best interest when it may guide diagnosis and therapy, but most ICUs do not have established policies and protocols to guide such HIV testing. A way forward would be for ICU directors to develop ethical protocols for HIV testing in the ICU. HIV positive patients are socially vulnerable and it may be difficult to establish protocols for HIV testing without consent.

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LIST OF ABBREVIATIONS

AIDS	Acquired immunodeficiency syndrome
ARV	Antiretroviral therapy
ARDS	Acute respiratory distress syndrome
CEO	Chief executive officer
CDC	Centres for Disease Control and Prevention
CD4+ count	CD4+ T lymphocytes in a blood sample
HAART	Highly active antiretroviral therapy
HCW	Health care worker
HIV	Human immunodeficiency virus
HPCSA	Health Professions Council of South Africa
ICU	Intensive care unit
IRIS	Immune reconstitution inflammatory syndrome
PCP	*Pneumocystis carinii* pneumonia (renamed *Pneumocystis jiroveci* pneumonia)
SAMA	South African Medical Association

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CHAPTER 1

INTRODUCTION AND LITERATURE REVIEW

1.1. Background to the research question and problem statement

South African law and ethical guidelines from professional bodies defend the right of patients to self-determination when it comes to health care decision making. Therefore, consent for Human Immunodeficiency Virus (HIV) testing presents an ethical challenge for intensivists who would prefer to ascertain the HIV status of selected patients for the purposes of earlier diagnosis and improving medical care. However, there are social consequences to being HIV positive including stigmatization within communities. There are also financial implications when it comes to insurance and obtaining employment.

It is therefore necessary to consider whether it is ethical to perform an HIV test in a patient who is critically ill and unable to give full informed consent. It is also important to determine whether available guidelines and health policies relating to consent allow intensivists to provide management that is in the best interests of the patient, whether surrogates (e.g., a close family member) can reliably represent the patient's wishes as far as consent for testing is concerned, and the perceptions of physicians regarding the confidentiality of HIV test results.

1.2. Prior research in this area and problems with the research findings

There is not much research in this area in South Africa. A study by Bhagwanjee *et al* (1997: 1087-1084) at a tertiary hospital in South Africa examined the impact of HIV status on the outcome of patients admitted for diseases unrelated to HIV versus admission diagnoses related to HIV. HIV testing was performed on these patients without informed consent, however the patients were offered the results of the test when they recovered. The key finding was that there was no difference in outcome between patients who were HIV positive and those who were HIV negative

when the diagnosis was non-HIV related, but outcomes were worse in HIV positive patients if the primary diagnosis was related to HIV. This survey was performed in a surgical Intensive Care Unit (ICU), and suggests that knowledge of HIV status is important in terms of patient management and prognosis, but should not be a criterion for exclusion from ICU. Significantly this study demonstrated that HIV testing, even if unconsented, may well be to the patients benefit in the ICU setting.

In 2013, a survey of intensivists showed that patients who were known to be positive for HIV infection were not discriminated against in terms of admission to ICU (Naidoo 2013: 28-32). This survey established that practitioners also viewed directed unconsented testing for HIV as beneficial and in the best interest of selected patients. This suggests that more research in this area is required to inform the development of guidelines for testing. Views on surrogate consent for testing imply that guidance from professional bodies need to be revisited. In addition, the opinion on confidentiality implies that HIV test results should be disclosed only in specific circumstances.

One difficulty with the findings from previous studies is that they may not be generalizable, because due to lack of resources the majority of critically ill patients in South Africa are not admitted to academic ICUs. Many patients will be managed by different ICUs offering varying levels of care and where protocols and policies are unlikely to be in place.

An additional limitation of the studies in this area is that antiretrovirals (ARVs) may have adverse effects in certain settings. Consequently, a further ethical question arises – is it ethical to provide antiretroviral therapy in the event of a positive HIV test, when neither consent for the test nor consent to treatment can be provided by the patient?

1.3. Motivation for the study

It has been shown that early diagnosis of HIV infection and commencement of therapy has changed the natural history of HIV from being uniformly fatal, to a chronic manageable condition (Rosen 2006: 245). Nevertheless, HIV/AIDS is regarded as a disease of exception, where a positive test result can result in discrimination and stigmatization. Many patients who are admitted to ICU have undiagnosed HIV infection, or are unable to disclose their HIV status and obtaining consent for HIV testing is unlikely as these patients are often incapacitated. Therefore, the legal and ethical requirement for full informed consent with pre- and post- test counselling presents a dilemma for physicians who consider testing for HIV in critically ill patients. With the availability of antiretroviral medication (ARVs), HIV infection has a favourable outcome if diagnosis is made early. This may extend into the intensive care unit where early diagnosis and treatment of HIV infection may be beneficial in selected instances. Intensive care units that are associated with academic centres in the public sector admit patients with complex medical conditions who require extensive investigation as part of their care. It is this group of patients who are likely to be considered for HIV testing. As these ICUs are staffed by senior clinicians, many of whom are subspecialists in the management of critically ill patients (intensivists), ascertaining their practices and perceptions may contribute positively to the debate on whether or not to test for HIV in ICUs.

1.4. Definition of key concepts

- *Critical illness and ICUs*

ICUs in hospitals are areas that care for patients with life-threatening disorders and who need constant monitoring and life support. Critically ill patients suffer from failure of one or more organ systems. They are almost always sedated and may be on mechanical ventilation (Oh T, 2003: 1-10).

- *HIV infection in critically ill patients*

HIV can vary from asymptomatic to a severely immunocompromised state. The CD4+ count is used to monitor the stage of the disease (Jones et al, 2008: 466).

- *AIDS in critically ill patients*

The late manifestation of HIV infection when CD4+ counts decrease and opportunistic infections are likely to occur (Jones et al. 2008: 466).

- *Intensivist*

A specialist in a major discipline in medicine who has completed an additional two year fellowship. Most, however, are specialists in Anaesthesiology, Internal Medicine or General Surgery. Physicians targeted in this survey were specialists in ICUs at academic hospitals, and are referred to in the report as intensivists (Irwin R. et al. 2014: 1-10).

- *Informed consent*

Beauchamp and Childress (1994: 143) define informed consent as "an *autonomous authorization* by individuals of a medical intervention or of involvement in research". For informed consent to be valid, the following ethical and legal requirements must be present: Disclosure, Understanding, Capacity and Voluntariness. Capacity according to Dhai (2008: 28) refers to the mental and legal capacity to consent. Due to the nature of critical illness, ICU patients are usually sedated and often dependant on life supporting drugs and mechanical ventilators. A substantial proportion of ICU patients may therefore be said to be incompetent to consent as they lack capacity. Legally relevant criteria for decisional capacity according to Appelbaum (2007: 1834) include the ability to:

- ✓ Communicate a choice
- ✓ Understand the relevant information

- ✓ Appreciate the situation and its consequences
- ✓ Reason about treatment options

- *Surrogate*

Decision maker for non-autonomous patients. This may be a health professional, spouse, relative or other individual. She or he may have partial or full authority over the incompetent individual, within limits, based on assessment of incapacity (Beauchamp 2013: 114-115).

- *Incapacitation*

This refers to the inability of patients to make reasonable choices, including the ability to give informed consent. This is also related to impaired competence and autonomous decision making. In critically ill patients, incapacitation is usually due to both sedation and severe illness. Depending on the clinical outcome, this may resolve (Beauchamp 2013:114).

- *Opportunistic infection*

This refers to infections in immunocompromised individuals, including patients with HIV/AIDS. These represent late manifestations of HIV infection. An example is *Pneumocystis* pneumonia (CDC definition: 2015).

1.5. Literature review

1.5.1. Introduction

The development of intensive care units (ICUs) as closed specialist staffed units began in the late 1960s and early 1970s (Mathiva 2002: 22). By the early 2000s, Critical Care had developed into a subspecialty and ICUs were beginning to be staffed by specialists who were engaged in formulating clinical protocols, policies, and development of research programs. The disease profile in South Africa has presented challenges to intensivists who are faced daily with triage decisions due to a

shortage of beds. Ethical dilemmas in South African public sector ICUs regarding HIV positive patients often arise when considering admission criteria, laboratory testing for HIV infection, clinical management, prognostication and consent for research. It is in the context of targeted diagnostic testing that this study was performed, rather than routine screening or research.

This review of the literature will examine the following:

- The reasons for admission of HIV positive patients to ICUs
- Factors associated with outcome from ICU admission
- Bioethical models in the critically ill in terms of the principles of beneficence, autonomy and nonmaleficence
- The relative risks and benefits of HIV testing
- Surrogate consent for HIV testing and the confidentiality of HIV test results
- South African law and HPCSA guidelines applicable to HIV testing in incapacitated patients

1.5.2. Reasons for ICU admission of HIV positive patients

There was an estimated thirty five million people living with HIV worldwide by the end of 2012 (UNAIDS Factsheets: 2012) with South Africa being home to the largest number. Almost 20% of all HIV positive patients globally live in South Africa, where 19% of adults or 12% of the total population live with the virus (Simelela 2014: 249). The first AIDS-related death in South Africa occurred in December 1981 and deaths due to AIDS in Eastern and Southern Africa were estimated to be four hundred and seventy thousand annually by 2015 (UNAIDS factsheet: 2016). The AIDS epidemic has, however, levelled off in South Africa, largely due to the availability of combination antiretroviral medications (Shisana, O et al: 2012).

Patients with HIV infection admitted to ICUs in South Africa fall into three distinct populations: those with opportunistic infections, those admitted with conditions unrelated to HIV/AIDS such as trauma, and a third group is admitted due to acute or chronic complications of ARVs (Antiretrovirals). Critically ill patients with opportunistic infections often present as "late testers" to hospital emergency departments. This group of patients often have not had HIV testing until life-threatening opportunistic infections result in hospital admission and they are therefore not usually diagnosed until their CD4 counts are less than 200, when opportunistic infections are likely to manifest (Masur 2009: 135).

Prior to the development of highly active antiretroviral therapy (HAART), 5-10% of HIV positive patients who were admitted to hospital were eventually admitted to ICUs (Rosen and Narisimhan 2006: S245). These patients may be hospitalised and cared for in an ICU for a variety of reasons. In developed countries, although admissions for opportunistic infections have decreased (Masur 2006: 96), the most common cause for ICU admission remains respiratory disease (Venturas 2011: 132). AIDS-related sepsis, gastrointestinal disease, neoplasms, cardiovascular disease and medication toxicity account for the rest of the admissions directly related to HIV infection (Akgun *et al* 2011: 151).

1.5.3. Factors influencing the outcome of HIV positive patients admitted to ICU

Indications are that short term survival of HIV-infected patients admitted to the ICU is primarily dependant on the severity of the acute disease (Casalino et al. 2004: 1433). Other predictors of ICU outcome include the need for inotropic support and mechanical ventilation, low CD4+ counts, low albumin levels and Kaposi's sarcoma (Corona and Raimondi 2007: 635). Overall intensive care mortality of HIV-infected patients has decreased from 37%-57% to 29%-37% (Croda et al. 2009: 1605), but it is not clear if testing and diagnosis in the ICU had any direct benefit.

It is widely accepted that patients in the general population diagnosed with HIV benefit from early commencement of ARVs. Recent evidence has shown that early initiation of antiretroviral drugs during tuberculosis therapy positively affects outcome (Abdool Karim et al. 2010: 697-703). Zolopa et al (2009: 5575) demonstrated in a randomised trial that early ARV therapy reduced the rate of progression of opportunistic infections.

Studies indicate that outcome may also be improved if antiretroviral medications are commenced early in critically ill patients with opportunistic infections and low CD4+ counts (Casalino et al. 2004: 1429; Zolopa et al. 2009: e5575; Morris et al. 2003: 73; Miller et al. 2006: 7161-7162; Powell et al. 2009: 11-17; Afessa et al 2000: 2000: 138-145; Dickson et al. 2007: 964-968; Corona et al. 2009: 569-579; Corona et al. 2009: 635-645). Potential benefits of the administration of ARVs in critically ill patients are suppression of the viral load, improvement in CD4+ counts and reconstitution of the immune system (Corona and Raimondi 2009: 570). In a retrospective study of 278 HIV-infected patients admitted to a university ICU over a period of ten years, the administration of ARVs in ICU was associated with a significantly better outcome at six months after ICU admission (Croda et al. 2009: 1605-1611). A smaller study, also retrospective, demonstrated a significant decrease in mortality among patients with *Pneumocystis carinii* pneumonia (PCP) (renamed *Pneumocystis jiroveci* pneumonia) admitted to an ICU who either were receiving HAART at the time of admission or had HAART initiated during the ICU stay (Morris et al. 2004: 1713).

A targeted HIV testing approach has been suggested to be beneficial under certain circumstances, where ARVs can then be commenced early in ICU if an AIDS defining condition is present, the CD4+ is low and a prolonged stay in ICU is anticipated (Venturas and Richards 2012: 10-14).
It is in the setting of AIDS-related sepsis where earlier diagnosis may be of benefit. Accounting for up to thirty percent of all ICU admissions, sepsis in HIV positive patients may present with distinctive

laboratory and prognostic features. These include polymicrobial infections, nosocomial infections, infections without fever and catheter-related bacteraemia (Morero 2014: 2-5). Venturas and Richards (2012: 10-14) argue that knowing the HIV status is likely to influence the differential diagnosis and/or empiric treatment decisions and therefore there is a case for testing and treatment. An audit conducted by the British HIV Association into HIV-related deaths found (by retrospective examination of patient records) that there were several clinical indicator conditions and minor laboratory abnormalities for some time before HIV was diagnosed (Taegtmeyer: 2008: 38-39). Early testing when there is a high index of suspicion may therefore be to the patient's benefit as treatment may be commenced earlier. Examples would be unexplained and atypical infections, loss of weight and anaemia.

There are, however, also a number of potential risks associated with the use of highly active antiretroviral therapy (HAART) in the critically ill, which include multiple drug reactions and toxicities, mitochondrial dysfunction, kidney injury, potential development of antiretroviral drug resistance, noncompliance after discharge and the development of immune reconstitution inflammatory syndrome (IRIS), all of which are associated with significant morbidity. Concurrent treatment of opportunistic infections and HIV might increase the frequency of IRIS depending on the infection and whether corticosteroids are used concurrently. The effect of timing of initiating therapy in certain opportunistic infections, notably extra-pulmonary tuberculosis, tuberculous meningitis and cryptococcal meningitis, indicate that early initiation of ART may result in a poor outcome (Boulware, DR 2014: 2487; Naidoo, K 2013: 35-42). In addition, there is limited availability of intravenous or liquid preparations and erratic drug absorption in the critically ill (Corona and Raimondi 2007: 642), making routes of administration, timing and dosage of antiretrovirals challenging.

For a seropositive individual, psychological risks after ICU recovery include anxiety and depression, while social risks include stigma, discrimination and breaches of confidentiality. In South Africa, social risks have posed the biggest barrier to testing, with HIV positive individuals facing threats of ostracization and violence, inability to find employment and exclusion from being able to obtain insurance in the past (Hoffman *vs* South African Airways 2001).

From the above, it can be concluded that testing for HIV for the purposes of diagnosis and to guide initiation of ARVs has both risks and benefits, and ICU physicians are faced with an ethical conflict when considering whether or not to screen for HIV.

1.5.4. Ethical considerations

Critically ill patients have a decreased capacity to understand, inability to refuse intervention and loss of confidentiality. Informed consent for treatment is most often impossible and intensivists are left to make management decisions for these patients. The arguments around HIV testing have focussed on patient autonomy with a paucity of discourse on the principles of beneficence, nonmaleficence and best interests. Each of these is influenced by the physician-patient relationship. Will (2011: 1491) describes two models of this relationship in critically ill patients, the beneficence model and the autonomy model.

The beneficence model, traced back to the Hippocratic Oath, holds physicians to act in the benefit of their patients to the best of their judgment. The British philosopher Thomas Percival wrote that beneficence trumps veracity when it comes to acting on the behalf of patients (Will 2011: 671). Beauchamp (2013: 202) describes beneficial actions as those which contribute to patient welfare and are part of the general norms of physicians.

A shift from the model based on the beneficence of the physician to one based on the autonomy of the patient occurred with the advent of the doctrine of informed consent, with autonomy and self-determination now trumping the principles of beneficence and distributive justice, and providing

protection against paternalism by the well-meaning physician (Tonelli MR, Misak J: 2010). However, in the case of critically ill patients, arguments have been made that clinicians should not consider patient autonomy to be preeminent as these patients lack the capacity to make informed decisions, understand and communicate a decision. (Rodriguez CA, Dominguez G: 708).

The patient who is admitted to ICU, but who has never been tested for HIV presents an ethical problem for the physician, who may be of the opinion that the patient has not benefited from the recent advances in care that are available and which may improve outcome.

Justification for HIV testing in critically ill patients must take into account the patient's best interests, risks versus benefits and a positive outcome, as well as patient's autonomy.

Intensivists are obliged to act in the patient's best interest and to provide best available care which is supported by the constitutional right of the patient to available health services. On the other hand, both law and ethics requires that physicians must take into account the risks of commencing ARV therapy. The principle of nonmaleficence in the Hippocratic tradition obliges the physician to abstain from causing harm, and this obligation not to harm is often more stringent than obligations to help (Beauchamp 2013: 150-151).

A weakly paternalistic position may be an option when physicians choose to test for HIV on the balance between risk and best interest. This is a position where the physician judges how a patient would act if given the choice, and thereafter acts accordingly. Weakly paternalistic interventions may be justified when an intervention is responsive to the welfare of an individual whose autonomy is significantly diminished (Mappes et al. 2001: 48-49). Libertarian paternalism similarly proposes that it is justifiable and desirable to use mechanisms that will improve individuals' lives providing it is done in an unobtrusive and non-coercive manner (April 2010: 703).

Clinicians thus face a dilemma when balancing their desire to respect and foster patient autonomy, and their responsibility according to what they perceive to be in the patient's best interest. Tonelli and Misac (2010: 926) argue that to fulfil their moral duties toward their patients, physicians should

not take the principle of patient autonomy to be preeminent with respect to critically ill patients. Paternalistic intervention may not only seem to be justified, but morally imperative (Gillon: 1986). Cameron (2005: 8) suggests that the health carers' duty of beneficence to the patient demands that accurate, early diagnosis of the treatable condition be encouraged, where possible diagnosis should be a routine and uncontroversial element in the patient management process. However, while autonomy may be compromised in the ICU patient, it is important that the important values of respect for patients and beneficence are protected.

A further moral theory that may influence the decision to test for HIV is that of consequentialism, which holds that morality should guide one in such a way that the outcome is the best, or that actions are right or wrong according to the balance of their good and bad outcomes (Beauchamp 2013:354). The decision to perform an unconsented test may be based on the positive medical consequences, which is the approach favoured in public health. As an example, HIV/AIDs in Africa has not been addressed as an infectious disease emergency and this has retarded testing practices. In comparison, it has been suggested that if the incidence was 30% in a westernised country, HIV would be treated as a public health crisis and steps would be taken immediately to address testing practices in the interest of a positive outcome (de Kock 2002: 67-68). Again, this may not be applicable to ICU patients in general due to the relative risks of ARVs, but it may help to guide considerations for selected patients.

1.5.5. HIV exceptionalism

Except for tests for heritable genetic disorders, HIV testing is the only laboratory or pathology test for which specific consent is required. For all other tests, there is widespread acceptance that either implicit consent, or tacit consent to medical care, is adequate to protect autonomous choice. Beauchamp & Childress (1994: 128), Halpern (2005: 734) and Nyrihan and Leino - Kilpi (2000: 54)

examined ethical problems arising in laboratory examinations. They identified genetic testing, autopsies, prenatal tests and HIV tests as the most problematic ethically, and that problems arose most often when test results are associated with discrimination and stigmatization. It is unclear if there has been legal action on the basis of routine laboratory testing without consent. This is conceivably due to the understanding between patient and physician that decisions will have been taken with a beneficial intent.

The case for viewing HIV infection as an exceptional disease requiring exceptional policies has been weakened since the development of ARVs. The advocates of a change to this view maintain that the "transformation of HIV disease into a complex chronic condition requiring long term on-going clinical management means that the limits imposed when medicine had little to offer have outlived their justification" (Bayer 2006: 649). Smith and Whiteside (2010: 3-8) argue that the development and efficacy of antiretroviral medication makes a strong case for "moving beyond HIV exceptionalism and treating HIV antibody tests like other blood tests". Halpern (2005: 736) states that "requiring consent for HIV testing risks perpetuating stigmatization while simultaneously limiting the quality of care that at-risk patients might receive".

The consideration of HIV/AIDS in the general population as a disease of exception has influenced testing practices worldwide, but diagnostic testing has been accepted as standard of care by the Centres for Disease Control and prevention (CDC) since 1999 (CDC MMWR 1999: 1-31), with some western countries recommending routine screening and/or mandatory screening in certain situations. In South Africa, HIV testing is governed by strict protocols published by the Department of Health. Pre and post-test counselling and full informed consent are mandatory. In the case of a patient who is unable to make a decision, such as an incapacitated patient, according to the National

Health Act of 2003, such consent may be given by a person authorised in terms of any law or court order.

In Europe, in cases where HIV testing is performed without consent, the health care provider must be able to justify his/her actions according to national regulatory and legal frameworks. Guidelines on HIV testing in the United Kingdom mention that where patients lack the capacity to consent, testing should proceed if it is necessary to save the patient's life (UK National Guidelines for HIV testing 2008: 15).

In the United States, specific consent for HIV testing is required for HIV testing in all fifty states, while nineteen have enacted rules to allow testing in incompetent patients, in life threatening situations or when physicians believe the test will influence management (Halpern 2005: 736).

The HPCSA referring to the requirement for informed consent for HIV testing, emphasises that: "…testing for HIV is unlike testing for any other medical condition and that special conditions apply" (HPCSA Guidelines 2008: Booklet 12 Guideline 6.1).

Edwin Cameron, Justice of the Constitutional Court, and himself a person living with HIV, has made impassioned pleas for the de-exceptionalisation of HIV/AIDS. His call has been echoed by HIV/AIDS advocacy groups such as the Treatment Action Campaign (TAC). Cameron suggests that the human rights protections created around HIV infection contributes to and reinforces stigmatization: if we treated HIV/AIDS purely as a disease with a cause and natural history we would treat it merely as a disease occurring commonly in our society that demanded specific interventions. Cameron goes further to suggest that the continued exceptionalisation of HIV/AIDS may be considered as undermining human rights. (Cameron 2005: 23, Cameron 2006: 1-9).

De-exceptionalisation of HIV infection, placing less emphasis on counselling and informed consent for diagnostic testing at the discretion of the physician may be feasible in the general population but needs to be examined carefully in the critically ill.

Critically ill patients must be regarded as a vulnerable group who lack or have decreased autonomy. They are most often sedated and unable to fully comprehend the nature of their illness and treatment. Rapid progression of disease makes choice of physician or hospital impossible. They are subjected to invasive procedures often without consent. Surrogate consent may not be suitable or available (Schweikert, W., Hall, J: 2005). Hence, rules requiring additional protection for populations judged to be vulnerable are essential to ethical, clinical and research activity (Beauchamp and Childress 2013: 267). Proposed rules that are justified to provide additional protection include surrogate consent and lowered limits of acceptable risk.

1.5.6. Surrogate consent

A number of weaknesses have been stated in using a surrogate decision-maker to provide consent for testing in sensitive situations. Halpern (2005:734) has three objections to surrogate consent for HIV testing. Many critically ill patients may lack surrogates who have sufficient insight into her/his wishes. Raising the spectre of HIV among relatives who believe the patient has no risks of infection may be potentially antagonizing, and thirdly, surrogates will have their own biases given the social and political sensitivity around HIV. A systematic review of the accuracy of surrogate decision makers found that overall surrogates predicted patients' treatment preferences with sixty eight percent inaccuracy (Shalowitz 2006: 493).

Surrogate decision making according to Beauchamp (2013: 63) raises questions about moral status. He questions whether the patient's moral status is lowered if he has lost some right of decision-making. However a surrogate decision may be viewed as an extension of the incapacitated person's autonomy or "substituted judgement". The family may be best able to represent what the patient wanted, if she/he were competent. The family/surrogate may be seen to have the ability to "speak for the patient" thus promoting the patient's values and autonomy.

1.5.7. Disclosure of HIV test results

Disclosure of HIV tests presents a separate ethical problem - whether it is to a relative or to a surrogate. Vernillo et al (2007: 1-3) suggests that two distinctions be made that affect disclosure: Firstly whether HIV infection represents the primary cause of the critical illness, such as a life-threatening opportunistic infection, and secondly, whether the relative/surrogate could possibly be harmed by failure to disclose HIV status, such as the case of the partner who has been exposed to HIV.

i. Disclosure to partners

The legal and ethical position on the confidentiality of test results has been alluded to above. There may be good reasons to breach confidentiality of test results in critically ill patients. Firstly, disclosure may be justified on legal and ethical grounds if nondisclosure poses a direct and foreseeable risk to the surrogate. The case of *Tarasoff* vs *Regents of the University of California* (1996) established that confidentiality may be breached if there is a "duty to warn" (Vernillo 2007: 125). The HPCSA recommends that confidentiality may be breached in the interests of the sexual partner in the case of *refusal* to disclose (HPCSA Guidelines 2008: Booklet 11 Guideline 9.2.4). The *inability* to consent or refuse to disclose one's HIV status has not been clarified.

ii. Disclosure of the HIV status of deceased persons

It has been argued that the law does not protect the confidentiality of deceased persons and that when people die their "constitutional and common law personality rights, including their right to privacy and confidentiality, die with them" (McQuoid-Mason 2007: 920). However, although the law may appear to be unsympathetic toward protecting the privacy of a deceased person, the ethical rules that recognise the importance of privacy and confidentiality during life for a person with HIV/AIDS should continue after death (Dhai *et al* 2001: 125).

Critical care staff are often faced with the decision of whether to disclose on a BI 1663 form (The death certificate) the fact that HIV was a contributory cause of death. However, even though the confidentiality of the form cannot be guaranteed, the law imposes a positive duty on the medical practitioners to provide the required information accurately (The Births and Deaths Registration Act No 51 of 1992) (McQuoid-Mason 2007: 923).

1.5.8. Informed consent and available rules, guidelines and protocols from professional bodies

The following protect patient autonomy and ensure confidentiality of medical information:

i. *The Bill of Rights of the Constitution of South Africa*: The Bill of Rights enshrined in the Constitution of The Republic of South Africa (Act 108 of 1996) provides for the autonomy of individuals as indicated in section 10 (dignity), section 12 (bodily integrity) and section 14 (privacy).

ii. Chapter 2 of the *National Health Act of 2003*: "Rights and duties of users and health care professionals":

Section 7 (Consent of user) stipulates that a health service may not be provided to a user without the user's informed consent unless:

- "Failure to treat the user, or group of people which includes the user, will result in a serious risk to public health" (s7(1)(d)).
- "Any delay in the provision of the health service to the user might result in his or her irreversible damage to his or her health and the user has not expressly, impliedly or by conduct refused that service" (s7(1)(e)).

Section 8 (Participation in decisions) provides for self-determination as:

- "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" (s8(3)):

Section 14 provides for confidentiality:

- (s14(1)) "All information concerning a user, including information relating to his or her health status, treatment or stay in a health establishment, is confidential".

iii. *Ethical guidelines set out by the HPCSA* (a statutory body) emphasize patients' right to autonomy. The ethical guidelines on seeking patients consent (Booklet 9) state:

- In an emergency, where consent cannot be obtained, health care practitioners may provide medical treatment which is lifesaving or which is immediately necessary to prevent deterioration in the patient's health (guideline 8.1).
- In deciding what options may be reasonably considered for the patient who lacks the capacity to decide, the health care practitioner should take into account "The Best Interests Principle" (guideline 10).
- Where a patient's capacity to consent is in doubt, more experienced colleagues should be consulted, failing which legal advice may be sought on whether to apply to the court for a ruling (guideline 11.1).
- As far as possible, practitioners should ensure that screening or testing is not contrary to the patient's interests (guideline 17.2).

Referring to medical emergencies the rules emphasize that it may be difficult legally to justify that "testing without consent was necessary in order to save a person's life" (guideline 8.3).

In addition to the above, The South African Medical Association (SAMA) has published guidelines on management of HIV and AIDS which endorse the National Health Act, but further emphasise the positive value of testing and the confidentiality of test results. In guideline 3.3, dealing with unconscious patients, the recommendation is that a surrogate

gives consent. The list of acceptable surrogates does not include the physician but does include the Medical Superintendent.

iv. *The Patients' Rights Charter* emphasizes the right of patients to confidentiality, privacy and informed consent.

v. *The National HIV Counselling and Testing (HCT) Policy Guidelines* (Department of Health, 2010) state that in the inability to make a decision (Section 6.2.2), such as in the case of unconsciousness, such consent may be given by a person authorised to give such consent in terms of any law or court order.

Therefore it can be said that ethical, legal and moral arguments must be considered when deciding to test for HIV in the ICU. In addition the Constitution, South African Case Law, ethical guidelines from professional bodies and medical evidence are important considerations.

1.5.9. Examples from case law in South Africa

i. VRM vs *Health Professions Council of South Africa (2003).*

Dr L practised as a family physician in a small town in South Africa. In 1999, VRM, a resident of this town, consulted Dr L to manage the course of her pregnancy. Dr L performed an HIV test as part of other routine tests without consent and counselling. The test was positive. He, however, did not disclose the test result to VRM and also failed to take measures to reduce the risk of mother to child transmission. The baby was stillborn and the patient only subsequently discovered the test had been done without her consent. VRM claimed that Dr L acted unethically and unlawfully as the test was performed without consent and the necessary counselling. The committee of preliminary enquiry of the HPCSA found that there had been no improper or disgraceful conduct on his part. An appeal was

subsequently launched to review and set aside the decision of the Health Professions Council of South Africa (HPCSA) in 2001. This application was dismissed. The matter went to the High Court who set aside the original decision of the HPCSA. The High Court found that "the committee of the HPCSA who heard the complaint were not entitled to adjudicate on complaints that raise disputes of fact and that the committee must refer the complaint to a disciplinary enquiry". As the HPCSA had not adequately considered the facts of the case, the HPCSA judgement was set aside. A civil claim was subsequently instituted against Dr L.

ii. C vs *Minister of Correctional Services (1996).*

In C vs. Minister of Correctional Services (1996), a lawsuit was instituted successfully by a prisoner who had been subjected to an HIV test without privacy, without full information on the right to refuse and without the appropriate standard of counselling. The court found that The Department had acted wrongfully in that it had not followed the correct protocol. The complainant was awarded R1000.00.

iii. Jansen van Vuuren vs *Kruger (1993).*

In *Jansen van Vuuren* vs *Kruger* (1993), the results of a patient's HIV test were disclosed between doctors during a game of golf and subsequently became known to other individuals in the community. The plaintiff sued for breach of confidentiality. The matter went to the Supreme Court who found that Kruger had not erred in the disclosure. The plaintiff appealed this verdict and the appellate division overruled the original judgement and found in favour of the plaintiff. The judgement emphasised the importance of doctor-patient confidentiality and considered that the stress caused by the disclosure could have hastened the onset of AIDS in the plaintiff. The patient was awarded R250 000 (Dancaster JT, Dancaster LA: 1995).

iv. Hoffmann vs. *South African Airways (2001).*

In *Hoffmann* vs *South African Airways (2001),* an applicant for a job as cabin attendant on South African Airways (SAA) was turned down because a compulsory HIV test during the job screening process showed that he was HIV positive. He was otherwise a suitable candidate for the job and was asymptomatic from the HIV infection. SAA refused to employ the applicant giving the reason that he was unsuitable for practice as an attendant on overseas flights. The court found that the refusal by SAA to employ the cabin attendant violated his right to equality guaranteed by section 9 of the Constitution.

1.5.10. Conclusion

The decision to test for HIV without consent in critically ill patients raises a number of ethical and legal questions. Firstly, in the physician-patient relationship, does autonomy trump beneficence? Secondly, should the infection be treated as a public health matter rather than a civil liberties-based issue and if so, can this be extended into the ICU? Finally, do the South African law and ethical guidelines protect the best interests of critically ill patients? Intensivists grapple with these dilemmas when faced with the decision to perform an unconsented HIV test. It is therefore necessary to examine their perceptions on the ethics of HIV testing and to ascertain whether they consider these legal and ethical guidelines to be in patients' best interests.

CHAPTER 2

METHODOLOGY

2.1 Aims and objectives

i. Aims

To ascertain the views of intensivists with respect to unconsented HIV testing of patients in South African ICUs and to investigate the factors that influence their current practice in that regard.

ii. Objectives

The objectives of the study were (1) to determine the availability of protocols to guide unconsented HIV testing in different South African ICUs; (2) to assess the views of South African intensivists on (i) the importance of HIV testing in their ICU; (ii) the ethics of unconsented HIV testing; (3) to describe the current practice of intensivists when they consider HIV testing is necessary, but are unable to obtain informed consent from the patient; and (4) to provide some practical recommendations regarding HIV testing in the ICU.

2.2. Study design

The study was a descriptive cross-sectional survey using a questionnaire (Appendix A) to probe HIV testing practices of intensivists at academic hospitals. The survey was disseminated in the form of a web-based online survey (Survey-Monkey©).

2.3. Survey design

The questionnaire examined the following aspects of the research question using both closed- and open-ended questions:

2.3.1. The practices of the intensivists at their ICUs regarding HIV testing.

2.3.2. Their perceptions regarding the ethics of unconsented HIV testing.

2.3.3. Their opinions regarding:

i. The importance of HIV testing in this setting

ii. Current guidelines on HIV testing

iii. Surrogate versus intensivist consent for HIV testing

iv. Disclosure of HIV test results on recovery or death

2.3.4. The age and experience of the respondents.

The rationale for the type of questions included in the survey was as follows:

- The variables chosen aimed to firstly establish whether any formal protocol or policy existed in the ICU insofar as HIV testing is concerned.
- The ethics of HIV testing as interpreted by the respondent was explored on the assumption that each respondent would have a particular ethical viewpoint and that physicians may be conflicted or experience discomfort given their ethical viewpoint. Physicians from different levels of maturity and experience may view consent for HIV testing differently from younger, less experienced physicians, and this may also influence interpretation of the results.
- The degree to which respondents may consider HIV testing to be in the best interests of the patient may be different.
- Physicians are exposed to guidelines from the HPCSA and bodies such as the South African Medical Association (SAMA), but awareness of the laws regarding consent for testing may be variable.

- It is common practice in ICUs to turn to surrogate consent for various reasons, but physicians may have different levels of confidence in surrogates' ability to reflect the wishes of the patient, especially when considering testing for HIV.
- Disclosure of test results depending on demise or recovery is an important issue related to consent for HIV testing which needed to be addressed.

Given the scope of the study, each variable could not be explored fully, but unanswered questions may be subjects for future research.

2.4. Target population and recruitment strategy

This group of physicians was chosen as they are senior clinicians with a broad range of experience in managing critically ill patients and are influential in the formulation of policies and protocols at a local and national level. The Critical Care Society of Southern Africa was initially approached with the intention of using its database to invite member intensivists. However, the Society declined access to the database due to policy regarding open access to contact details of members. Therefore, the academic centres were approached directly.

2.5. Sample size & site

Forty seven specialist physicians at adult ICUs at the following academic hospitals were invited to participate:

- University of Witwatersrand (Chris Hani Baragwanath Academic Hospital, Charlotte Maxeke Johannesburg Academic Hospital);
- University of Pretoria (Steve Biko Academic Hospital);
- University of KwaZulu-Natal (King Edward VIII Hospital, Inkosi Albert Luthuli Hospital, Greys Hospital);

- University of Orange Free State (Universitas Hospital);
- University of Stellenbosch (Tygerberg Hospital);
- University of Cape Town (Groote Schuur Hospital).

2.6. Data collection

After disseminating the questionnaire, responses were collected over a four week period. Reminder e-mails were sent two weeks after the initial request and the survey was closed at the end of the fourth week.

2.7. Data management and analysis

Data Management and Statistical Services were used for statistical analysis. Analysis of the results was carried out using SAS version 9.3 software. Tests for significant relationships were performed using Pearson's X^2 test at the 95% confidence level.

2.8. Ethical considerations and processes (Appendix D)

Ethics approval was obtained from the *Human Research Ethics Committee of the University of Witwatersrand* (Clearance certificate M111139).

The Biomedical Research Ethics Committee of the University of KwaZulu-Natal granted a waiver of review as the study had ethical approval from the Wits HREC.

2.8.1. Confidentiality

The questionnaire was anonymous and returned to the investigator via a secured web-based collector (SurveyMonkey©). Even though respondents belonged to an identifiable cohort, there was no link to individuals.

2.8.2. Informed consent

Prior to distribution of the questionnaire, a letter was sent to the Chief Executive Officers (CEOs) of the hospitals at each centre requesting permission to conduct research in their ICUs (Appendix E). Permission was not granted to conduct the study in the ICUs at the following:

i. Charlotte-Maxeke Johannesburg Academic Hospital.

ii. Chris Hani-Baragwanath Academic Hospital.

Response to letters requesting permission was not received from either the hospital management or the academic heads.

A copy of the protocol and the questionnaire was e-mailed initially to the Heads of Department at each participating centre and permission was sought to distribute the questionnaire to the staff intensivists at that centre (Appendix F). The questionnaire and an information sheet were then e-mailed to staff intensivists at that centre. The information sheet set out the objectives, benefits and design of the questionnaire. Thereafter, each participant was invited to respond or to refuse participation in the questionnaire. As a response to the questionnaire indicates tacit consent, no formal consent was deemed necessary.

2.9. Closure of the study

The research methodology allowed for dissemination of the survey and collection of the results over a period of four weeks, after which the survey was closed.

CHAPTER 3

RESULTS AND DATA ANALYSIS

3.1. Response rate

Twenty four completed questionnaires were received, giving a response rate of fifty one percent. Permission to conduct the questionnaire was not obtained from two academic hospitals in Johannesburg due to bureaucratic or administrative processes.

3.2. Data analysis

The analysis was carried out by using *Data Management and Statistical Services* using SAS (Version 9.3) software. Tests for significant relationships and strengths of association of variables were carried out using Pearson's X^2 test (95% confidence level) and Cramer's V test, respectively. In the case of 2 X 2 tables, the Phi coefficient was used. This allows interpretation of relationships between variables and defines the association as strong (> 0.5), moderate (0.3-0.5), weak (0.1-0.3) or none (0-0.1).

The responses to the questionnaire were analyzed by grouping the variables into the following:

1. Protocols and policies for HIV testing (Question 1 – 3).
2. Whether respondents would want to know every patient's HIV status (Question 4 – 6).
3. Ethical perceptions and comfort with HIV testing in critically ill patients. (Question 7 – 9).
4. Opinions regarding the relevance of guidelines and whether they were in the best interests of the HIV positive patient in ICU (Question 10).
5. Whether surrogate consent was reliable and acceptable (Question 11).
6. Whether intensivists should be the sole givers of consent (Question 12).

7. Disclosure of the patient's HIV results if the patient recovered in ICU (Question 13).
8. Disclosure of the patent's HIV results if the patient demised in ICU (Question 14).
9. Age and experience in ICU practice of respondents (Question 15 – 16).

After primary analysis, the results were stratified by the demographic variables of age and experience.

The age and clinical experience of the respondents are shown in Table 1 and an overall view of responses to the questionnaire are presented in sections 3.3 to section 3.8. The results are summarized in section 3.4.

Responses to the questionnaire (Table 2), including responses to the open-ended questions appear in detail in Appendix B.

3.3. Responses to the survey

3.3.1. Age and experience of respondents (Table 1, Figures 1 and 2)

Fifty eight percent (14/24) of the respondents were between the ages of 31 and 40 years. Forty two percent (10/24) had at least five years of practice as subspecialists in critical care. Thirty three percent (8/24) had more than five years of practice. As would be expected, there was a significant association between age and years of practice (p=0.0024; Cramer's V=0.070).

Table 1. Age and years of practice of respondents

Age(years)	Respondents		*Years of practice*	Respondents	
	n	%		n	%
< 30	0	0	<5	6	25
30-39	14	58.3	5-10	10	41.7
40-49	8	33.3	11-20	6	25
50-60	2	8.3	>20	2	8.3
> 60	0	0	0		0

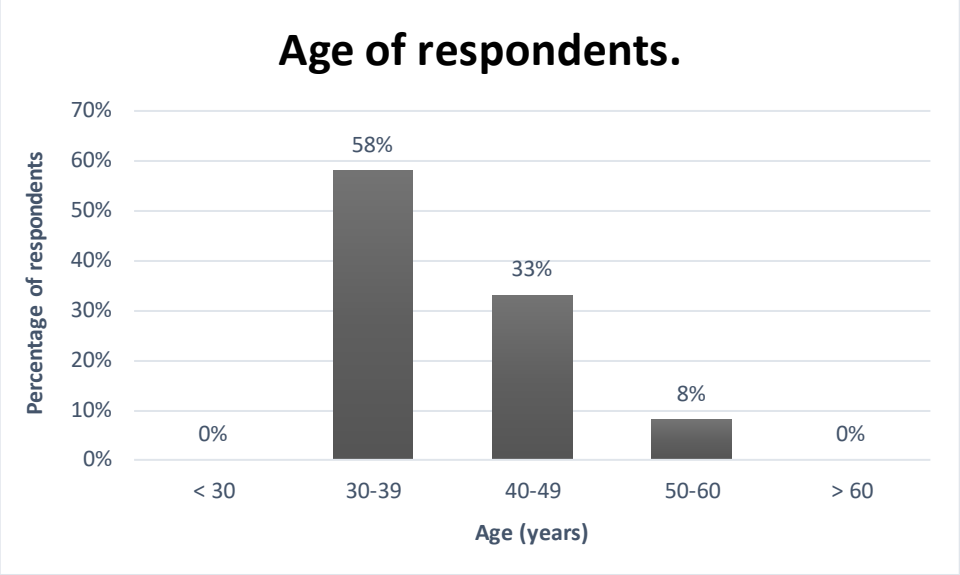

Figure 1. Age of respondents

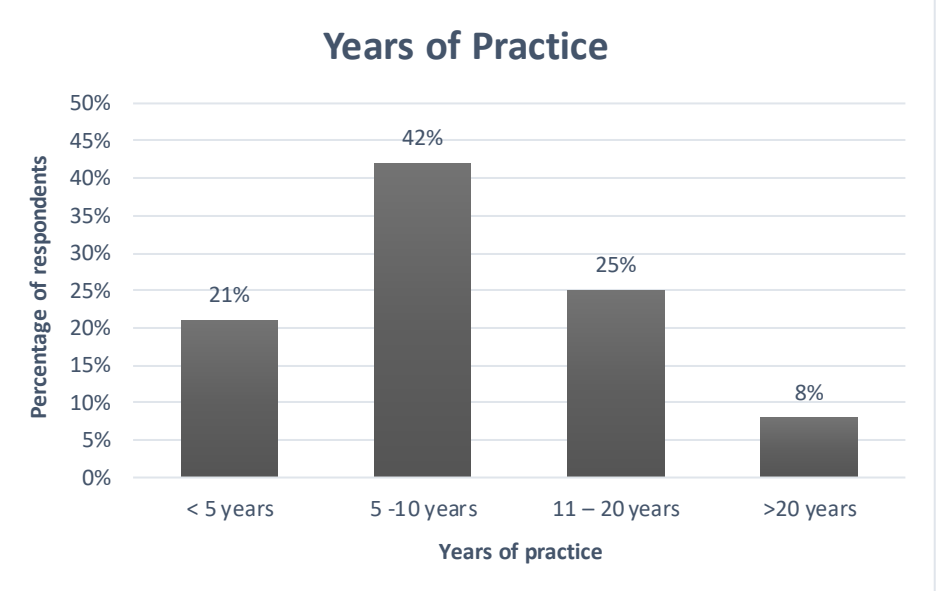

Figure 2. Years of practice of respondents in critical care

3.3.2. Protocols and policies (Figure 3, Table 2)

Twenty one percent (5/24) of respondents reported having a policy or protocol in place for HIV testing, while seventy nine percent (19/24) did not have a policy or protocol available (Figure 3).

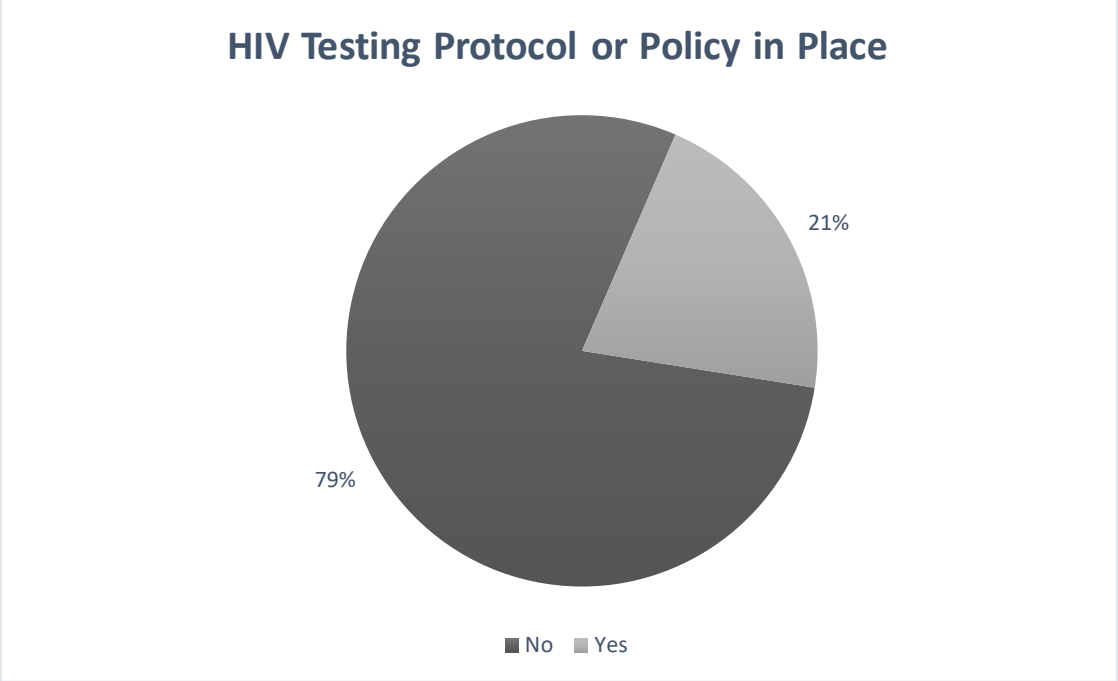

Figure 3. Proportion of ICUs with a policy for HIV testing in critically ill patients

The following themes emerged for not having a policy. As some respondents gave more than one reason, the total may not sum to 19. Verbatim responses are listed in Appendix B. Eight respondents did not provide reasons for absent policies.

i. Medico legal and ethical concerns (3)

- Current sensitivity around consent for testing and medico-legal concerns. HIV is an ethically charged area, which makes it difficult to establish a definite testing policy.
- No policy specific to the ICU, as standard/overall hospital policy regarding HIV testing is followed in the ICU.
- Standard rules for testing apply – obtain consent. National guidelines require full informed consent for HIV testing.

- HIV testing guidelines are clear that unconsented testing is not acceptable.
- No policy as one is not needed.

ii. Treatment should be individualised (2)

Appropriate investigations should be performed as necessary depending on the clinical management of the patient.

iii. No policy as it is not needed (1)

- HIV testing is hardly ever done as most patients have HIV results prior to ICU admission from referring disciplines.

iv. Logistics (1)

- Not enough staff to design a policy at present.

v. No reason given (8)

Twenty one percent of respondents reported having a policy, which included the following:

- *No unconsented testing.*
- *No unconsented testing, except in the event of exposure to potentially infective body fluids.*
- *Unconsented testing allowed if it will influence or guide the clinical management (2).*
- *Unconsented testing allowed with the aim of providing optimal patient care (1).*
- *Unconsented testing allowed as HIV is a chronic but manageable disease (1).*
- *An unwritten protocol exists (1).*

3.3.3. Physicians' perceptions regarding unconsented HIV testing in critically ill patients (Figure 4, Table 2).

Forty six percent (11/24) of respondents wanted to know the HIV status of every patient in their ICU. Eighty three percent (20/24) of respondents considered it ethical to perform unconsented testing in a critically ill patient, while eighty seven percent (21/24) of respondents were comfortable with unconsented testing in the critically ill patient. There was no significant association between considering it ethical and being comfortable with testing without consent. In other words, some who considered it ethical were not comfortable with it, and some who were comfortable with it did not consider it ethical.

The most common reason was that physicians felt it was to the patient's benefit. Other reasons given were that HIV needs to be destigmatised, and post-test counselling be made available on recovery. While opinion was split over wanting to know HIV status of all patients in the ICU, the majority of respondents who wanted to know the HIV status of all patients did so because it would guide management, including the commencement of ARVs. Only one respondent felt prognostication was a good reason for testing. Health care worker safety was also given as a reason.

There was a significant association between considering it ethical to perform unconsented HIV testing in a critically ill patient and wanting to know the HIV status of every patient in the ICU ($p=0.03$; Phi coefficient=0.49). There was no significant association between whether respondents found it ethical to perform unconsented testing in ICU patients and age ($p=0.61$), years of practice ($p=0.32$) or whether or not an ICU policy was in place ($p=0.54$).

There was also no significant association between whether respondents were comfortable with unconsented testing and age ($p=0.55$), years of practice ($p=0.59$), whether or not an ICU policy was in place ($p=0.52$) or wanting to know every patient's HIV status ($p=0.082$).

The following reasons were given for wanting to know the HIV status of every patient in the ICU:

- *It may guide the diagnosis and treatment, including the initiation of ARVs (9).* Specific reasons mentioned were selection of antimicrobials related to HIV and CD4+ count, to aid in screening for unusual organisms and explaining varied X- Ray findings.
- *It may help ensure health care worker safety (2).*
- *It may help in the decision to limit escalation of life support (1).*

The following reasons were given for not wanting to know the HIV status of every patient in the ICU:

- *This information is relevant to some patients only (9).*
- *It will not change patients' management (2).*
- *Universal precautions suffice for HCW safety (1).*
- *It has minor influence on treatment protocols (1).*

The following reasons for their approach to HIV testing were given by the respondents who were comfortable with unconsented HIV testing in critically ill patients:

- *It may be in the patient's benefit (19).*
- *HIV is now a disease like any other and needs to be de-stigmatised (4).*
- *Patients can receive post-test counselling and can choose whether to receive the result if they recover (3).*

In contrast, the respondent who was not comfortable with unconsented HIV testing in critically ill patients felt that *HIV testing always requires consent.*

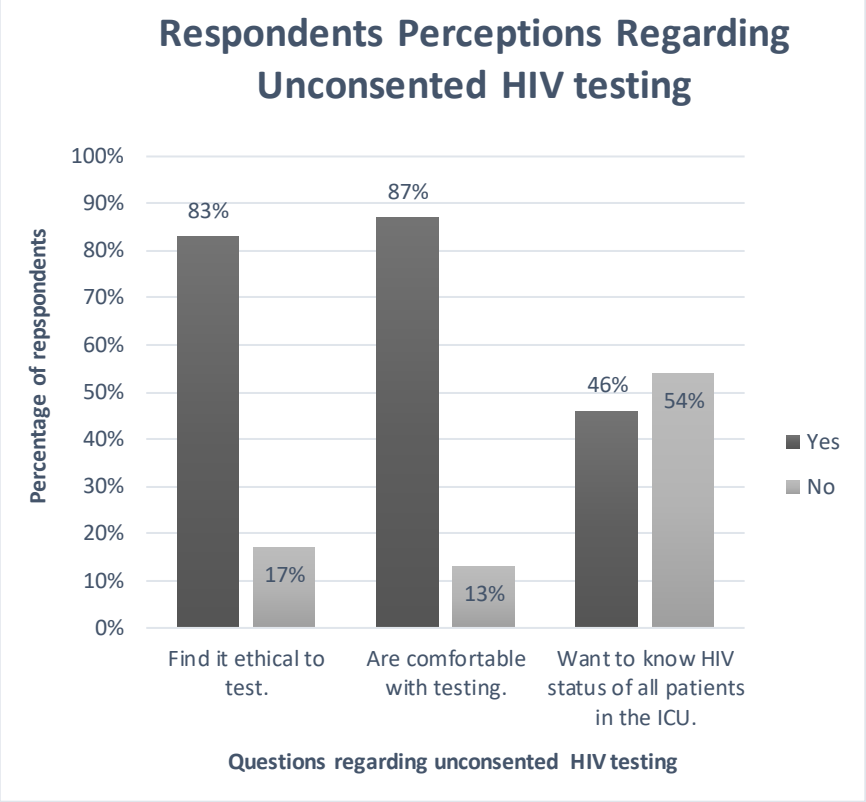

Figure 4. Respondents' perceptions of unconsented HIV testing in the ICU

3.3.4. Physicians' opinions of guidelines regarding HIV testing in critically ill patients (Figure 5, Table 2)

Eighty three percent (20/24) of respondents felt that the current guidelines were no longer relevant to critically ill patients. Ninety two percent (22/24) of respondents felt that the current guidelines did not serve the best interests of these patients (p=0.022). As expected, there was a strong significant association between these two questions. All those who thought the guidelines were no longer relevant also thought they did not serve the best interests of the patients, while a further two respondents who thought the guidelines were still relevant, also thought they did not serve the best interests of the patients.

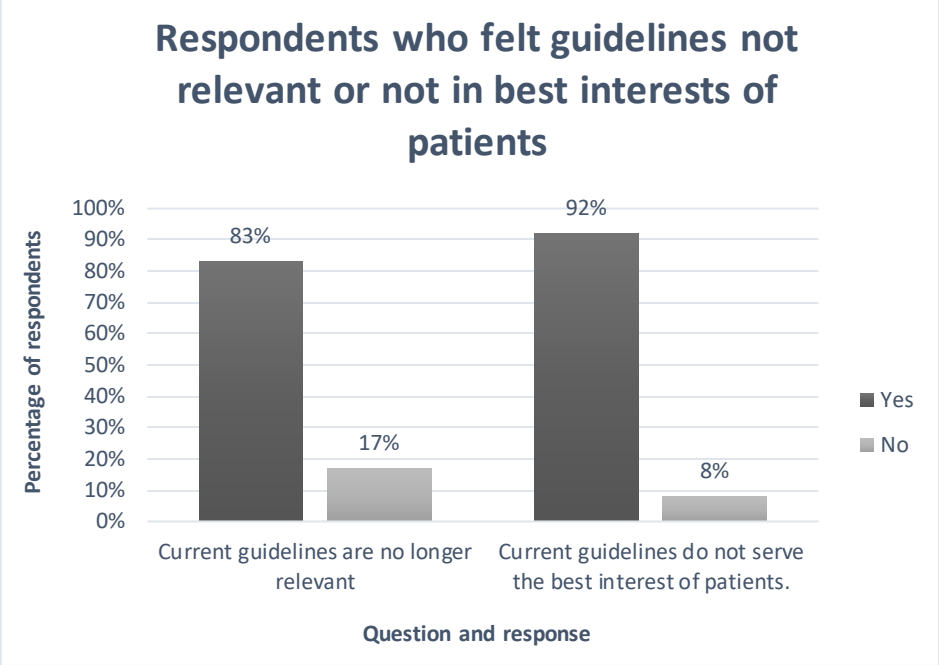

Figure 5. Respondents who felt current guidelines were not relevant or were not in the best interests of patients

3.3.5. Perceptions on surrogate authority for HIV testing (Figure 6, Table 2)

Thirteen percent (3/24) of respondents considered surrogate consent a reliable alternative to informed consent, while thirty three percent (8/24) of respondents considered surrogate consent an acceptable alternative to informed consent.

As expected, there was a strong significant association between these questions; all three respondents who considered surrogate consent a reliable alternative, also considered it an acceptable alternative. There was a significant association between whether respondents felt that surrogate consent was an acceptable alternative to informed consent and whether or not they considered it ethical to perform unconsented HIV testing (Question 7) (p=0.0066; Phi coefficient=0.63). There was no association between whether respondents found unconsented testing either reliable or acceptable and whether they considered it ethical, were comfortable with testing, or found the guidelines in the patient's best interests or not.

Ninety two percent of respondents (22/23) agreed that unconsented HIV testing should be solely at the discretion of intensivists, regardless of whether a surrogate is available. There was no association between whether they considered unconsented testing ethical, whether they were comfortable with it, or whether or not they felt that surrogate consent was an acceptable or reliable alternative.

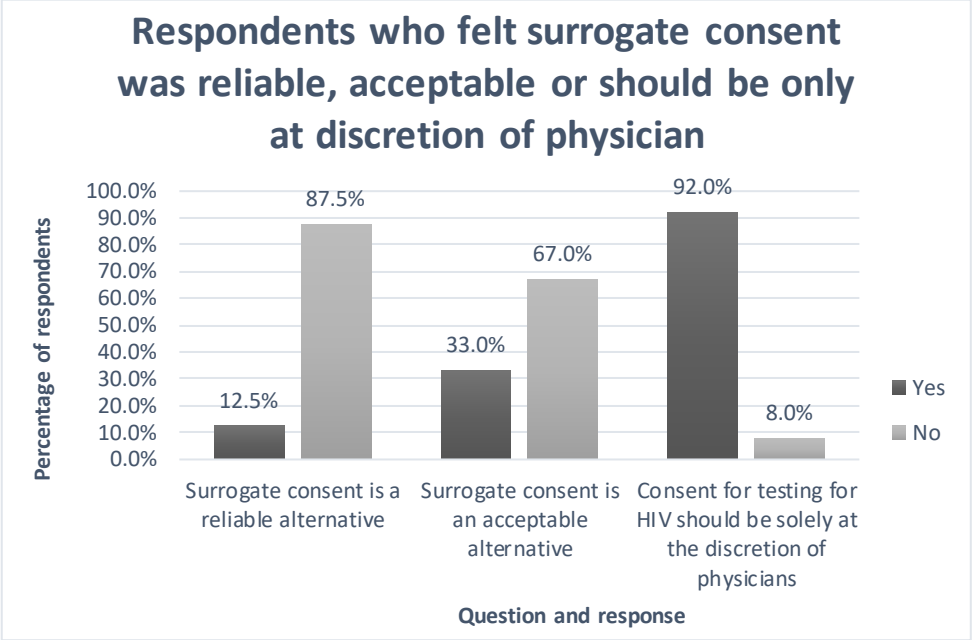

Figure 6. Respondents who felt surrogate consent was a reliable or acceptable alternative or who felt consent should be at the sole discretion of intensivists

3.3.6. Perceptions on the disclosure of HIV test results on recovery or demise (Figures 7 and 8, Table 2) (n=23 as one respondent did not comment on this question)

The majority of respondents felt that if the patient recovered, the results should be made available to the patient, but not to the family or partner. There was no significant association between whether or not the results should be made available to the patient and whether or not the results should be made available to the partner/spouse (p=1.00). There was also no association between

whether or not the result of the unconsented test should be made available to either patient or family/spouse and the demographics of respondents, or any of the other responses to the questionnaire.

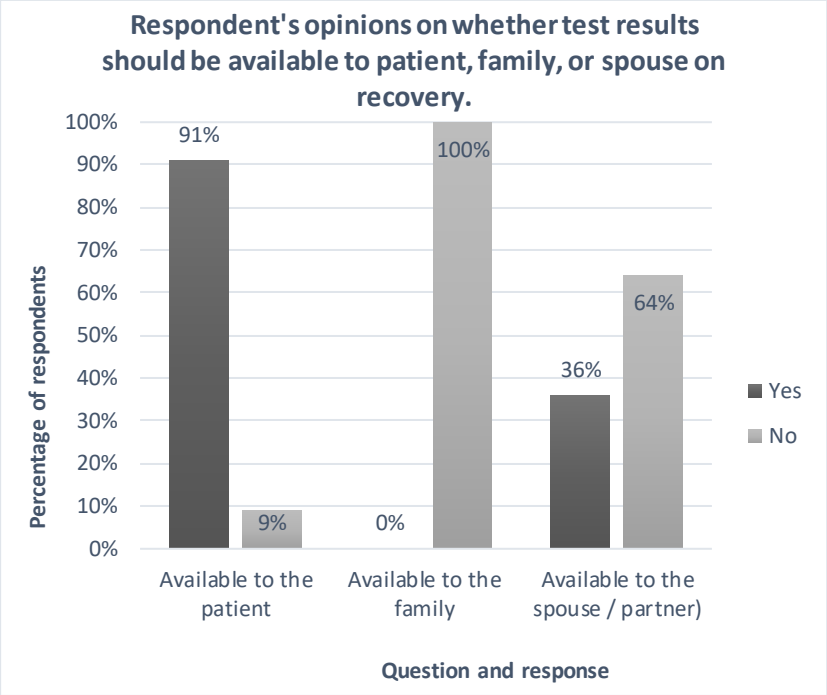

Figure 7. Respondents' opinions regarding disclosure of HIV status in the event of the patients' recovery in ICU.

When considering disclosure of HIV test results in cases where the patient did not survive, seventy four percent of respondents (17/23) felt that the HIV result should be included in the death certificate, ninety one percent (21/23) felt it should not be made available to the family, and eighty three percent (19/23) were of the opinion that the result should be made be available to the partner/spouse (Figure 8).

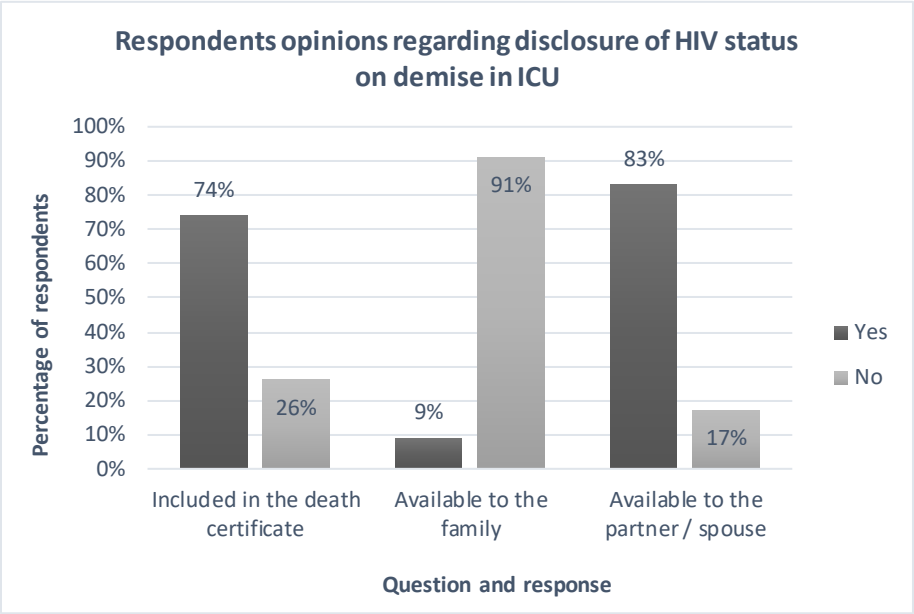

Figure 8. Respondents' opinions regarding disclosure of HIV status in the event of the patients demise in ICU

3.4. Summary of results

Respondents to the survey were mature, experienced physicians who had extensive experience in the field (Figures 1 & 2). The majority were in the age group which would have experienced the beginning of the HIV pandemic in South Africa. There were no respondents who were younger than 30 years or older than 60 years. The absence of respondents younger than 30 years can be explained by the time it normally takes for specialists to progress to subspeciality registration. The absence of respondents over 60 years may be explained by the fact that the subspeciality is relatively young and that until recently, critically ill patients were managed by specialists from their admitting discipline in an open ICU. There was a reluctance to develop policies and protocols for HIV testing in ICU (Figure 2). Reasons given by the respondents for not developing or implementing a policy indicate that they regard unconsented testing as an ethically charged issue associated with significant medico legal risks. Some respondents indicated that they respected current guidelines which discourage HIV testing in ICUs and/or that they followed hospital policy. ICUs that did have a policy had clearly

defined indications for unconsented HIV testing, such as after staff contamination. The results show that the majority of respondents were in favor of HIV testing - that is they felt it was ethical to test for HIV or they were comfortable with performing the unconsented test (Figure 4). Reasons given indicate that the overall perception is that it is in the patient's interest as it would aid management. Stigmatization of the disease was mentioned as well as the lack of clarity regarding legislation. Those ICUs that allowed HIV testing did so because information about the HIV status was considered important to guide management decisions. Some of the institutions regard HIV merely as a chronic condition that requires consideration during patient assessment and management.

Opinion was split over wanting to know the HIV status of all patients in the ICU. However, those who did want to know had clear reasons for this, such as for diagnosis and treatment of unusual or opportunistic infections where commencement of ARVs could be of possible benefit if commenced early. Making a full diagnosis, which would necessitate HIV testing, was mentioned as an ethical imperative, as well as post-test counselling on recovery. One respondent had discussed the issue with experts and they felt that consent should not be required as HIV is now a chronic manageable disease. One respondent referred to the HPCSA guideline regarding substituted consent. One respondent referred to HPCSA guidelines governing consent in patients who are mentally ill and unable to give informed consent. The results show that there was a clear distrust of guidelines that are currently available to guide HIV testing in this group of patients, and that these guidelines are not in the best interest of the patient (Figure 5). Surrogate consent was shown to be distrusted by the respondents and the majority felt that the intensivist in charge should have discretion over the decision to test for HIV (Figure 6). Views on disclosure of HIV test results indicated that the majority of respondents respected the right of the individual. If she/he recovered, the test result would be made available to the patient. All respondents would not provide the results to the family. However, opinion was split over making the result available to the spouse/partner (Figure 7). One third of respondents viewed the safety of the "at risk partner" as sufficiently important to make the results

available despite the ethical implications. If the patient demised, most respondents would release the results to the spouse (Figure 8). Insofar as death certification is concerned, most respondents were of the opinion that the result should be recorded. This is a legal requirement and twenty six percent were either unaware of this requirement or disagreed with it.

The results of the survey indicate that, overall, policies and protocols for HIV testing are lacking in ICUs. Perceptions, however, indicate that intensivists may be in favor of testing without consent. Perceptions are also that the current guidelines are not in the best interest of the patient and that the intensivist should have a greater role in deciding whether to perform the test or not.

Limitations of the study include the small sample size of respondents and that the two Gauteng Academic hospitals did not provide permission to conduct the survey. These are a possible source of bias, and the latter especially so in questions regarding policies and protocols. The results may not be generalizable given the small number of academic ICUs in South Africa and the great disparities in ICU services across the provinces.

CHAPTER 4

DISCUSSION AND CONCLUSION

4.1. Introduction

Ethical issues influencing HIV medicine include human rights, standards of care, privacy and confidentiality, stigmatization, informed consent and protection of vulnerable groups (International guidelines on AIDS and Human Rights: 2006). Due to the influence of perceptions on behaviour, the perceptions of ICU physicians regarding these ethical aspects of HIV medicine are important when they have to decide whether or not to perform an HIV test in critically ill patients. As in other aspects of HIV medicine, the maxim "*Primum non nocere*" (first, do no harm) applies to consent for HIV diagnostic testing.

4.2. Key findings of the survey

Age, experience and wisdom influence physicians (Choudry et al. 2005:260), and those physicians who have witnessed the progression of the HIV epidemic until the rollout of ARVs may have perceptions and opinions that are different from younger, less experienced physicians. The survey represents views of physicians with extensive experience in the field.

The key findings of this survey reflect HIV testing practices by intensivists at academic hospitals who treat critically ill patients. The study sought to investigate availability of protocols relating to HIV testing, doctors' perceptions of guidelines, whether they feel comfortable with performing unconsented HIV testing, and whether they feel it is an ethical practice. Key perceptions relating to surrogate consent and disclosure of results were also examined.

Here, I will discuss the results of the examination of intensivists' practices and perceptions regarding policies and protocols for HIV testing. Thereafter, beneficence, non-maleficence and the law with regard to consent for HIV testing in ICU will be explored. Finally intensivists' views on the relevance of guidelines, surrogate consent and the confidentiality of HIV test results will be discussed. I will thereafter suggest implications for policy.

The practice of avoidance of protocols for HIV testing is significant. In the ICU, implementation of protocols for patient management have been shown to improve outcome and are often implemented routinely. Examples include protocols for lung protective strategies in mechanical ventilation for acute respiratory distress syndrome (ARDS), and employing thresholds for blood transfusion and care bundles for sepsis (Oh, TE. 2003: 329, 915, 59). However, this survey revealed that protocols for HIV testing have not been adopted by the majority of responding ICUs.

The emphasis on full informed consent may discourage clinicians from implementing a protocol. Ethical guidelines of the HPCSA (Booklet 9. Guideline 8.3) and the National Health Act, 2003 (Act No 61 of 2003) do not encourage unconsented testing, and no guidance is provided, such as seeking surrogate consent, for an alternative when it is not possible to obtain informed consent from the patient.

Unconsented HIV testing is an ethically charged issue and carries with it connotations of malpractice. Targeted testing where a patient is tested only if clinically indicated and in the patient's best interest could in fact be regarded as a protocol, provided that certain conditions are met prior to ordering the test. Such an approach has been adopted by critical care authorities in South Africa who advocate early initiation of ARVs in certain cases, such as patients with AIDS-defining conditions with

a low CD4+ count, and in whom a prolonged ICU stay is anticipated (Venturas and Richards 2012: 10-14).

The majority of intensive care physicians were comfortable with HIV testing and were of the opinion that it was ethical. Two models of medical ethics may be applied to critical care (Wills 2011:1491). The model that views patient autonomy and self-determination as being of primary importance regards unconsented testing as a breach of the patient-physician contract. However, breaching autonomy may not be permanent as patients may still have a limited right over the confidentiality of their test results on recovery. Conversely, a beneficence-based model would suggest ICU physicians regard unconsented testing as permissible as it may be in the interest of the patient. However, the evidence for an advantage of antiretroviral therapy in critically ill patients is not consistent, and while it is accepted to be beneficial in certain cases, it may be harmful in others. A limitation of studies into the use of ARVs in critical illness is that there are no prospective trials that could establish the true risk and benefit.

However temporary, disregard for the doctrine of informed consent was a concern to some respondents. Compromised autonomy accompanies the impaired capacity in critical illness (Tonelli MR: 2010) and this may shift the physician-patient relationship to unconsented testing in the interest of beneficence, rather than denial of the possible benefit of the test in the name of autonomy. A weak paternalistic approach may be preferable if one considers that the choice of intervention can be justified if it is in the interests of the individual.

A minority of physicians wanted to know the HIV status of all patients in the ICU, reflecting that they considered that breaching autonomy was acceptable, because it was done in the best interests of the patients and would guide management.

Utilitarian views of triage for ICU beds given the limitation of resources are also very real concerns. Intensive care units are less likely to offer ICU admission to patients if they have a poor chance of survival. Given the concerns around HIV infection such as the poor outcome from opportunistic infections, this is an often unspoken ethical problem for the intensivist, resulting in a reluctance to perform the diagnostic test.

The survey uncovered a largely negative perception of guidelines pertaining to unconsented HIV testing. Available guidelines for HIV testing in South Africa are drawn from Chapter 2 of the National Health Act (2003) and Ethical Guidelines of the HPCSA. Both legal and ethical guidelines do not favour unconsented testing. Respondents' negative perceptions regarding these guidelines again reflect the opposing forces of respect for autonomy and best interest of the patient. While allowances are made for HIV testing under specific circumstances in the law and ethical guidelines, their limitations may result in negative perceptions.

The survey found that surrogates were perceived as neither reliable nor acceptable as they were unlikely to represent the true wishes of the patient. According to Beauchamp (2013:190), surrogate decision-makers should be qualified by adequate competence, knowledge, emotional stability and a commitment to act in the patient's best interest. This, however, cannot be assumed to be true for all relatives. Previous studies (Shalowitz 2006: 493) found that the majority of ICU physicians felt that families did not generally meet the above criteria when it came to HIV testing. When considering disclosure of HIV test results, respect for the patient's autonomy was evidently paramount, in that most doctors would reveal the results to the patient only or, in the event of the patient's death, to the spouse only. Disclosure to the spouse or partner may be in her/his best interests due to the transmissibility of the HIV.

4.3. Implications for policy

Policy-driven care in the ICU has improved outcomes in critically ill patients and is associated with shorter length of stays in ICU and an overall improved quality of care (Wall 2001:283). Policies and protocols regarding HIV testing are influenced by medico-legal and ethical concerns, the desire to individualise treatment, and either the opinion that no policy is needed or that a hospital policy should be sufficient. The CDC revision of guidelines for HIV screening and testing in the general population reflected a shift to viewing HIV as a public health issue. Previously HIV testing without consent was considered an infringement on civil liberties of patients. This shift encouraged the development of protocols, such as opt-out testing where individuals are routinely tested unless he or she specifically refuses (MMWR 1991: 1-31

Policies and protocols are concerned with diagnosis and management of disease. In the case of patients admitted for an AIDS related condition, these would include testing for HIV and opportunistic infections, determination of the CD+ count and, thereafter, further management based on these findings. However, HIV infection is regarded as a disease of exception and protocols for testing in the ICU either do not exist, or are informal. The thresholds for testing may be inconsistent; this is in contrast to testing in the general population, which is governed by guidelines published by the Department of Health that mandate pre- and post-test counselling and full informed consent (National HIV Counselling and Testing Guidelines: 8-12). Physicians may then not routinely consider unconsented testing and test only in exceptional cases, such as pre-dialysis or in the event of staff contamination. National Department of Health Guidelines for infection control should be adhered to at all times (South African Guidelines for Renal Replacement. 2008:34).

In contrast to the early phases of the epidemic, rapid testing now enables HIV status to be available within 20 minutes. If early access to antiretroviral treatment is also available, interpretation of the law must take into consideration that the intention of the physician is to act in the patient's best

interest, and in those terms a positive result would significantly change the clinical management strategy.

Furthermore, the perception is that surrogate consent is unsatisfactory, meaning that the decision to perform the HIV test and whether it was necessary or not would rest with the intensivist, who is the best person to make that decision.

4.4. Limitations of the study

There were a number of limitations to the study. As a survey limited to 47 participants, the study cannot claim to represent the views of the majority of intensivists in South Africa, but rather of a select group, which excluded ICU physicians from centres whose views would have been valuable, and which may have significantly influenced the results as well. Hospitals that declined permission were large academic centres and exclusion of these centers may be a source of bias, particularly in questions one to three. Not all critically ill patients are admitted to academic ICUs of which the survey respondents were representative. Due to a shortage of ICU beds in South Africa, the majority of critically ill patients with complex disorders may be managed in smaller, less specialised hospitals. Given the shortage of specialists practising in the public sector, many critically ill patients are managed by non-specialists in intensive care who were not invited to participate in the study.

The survey did not include the perceptions and practices of private sector physicians, which could be a subject for future research. An audit of critical care services in South Africa by Scribante and Bhagwanjee (2007: 1311) found that the total number of ICU beds in the private sector exceeded the number in the public sector.

Critical care medicine is still developing as a discrete subspecialty, and specialists who run ICUs in South Africa have different base specialities, for example internal medicine, anaesthesiology, or surgery. This may result in different management approaches and level of exposure to critically ill, HIV positive patients during training, which could influence perceptions of HIV testing. Examining the bioethical aspects of the limitations mentioned above could be a subject of further research. The results of the present survey may, however, be valuable, because consent for HIV testing in ICUs has not been studied previously in the field of HIV medicine in South Africa. A strength of the study was its anonymous nature, which allowed expression of opinion on a sensitive issue.

4.5. Conclusion

The results of this survey indicate that physicians who work in South African academic ICUs regard unconsented HIV testing among critically ill patients as ethical. Despite the possibility that such testing might be seen as practicing outside of the available more general guidelines pertaining to HIV testing (which do not provide recommendations for patients in ICU who cannot communicate), intensivists are comfortable with performing the test. Furthermore, they believe that, when the patient is unable to give consent, the clinician is the best person to decide whether or not to test for HIV, and surrogate decision-makers cannot be trusted to be objective or to reliably reflect the true wishes of the patient. Clinicians believe that the results of HIV tests should be kept confidential and shared only with the patient, or where appropriate with the spouse, and they respect the legal requirement to disclose the diagnosis on the death certificate.

Current general guidelines for HIV testing are not perceived by intensivists as being in the best interests of patients. Unconsented HIV testing may be of advantage to patients in ICU where it facilitates early diagnosis, changes in management and administration of antiretroviral medication. Nevertheless, despite the necessity for performing the test, where the results could possibly improve outcomes in a select group of patients, only a minority of ICUs have their own policies and

protocols for HIV testing. Accordingly, new policies and protocols specific to the ICU scenario urgently need to be developed in accordance with ethical principles.

CHAPTER 5

REFERENCES

5.1. REFERENCES

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5.2. LAWS USED IN THE REPORT: ACTS OF PARLIAMENT

The Births and Deaths Registration Act 51 of 1992.

The National Health Act 61 of 2003.

5.3. CASE LAW

I. *C* vs *Minister of Correctional Services* 1996 (4) SA 292 (T).

II. *Jansen van Vuuren & Another NNO* vs *Kruger* 1993 (4) SA 842 (A).

III. *Hoffmann* vs *SA Airways* 2001 (1) SA 1 (CC).

IV. *Tarasoff* vs *Regents of California* 17 Cal.3d 425, 131 Cal.Rptr. 14, 551 P.2d 334 (1976)

V. *VRM* vs *Health Professions Council of South Africa and Others 2003* (JOL) 11944 (T).

5.4. The South African Patient's Rights Charter (National Department of Health, 1996)

CHAPTER 6

APPENDIX

Appendix A: THE QUESTIONNAIRE

	Yes	No	
1. Does your ICU have a policy or protocol for HIV testing?			
2. If yes, what is the policy?			
3. Are there any specific reasons for introducing/not introducing a policy?			
4. Would you want to know every patients' HIV status in your ICU	Yes	No	
5. If Yes, why?			
6. If No, why not?			
7. Do you consider it ethical to perform unconsented HIV testing in critically ill patients?	Yes	No	
8. Are you comfortable with HIV testing with unconsented HIV testing in critically ill patients?	Yes	No	
9. Explain why			
10. Insofar as current guidelines regarding HIV testing is concerned:			
Are they still relevant with regard to critically ill patients	Yes		No
Do they serve the best needs of the patient	Yes		No
11. If informed consent cannot be obtained, is surrogate consent from a spouse or partner:			
A reliable alternative	Yes		No
An acceptable alternative	Yes		No
12. Should unconsented testing be solely at the discretion of the intensivist, whether or not a surrogate is available?	Yes		No

13. On recovery, should the result of the unconsented test be made available to:		
The patient	Yes	No
The family	Yes	No
The spouse	Yes	No
14. If the patient does not survive, should the result of the unconsented test be:		
Included in the death certificate	Yes	No
Made available to the partner/spouse	Yes	No
Made available to the family	Yes	No
15. Please enter your age:	×	×
<30yrs		
31-40yrs		
41-50yrs		
51-60yrs		
>60yrs		
16. Please enter your years of practice as an intensivist	×	×
<5yrs		
5-10yrs		
10-20yrs		
>20yrs		
In training		

Appendix B: Responses

Table 2. Responses to the questionnaire

	Yes	No
1. Protocols and policies		
• Protocol or policy in place.	19	5
2. *Perceptions regarding unconsented HIV testing in ICU*.		
• Find it ethical to test.	20	4
• Comfortable with testing	21	3
• Would like to know HIV status of all patients in ICU.	11	13
3. *Perceptions of guidelines*.		
• Current guidelines are no longer relevant.	20	4
• Current guidelines do not serve the best interests of the patient.	22	2
4. Perceptions of surrogate consent.		
• Surrogate consent is a reliable alternative.	3	21
• Surrogate consent is an acceptable alternative.	8	16
• Consent should be at sole discretion of ICU physician (n = 23, one respondent did not answer this question).	22	1
5. Disclosure of HIV test results.		
On recovery the HIV result should be:		
• Made available to the patient. n = 23 (one respondent did not answer this question)	21	2
• Made available to the family. n = 23 (one respondent did not answer this question)	0	23
• Made available to the spouse or partner. n=22 (Two respondents did not answer this question).	8	14
On demise the HIV test result should be:		
• Made available to the family.	2	21
• Included in the death certificate	17	6
• Available to spouse / partner	19	4

Appendix B (continued): Responses to the open ended questions:

QUESTION 2.

The following policies were described:

- No unconsented testing.
- Only testing without consent for ventilated patients unable to consent if a staff contamination occurs or if required pre-dialysis; all others will be tested only after fully informed consent and after recovery. No testing without consent for other indication is presently permitted.
- We do not test without patient consent except in the event of a needle stick or splash to a health care worker.
- VCT if possible, otherwise test if result may alter clinical approach.
- This is not a written protocol but most patients are tested with the aim of providing optimal care, as a positive test might influence management. HIV is viewed as a chronic but manageable disease, just like Hypertension or Diabetes.

QUESTION 3.

The following reasons were given by the respondents who indicated that their ICU did not have a policy:

- The director of ICU has just not put one in place.
- Not enough staff to design policy at present.

- We do not regard HIV as being inherently different from any other medical illness. We believe that investigations be dictated by the patient's medical condition and be performed when appropriate.
- Can improve patient management. May result in better patient outcomes if appropriate treatment implemented.
- Every patient is different (to allow for individualisation).
- Current sensitivity around testing and medico legal concerns regarding a formal policy.
- Concerns about consent and legislation.
- Ethically charged area makes definite policy more difficult.
- Standard rules for testing apply - obtain consent.
- There is a hospital policy in place.
- HIV testing guidelines are clear that unconsented testing is not acceptable.
- HIV testing hardly ever done in our ICU. Most patients have HIV results prior to ICU admission (from referring disciplines).
- No reason given (8 respondents).

QUESTION 5.

The following reasons were given for WANTING to know the HIV status of every patient in the ICU:

- Healthcare worker safety
- Would make me cap therapy much sooner than equivalent non-HIV positive patient.
- Epidemiological reasons.
- I think it could change management in certain patients.

- It may change treatment of the patient and give better insight in disease processes.

- It may guide treatment in both positive and negative directions.
- It will allow for better selection of antimicrobials; enable better planning for dialysis. (Different machines for the HIV positive); Assist in screening for unusual pathogens and may assist in explaining x-ray findings that may be of varied causes.
- Multiple individual and social implications. Patients and family have right to treatment. Patients on ARVs are living long productive healthy lives.
- Safety of staff is important.
- To assist in prognostication.
- To possible initiate antiretrovirals early.
- To consider them for antiretrovirals.
- It may change the way we manage patients.
- To provide optimal care and give proper treatment as the spectrum of organisms changes.
- Depending on HIV status and CD4 count. Also it is better diagnosed early before the CD4 count drops and opportunistic infections occur.

QUESTION 6.

The following reasons were given for NOT wanting to know the HIV status of every patient in the ICU:

- A test in general should only be requested if it affects management, this would apply to HIV.
- Any investigation should only be done if relevant to the suspected/known disease. I would want to know the status if it would influence diagnosis or treatment. Being HIV positive per se may not influence care in many patients.
- Does not always impact on treatment. Would only like to know in select cases.

- Does not change how I manage the patient acutely.

- Has minor impact on current treatment protocols. Most patients have HIV results prior to ICU admission (from referring disciplines).
- I only need to know their status if it is going to impact on their ICU management.
- It does not alter management on all of the patients in the ICU.
- It won't always change management.
- Only if clinically relevant, VCT and ARVs (if necessary) can be implemented after recovery from acute illness.
- Testing is only carried out when it is believed that results will alter or direct therapy and intervention.
- Use of universal precautions is enough. Treat every patient for their presenting illness whether HIV related or not.
- This information would not be relevant in every patient.

QUESTION 9.

The following reasons given for being comfortable with unconsented HIV testing

- It would only be done in the patients benefit.
- If it's in the patients best interests.
- If it is in the patients' best interest and will affect therapy given, I think it is reasonable to test without consent. (Our current legislation is however against this or not clear).
- Justification that it may impact on treatment.
- I can start ARV treatment if I feel that t will benefit the patient's current condition.
- Would aid clinical management.

- It is information central to the care of the patient. While I am comfortable with the concept, I do not practice it as the unit's policy is one of no un-consented testing.

- It is an ethical imperative to make a full diagnosis in a critically ill patient. They can be counselled later and given the result if they so wish.
  - If I need to know their status to manage them better but am unable to get the consent because they are critically ill or intubated, then I feel it is ethical to do the test and manage them accordingly. If the patient recovers, then they should receive pre-test counselling and offered the opportunity to know the results.
  - Why should we treat HIV differently from any other disease? Testing helps diagnostically and leads to appropriate therapy. We perform many other tests in critically ill patients when indicated.
  - Survivors can be consented and those who refuse / die can have their results discarded.
  - Possibly early initiation of ARVs improves prognosis.
  - Knowledge of ARV status can improve diagnostics, treatments, management of individual patients. And epidemiological information can improve critical care service provision.
  - I do it for their benefit. If it were positive, it may change my treatment, but not be the cause for withdrawal (unlikely).
  - It offers the prospect of improving care for the patients that would not be there if we could not perform unconsented testing. It is also important to destigmatise HIV but this is not the main reason.
  - If the HIV status of the patient informs the intensivist as to what type of therapy the patient requires or prognosis the patient has, this is useful information and will have impact on the patient's management.

- I am comfortable as I have discussed this with experts in the field but we all feel that consent for HIV testing should not be required now that it has become a chronic manageable disease with good, near normal life expectancy. If anything there should be an opting-out policy. In many European countries and the US consent is not required for HIV testing, we also don't ask for consent of Hepatitis testing. With regards to patients unable to consent we refer to the HPCSA clause that asks for substituted consent. It is in the interest of the patient to know their status early and might influence ICU management. I am not sure what you mean by question 10: Obviously the principles of counselling apply. The critically ill patients should perhaps be mentioned as a specific subgroup where informed consent does not apply. Although one could apply the rules of the mentally unable to give consent patient.
    - Two main reasons: The current consent process actually adds to the stigma of the disease - it should be tested like any other disease for which there is a valid laboratory test; If the result may change my management of the patient it is then in the best interests of the patient.
- It will provide more background information.
- May markedly alter clinical approach and treatment; e.g. Pneumocystis pneumonia, chronic diarrhoea.
- HIV should be seen as any other disease process. Herpes, influenza, cancer. We test if clinically relevant and so we should test for HIV.

The following reasons were given for not being comfortable with HIV testing in critically ill patients:

- At the moment, we still require consent. Only when consent is obtained would it be correct.
- Medico-legal implications.
- It is unethical.

APPENDIX C: INFORMATION DOCUMENT

INTENSIVISTS' PERCEPTIONS OF UNCONSENTED HIV TESTING IN SOUTH AFRICAN ADULT INTENSIVE CARE UNITS

Dear Colleague

My name is Dr Dhivendra Singh. I am conducting a survey of intensivists' views regarding unconsented testing for HIV infection in South African adult intensive care units. This survey is part of my research report for the degree of MSc Med (Bioethics and Health Law) at The Steve Biko Centre for Bioethics, University of Witwatersrand, Johannesburg.

The study is descriptive, and involves a semi-structured once off questionnaire to which you are invited to respond. This questionnaire will be distributed to registered intensivists (in Critical Care) practicing at academic hospitals in South Africa. The questionnaire consists of questions regarding your practice regarding testing for HIV in your ICU and your views on testing and currently available guidelines that are available to you regarding this issue. The questionnaire should take no longer than 15 minutes to complete.

There is no direct benefit to participating in this research. The benefit of participating in the study is that your views regarding an issue that is of concern to intensivists will be expressed via this questionnaire. The results may be published.

Please note that this survey is not an enquiry into standards of care and neither you nor your institution will be identified. Participation is voluntary and you are free to refuse to participate or withdraw at any time.

The questionnaire is anonymous and information you provide will remain confidential. By completing the questionnaire and sending it back, tacit consent to participate is given.

My contact details are:

Telephone: Office: 0312604328

Cell phone: 0824483873

Email: singhd6@ukzn.ac.za

Contact details of the Research Ethics Administrator for the reporting of any complaints or problems with this study:

Anisa Keshav (Secretary of the HREC), WITS University, tel: 011 717 1234

APPENDIX D: LETTER OF ETHICAL APPROVAL FROM WITS UNIVERSITY

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG
Division of the Deputy Registrar (Research)

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)
R14/49 Dr Dhivendra Singh

CLEARANCE CERTIFICATE	M111139
PROJECT	Intensivist' Perception of Un-consented HIV Testing in South African Intensive Care Unit
INVESTIGATORS	Dr Dhivendra Singh.
DEPARTMENT	Steve Biko Centre for Bioethics
DATE CONSIDERED	28/10/2011
M1111390DECISION OF THE COMMITTEE*	Approved unconditionally

Unless otherwise specified this ethical clearance is valid for 5 years and may be renewed upon application.

DATE 28/10/2011 **CHAIRPERSON** .....
(Professor PE Cleaton-Jones)

*Guidelines for written 'informed consent' attached where applicable
cc: Supervisor : Professor Ames Dhai

DECLARATION OF INVESTIGATOR(S)

To be completed in duplicate and **ONE COPY** returned to the Secretary at Room 10004, 10th Floor, Senate House, University.
I/We fully understand the conditions under which I am/we are authorized to carry out the abovementioned research and I/we guarantee to ensure compliance with these conditions. Should any departure to be contemplated from the research procedure as approved I/we undertake to resubmit the protocol to the Committee. **I agree to a completion of a yearly progress report.**

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES...

APPENDIX E

LETTER OF PERMISSION TO HOSPITAL CEOS.

The CEO

Hospital: (Name of hospital to be inserted)

Re: Permission to conduct research in your intensive care unit

Dear Dr (Name of CEO to be inserted)

My name is Dr Dhivendra Singh. I am an MSc Med (Bioethics & Health Law) student at The Steve Bike Centre for Bioethics and Health Law, University of Witwatersrand, Johannesburg. As part of a research report, I intend to conduct a survey among intensivists at your hospital's intensive care units regarding unconsented testing for HIV infection in critically ill patients. The survey will be distributed to 7 academic hospitals in South Africa. It is a self-administered web based survey which is designed to guarantee anonymity. Neither the respondents, the academic unit nor the hospital will be identifiable. The Academic Heads and Directors of all ICUs involved in the survey will be asked for permission to conduct this survey among their staff intensivists prior to distributing the survey. A copy of the research protocol is attached.

I would like to request permission to conduct this survey at your hospital, pending ethical approval from the Research Ethics Committee at the University of Witwatersrand and the Biomedical Research Ethics Committee at the University of KwaZulu-Natal where I employed as a lecturer in Anaesthetics & Intensive Care.

Yours sincerely

Dr D Singh

APPENDIX F

LETTER OF PERMISSION TO ICU HEADS.

The Head of Departments

Department of Anaesthetics & Intensive Care

University of _____.

Re: Permission to conduct a survey in your intensive care unit.

Dear Professor

My name is Dr Dhivendra Singh. I am an MSc Med (Bioethics & Health Law) student at The Steve Biko Centre for Bioethics and Health Law, University of Witwatersrand, Johannesburg. As part of a research report, I intend to conduct a survey among intensivists at your hospital's intensive care units regarding unconsented testing for HIV infection in critically ill patients. The survey will be distributed to 7 academic hospitals in South Africa. It is a self-administered web based survey which is designed to guarantee anonymity. Neither the respondents, the academic unit nor the hospital will be identifiable. The Academic Heads and Directors of all ICUs involved in the survey will be asked for permission to conduct this survey among their staff intensivists prior to distributing the survey. A copy of the research protocol is attached.

I would like to request permission to conduct this survey at your hospital. Ethical approval has been obtained from the Research Ethics Committee at the University of Witwatersrand and the Biomedical Research Ethics Committee at the University of Kwazulu-Natal where am I employed as a lecturer in Anaesthetics & Intensive Care.

Yours sincerely

Dr D Singh

Dr Dhivendra Singh

MB ChB FCA Cert Crit Care (SA)

Principal Specialist & Lecturer

Anaesthetics & Intensive Care

King Edward VIII Hospital

Durban