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AN ETHICAL ANALYSIS OF HIV SELF-TESTING IN SOUTH AFRICA USING PRINCIPLIST, UTILITARIAN AND HUMAN RIGHTS APPROACHES, INCLUDING A BENEFIT/HARM ANALYSIS

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A research report submitted to the Faculty of Health Sciences, University of the Witwatersrand, Johannesburg, in partial fulfilment of the requirements for the degree Masters of Science in Medicine in Bioethics and Health Law.

Johannesburg, 2019

DECLARATION

I declare that this research report is my own, unaided work. It is being submitted for the Degree of Master of Science at the University of the Witwatersrand, Johannesburg. It has not been submitted before for any degree or examination at any other University.

_____

(Signature of candidate)

_____day of _____20_____at_____

ABSTRACT

This research report explores the ethical implications of using the HIV self-testing kit as an innovative testing tool to expand access to HIV testing services and potentially increase HIV testing uptake in South Africa among individuals who may otherwise not test, as they may want to test for HIV in private or at their own convenience. The arguments are drawn from the principle of autonomy, principles of beneficence and non-maleficence, as well as the principle of justice. In addition, the ethical theory of utilitarianism is used in a harm/benefit analysis to further support my arguments. The research method employed is purely normative and derives information from the available literature on HIV self-testing. The conclusion reached in this research report is that the implementation and scale-up of HIV self-testing in South Africa is ethical, as self-testing does not violate any of the ethical principles and has the potential to provide more benefits than harms. However, the potential for coercion and intimate partner violence surrounding HIV self-testing remain issues of concern, as these occurrences would challenge the principle of non-maleficence in the use of the kit. However, empirical data on the potential social harms do not provide compelling ethical grounds for restricting the sale of HIVST kits in South Africa.

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ACRONYMS

AIDS	**Acquired Immune Deficiency Syndrome**
ART	**Antiretroviral Treatment**
CICT	**Client-Initiated Counselling and Testing**
HIV	**Human Immunodeficiency Virus**
HTS	**HIV Testing Services**
HCT	**HIV Counselling and Testing**
HIVST	**HIV Self-Testing**
HSST	**HIV Self-Screening Test**
IPV	**Intimate Partner Violence**
MCC	**Medicines Control Council**
NDOH	**National Department of Health, South Africa**
PICT	**Provider-Initiated Counselling and Testing**
PLWH	**People Living with HIV**
PrEP	**Pre-Exposure Prophylaxis**
RDT	**Rapid Diagnostic Test**
SAHPRA	**South African Health Products Regulatory Authority**
SAPC	**South African Pharmacy Council**
VCT	**Voluntary Counselling and Testing**
WHO	**World Health Organization**

CHAPTER ONE - THE USE OF HIV SELF TESTING IN SOUTH AFRICA

1.1 Introduction

This report supports the decision taken by the South African Pharmacy Council to remove the ban on pharmacies to sell HIV self-testing kits to the public. The reason for introducing self-testing in South Africa is to expand access to HIV testing services and to increase HIV testing uptake among population groups who may otherwise not test, such as men and key populations (World Health Organization, 2016b; South African National Department of Health, 2018). This move was taken to reach the public health goal of reducing HIV transmissions, simultaneously protecting human rights and respecting the autonomy of the user. Key populations are groups of individuals "due to specific higher-risk behaviour, are at increased risk of HIV infection irrespective of the epidemic type or local context" and comprise men who have sex with men (MSM), female sex workers, transgender people, and people who inject drugs (World Health Organization, 2016b).

This research report explores the ethical implications of using the HIV self-testing kit in South Africa, introduced as an additional HIV testing tool in agreement with the World Health Organization (WHO) recommendations. My arguments are drawn from the principles of autonomy and beneficence that are important in assuring protection of dignity and human rights. Because the protection of human rights is of outmost importance, the South African government took almost four years after the first HIVST kit was approved for public use before implementing it in South Africa. In addition, the government required more research to be done before moving forward and implementing the newly innovated HIV testing modality (South African National Department of Health, 2015b). In South Africa, HIV self-testing is known as HIV self-screening, however, in this research report I will use HIV self-testing (HIVST).

Self-testing for HIV is defined as "a process in which a person collects his or her own specimen (oral fluid or blood) and then performs an HIV test, reads and interprets the results in a private setting, alone or with someone she or he trusts" (World Health Organization, 2016b). This report argues that the implementation and scale-up of HIV self-testing as a new health intervention in South Africa is ethical. Defined by Expand Net, scaling-up means "deliberate efforts to increase the impact of successfully tested health innovations so as to benefit more people and to foster policy and programme development on a lasting basis" (World Health Organization, 2010).

Because of limited resources in underdeveloped and developing countries, the perfect implementation of new interventions is an impossible mission, and decision makers must acknowledge this, but that should not stop them from trying (Gandjour, 2015). With regard to the implementation of HIVST, human rights are supported by the ability of this intervention to provide users with the opportunity to exercise their autonomy and protect their privacy (van Dyk, 2013; Indravudh et al., 2017). Respect for autonomy refers to respecting a person's ability to make a choice, self-govern, and the freedom of will or liberty of action (Beauchamp & Childress, 2013). This research report argues how the use of HIV self-testing benefits the individual user and further demonstrates how its use has the potential to help the South African government to achieve its public health goal of increasing HIV testing uptake among individuals who may want to test in private and at their own convenience.

A qualitative study conducted among men who have sex with men (MSM) living in North Carolina, USA, revealed that HIV self-testing has the potential to increase frequency of HIV testing (Hurt et al., 2016). Furthermore, it was found that increased HIV testing frequency benefits both the individual and the public at large (Sandfort et al., 2015). Moreover, a study conducted on MSM living in China showed that frequent HIV testing was associated with lower odds of HIV infection possibly as a result of reduced high risk behaviour (Liu et al., 2016). In addition, a study conducted in USA found that increased HIV testing frequency together with effective treatment or HIV care of HIV-positive individuals is likely to result in reduced HIV incidence (Delaney et al., 2015). Therefore, frequent HIV testing is one of many benefits to be derived from self-testing for HIV, and more will be discussed in greater detail in later chapters.

However beneficial HIV self-testing may be, it is not without challenges. The arguments against its use will also be discussed, including coercion, a violation of both human rights and respect for autonomy, as well as intimate partner violence (IPV). The potential harms stemming from the use of HIV self-testing raise ethical concerns relating to the principle of non-maleficence. The principle of non-maleficence "asserts an obligation not to inflict harm intentionally" (Beauchamp & Childress, 2013). Suicide is one of the most compelling arguments against HIVST as it lacks counselling, however, none of the studies conducted thus far have shown evidence of suicide as a potential harm related to the use of an HIV self-testing kit (Choko et al., 2011; Youngs & Hooper, 2015; Thirumurthy et al., 2016). These potential harms will be discussed in the later chapter, and

harm/benefit analysis will be used to show that the implementation of HIV self-testing in South Africa is ethical.

The HIV/AIDS pandemic continues to present a significant threat to global and local public health. The transmission of HIV mainly occurs through unprotected sexual intercourse, oral sex, and sharing of contaminated needles, behaviours that occur in private (Mann, 1988; World Health Organization, 2017c). Other ways of transmission include blood transfusion, and mother to child transmission (World Health Organization, 2017c). And, should others come into contact with someone's HIV-infected bodily fluids (blood, semen or vaginal fluids), they too may be infected with HIV, hence everyone has to take precautions and prevent this from happening (Bauer, 2010).

According to the UNAIDS, in 2018 there were 36.9 million people infected with HIV globally, with approximately 7.2 million living in South Africa (UNAIDS, 2018). Despite considerable progress in controlling the epidemic, in South Africa, 270,000 individuals were newly infected, and in 2017 alone 110,000 AIDS-related deaths were recorded (UNAIDS, 2018). Interestingly, the latest data shows that the new HIV infections between 2009 and 2016 declined by 39% (South African Institute of Race Relations, 2018). Moreover, in a global effort to end the AIDS epidemic, UNAIDS proposed the "90-90-90 targets", where the first 90 calls for 90% of HIV infected individuals to be aware of their status by 2020 (UNAIDS, 2016a).

South Africa has made great strides and has reached the first 90 of the 90-90-90 UNAIDS 2020 target, with an estimated 90% of individuals infected aware of their HIV status (UNAIDS, 2018). As amazing as this may be, we need to be aware that this data is largely obtained from women at antenatal clinics, and from nationally representative population-based surveys (UNAIDS, 2018). Therefore, women not attending antenatal clinics, as well as individuals missed by these surveys are not included. Moreover, infection rates together with AIDS-related deaths in South Africa are still very high (UNAIDS, 2018). In addition, UNAIDS reports that key populations, requiring frequent testing, still lag behind (UNAIDS, 2018). In turn, this has created a demand for innovative interventions targeted at increasing HIV testing uptake in all groups and closing testing gaps.

The success of the HIV/AIDS global response is hugely dependent on everyone knowing their HIV status (World Health Organization, 2016b). The South African government's strategic plan to increase HIV testing uptake, is to "expand HIV testing through diversifying testing approaches and services by combining provider-initiated testing, community-based testing and self-testing, and

promoting decentralisation of services to reach underserved populations and those with high HIV burden while ensuring equity" (SANAC, 2017). In addition, in September 2016, South Africa introduced the 'test and treat' strategy, where all individuals newly diagnosed with HIV regardless of their CD4 level are offered treatment (UNAIDS, 2016c). This move eliminates any ethical concerns over efforts to increase HIV status awareness in the absence of treatment (UNAIDS, 2016c).

Treatment and linkage to care offered to HIV-positive individuals are some of the benefits that come with the knowledge of an HIV-positive status. Moreover, receiving treatment also benefits the individual by improving the quality of life, increasing life expectancy, and it also benefits the public through reduced onward transmission, ultimately resulting in a decreased population incidence rate (Cohen & Gay, 2010; South African National Department of Health, 2015). The WHO defines HIV incidence as "the number of new HIV infections in a population during a certain time period", and is important in evaluating the prevention and treatment effectiveness (2018).

This research report argues that HIVST is ethical using a principled-based approach, and by conducting a harm/benefit analysis under the ethical theory of utilitarianism. The action taken by the South African government to allow use of HIV self-testing is not only for public health benefit, but also for the benefit of the user directly. Exploring the ethical principles with regard to using HIV self-testing in South Africa will demonstrate whether this new intervention respects human rights, respects autonomy, and provides more good than harm, and if it is indeed ethical. I will also explore the barriers to testing for HIV among men, such as lack of confidence in health care and fear of stigma and discrimination, and show how HIV self-testing promises to overcome these barriers and increase HIV testing uptake.

1.1.1 HIV testing modalities in South Africa

The goal of HIV testing services (HTS) is "to identify people living with HIV timeously through the provision of quality testing services for all and effectively link them to appropriate prevention, care, treatment and support services" (South African National Department of Health, 2016). Testing for HIV is regarded as the entry point of care, as it offers individuals the opportunity to be aware of their HIV status and access appropriate care if found to be HIV-positive (South African National Department of Health, 2015). Moreover, testing for HIV must always be voluntary, and

linkage to treatment, care and other services must be available (World Health Organization, 2012). Over the years South Africa has embarked on different HIV testing strategies in the hope of increasing HIV testing uptake and to reach the public health goal of fewer HIV transmissions (South African National Department of Health, 2016).

An HIV test that is conducted at health care facilities consists of either client-initiated counselling and testing (CICT) or provider-initiated counselling and testing (PICT), and in both instances counselling is offered (Menna et al., 2015; South African National Department of Health, 2016). Facility based testing is offered at clinics, and mobile or fixed stand-alone voluntary counselling and testing services and in hospitals (South African National Department of Health, 2016). The CICT mode of testing requires patients to walk in with the intention of testing for HIV, whereas with PICT, HIV testing is routine for all patients coming into health care facilities, unless they opt-out from being tested (South African National Department of Health, 2016).

In South Africa, the PICT approach was adopted as an intervention to increase HIV status awareness (Madiba et al., 2015). It resulted in increased HIV testing rates and early diagnoses of HIV infected individuals (Groves et al., 2010; Dalal et al., 2011; South African National Department of Health, 2016). The PICT approach of testing employs a population-based approach to autonomy, where the notion of autonomy is applied to the population as a collective for the good of the society, rather than for individuals (Munthe, 2008). However, it raises ethical concerns, as it may erode the importance of informed consent, which is a human rights violation (Groves et al., 2010; Fields & Kaplan, 2011; van Dyk, 2013).

My research does not encompass arguments around informed consent or the lack thereof in PICT HIV testing. The facility-based testing approach plays an important role and provides a service to many people, however it continues to miss those at high ongoing risk (Johnson et al., 2017). I now shift my attention to the benefits derived from knowing one's HIV status through testing.

1.1.2 Benefits of HIV testing

Factors that drive individuals to test for HIV include pregnancy in women, frequent visits to clinics, and men showing symptoms of infection (MacPhail et al., 2009). Testing for HIV has the potential to enhance one's quality of life and the country's health outcomes, and it is a necessity before

receiving treatment that will prolong the lives of individuals who test HIV-positive (South African National Department of Health, 2015; World Health Organization, 2016a). Moreover, testing for HIV or self-testing for HIV "must always be to benefit the individual screened and improve health outcomes at the population level" (South African National Department of Health, 2018). In a utilitarian ethical view, testing for HIV is beneficial in the sense that it benefits the greater public by helping public health to reach its goal of lowering new HIV infections without infringing human rights and violating autonomy. Utilitarianism is an ethical theory that proclaims we ought to choose an act that produces the maximal overall welfare (Beauchamp & Childress, 2013).

Increasing HIV testing rates along with the availability of treatment, supports section 11 of The South African Constitution, that, "Everyone has the right to life" (Republic of South Africa, 1996). According to John Harris, "persons are beings capable of valuing their own lives", and we demonstrate the value we place on life through health care (1992). Therefore, individuals who have no knowledge of their HIV-positive status miss out on benefiting from early treatment and may continue with their risky sexual behaviours, thus unknowingly transmitting HIV to others (Chesney & Smith, 1999).

South Africa has the largest antiretroviral therapy (ART) programme in the world, with an estimated 3.9 million people living with HIV currently receiving HIV treatment (South African National Department of Health, 2016; UNAIDS, 2017). Early initiation of treatment is one of the main benefits of testing for HIV. However, many people are still unaware of the treatment's preventative benefits, and most access treatment late in the infection due to various reasons (UNAIDS, 2016b; Mooney et al., 2017). Furthermore, a study found that mortality within 1 year among newly diagnosed HIV-positive patients was associated with perceived barriers to care (Bassett et al., 2016). Therefore dispensing information about benefits of HIV treatment and as means of prevention is vital, as this may affect HIV testing uptake, early linkage to care, and treatment adherence (Mooney et al., 2017).

Linkage to care is defined in South Africa's National Policy as, "a process of actions and activities that support people testing for HIV and people diagnosed with HIV to engage with prevention, treatment and care services as appropriate for their HIV status" (South African National Department of Health, 2016). Currently, South Africa has 61% of HIV-positive people enrolled on treatment, and with an estimated 47% being virally suppressed (UNAIDS, 2018). These estimates indicate that there are issues in initiating and adhering to treatment by individuals infected

with HIV. Barriers to treatment and care include stigma and discrimination, long distances to clinics, long waiting times at clinics, inflexible clinic operating hours, and inability of individuals to take time off work for clinic visits (South African National Department of Health, 2015a; Bassett et al., 2016).

Late HIV diagnosis may limit the impact of treatment and delay risk behaviour change by individuals infected with HIV (World Health Organization, 2012). The use of HIVST does not promise to improve linkage to HIV care and treatment, as this decision is at the discretion of the kit user. Therefore, linkage to care after self-testing HIV-positive may remain an issue of serious concern (Chipungu et al., 2017). It is therefore imperative that the counsellor on the South African National Hotline encourages those who self-tested HIV-positive to seek confirmatory testing and outline the benefits of initiating treatment early in infection.

1.2 Rationale for the Study

The rationale for the research study is based on the announcement made in December 2016, when the ban on pharmacies to sell HIV self-testing kits to the South African public was lifted. South Africa is unique in a sense that it has: (1) the highest estimated number of people infected with HIV in the world; (2) a slow reduction of new HIV infections; and, (3) a need to increase HIV status awareness among men and members of key populations. Consequently, South Africa's uniqueness could be viewed as having the greatest need in the world for greater uptake of HIV testing. Therefore, this need for increased HIV testing makes it important to discuss and evaluate the ethical issues surrounding HIV self-testing in South Africa.

The implementation of HIV self-testing in South Africa promises to offer benefits for the following reasons:

- To respect the individual's autonomous decision;
- To protect human rights and human dignity;
- To reduce some of the barriers to HIV testing, such as lack of privacy and confidentiality at some clinics;
- To promote couple and partner testing;

- To achieve the South African public health goal through increased HIV testing uptake and practice of HIV-prevention methods, including accessing ART, if needed, thus reducing the potential for new infections, i.e., lowering HIV incidence rates.

However, HIV self-testing is not immune to potential harms; it may make already vulnerable groups, such as women, at increased risk of coercive testing and intimate partner violence. By reviewing existing empirical data, including existing guidelines and ethical issues regarding the implementation and use of HIV self-testing, my research will examine the potential benefits as well as the potential social harms derived from HIV self-testing.

1.3 Brief History of HIV Self-Testing

The HIV self-testing method should never be used to replace existing HIV testing services, but rather as a first step towards learning one's own HIV status (Majam, 2017). In 2012 the U.S. Food & Drug Administration approved the first HIV self-testing kit as a diagnostic tool using oral mucosal specimens to test for HIV for use in the United States (U.S. Food & Drug Administration, 2014; McNeil, 2012). The FDA is a regulatory body in the United States "responsible for protecting public health by assuring the safety, effectiveness, and quality of medical devices" (U.S. Food & Drug Administration, 2018).

Medical devices are instruments used in homes by lay persons and in remote clinics and advanced medical facilities by health care professionals to diagnose illneses and monitor treatments (World Health Organization, 2017). As medical devices, HIVST kits are modified rapid diagnostic tests (RDTs) repackaged for untrained lay persons, with easy to use clear instructions, and easy to interpret test results (Southern African HIV Clinicians Society, 2017). Following the WHO recommendation, there has been a rise in the number of countries that recognise the need to implement HIVST (World Health Organization, 2016b).

The HIV Self-Testing Assessments and Research (HSTAR), a programme run by the Wits Reproductive Health and HIV Institute (WRHI), is actively engaging with the National Department of Health in shaping the HIV self-testing policy for South Africa and ensures that the HIVST kits formally available for purchase are of high quality (Majam, 2017). However, HIV rapid test kits for home use have been available through informal routes such as online purchases, retail outlets

and private community pharmacies for a number of years, and the quality, safety, and performance of these kits is unknown (Southern African HIV Clinicians Society, 2017).

The HIV self-testing kit comes with the manufacturer's instruction leaflet, and a care card, which contains contact details of the toll-free National AIDS Helpline that provides post-test counselling referral for confirmatory testing. It is important to highlight that the HIV self-testing kits formally available for purchase in South Africa are only blood-based, and the vast majority of studies reviewed in this report used oral-based HIVST kits. Interestingly, the sensitivity of the HIVST kits using either oral or blood-based specimen were found to be similar in HIV high-prevalence settings (Pai et al., 2012).

1.4 Literature Survey

In 2016, the South African Pharmacy Council approved the sale of HIV self-testing kits to have them available for use by the public (South African National Department of Health, 2016; South African Pharmacy Council, 2016). This research report will make principle-based arguments using the principle of autonomy, principle of beneficence and non-maleficence, as well as the principle of justice to justify the implementation of HIVST in South Africa. In addition, I will use the bioethical theory of utilitarianism and perform a harm/benefit analysis to support my arguments. The literature review included in this report entails literature relating to the acceptability, uptake and ethics of HIV-self testing in South Africa and other countries.

1.5 HIV Self-Testing and Impact on Ethical Principles

South Africa carries the heaviest burden of HIV globally, and over the years there have been a variety of HIV testing protocols introduced in an effort to increase testing uptake and to reduce transmission (UNAIDS, 2018; South African National Department of Health, 2016). Moreover, all HIV testing protocols be implemented in a way that safeguards human rights and does not violate the principles of autonomy, beneficence, and justice (Spielberg et al., 2004; South African National Department of Health, 2016). In addition, all health policies on HIV should always encompass an ethical framework that includes three components: the benefits and harms; distribution of these benefits and harms, and the liberty-rights or autonomy of those affected

(Walters, 1988). All these three components will be discussed under my ethical argumentation strategies.

The current HIV testing protocols do not fully protect people from violations of human rights, as stigma, discrimination and breaches of confidentiality still remain issues of concern. According to Gillon, "medical ethics seems to fit well into an absolutist deontological ethical system, for they contain some moral rules that apply without exception, and that explicitly or implicitly reject considerations of overall happiness and suffering" (1985). This means the medical interventions should be implemented for the benefit of the individual first, before considering public health benefits. The implementation of HIVST recognises this, as the benefits of using the kit are first enjoyed by the user before becoming a public health benefit. Hence, it is important to identify and explore the ethical issues surrounding the use of HIV self-testing in South Africa, and also show how this testing protocol recognises the bioethical principles, human rights, respects dignity, and is beneficial to the user.

Testing for HIV regardless of the testing tool used "must always be voluntary and free from coercion" (South African National Department of Health, 2016). And, self-testing for HIV empowers individuals by giving them control in making decisions that will affect their health (van Rooyen et al., 2015; Mugo et al., 2017). The use of HIVST kit enables individuals to test privately in their own homes whenever and however they want, therefore privacy and confidentiality are ensured (van Rooyen et al., 2015; Indravudh et al., 2017; Mugo et al., 2017). This research report argues that the principle of respect for autonomy is realised, as the user makes a choice to test in addition to having their privacy and dignity respected. Furthermore, informed consent and respect for confidentiality are also embraced when the HIV self-testing kit is used.

According to the South African testing guidelines on HCT, justice is realised when the services are made accessible, convenient, and affordable to people who need the services (South African National Department of Health, 2016). Therefore with respect to HIV self-testing, all these requirements need to apply to ensure that the principle of justice is respected. The principle of justice will be included in my arguments, as it is important that the HIVST kits are distributed fairly across the country in order to ensure access. In addition, affordability as an ethical issue will also be discussed, as affordability has the potential to be a barrier to accessing the HIV self-testing kits.

1.6 HIV Self-Testing and the Legal Framework

In the same year the WHO released its Guidelines on HIV Self-Testing and Partner Testing, the South African Pharmacy Council (SAPC) gave permission to pharmacies to sell HIVST to the public (South African Pharmacy Council, 2017). These WHO guidelines were used to develop the first South African guideline policy on HIV self-testing to supplement the existing National HIV Testing Services Policy (South African National Department of Health, 2018). The HIV self-testing method is used in addition to the existing HIV testing services (HTS) currently employed in South Africa, as recommended by the WHO (South African National Department of Health, 2016; 2018). Furthermore, the World Health Organization requires all medical devices entering the market to be safe and to perform as intended (2017).

The HIVST kits are classified as medical devices, however, South Africa currently does not have a fully developed regulatory system for medical devices (World Health Organization, 2017; South African Department of Health, 2018). Until this regulatory body is fully established, the National Department of Health recommends that only HIV self-testing kits approved through the WHO pre-qualification and diagnostic assessment programme are to be procured or sold at pharmacies (South African National Department of Health, 2018). The WHO recommends that countries develop policies and regulatory frameworks for HIVST and include human rights laws; age of consent for use; laws permitting sale, distribution and advertisement; national policies on how to confirm HVTS results; and quality assurance, as well as post-market surveillance systems (2016b).

The South African National Health Department recently developed and published a policy that provides guidelines for HIVST, and it is to be read in conjunction with the national HIV testing services policy (2018). Furthermore, it is recommended that the use of HIVST "adhere to the WHO's 5Cs, consent, confidentiality, counselling correct results, and connection" (South African National Department of Health, 2018). The WHO prequalification and diagnostic assessment determines the safety, quality and performance baseline for HIVST manufacturers (World Health Organization, 2016c). The quality and performance of HIVST kits formally distributed through pharmacies is derived from clinical data and published literature, and this is regarded as adequate by the WHO (World Health Organization, 2017). However, the quality and performance of HIV rapid tests currently available informally, via the online channels and in private community pharmacies is unknown (Southern African HIV Clinicians Society, 2017).

1.7 HIV Self-Testing Challenges

The HIVST is an innovative testing technology that could potentially increase HIV testing uptake by identifying new and previously undiagnosed cases of infection (Wirtz et al., 2017). As beneficial as HIV self-testing promises to be, it is not without challenges. Firstly, for the self-testing user, it separates testing from other health services, where counselling and treatment as well as prevention services are provided (Ortblad et al., 2017). Consequently, self-testing for HIV could potentially miss the opportunity for timely linkage to care, as the initiation of treatment will be left to the user's discretion (Walensky & Bassett, 2011).

For the benefits of early diagnosis to be realised, HIV-positive individuals must be successfully linked to uninterrupted HIV care (South African National Department of Health, 2015a). In facility-based HIV testing, health care workers are responsible for identifying and linking those who are HIV-positive to health care services close to where they live (South African National Department of Health, 2015a). However, with regard to HIVST, the telephone counsellor available via a toll-free call provides a referral to the nearest health care facility for confirmation of the HIV-positive test result, thus creating a link to counselling and HIV care (Spielberg et al., 2004).

Because HIV self-testing is performed in private, linkage to care may remain a serious issue, as the onus to be linked to care is on the HIV self-testing kit user (Chipungu et al., 2017). There was a reported case where a partner discovered he was HIV-positive through HIVST and failed to seek a confirmatory test, as he took the screening results as final and did not want to initiate antiretroviral therapy (Katz et al., 2012). However, he did seek confirmatory testing two months later and initiated therapy two months post the confirmatory test (Katz et al., 2012).

The delay in linkage to care following HIV self-testing may be as a result of being in denial after testing HIV-positive, where the tester requires more time to process the results psychologically and gather emotional strength before approaching a health facility to seek confirmatory testing (Katz et al., 2012; Burke et al., 2017). This delay in linkage to care or treatment initiation may result in continued HIV transmission (Cohen et al., 2011). However, a study conducted in Uganda showed no significant difference in ART initiation between self-testing and facility-based testing (Ortblad et al., 2017).

According to van Dyk, "education and advocacy will be required to encourage individuals who test positive to access early treatment" (2013b). With a great deal of uncertainty regarding linkage to

care following a positive result from an HIVST, the on-call counsellors will need expertise in navigating and encouraging timely linkage to care of all those who call with an HIV-positive self-test result. In order for the benefits of using HIVST to be realised, more investigations are required to identify ways of enhancing linkage to care and encourage treatment adherence (Johnson et al., 2017). Moreover, without linkage to care, testing for HIV has limited value (World Health Organization, 2015a). Furthermore, a systematic review recognised the need to develop public health monitoring systems for HIV care and treatment initiation, especially in the era when there is effective therapy (Croxford et al., 2018).

The HIVST reading times, specimen collection and transfer steps are more prone to error by an inexperienced user, thus resulting in incorrect results (UNITAID, 2017). Interestingly, some of the HIVST kits have been improved with an integrated specimen collection system, for ease of use and to regulate specimen transfer, thus reducing specimen collection errors and improving the performance of the kits (UNITAID, 2016). Furthermore, the interpretation of test results may be challenging to some when the lines are faint, giving room for incorrect interpretation of the results (Krause et al., 2013; UNITAID, 2017). Moreover, individuals on ART are advised not to use the HIV self-test kit, as this may lead to false HIV-negative results (South African National Health Department, 2018).

Correct HIV test results are important and have an impact on life-long consequences (World Health Organization, 2015b). Therefore, it is important to realise that if one receives a false negative result, the person misses out on benefiting from treatment, thus compromising his/her health, and potentially the health of others through the possibility of onward sexual transmission (Katz et al., 2012). The language used in a test kit's instruction manual may pose a challenge for some users, as the instructions are only written in English and Zulu. Since Afrikaans, one of the eleven official South African languages, is often used in medicinal packages, I believe including Afrikaans as one of the languages used as instruction in the HIVST kit would be appreciated. The picture illustrations provided in the HIVST kit benefit everyone, including the illiterate.

Lastly, the use of oral-based HIVST kit may pose a challenge, where the mode of transmission may be misunderstood, thus resulting in further perpetuation of stigma towards people living with HIV (Wirtz et al., 2017). The knowledge of HIV transmission may be negatively impacted, where individuals may misinterpret that HIV could be transmitted through saliva (Wirtz et al., 2017). It is therefore important to emphasise the routes of transmissions that HIV is not transmitted through

kissing, or from sharing kitchen utensils. In my opinion, the instruction manual of the oral-based kits should highlight the routes of HIV transmission. However, in South Africa, only blood-based HIVST kits are available for purchase from pharmacies, the oral-based HIVST kits are currently available in research and implementation studies.

1.8 Research Method Limitations

This research report is purely a normative study, using a desk-research methodology and deriving information from available literature on HIV self-testing. Published journal articles; books (both electronic and hard copy); WHO guidelines and UNAIDS reports; South African policy documents, and other national policies relating to the use of HIV self-testing are used. Moreover, search engines available through the Wits Library catalogue and books from the Wits library, as well as other search engines such as Science Direct and PubMed, Google Scholar, etc., were used as resources for relevant material. It is important to highlight that this research is primarily theoretical, although relevant data from empirical studies has also been included.

The empirical research results on the feasibility, acceptability and ethical implications, relating to the use of HIV self-testing in different population groups were assessed. Even though the HIV test kits available for purchase at South African pharmacies are blood-based, it is important to bring to your attention that my research was mostly based on empirical data derived from oral-based HIV self-testing kits. A meta-analysis study found that in low-prevalence HIV settings, the test that used a blood specimen from a finger prick was 2% higher in sensitivity, compared to the test kit that used an oral specimen (Pai et al., 2012). However, my research focus is on HIVST used in a high-prevalence HIV setting, where Pai found no differences, in terms of sensitivity and specificity between oral- and blood-based test kits (2012).

Relevant study results and other data published prior and during the course of writing my research report is included. Furthermore, the study design involved a review of literature related to human rights, bioethical theories, ethical principles, medical ethics, and relevant legal frameworks of HIV self-testing. However, since my research objectives are to support the use of HIV self-testing in South Africa, which is for the purpose of increasing HIV testing uptake among groups missed by already existing HIV testing services, there is a possibility of bias towards published material that promotes the use of HIV self-testing. To guard against this, I included arguments against the use

of HIV self-testing. Moreover, I have also performed a harm/benefit analysis, using a utilitarian approach, thereby determining whether or not the potential benefits of self-testing for HIV outweigh the potential harms.

The limitations in this research report included not examining the use of HIV self-testing in incompetent people, individuals with diminished capacity, and children. The minimum age of consent for use of HIVST in South Africa is 12 years (South African National Department of Health, 2018). However, it is recommended that consenting children be assisted by a health care professional when self-testing for HIV (South African National Department of Health, 2018). But, for the purpose of this research report, the use of HIV self-testing kits in children is not included in the arguments. Moreover, the potential harms caused by the lack of a face-to-face counselling when self-testing is not discussed, as the hypothesis on the effects of counselling in HIV testing is beyond the scope of my research; however, it is mentioned as a potential harm and included in the benefit/harm analysis.

CHAPTER TWO - PRINCIPLE OF RESPECT FOR AUTONOMY

2.1 Introduction to Autonomy

The word autonomy is taken from "the Greek words *autos* ("self") and *nomos* ("rule", "governance", or "rule"), was first used to refer to self-rule or self-governance" (Beauchamp & Childress, 2013). In addition, autonomy "is a property intrinsic to personhood, and could be described as the power of self-direction or possession of the ability to act as one decides" (Fields & Kaplan, 2011). In medical ethics, autonomy has played a crucial role and is a fundamental moral value that refers to the ability to make a choice, to have your rights and privacy respected, and the freedom of will or liberty of action (Barilan, 2011; Beauchamp & Childress, 2013). Moreover, a decision relating to one's health is grounded on the notion of self-governance, and the right to privacy (Pellegrino & Thomasma, 1987).

Autonomy is a deliberative voluntariness, that shapes actions and directs one's life in terms of desires and preferences (Barilan, 2011; Bullock, 2016). Furthermore, autonomy allows one to have special access to one's own desires, thus making one to be "epistemically privileged" to what is in one's best interest (Bullock, 2016). Autonomous agent's actions are in accordance with one's moral values, based on a self-chosen plan and are also in line with rational deliberation and understanding capacity (Harris, 1992; Barilan, 2011; Beauchamp & Childress, 2013; Jennings, 2016). And, they give autonomous individuals full control over their own lives and their own destiny (Harris, 1992). Therefore, autonomous actions are actions identified to have been chosen independently, with understanding and free of coercion (Varelius, 2006; Beauchamp & Childress, 2013).

Respect of an autonomous agent is shown when one respects the person's ability to have opinions, make a choice, and to act according to those choices based on beliefs and personal views (Beauchamp & Childress, 2013). Furthermore, a competent individual, independent of external influences, has the capacity to make independent choices and actions (Dworkin, 2003). The Republic of South Africa's National Health Act, section 8, states that "the user has the right to participate in any decision affecting his or her personal health or treatment" (2004). At a health facility, it is therefore the duty of a health care worker to respect a patient's autonomy, thereby enhancing decision-making and reaching a patient's health goals (Fields & Kaplan, 2011). With

respect to HIV self-testing, the autonomous choice made by individuals to purchase the HIVST kits must be respected (Scott, 2014).

This chapter will explore respect for autonomy and expand the discussion to include protection of human dignity, informed consent, and confidentiality, which are requirements for an effective HIV testing service. In these discussions, I will review the relevant empirical data and international regulatory policies that recognise respect for autonomy, and identify gaps in the current South African policy and provide recommendations. Furthermore, I will identify the potential situations or scenarios where the rights, dignity, and autonomy of the individual could be violated when using the HIV self-testing kit and also make recommendations on how this could be prevented. These violations or harms will be discussed in greater detail in the later chapter on non-maleficence.

In this chapter, I will use a rights-based approach as well as a principle-based approach as an argumentative strategy to answer the following question: Are the rights of the HIV self-testing users protected and is the autonomy of the users respected? To answer this question, the following sections will address autonomy in relation to HIV self-testing, looking at: (i) the impact on human rights, (ii) the impact on human dignity, and (iii) the impact on the right to correct comprehensive health information for home use medical devices.

2.2 Respect for Autonomy and Self-testing

Autonomy is an intrinsic value, as it is "the value that autonomy has in itself or for its own sake, as opposed to it being valuable for the sake of something else" (Varelius, 2006). Furthermore, autonomy as the central moral value links together elements of identity, personal interests, and chosen goals (Barilan, 2011). Moreover, having choices available enable individuals to feel in control of their own lives, and contributes positively to psychological and physical wellbeing (Botti & Iyengar, 2006). According to Mill, individuals fully exercise liberty by doing as they like, so long as those actions do not harm others (1859). Consequently, the provision of different HIV testing options allows individuals to choose the type of testing modality they prefer (Kelvin et al., 2016).

In an HIV self-testing setting, respect for autonomy is realised when the person voluntarily seeks and buys the test kit, and makes an informed choice to test based on the pre-meditated desire to

self-test (Barilan, 2011; World Health Organization, 2016b). Hence, the addition of HIVST into the existing HIV testing services offers an individual the opportunity to make a choice between the different options of either choosing to self-test or to conduct the HIV test at a health care facility. Autonomy was exercised in a study conducted in Kenya, where the majority of truck drivers who had previously tested for HIV still preferred facility-based testing instead of self-testing (Kelvin et al., 2018; Strauss et al., 2018). Conversely, first-time testers in the study preferred to use the HIVST mode of testing (Strauss et al., 2018).

In addition to decision-making, HIVST provides the user with a new dynamic of the control to initiate and conduct the test at his or her own convenience (Kumwenda, et al., 2014). This control allows an individual "the right to act in one's own judgement about matters affecting one's life, without interference by others" (Stirrat & Gill, 2005). The use of the HIVST kit, empowers users to make choices that will affect their own health, and therefore respects the freedom of the users, that should they test HIV-positive, they should be trusted to make the right choices (van Dyk, 2013).

The autonomous decision-making ability of all individuals must be assured when HIVST is introduced as a public health HIV screening tool (Scott, 2014). In the section below, I will show how the addition of HIVST in South Africa demonstrates the protection of human rights and respects the dignity of those who self-test for HIV.

2.3 Protection of Human Rights and Dignity

According to the WHO Constitution, "the enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, and political belief, economic or social condition" (2006). The success of any HIV intervention is dependent on safe-guarding and promoting human rights and empowering people to claim their rights (Ganju et al., 2016). Wikipedia defines human rights as "moral principles or norms that describe certain standards of human behaviour, and are regularly protected as natural and legal rights in municipal and international law". Moreover, human rights are vital in moulding societal values that are fundamental in shaping human-kind (Rapatsa, 2015). Dignity on the other hand, is defined as something you are born with and is in all human beings (Rapatsa, 2015).

Human dignity is the foundation of human rights and is recognised in human rights-based frameworks, including South Africa's Bill of Rights and the Universal Declaration of Human Rights (UDHR) (Republic of South Africa, 1996; United Nations, 2015; Zylberman, 2016; Rapatsa, 2015). Article 1 of the UDHR states that "All human beings are born free and equal in dignity and rights" (United National, 2015). Also recognised by the United Nations Educational Scientific Cultural Organization (UNESCO) is that all human beings, "irrespective of gender, age, social status or ethnicity", are equal in dignity (2011). In a health setting, respecting a patient's dignity, is respecting a patient's rights and any threat that may compromise the relationship between patients and health care providers ultimately affects the quality of care (Zirak et al., 2017).

Respect for human rights includes: "the right to be treated as autonomous individuals who participate in the decision making processes that affect their lives" (Steen et al., 2017). In HIV testing the protection of human rights is recognised when everyone has "the right to voluntary HIV counselling and testing, and to ongoing prevention, care and treatment" (World Health Organization, 2012). This means HIV testing must "protect, respect and fulfil human rights standards and norms", thereby making sure that the interests and dignity of potential users are respected and protected (World Health Organization, 2012). Hence, all modes of HIV testing used in South Africa, including HIVST, must adopt a rights-based approach (South African National Department of Health, 2016; 2018).

Self-testing for HIV must be harmonious with the rights enshrined in the South African Constitution, where "everyone has inherent dignity and the right to have their dignity respected and protected" (Republic of South Africa, 1996). Therefore, for the success of HIV self-testing to be realised, it is important that a human rights-based approach is used in ensuring that HIVST is offered in a way that prioritises quality services, universal health coverage and gender equality (South African National Department of Health, 2018). Moreover, the autonomous choice to refuse to use a self-test should be respected, and no one should be forced to use an HIVST kit (Scott, 2014).

In my opinion, the implementation of HIVST in South Africa is morally justified because it empowers individuals with the opportunity to make a choice of when, where and how to test for HIV. To further illustrate that autonomy is respected when using HIVST, I will examine the HIVST kit insert to determine whether or not the information provided is sufficient for home use.

2.4 Are HIV Self-ting Users Well Informed?

Self-testing for HIV does not involve a health care worker to provide all the necessary facts about HIV pre- and post the test; instead, the individual performs the test by him/herself in the privacy of their home. The consenting process in HIV self-testing involves voluntarily seeking to purchase the kit, and one is informed about the process through the information provided in the instruction leaflet. It is argued that an individual cannot make a decision that is in his or her best interest when he or she is provided with inadequate information (General Medical Council, 2008). Because all adults are of a high level of maturity, with cognitive ability to make decisions, they are presumed competent (Cocanour, 2017). Hence, if a competent morally committed individual makes a wrong decision due to insufficient information that he or she is provided with, that person should not be held accountable for his/her actions (Meyers, 2003).

In my opinion, deciding to undergo self-testing for HIV is an indication of competency, which means the individual considered the different modes of testing available to him or her and understands the consequence of using an HIVST. And, I would argue that the HIVST kit provides individuals with adequate information and therefore respects the individual's right to correct comprehensive health information related to the use of health products purchased for home use. According to the WHO, the manufacturer of medical devices must provide the user, especially a lay person, with sufficient information on how to properly use the device (2017). In addition, the language used as instruction for use must be an official language used in the country and, if possible, provide additional media of instruction such as via the Internet (Global Harmonization Task Force, 2011).

In order to determine if the HIVST kit leaflet is in accordance with the rights to correct comprehensive health information for home use devices, I will review the information on the kit's leaflet or instruction manual. For this purpose, I will use an instruction manual from an HIVST kit manufactured by *Atomo Diagnostics*, the only kit formally available for purchase in South Africa.

2.4.1 Information on the process and procedure of testing

The kit contains two instruction leaflets, one written in English and the other in isiZulu, both providing pre-test and post-test information, and a step-by-step procedure on how to conduct the

test. Both instruction manuals have picture illustrations for ease of use, and for the benefit of individuals who are illiterate. Furthermore, the instruction manual also provides an Internet website for a video demonstration for those with Internet access, to demonstrate how to use the HIVST kit. In my opinion, the information on the process and procedure of testing satisfies the WHO requirement for home-use medical devices.

2.4.2 Benefits and implications of testing

The benefits of testing are not listed on the instruction manual; however, it does have information on the importance of testing, which is "to prevent passing on the virus to others without knowing" (Atomo Diagnostics, 2016). Furthermore, information on the benefits of early diagnosis and early treatment initiation are not included. I regard this as vital information, as it may increase awareness of the benefits of early diagnosis, consequently, encouraging frequent testing. The lack of this important information on the instruction leaflets was echoed by men, when they pointed out that the inclusion of benefits in the information leaflet was critical and would enable them to appreciate its value more (Jennings et al., 2017). Lastly, information on the implications for testing HIV-positive is also not included.

2.4.3 Linkage to treatment and care

Linkage to care starts with HIV diagnosis and ends with enrolment on treatment and care, and is regarded as the most important step in the HIV patient pathway (Croxford et al., 2018). However, timely linkage to HIV care and treatment retention remains a challenge regardless of the mode of HIV testing. According to Spielberg, the use of HIVST is cost effective when HIV-positive individuals are successfully linked to care, when they are put on life-prolonging treatments immediately after confirmatory testing (Spielberg et al., 2004). But, it can also be said that learning an HIV-negative status from using an HIVST can be cost-effective, where one can make life style changes, such as a change in sexual behaviours to avoid being infected. Therefore, I believe the use of HIVST can be considered cost-effective for all individuals, whether the outcome is a negative or positive HIV result.

To ensure linkage to care, the kit provides a care card listing the 24-hour toll-free National AIDS Helpline to refer the tester for a confirmatory test. However, due to the private nature inherent to HIVST, it is difficult to measure and track how many of individuals who self-tested HIV-positive are successfully linked to care and treatment, as it requires individuals to present themselves at a health care facility after they have had a positive HIVST result (Cambiano et al., 2014).

2.4.4 Information on prevention and importance of disclosure

The HIVST kit contains information on prevention, which includes the use of pre-exposure prophylaxis (PrEP) and also encourages sexual partners to test. The PrEP approach involves giving antiretroviral treatment to HIV-negative individuals in order to protect themselves from acquiring HIV (McCormack et al., 2016). In my opinion, the information provided with the device relating to the prevention of HIV is sufficient. And as a last step, WHO requires that medical devices are disposed of safely after use (World Health Organization, 2017). In my opinion, the HIVST device meets this requirement, as the kit comes with a red plastic bag and information on how to properly dispose of the used device.

Based on this analysis, HIVST users are provided with correct comprehensive information relating to the use of the HIVST kit for home use; however, there is room for improvement, and these recommendations will be provided in the final chapter. The next chapter will present arguments on the principle of non-maleficence, the duty not to cause harm relating to the implementation of HIVST in South Africa. It is therefore crucial that the policy makers together with the HIVST kit manufactures ensure the “duty not to cause harm” is respected, and the potential social harms resulting from HIV self-testing are minimised.

CHAPTER THREE - NON-MALEFICENCE AND HIVST

3.1 Introduction to Non-maleficence

The concept of harm includes "setbacks to physical and psychological interests, privacy and liberty" (Beauchamp & Childress, 2013). It is known that different types of medical devices have varying potential for harm to the user, and some medical interventions can be associated with some psychological and societal harms (Allais & Venter, 2014; World Health Organization, 2017b). Early literature relating to the use of HIVST focused more on the potential harms, and it was thought that the potential harms outweighed the potential benefits; only recently has the emphasis been placed on the benefits (Gagnon et al., 2018). My argument will use empirical data and show how the principle of non-maleficence should be applied by the medical device manufacturers and policy makers in ensuring that the vulnerable groups are protected from harm.

The necessity of an ethical approach to health care was realised following scientific atrocities, where medical doctors in Nazi Germany deprived extremely vulnerable individuals of their human rights, and used them in unethical medical experimentations during World War II (European Molecular Biology Organization, 2001; Ghooi, 2011; Paranhos et al., 2015). The discussions and conclusions drawn from these unethical medical experiments led to the development of the first international ethics document, the Nuremburg Code, which strives to minimize risks and maximize benefits in research (Ghooi, 2011; Paranhos et al., 2015). In addition the Universal Declaration on Bioethics and Human Rights, Article 4 states that "direct and indirect benefits to patients/ research participants and other affected individuals should be maximized and any possible harm to such individuals should be minimized" (UNESCO, 2005).

The Nuremburg Code document became the foundation for the development of the basic principles of the Belmont Report, a report created by the United States National Commission for the protection of rights and interests of humans participating in biomedical and behavioural research (National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 1979; Paranhos et al., 2015). The Belmont Report was drafted in Belmont and published in 1979, and it provides the three core ethical principles: "respect for persons, beneficence and justice" (National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 1979; Paranhos et al., 2015). These ethical principles provide guidance to health research (Beauchamp & Childress, 2013).

Beauchamp and Childress proposed non-maleficence as one of four ethical principles, and it obligates one not to intentionally inflict harm (2013). Furthermore, the principle of "do no harm", is included in the World Medical Association Declaration of Geneva, where the physician pledges not to use medical knowledge "to violate human rights" (2017). Therefore, failing to avoid or minimize harms violates the principle of non-maleficence. In the mid-1980s, HIV/AIDS was an issue of social justice, where "human rights violations and state failure to fulfil human rights obligations, negatively impact health and thwart the fight against HIV/AIDS" (Stemple, 2008). Despite the absence of a cure, the availability of treatment encourages many individuals to voluntarily seek HIV testing (Omonzejele, 2014). And, when testing, the potential benefits derived from knowing your HIV status must always outweigh the potential harms or risks (World Health Organization, 2012).

In routine facility-based HIV testing, psychological harm may be inflicted through a breach of confidentiality, violation of privacy, coercive testing, and social injustices, including stigma and discrimination (HPCSA, 2008; Naidoo & Vernillo, 2012; World Health Organization, 2012; Mohlabane et al., 2016). At health facilities, the person conducting the test has a legal duty to protect confidentiality and respect the privacy of the tester (HPCSA, 2008). However, when it comes to self-testing for HIV, breaches of confidentiality and the violations of privacy are not issues of concern, because the test is conducted at home, in a controlled environment (South African National Department of Health, 2018). Furthermore, if one chooses to self-test in the presence of another, it is important to maintain confidentiality (South African National Department of Health, 2018).

Even though the HIVST mode of testing has the potential to minimise harms that are associated with facility-based testing, it, too, has the potential to be misused and violate human rights, therefore potentially causing harm. These include psychological harms (depression, distress, and suicidal ideation), and social harms (coercion, and intimate partner violence (IPV)) (van Dyk, 2013; Scott, 2014; Wood et al., 2014; Youngs & Hooper, 2015; Thirumurthy et al., 2016; Choko et al., 2017; Qin et al., 2017; Gagnon et al., 2018; Ong et al., 2018; Ong et al., 2018b). However, there has been little to no empirical evidence of psychological harms, and no study thus far has shown evidence of suicide relating to the absence of counselling when self-testing for HIV.

In this chapter, my argument will address the obligations and responsibilities of different stakeholders and answer the following question: Is the principle of non-maleficence a duty the

manufactures and policy makers have towards their potential clients? Furthermore, my argument will also encompass potential social harms, coercion and intimate partner violence (IPV) and show how the vulnerable groups can be protected from harm.

3.2 Obligations and Responsibilities of Medical Device Stakeholders

There is no medical device developed that is error-proof or risk free; some residual risks will remain, hence, the manufacturer is tasked with the duty to ensure that the risks of harms are minimized or eliminated (de Mol, 2014; U.S. Food & Drug Administration, 2016; World Health Organization, 2016d). Medical devices are defined as instruments crucial in delivering better health outcomes, particularly for prevention, diagnosis, monitoring, and treatment of diseases, as intended by the manufacturer (World Health Organization, 2017; 2017b). Furthermore, as the world becomes more technologically driven by the innovations, the patient or the end user safety associated with the medical devices needs to be ensured (Kelly & Jones, 2018).

The use of a medical device is justifiable when potential benefits outweigh the risks of potential harm (de Mol, 2014; U.S. Food & Drug Administration, 2016). The ethical duty to not cause harm, with regard to a medical device, lies with the medical device manufacturer, policy makers and health care professionals (Youngs & Hooper, 2015). With regards to the implementation of HIVST in South Africa, in this chapter I seek to answer the following question: is the principle of non-maleficence a duty the manufacturers and policy makers have towards their potential clients?

3.2.1 The principle of non-maleficence and the potential user

Medical devices are widely used and are a crucial component of health care, and without them, the diagnosis of HIV would not be possible (World Health Organization, 2011). The HIVST is an in vitro diagnostic (IVD) medical device for self-testing, explicitly designed for single use by a layperson (World Health Organization, 2017). The device itself is not associated with physical harms, however, it does have the potential to cause psychological and societal harms. Psychological harm may occur before the diagnosis, in anticipation of a positive result, and may also occur following an HIV-positive diagnosis (Harris et al., 2012; de Frank et al., 2015; Kirkøen et al., 2016).

Because users differ in terms of physical, sensory, cognitive skills, and emotional capabilities, these medical devices need to be "appropriate for the people who use them, and for the environments in which they are used" (National Research Council, 2010; U.S. Food & Drug Administration, 2016; World Health Organization, 2016d). Therefore the medical device user must be able to operate the device as instructed to avoid making mistakes that could cause harm or jeopardise the user's safety (U.S. Food & Drug Administration, 2016). Environmental factors such as low lighting may make it hard to see the device display (National Research Council, 2010; U.S. Food & Drug Administration, 2016). Therefore, the design and the environmental setting need to fit well with the intended use in order to maximize its effectiveness (World Health Organization, 2010b; 2011; 2016d).

The instructions in the package insert must be easy to understand, involving few steps, and the results must be easy to interpret (Knight et al., 2017). Before conducting the self-test, lay users in one study were concerned that they would not be able to perform the test properly (Witzel et al., 2017). However, a qualitative study conducted in South Africa, where participants were given a prototype to investigate the usability of the HIVST, resulted in an overwhelming high-perceived ease of use of the kit by the users (Knight et al., 2017). Consequently many studies have demonstrated high acceptability of HIV self-testing in different population groups, with the majority of participants citing ease of use and performing the test accurately (Choko et al., 2011; Ng et al., 2012; Indravudh et al., 2018; Krause et al., 2013; Figueroa et al., 2015).

The most compelling argument against the use of HIVST is the potential of a positive self-test result to cause psychological harm, which may lead to an individual committing suicide due to the absence of pre-test counselling and lack of on-site post-test counselling (Youngs & Hooper, 2015; Pando et al., 2017). However, none of the studies conducted thus far have shown evidence of suicide as a potential harm relating to the use of an HIVST kit (Choko et al., 2011; 2015; Thirumurthy et al., 2016; Qin et al., 2017). Since none of the empirical data have shown evidence of suicide pertaining to the use of an HIV self-testing kit, suicide as a potential harm will not be included further in my argument.

Because linkage to care is the "endpoint" goal of HIV diagnosis, linkage to care following an HIV-positive self-test is likely to be a challenge (Wallensky & Basset, 2011). Since the onus of linkage to care is on the kit user, potential harm resulting from a delayed linkage to care is of serious concern, as this may lead to disease progression and continued transmission (Choko et al., 2011;

Chipungu et al., 2017). In a qualitative study conducted in Zambia, an overwhelming majority of participants indicated willingness to initiate treatment within a week following an HIV-positive self-test result (Chipungu et al., 2017). It is important to highlight that during the writing of this research report, there were no published empirical studies that investigated actual linkage to care following an HIV-positive self-test result. Therefore, this calls for a need to investigate actual linkage to care of HIV-positive individuals following the use of an HIVST kit.

According to Wong et al., HIV rapid testing devices are classified as "high risk devices," as false results may cause serious harm to the individual (2014). The HIVST kits approved through the WHO prequalification series were found to be highly accurate, with the specificity reported in many studies to be 100%; however, sensitivity remains an issue, where it ranges between 93% - 97% (Ng et al., 2012; Pai et al., 2012; Choko et al, 2011; 2015). More importantly, a literature review on harms found no evidence of delayed treatment initiation due to false-negative HIV self-test results (Brown et al., 2014). In addition, the occurrences of false positives are mitigated through confirmatory testing at a health facility (Ng et al., 2012; World Health Organization, 2016).

In summary, the HIVST kits were found to be easy to use, accurate and safe; however, linkage to care remains a serious concern. Therefore, more research needs to focus on this area, and explore if there is generally a delay in initiating treatment following an HIV-positive self-test result. Overall, many studies reported high acceptance and accuracy, and study participants reported that they would endorse the use of HIV self-testing kits to family members and friends. Moreover, none of the studies reported the occurrence of suicide as a serious adverse event caused by the absence of counselling following an HIV-positive self-test result. Therefore, empirical data presented above on potential psychological harms resulting from using HIVST, in my own opinion, is no different to psychological harms experienced at health facilities following an HIV-positive diagnosis. Therefore, these potential psychological harms are not enough to prevent the availability or use of HIVST kits in South Africa. Moreover, when a potential kit user makes an autonomous decision to self-test, non-maleficence to oneself is a duty the HIVST kit user has accepted.

3.2.2 Medical device manufacturer's duty to protect

Manufacturers are responsible for designing, determining the intended use, the level of risk to the user, degree of invasiveness in the body, as well as the duration of use of the medical device

(Medicines Control Council, 2016; 2016b). In addition, medical device manufacturers have an obligation and responsibility to ensure that medical devices are effective and safe (National Research Council, 2010). Therefore, one of the principles manufacturers need to comply with, is to ensure that the medical device is designed in a way that minimises risks associated with its use (Medicines Control Council, 2016b). Because of these obligations, I would argue that the principle of non-maleficence is the duty the manufacturers have towards the intended user in making sure that intended users are protected from harm.

According to the National Research Council, "medical device manufacturers need to ensure device safety before marketing, and they also need to make a commitment to post-market surveillance of their products, to make sure that no unforeseen problems appear with long-term use" (2010). Furthermore, manufacturers have a responsibility to verify through testing to ensure that the safety and performance of the medical device are not adversely affected by any changes that may occur during testing (World Health Organization, 2016c). Therefore, as the manufacturer's duty in ensuring safety, they must recognize, mitigate and prevent harm to the greatest extent possible (National Research Council, 2010). The WHO Prequalification Diagnostic Assessment provides the minimum requirements for quality, performance, and safety to IVD medical devices manufacturers (2016c).

The design of medical devices, more specifically the IVD, must reduce the risk of error related to use that could cause harm, such as the handling of samples and the interpretation of results (Medicines Control Council, 2016b). In addition, the stability of the medical device or IVD in warmer climates, precision, accuracy, sensitivity, and specificity must also be addressed (Medicines Control Council, 2016b). The HIVST kit formally available for purchase in South Africa is manufactured by the Atomo Diagnostics and has a specificity and sensitivity of 99.7% (UNITAID, 2018). Therefore, in my opinion, false positive and false negative results are not issues users and manufacturers need to worry about. Consequently, psychological harms pertaining to test errors are not of great concern. However, if issues do arise, including issues of accuracy, the manufacturer is expected to address the problem by notifying users and/or recall the product if need be (National Research Council, 2010).

Related to the use of HIVST, and in an effort to mitigate or eliminate any safety issues that may arise, and to ensure quality assurance, the test kit comes with a care card that provides a telephone hotline number, as well as a referral to a website with a video demonstration. For clarification on

the responsibilities or obligations of the manufacturer of one of the HIVST formally available for purchase in South Africa, the *atomo* HIV self-test kit, I will review the package insert as well as their website. There are many other HIV rapid test kits available for purchase in South Africa via "online channels, retail outlets and community pharmacies"; however, the quality of these test kits is not known (Venter et al., 2017). For the purpose of this research report, my focus is limited to the HIVST kits, which are designed for self-testing by lay persons and are approved through the WHO Prequalification Diagnostic Assessment programme, and registered with South African Health Products Regulatory Authority (SAHPRA).

The *atomo* HIV self-test kit is formally available for purchase in South Africa, and is a lay user-centred designed HIVST kit, as it comes with an integrated sample collection, for collecting the right sample volume, thus reducing user error and ensuring optimal test performance (Atomo Diagnostics, 2018). Moreover, the risk of injury is minimised as the needle is locked inside the device for safe disposal after use (Atomo Diagnostics, 2018). In addition, the instructions in the leaflet are also provided as picture illustrations, which accommodates potential users who may be illiterate or not able to read either English or IsiZulu. The outside packaging of the kit clearly states the intended use or purpose of the kit, that it is an "HIV self-test" kit, and that "it is safe, easy and convenient". In addition, there is also a warning sign, which states that it may be unable to detect recent HIV infection. This warning, therefore, addresses the issue of accuracy and advises the user to test again after 3 months and contact a healthcare professional for more information.

Also displayed on the outside and important for safety and accuracy of the kit, is the expiration date and storage condition. For issues of stability, the acceptable storage temperature ranges from 2 – 30^{o}C, which is suitable for the South African climate most of the time. Furthermore, the kit can be used by all individuals regardless of socio-economic status, as it does not require the user to have a refrigerator. The acceptable temperature ranges may be an issue in certain regions in the country, where temperatures may reach as high as 40^{o}C. In my opinion, this may require potential users residing in high-temperature regions to take extra precautions by making sure that the test kits are kept in cooler areas, and away from direct sunlight.

The inside of the test kit contains two package inserts, one written in English, and the other in IsiZulu. Both provide important information that complies with the Medicines Control Council (MCC) requirement regarding manufacturers' responsibilities. Concerning manufacturers' obligations, the kit provides detailed information on: (i) the intended use of the kit; (ii) test

performance; (iii) storage; (iv) limitations of the test; (v) warnings and precautions; and, vi) disposal. Based on this information, in my opinion, the manufacturer of the *atomo* HIV self-test kit complies with the WHO, FDA, and MCC requirements in ensuring quality performance, intended use, and safety.

The kit manufacturers must make information on all the potential harms resulting from using HIVST available in the test kit package inserts, and it should be stressed that the test kits are only for voluntary testing (Southern African HIV Clinicians Society, 2017). However, the instruction leaflet of the *atomo* HIVST kit does not have a list of potential harms of self-testing. In my opinion, it would be beneficial to make HIVST kit users aware of all potential harms by having this information available in the instruction insert. The WHO requires that the instruction manual include information on proper disposal after use in order to ensure that other people or the environment are not harmed (World Health Organization, 2017). The *atomo* self-test kit complies with this requirement, as it provides information on how to safely dispose of the used kit and also includes a disposal bag.

Medical device manufacturers violate their obligatory duty when there are defects in safety and product design (Graham & Vest, 2005). It is therefore fitting to say that the manufacturer of the HIVST kits formally available for purchase in South Africa do not violate the principle of non-maleficence, as the manufacturer fulfils its obligation in protecting users from harm. However, in the event that the medical device does not perform as intended or may endanger the health of the public, it is the responsibility of the regulatory authority to take action (World Health Organization, 2017b). In the next section, I will explore the ethical duty policy makers have towards the potential HIVST kit users in South Africa.

3.2.3 Policy maker's duty to protect

The use of an HIVST kit medical device has the potential to increase the HIV testing uptake among groups who otherwise would not test as a result of barriers encountered in health facility- based settings (World Health Organization, 2016b; Southern African HIV Clinicians Society, 2017; Venter et al., 2017). It is recommended that all medical devices be governed by a national regulatory body, which provides a set of rules that serve to minimize the risks of medical devices to cause harm or not comply with quality standards (World Health Organization, 2010b; 2011;

Southern African HIV Clinicians Society, 2017; Venter et al., 2017). The duty of the policy makers is to ensure safety and effectiveness of the HIVST kit when it is used by the intended users as defined by the regulatory systems, thereby ensuring maximisation of the benefits and minimisation of the harms to individuals and to public health (Wong et al., 2014). Consequently, I would argue that the principle of non-maleficence is the duty policy makers have towards the intended HIVST kit users and towards the public as a whole.

Globally, policy makers are gaining interest in HIVST as an innovative intervention and a potential tool for HIV prevention (Witzel et al., 2017). The medical device regulatory system's key role is to ensure safety, high quality performance that ensures accurate results and protects public health throughout the lifespan of the medical device (World Health Organization, 2016d). Together, the medical device manufacturers and the policy makers have established minimum safety and performance standards of HIVST intended for use by diverse populations (Wong et al., 2014).

Many studies demonstrated high acceptability of HIVST in diverse populations (Choko et al., 2011; Kalibala, et al., 2014; Figueroa et al., 2015; Choko et al., 2017; Johnson et al, 2017; Knight et al., 2017; Pando et al., 2017). These positive findings, along with increasing global interest, has led to increased implementation of HIV self-testing in many countries. In addition, the risk-benefit analysis is important in evaluating and informing acceptance of HIVST (Wong, et al., 2014). Furthermore, risk-benefit analysis, and evidence-based studies, including pilot projects, continue to inform HIVST national policies together with the regulatory systems (Wong et al., 2014).

The South African National Department of Health requires that all HIVST kits entering the country be approved by the WHO prequalification programme until the national regulatory system is in full operation (2018). In addition, the National Institute of Communicable Diseases (NICD) ensures that the HIVST kits entering the country meet the minimum quality standards of the national reference laboratory (South African National Department of Health, 2018). Furthermore, the South African government recently formed an agency known as the South African Health Products Regulatory Authority (SAHPRA), formerly known as the Medicines Control Council, to oversee the registration and certification of all medical devices (South African National Department of Health, 2018).

Because linkage to care following the use of an HIV self-testing kit remains a serious concern, policy makers need to develop programmes that will facilitate, monitor, and evaluate the linkage

to care (World Health Organization, 2016b). Because of the discreet nature of HIVST, and in addition to developing post-market surveillance systems, the policy makers together with the regulatory system must develop systems to monitor and report social harms (Johnson et al., 2014; World Health Organization, 2016b). Furthermore, in the event that there are risks to potential users, the regulatory authority will need to "establish a procedure to withdraw medical devices from the market" (World Health Organization, 2016d).

The South African government is in a unique position where it is implementing HIVST, and at the same time it is in the process of fully developing regulatory systems for medical devices. In my opinion, the policy makers in South Africa realised their duty of protecting the public by allowing use of HIVST kit, as it may to offer maximisation of benefits and minimisation of harms. In the following sections I will explore the social harms, coercion and intimate partner violence resulting from using HIVST and argue that the empirical data on potential social harms does not provide compelling ethical grounds for restricting the sale of HIVST kits in South Africa.

3.3 Social Harms and HIV Self-Testing

Social harm is defined as a physical, economic, emotional or psychosocial harm caused by one person to another, or a person to themselves, as a result of a threat or imbalance of power (HIV Self-Testing Research and Policy Hub, 2018). In a study investigating the constraints and opportunities for the scale-up of HIVST in three African countries, stakeholders from these countries raised concerns regarding human rights violations (van Rooyen et al., 2015). Related to HIV self-testing, human rights violations include pressure put on someone else to self-test; intimate partner violence; and, verbal and emotional abuse following a self-testing result (HIV Self-Testing Research and Policy Hub, 2018). For my argument, I will focus on two human rights violations, coercion and IPV, as potential social harms resulting from HIV self-testing and, argue that these potential social harms do not make the implementation of HIVST in South Africa unjustified, so long as the harms do not outweigh the potential benefits.

3.3.1 HIV self-testing and coercion

In addition to having the right to choose a health care intervention, individuals also have the right not to be coerced into testing for HIV (Fields & Kaplan, 2011). Therefore, testing for HIV must always be a voluntary choice, and everyone's right to decline the offer to test must be respected (HPCSA, 2008; National Department of Health, 2016; World Health Organization, 2016b). Coercion is a serious human rights violation and a serious concern associated with the use of an HIVST kit (Allais & Venter, 2014). Furthermore, coercion violates the right to the ethical principle of respect for autonomy, and occurs when one is forced against his/her will to self-test for HIV (Bruers et al., 2016; Qin et al., 2017). I will explore the concept of coercion related to the use of HIVST and argue that coercion as a potential harm is a violation of human rights, but does not justify restricting people from accessing the HIVST kit.

Coercion is a violation of article 01 of the Universal Declaration of Human Rights, which says "All humans are born free and equal in dignity and rights" (United Nations, 2015). The WHO is against any form of coercion, either from a care worker, a sexual partner or a family member (2016). A study conducted in China showed that the most common setting for coercion was at home, followed by at health facilities and then workplaces (Ong et al., 2018b). Those who coerce direct their actions through the use of force or threat, thereby restraining their victims from acting as they see fit, and therefore, fail to respect the victim's autonomy (MacKay, 2016). Moreover, coercion tends to stem from relations of power imbalances, for example, in one case, a participant was put in vulnerable position, when the doctor refused to perform surgery unless the participant tested for HIV (Ong et al., 2018b).

Because HIVST is conducted in private, generally at home, an increase in coercive testing may be one of the unintended consequences, and thus, it remains a major concern (van Dyk, 2013; Wood et al., 2014; Choko et al., 2015; Youngs & Hooper, 2015; Qin et al., 2017; Ong et al., 2018). Coercive HIV self-testing may occur between sexual partners, between sex workers and their clients, employers testing domestic workers, as well as parents testing their teenage children (van Dyk, 2013; Woods et al., 2014; Ong et al., 2018). In most instances, coercion could involve threats to take away something, end the relationship, end employment, and withholding money in the case of sex workers, if one does not agree to test (Ong et al., 2018; 2018b).

A study investigating harms related to HIV self-testing found that 8% to 9% of participants were coerced into self-testing (Qin et al., 2017; Ong et al., 2018b). Furthermore, 3% of coercive self-testing incidents were by the main sex partner (Choko et al., 2015; Qin et al., 2017). In addition, a study conducted in China on men who have sex with men (MSM), showed a significant increase in coercive testing among HIVST users compared to men who had not used the HIVST kit (Ong et al., 2018). The increase in coercive testing was attributed to being used as a "point-of-sex" decision, a risk reduction technique, where sexual partners were screened for HIV infection before sex (Ong et al., 2018). Therefore, coercive HIV self-testing was used to reassure that there is no risk of HIV infection, and for some, as a healthy start to a happy relationship (Ong et al., 2018b).

To prevent this unethical use of HIV self-testing kits, Choko et al., suggest that the package inserts must include information about human rights violations and provide systems to report coercive testing (2015). The same sentiments were echoed by Ong et al., where they advise policy makers to put in place measures to guard against coercion and put in place systems that will monitor and prevent the occurrence of such violations (2018). Moreover, the WHO Global Model Regulatory Framework for Medical Devices, recommends the national regulatory authority, together with the manufacturer's representative, to devise a channel for timely reporting of harms associated with the medical device (2017).

The implementation of HIVST without the assurance of respecting autonomous decisions is equivalent to ignoring the rights, dignity, and autonomous capability of potential users (Scott, 2014). Furthermore, the autonomous choice to refuse to use a self-test kit should be respected, and no one should be forced to self-test for HIV (Scott, 2014). South Africa has a very robust legal framework that protects the most vulnerable, and it includes: The South African Constitution, No.108 of 1996; National Health Act, No.61 of 2004; Patients' Rights Charter, and Children's Rights Act, No.35 of 2005.

The empirical data has little evidence of coercion relating to the use of HIVST, and it does not present convincing evidence of coercion as a severe adverse effect or provide convincing ethical grounds for not allowing the use of HIVST in South Africa. Moreover, research on the context of HIVST coercion, especially in vulnerable groups, such as teenage children, sex workers, domestic workers and prisoners, needs further attention and investigating. Furthermore, in my opinion, the manufacture's and government's duty to protect must also be reflected on the package, where there

should be a display note on the outside that says "Not for coercive testing"; and, test kit users should be advised to report unconsented testing to the toll-free number provided.

3.3.2 HIV self-testing and intimate partner violence

In an effort to increase HIV testing uptake, especially among men, the WHO recommends "the increased offering of voluntary HCT to couples, with support for mutual disclosure" (World Health Organization, 2012). Couple testing has many beneficial outcomes, including access to treatment and making informed decisions about reproductive health (World Health Organization, 2012). However, couple testing and partner testing also has the potential to cause harm, including IPV, especially in low-income countries, where the prevalence of IPV is high (World Health Organization, 2013; 2016b). The WHO refers to IPV as "any behaviour within an intimate relationship that causes physical, psychological or sexual harm to those in the relationship" (World Health Organization, 2013). In this section, I will explore available empirical evidence on IPV related to HIV self-testing and argue that the potential for IPV occurrence does not justify restricting people from accessing HIVST.

Women bear an overwhelming burden of IPV, and violence against women is regarded as a serious problem to public health and a fundamental violation of human rights (UNAIDS, 2013b; World Health Organization, 2013). South Africa has a high prevalence of violence perpetrated against women, and the recent national crime statistics reported that 66% of women experienced assault in the year 2016/2017 (South African Government News Agency, 2018; Statistics South Africa, 2018). Moreover, domestic violence or violence emanating from relationships which leads to female homicide is exceptionally high (Statistics South Africa, 2018).

The key factors that predispose women to IPV include poverty associated with stress, level of education, and power imbalances within intimate relationships (Jewkes, 2002; Jewkes et al., 2006; Ahinkorah et al., 2018). Moreover, a study conducted in sub-Saharan Africa showed that IPV was triggered in situations where women had decision-making capacity, including health care-related decisions (Ahinkorah et al., 2018). This was observed in a qualitative study conducted in Kenya, where testing of a pregnant woman occurred without the partner's or husband's permission, triggered the occurrence of IPV (Hatcher et al., 2013). This was consistent with another study, in which similar findings were observed when investigating the acceptability of HIVST, where a

female participant experienced IPV, not from using HIVST, but from participating in the study without obtaining permission from her husband (Johnson et al., 2017).

In countries with generalised HIV epidemics, most new infections occur in sero-discordant couples, where one partner in the relationship is HIV-positive (World Health Organization, 2012; 2015; 2016b). The WHO recommends that "voluntary assisted partner notification services should be offered as part of a comprehensive package of testing and care offered to people with HIV" (World Health Organization, 2016b). Studies conducted in Kenya and in Zimbabwe showed that experiences of IPV following a sero-status disclosure were higher among women who tested HIV-positive, than among those who reported an HIV-negative result (Shamu et al., 2014; Maman et al., 2017). Consequently, fear of IPV is a barrier to women seeking HIV testing; as a result, some women who do seek HIV testing choose not to disclose their HIV status to their sexual partners (UNAIDS, 2013b; Hatcher et al., 2013; Etudo et al., 2016).

In a health care facility, HIV counselling and testing (HCT) provides successive stages of the "continuum of care", from diagnosis to treatment and care, and it has been a platform used to identify IPV (Brown & van Zyl, 2018). In addition, South African health care workers are required to find out from those who tested HIV-positive if disclosure of an HIV status to sexual partners resulted in intimate partner violence (HPCSA, 2008). However, this opportunity to identify IPV and provide additional support may be missed when self-testing for HIV, as self-tests are conducted generally at home, in a private setting. It is, therefore, important to assess the potential impact, and the safety of distributing HIVST to sex partners in order to understand the link between IPV and self-testing (Schaffer et al., 2017).

In a study conducted in Malawi, one male participant echoed concerns of IPV related to the use of HIV self-testing, mainly driven by the way the women present the issue of testing to their sexual partners (Choko et al., 2017). This male participant was quoted as saying: "There are some women with poor approach. They just begin by saying here are the test kits, you have been dodging the subject, and today I have brought them and we will test here at home [...laughs]. So you can just slap her [...laughs] and say, go tell your Doctor to self-test with you, not me [... laughs]" (Choko et al., 2017). According to Johnson et al., the use of an HIVST kit might not be suitable for vulnerable populations; hence, populations at high risk of abuse will need to be consulted prior to HIVST implementation (2017). This caution was demonstrated in a study conducted in Kenya, where

individuals who believed that distributing test kits to their partners would result in intimate partner violence were excluded (Thirumurthy et al., 2016).

A study conducted in Kenya by Schaffer et al., showed that the history of experiencing IPV reduced the likelihood of partner or couple self-testing (2017). Furthermore, in a study conducted in Kenya, Thirumurthy, et al. advise individuals who decide to distribute the test kits to their partners to use the toll-free number provided with the self-test kit to report any IPV occurrences (2016). In my opinion, South African kit users should be encouraged to report IPV to the toll-free National AIDS Helpline provided with the test kit. The potential for IPV could have a detrimental effect on the success of the intervention that aims to increase male partner HIV testing uptake through the secondary distribution of self-testing kits by the female partners (Schaffer et al., 2017).

Importantly, studies have shown little to no evidence of IPV resulting from using HIVST in couple or partner testing (Choko et al., 2015; Figueroa et al., 2015; Masters et al., 2016; Thirumurthy et al., 2016; Johnson et al., 2017). However, occurrences of IPV remain a concern, and because IPV prevalence is high in sub-Saharan Africa, it may affect the use of HIVST in couple testing (Schaffer et al., 2017). This highlights the importance for South African users of reporting all cases of IPV to the toll-free number, following the use of HIVST; to allow policy makers to monitor adverse events, and if cases continue to rise, to take the HIVST kit off the market. However, since there is little to no evidence of IPV related to the use of HIVST in available empirical data, the implementation of HIVST in South Africa seems justified.

In general, there has been no evident increase in reported social harms relating to the use of HIVST compared to facility-based HIV testing (South African National Department of Health, 2018). Moreover, there was very little evidence of reported psychological, medical and social harm resulting from using an HIVST (Choko et al., 2015; Qin et al., 2017; Ong et al., 2018b). In South Africa, social harms will be assessed through the feasibility and acceptability studies conducted on a larger scale, by the UNITAID-funded STAR research project, where an estimated 9 million HIVST kits will be distributed for use in South Africa, Malawi, Zambia, Kenya and Zimbabwe, by 2020 (UNITAID, 2017; 2018). This research study will provide valuable information to policy makers and the national regulatory bodies to continue to monitor and reassess the risk-benefit analysis of HIVST implementation in South Africa and take action to stop the implementation if found to cause more harms than benefits.

In a brochure available in South Africa that provides guidance on how to introduce HIV self-screening to a partner, individuals are advised to offer it only when they feel comfortable and safe (Wits Reproductive Health and HIV Institute, 2018). According to Youngs and Hooper, the duty to protect vulnerable groups from harms related to the use of HIVST kits lies with the medical device manufacturer and the policy makers (2015). In addition, Brown & Djimeu advise researchers and policy makers to continue to monitor and measure unintended harms (2014). Since the bioethical principle of non-maleficence is grouped together with the principle of beneficence, the ethical principle of beneficence will be examined in the next chapter. Since the move to allow pharmacies to sell HIVST kits to the South African public was to increase HIV testing uptake, and consequently, to reduce HIV transmissions, beneficence is an important argument for this research report.

CHAPTER FOUR - PRINCIPLE OF BENEFICENCE AND HIVST

4.1 Introduction to the Principle of Beneficence

Beneficence is one of the three principles that govern how patients should be treated and refers to a moral obligatory act that promotes the wellbeing of others (Pellegrino & Thomasma, 1987; Beauchamp & Childress, 2013). Wellbeing is defined as "the ends the individual would choose, if he or she was rational, well informed, and acquainted with the possible ends" (Rajczi, 2016). Beneficence is the only moral duty that requires or motivates us to act (Beauchamp & Childress, 2013; Schroeder, 2014). Moreover, in medical settings, beneficence requires the physicians or health care professionals to prevent harm and promote good health to patients (Mawere, 2012). In this chapter, I will use the principle of beneficence to argue that the addition of HIVST, as one of South Africa's HTS tools, is for the benefit of the user and has the potential to contribute to the public health imperative of reducing annual HIV infection rates.

In moral philosophy, there are two duties required, ones that command actions, known as positive duties and those that prohibit certain actions, known as negative duties (Yudanin, 2015). Positive duties compel one's actions to be for the benefit of others, and these include preventing and/or removing conditions that could cause harm, and protecting and defending the rights of others (Mill, 1859; Beauchamp & Childress, 2013). The importance of the duty of beneficence is grounded in the National Health Act, section 3, where the Ministry of Health is tasked with the duty "to protect, promote, improve and maintain the health of the population"; and to "determine the policies and measures necessary to protect, promote, improve and maintain the health and wellbeing of the population" (2004). Therefore, the duty of beneficence falls on South Africa's Ministry of Health to maximise health and provide people with the opportunity to derive happiness from living a healthy life (Misselbrook, 2016).

Testing for HIV must always be for the benefit of the person testing and to improve the population health outcomes (World Health Organization, 2015a). The HIV self-testing mode, newly implemented in South Africa, has the potential to offer several benefits, including ease of use; increase HIV testing uptake; convenience; protection of confidentiality; and, respect for privacy (Kelvin et al., 2016; Witzel et al., 2016; Choko et al., 2017; Indravudh et al., 2017; Jennings et al., 2017; Spyrelis et al., 2017; De Boni et al., 2018; Tun et al., 2018). It can be argued that increasing HIV testing uptake through the use of HIVST in a country like South Africa burdened with

HIV/AIDS, and having a successful rollout of ART, can be in the best interest of its citizens, as it may potentially improve the population health outcomes.

Breach of confidentiality, violation of privacy, and inconvenient clinic hours were found to contribute significantly to men not seeking testing services at health facilities (Koo et al., 2013; Sandfort et al., 2015; Mohlabane et al., 2016). It is important to highlight that the South African government has made efforts to encourage men to test through partner and couple testing at health facilities, which has been shown to work; however, men still lag behind in HIV testing (Tabana et al., 2013; South African National Department of Health, 2016; Dalal et al., 2017; UNAIDS, 2017). Therefore, because HIVST involves individuals purchasing a kit directly from a pharmacy, and conducting the test in the privacy of their own home or in other private settings, I would argue that HIVST has the potential to encourage more men to test for HIV.

The protection of confidentiality, respect of privacy, and the ability to promote couple or partner testing are some of the potential benefits offered by the implementation of HIVST, and these will be discussed in greater detail in this chapter. In addition, I will examine how the current barriers to testing encountered at health facilities will be addressed by the implementation of the HIVST which potentially will help to bridge the HIV testing gap among men and those who otherwise would not test. The benefits to public health will be explored fully in the later chapter, where I will be discussing the utilitarian ethical theory.

4.2 Respect for Privacy and Protection of Confidentiality

Respect for privacy and protection of confidentiality are founded on the principle of respect for autonomy and human dignity (Noroozi et al., 2017). Moreover, privacy is regarded as a patient's right and refers to respecting personal boundaries (Noroozi et al., 2017). South Africa's Promotion of Access to Information Act defines personal information as "information about an identifiable individual including, but not limited to information relating to race, gender, sex, pregnancy, marital status, national, ethnic or social origin, colour, sexual orientation, age, physical or mental health, well-being, disability or medical history of the individual" (Republic of South Africa, 2000). Confidentiality on the other hand, is the moral and legal duty of the health professional and refers to the limitation of access to a patient's personal information by a third party (HPCSA, 2008; Noroozi et al., 2017). However, I would argue that issues of breach of confidentiality and invasion

of privacy are issues HIVST kit users need not concern themselves with as the test is conducted in a controlled environment such as homes and other private settings.

The right to privacy enables individuals to exercise their autonomy by determining when and how much personal information is shared with the public (UNESCO, 2011). In South Africa, the right to privacy is enshrined in the Constitution, section 14, stating, "Everyone has the right to privacy" (Republic of South Africa, 1996). The appreciation of respect for privacy was demonstrated in a survey conducted by Trachtenbarg, et al., where participants indicated that they were willing to spend extra time in the consulting room to ensure that their privacy was protected (2017). With regard to confidentiality, The South African National Health Act, section 14, states that: "all information concerning a user, including information relating to his or her health status, treatment or stay in a health establishment is confidential" (Republic of South Africa, 2004).

Respect for privacy and protection of confidentiality are grounded in article 9 of the Universal Declaration on Bioethics and Human Rights, where it states: "Privacy of the person concerned and the confidentiality of their personal information should be respected" (UNESCO, 2009). In health facilities, privacy of the individual testing for HIV, is ensured by performing the test behind closed doors (HPCSA, 2008). Violation to the right to privacy may occur when HIV testing is conducted in a setting where a third party may hear personal information about the person being tested, including information on sexual behaviour and the HIV test results.

In routine HIV testing, respect for confidentiality requires that the information shared or discussed between the HIV testing service provider and the client or patient "not be disclosed to anyone without the consent of the person being tested" (South African National Department of Health, 2016). Occurrences of a breach of confidentiality may jeopardise a patient's future desire for interactions with the health facilities, critical for effective lifelong HIV care, as the trust between the patient and the health care worker would be compromised (Wringe et al., 2017). Hence, some individuals even go to lengths of seeking testing at clinics far from where they live in order to ensure that their privacy and confidentiality protected (Sandfort et al., 2015).

Because HIVST is conducted in a private setting, generally at home, respect for privacy is further strengthened and a breach of confidentiality is eliminated as the tester has full control of the testing environment (Mavedzenge et al., 2013; van Dyk, 2013b; Choko, 2017; Indravudh et al., 2017; South African National Department of Health, 2018; Tun et al., 2018). Therefore, the potential for

a violation of privacy and a breach of confidentiality are minimised and may not pose as issues of concern in HIVST (van Dyk, 2013b). Participants in a study conducted in the United Kingdom (UK) associated willingness to self-test for HIV, with the ability to use the kit privately (Dodds et al., 2018). Moreover, one participant in a qualitative study conducted in Myanmar investigating the use of HIVST was quoted as saying, "I can do it just by myself, no matter what the results are, I will be only one who knows, no one else will know it" (Wirtz et al., 2017).

The increased privacy offered by HIVST can help avert widely perceived stigma that discourages many from seeking HIV testing at health care facilities (Dodds et al., 2018). The appreciation of respect for privacy and protection of confidentiality in relation to using HIVST kits was evident in two studies conducted in South Africa and in Singapore, where the majority of the study participants showed a preference to conduct the HIV test at home, as opposed to testing in a health facility (Ng et al., 2012; van Dyk, 2013b). Therefore, being able to learn one's HIV status privately was regarded as a considerable strength, and it provided the means of enhancing a willingness to test among individuals who would not likely test otherwise (Dodds et al., 2018).

4.3 Couple or Partner Testing

Heterosexual HIV transmission is the primary contributor to the scale of the epidemic in sub-Saharan Africa (UNAIDS, 2014). Couple testing involves two or more people, either heterosexuals or homosexuals, in a sexual relationship, who want to test for HIV together and mutually disclose their test results (Thirumurthy et al., 2016; South African National Department of Health, 2016). Moreover, couple or partner testing comes with many potential benefits, and these include mutual disclosure, making informed decisions and increased adherence to HIV treatment services (World Health Organization, 2012; Tabana et al., 2013; DiCarlo et al., 2014; South African National Department of Health, 2016). Because HIVST kits are purchased directly from pharmacies, I would argue that HIVST enables individuals to introduce the test kits to their sexual partners for partner and/ couple testing and facilitates mutual disclosure.

A study found that couples are motivated to seek HIV testing when: one partner in the relationship is feeling sickly; couples are preparing for marriage; there is mistrust within the relationship; couples are attending antenatal care; and, there are perceived benefits of HIV testing (Kumwenda et al., 2014; Nannozi et al., 2017). And, the World Health Organization strongly recommends that

"HIV testing services for couples and partners, with support for mutual disclosure, should be offered to individuals with known HIV status and their partners" (2016b). Mutual disclosure was found to contribute positively on couple's ability to navigate HIV-related challenges, such as prevention of HIV acquisition in HIV-negative couples and adherence to treatment for sero-discordant and HIV-positive couples (Koo et al., 2013; Tabana et al., 2013; Rogers et al., 2016; Nannozi et al., 2017).

The uptake of HIVST was found to be associated with being sexually active, willingness to buy an HIVST kit, and, interest in couple or partner testing (Mokgatle & Madiba, 2017). Because women contact health care facilities more frequently than men, they are more likely to test for HIV; men have been known to avoid HIV testing and use their partner's HIV status as a proxy for their own (DiCarlo et al., 2014). A research study conducted in Durban, South Africa, showed that half of the participants reported that they would be willing to self-test for HIV with their sexual partners, and that testing together would benefit the couple by strengthening their relationship and increasing intimacy (Kelvin et al., 2016).

Couples viewed HIVST as non-invasive and easy to use, and the benefits derived from HIV testing motivated couples to conduct HIV self-testing together as a couple (Kumwenda et al., 2014). Furthermore, studies conducted in South Africa, using an Oraquick HIVST kit, showed increased uptake of HIV testing among men through secondary distribution by their female sexual partners, thus promoting partner and couples testing (Masters et al., 2016; Thirumurthy et al., 2016). Consequently, HIVST provides an opportunity for women to introduce the testing kit to their partners, who otherwise would not test (Kumwenda et al., 2014).

Self-testing for HIV offers an opportunity to confirm a new sexual partner's self-disclosed HIV status before engaging in unprotected sex (Burke et al., 2017). A study conducted in New York City, USA, explored the reaction when one partner tests HIV-positive through HIVST, and they found that the partner was provided with emotional support and encouraged to seek treatment and other support services (Omar et al., 2014). Moreover, individuals are encouraged to support their partners with the HIV self-test results by providing comfort, and encouraging the partner to confirm the positive results at a health care facility (Wits Reproductive Health and HIV Institute, 2018). However, individuals need to be aware that couple or partner testing using HIVST may have the potential to cause harm, such as gender-based violence, a concept that was discussed in the previous chapter focusing on the duty of non-maleficence. Therefore, one should only introduce HIVST to

a partner in a comfortable and safe environment (Wits Reproductive Health and HIV Institute, 2018).

4.4 Impact of HIV Self-Testing on Risk Behaviour

During an HIV counselling and testing session, the health professional provides sexual behaviour risk reduction counselling, thereby reinforcing sexual risk behaviour change and links all individuals who are HIV-positive to care and treatment (South African National Department of Health, 2016). However, because sexual behaviour is not observed, it is difficult to measure, and self-reported sexual behaviour mostly leans towards social desirability bias; hence individuals under-report actual risky sexual behaviour (Palen et al., 2008; Gong, 2015; Huerga et al., 2017). According to Grimm, "social desirability bias refers to the tendency of research subjects to give socially desirable responses instead of choosing responses that are reflective of their true feelings" (2010).

Spielberg et al., believe that knowledge of HIV status is a major contributor to sexual behaviour change (2004). Hence, for a successful risk-reduction behaviour and a continued positive change over time, individuals need to be continuously motivated to test frequently (Huan et al., 2013). Moreover, studies conducted in Kenya and Tanzania showed that testing for HIV has a positive effect on risky sexual behaviour, as those surprised by their HIV-negative results reduced their sexual risk behaviour (Gong, 2015). Therefore, I would argue that since HIV self-testing has the potential to increase couple testing uptake and increase the frequency of testing, it has the potential to encourage users to reduce their sexual risk behaviour.

Risky sexual behaviour reduction was observed in a study conducted in the USA, where following an HIV-positive HIVST result of sexual partners, there was a change in sexual risk behaviour despite the absence of counselling (Katz et al., 2012). In another study a significant increase in condom use and a reduction in sexual intercourse following an HIV-positive HIVST result of a sexual partner was observed (Thirumurthy et al., 2016). In addition, a study conducted in Malawi found that discordant couples who learnt of their HIV status together found this to be beneficial, as they reported a decrease in sexual risky behaviour (Delavande & Kohler, 2012).

Studies conducted in Kenya, China and in the USA found the use of HIVST to be instrumental in point-of-sex decisions, and this provided individuals with more informed sexual decisions (Katz et al., 2012; Thirumurthy et al., 2016; Ong et al., 2018b). Moreover, a study conducted in New York, USA, found that when the partner tested HIV-positive after self-testing for HIV, the sexual encounter was stopped based on the test result (Omar et al., 2014).

In summary and based on the empirical data mentioned above, HIVST has the potential to empower individuals to reduce risky sexual behaviours, to make informed point-of-sex decisions, and demand condom use following an HIVST result.

4.5 Impact of HIV Self-Testing on Testing Barriers

The first HIV test, known as the first generation HIV diagnostic test, was licensed in the USA in 1985 (Pear, 1985; Higgins, 1991). The process of HIV testing has since become the only procedure used in discovering if one is infected with HIV (World Health Organization, 2012). However, individuals who are infected with HIV often test late and initiate treatment when already immune-compromised, potentially resulting in transmission to their sexual partners (World Health Organization, 2012). The WHO advises that "re-testing every 6-12 months may be beneficial for individuals at high risk of HIV exposure" (World Health Organization, 2007). However, barriers to HIV testing prevent this from happening. These barriers include inconvenient clinic hours, not being able to take time away from work to go and test for HIV, the possible breach of confidentiality by health workers, stigma towards people living with HIV (PLWH), and discrimination against PLWH (Parker & Agleton, 2003; Koo et al., 2013; Mohlabane et al., 2016; Pérez et al., 2016; UNAIDS, 2016b).

According to Turan et al., stigma towards PLWH is usually associated with unhealthy sexual behaviours, which then, makes them less likely to visit HIV testing facilities (2017). In addition, clinic staff in one study by Koo et al., admitted that they may have contributed to men not seeking HIV testing at clinics, as they pass judgement to men who test positive and label them as promiscuous (2013). Because HIVST offers convenience in testing, where one can test for HIV whenever and however one wants, I would argue that HIVST may have the potential to eliminate barriers to HIV testing experienced at health facilities, potentially increasing HIV testing uptake.

The Joint United Nations Programme on HIV/AIDS (UNAIDS) refers to HIV/AIDS-related stigma as "negative beliefs, feelings, and attitudes towards people living with HIV" (2014). Stigmatization is further strengthened by a well-researched concept that certain groups, such as men who have sex with men (MSM) and female sex workers, are at high risk of infection as a result of their behaviour (Chesney, 1999; UNAIDS, 2001; Courtenay-Quirk, 2006; Jeffries, 2015). Moreover, punitive laws and policies that criminalise and discriminate against MSM can hinder their access to HIV testing and prevention services, thus increasing their vulnerability to the infection (UNAIDS, 2016b). In addition, clinic-rooms at some health facilities that offer care to HIV-infected individuals are isolated from the general health care services, and this further perpetuates and reinforces stigma and discrimination towards people living with HIV and also inadvertently discloses their HIV status (Chambers et al., 2015; Senyalo et al., 2015).

According to UNAIDS, HIV-related discrimination "refers to the unfair and unjust treatment (act or omission) of an individual based on his or her real or perceived HIV status" (2014). The protection from discrimination is grounded in the South African Constitution, where section 9, subsection 4 states: "No person may unfairly discriminate directly or indirectly against anyone" (Republic of South Africa, 1996). Moreover, Jonathan Mann, the founder and a former head of the first WHO Global Programme on AIDS and a pioneer in HIV research, identified the necessity of protecting human rights and dignity of all those infected with HIV regardless of their population group association (Mann, 1988; Fee & Parry, 2008). Mann stressed that public health officials must ensure that services that facilitate the realization of public health goals are closely linked with rights to non-discrimination (Piot & Tarantola, 1998; Fee & Parry, 2008).

The use of HIVST was found to be associated with fewer test-related stigma experiences when compared to facility-based testing, and self-testing was found to be the preferred mode of testing (DiCarlo et al., 2014; Ortblad et al., 2018; Qin et al., 2018). Furthermore, the ability of HIV self-testing to de-stigmatize HIV was appreciated by individuals using HIVST in Zimbabwe (Moyo, 2018). In Zimbabwe, one user was quoted as saying, "I could have just lived in the dark and fallen sick because I was afraid of visiting public testing centres, but thanks to self-testing, I now know my HIV status and went on treatment earlier" (Moyo, 2018). Therefore, the convenience, and the ease of self-testing have the potential to lessen the number of people testing at health facilities associated with HIV-related stigma experienced when queuing for testing, as they now have the option to test in a private setting if they can afford the test kit.

The lack of HIV-related stigma resulting from using HIVST could encourage naïve testers to initiate HIV testing (Knight et al., 2017; Wirtz et al., 2017). Thereby, it potentially could increase the testing uptake among men and other members of the general population, who would otherwise not seek HIV testing (World Health Organization, 2016b; Ortblad et al., 2017). A study participant in South Africa was quoted as saying, "Self-testing is the only way to assure that nobody will judge me or discriminate against me" (van Dyk, 2013b). Some study participants alluded to their interest in using HIVST for its ability not to interfere with their daily activities and the ability to test without losing time off work (Jennings et al., 2017). Therefore, regarding the convenience that comes with using HIVST, as a major benefit some people may be willing to test at home who otherwise may not have time to travel to clinics (Burke et al., 2017).

Self-testing for HIV was also associated with increased testing uptake among first-time testers (Krause et al., 2013; Qin et al., 2017; De Boni et al., 2018). Furthermore, a study conducted in Australia showed a significant increase in the uptake of HIV testing using HIVST among MSM and bisexual men who never tested before or who delayed testing, compared with the standard facility-based testing (Jamil et al., 2017). In addition, the use of HIVST was found to have the potential to allow for frequent testing; and this was seen in a study conducted in Uganda, where participants who were provided with HIVST kits were found to be more likely to test frequently than those who tested at health facilities (Ortblad et al., 2017). Several studies also observed an increase in HIV testing frequency when using the HIVST kit, resulting in increased HIV status awareness and potentially reducing the rate of transmission (Katz et al., 2012; Grésenguet et al., 2017; Jamil et al., 2017; Knight et al., 2017; Qin et al., 2017).

Even though empirical studies show an increase in HIV testing uptake through couple testing, and frequent testing and an increase in first-time testers when using HIVST, more work still needs to be done in eliminating HIV-related stigma at health institutions. HIV-related stigma can have a detrimental effect on health care utilization when some individuals requiring care find themselves avoiding health care services altogether, thus compromising their own health (Chambers et al., 2015). Hence, local and global interventions focusing on stigma reduction are required to form a collective, societal response to combat stigma and discrimination towards people living with HIV, both within and outside health facilities (Chambers et al., 2015).

In this chapter, I have demonstrated using published empirical data that the benefits derived from using an HIVST kit may minimise HIV-related stigma and discrimination, thus potentially

increasing HIV testing uptake among those who need it the most. In the next chapter, I will focus on the potential benefits of HIVST to public health using the ethical theory of utilitarianism and later perform a harm/benefit analysis to determine whether if HIVST implementation in South Africa is ethical. My intention is not to cause confusion but I decided to jump straight to the ethical theory of "utilitarianism" before embarking on the final ethical principle "the principle of justice", a concept that will be discussed as a final argumentative strategy, because in this research report utilitarianism offers a logical flow from the principles of beneficence and non-maleficence as it will explore the public health benefits of HIVST and also includes a benefit/harm analysis.

CHAPTER FIVE - HIVST AND THE PUBLIC HEALTH IMPERATIVE

5.1 Introduction to Utilitarianism

Utilitarianism is a consequentialist theory where "the outcomes determine the morality of the intervention" (Mandal et al., 2016). And, according to utilitarianism, the action that produces more benefits, such as good health or a reduction in the burden of diseases, is regarded as the right choice (Roberts & Reich, 2002). Furthermore, decisions on public health policies involve ethical principles, often based on the analysis of consequences (Roberts & Reich, 2002). Therefore, the morally right action is chosen after the consequences of each action have been assessed (Elqayam et al., 2017). In addition, morally right actions are aimed at maximising benefits and minimizing harms, thereby maximizing overall welfare (Sheskin & Baumard, 2016). In this chapter, I will explore the public health benefits of HIVST and argue that the consequences of using the HIV self-testing kit will produce overall good, and HIVST has the potential to maximize the public health benefit of increasing HIV testing uptake and practice of HIV-prevention methods, including accessing ART, if needed, thus reducing the potential for new infections, i.e., lowering HIV incidence rates.

In public health, "when choosing between several competing interventions or programmes, states and policy makers ought to opt for those that are likely to produce the greatest aggregate benefit" (Nuffield Council on Bioethics, 2007). Moreover, article 4 of the Universal Declaration on Bioethics and Human Rights states: "In applying and advancing scientific knowledge, medical practice and associated technologies, direct and indirect benefits to patients, research participants and other affected individuals should be maximized and any possible harm to such individuals should be minimized" (UNESCO, 2005). In medical ethics, utility can be used as a principle of beneficence, where it requires health professionals to carefully analyse and evaluate individual situations and only take actions that promote more benefits than harms (Mawere, 2012).

In the last section of this chapter, I will use a benefit/harm-based approach to determine whether or not the implementation of the HIVST provides more benefits than harms. When conducting a benefit/harm analysis for a health intervention, "the public health benefits must always outweigh the potential harm or risk" (World Health Organization, 2016b). Furthermore, the rightness of using HIVST in South Africa is judged based on the overall goodness of the outcomes produced; hence, it is important to show that despite the potential risks, there is a substantial increase in

benefits (Scott, 2014). However, it would be unethical to implement HIVST in South Africa if it would substantially increase the vulnerability of one group within the population (Scott, 2014).

5.2 HIV Self-Testing and Public Health Benefit

According to the Nuffield Council on Bioethics, public health refers "to the efforts of society as a whole to improve the health of the population and prevent illness" (2007). Moreover, public health doesn't concern itself with the health of the individual, but rather the health benefits of the entire population (Kass, 2001; Lee, 2012). Therefore, public health agencies' key function is to assess the health needs of the community and respond to these needs by developing health policies specific to the community or population (Nuffield Council on Bioethics, 2007). In response to the HIV/AIDS pandemic in the mid-1980s, Mann echoed the view that the main objective in global health strategy related to HIV is to prevent HIV transmission (1988). Three decades later, Mann's view remains a primary goal for the South African government to reduce new HIV infections (SANAC, 2017).

One of the greatest successes in global response to HIV/AIDS is the scale-up of life saving treatment , and this has changed HIV from a deadly disease to a manageable chronic condition, resulting in reduced HIV transmission (UNAIDS, 2016b; Cornell et al., 2017). Moreover, public health's ultimate goal with regard to HIV screening programmes is to reduce infection rates (Kass, 2001). My argument will use a utilitarian ethical framework to show that the implementation of HIVST in South Africa has the potential to provide the greatest amount of benefits for the greatest number of people. I will do this by reviewing published empirical data that shows an increase in HIV testing uptake through the use of HIVST, which could potentially lead to early treatment initiation and ultimately benefit the population as a whole (Allais & Venter, 2014; Cambiano et al., 2014; Johnson et al., 2014; Harichund & Moshabela, 2017).

Public health relies on laws, with human rights protection being its foundation (Annas & Mariner, 2015). However, the debates around the promotion of public health, while at the same time protecting human rights in the midst of HIV/AIDS epidemic, are still relevant today (Fields & Kaplan, 2011). Hence, government policies on public health must promote a human rights framework and protect autonomy and privacy (Annas & Mariner, 2015; Rajczi, 2016). Combating HIV and AIDS is a public health goal that is realised through collective action, where individuals

are aware of their HIV status, and all HIV-positive individuals are put on treatment immediately after diagnosis (Carter et al., 2012; SANAC, 2017). The South African public health goal is to improve the health and wellbeing of the population by preventing and reducing disease burden and increasing the life expectancy to at least 70 years by 2030 (South African National Department of Health, 2015).

South Africa has an estimated 3.9 million people living with HIV currently receiving HIV treatment, the largest HIV treatment programme globally (South African National Department of Health, 2016; UNAIDS, 2017). And, in response to the HIV epidemic, the annual public health goal is to reduce new HIV infections to below 100,000 by 2022 and to eliminate HIV by 2030 (SANAC, 2017). In addition, South Africa offers a variety of testing tools, together with a 'test and treat' programme, therefore, making HIV treatment available to individuals as soon as they are diagnosed as HIV-positive (South African National Department, 2016; UNAIDS, 2016c).

A study conducted in 13 sites located in Africa, North and South America, and Asia, of which 54% of the participants were from Africa, showed that early treatment initiation reduced the rate of HIV sexual transmissions (Cohen et al., 2011). Because individuals on treatment are less infectious, increasing the uptake of HIV testing together with the linkage to care may result in reduced HIV transmissions. Furthermore, the test and treat strategy implemented in South Africa, where all people diagnosed HIV-positive regardless of their CD4 level will be offered treatment, aims to reduce the rate of HIV transmission among people (UNAIDS, 2016c; Nah et al., 2017). This approach is consistent with the government's vision of having "South Africa free from burden of HIV" (SANAC, 2017).

Cambiano, in his mathematical model, outlined parameters that would contribute to the reduction of HIV transmissions when using HIVST, and these included "increase in the rate of first-time testers; repeat testing; and, the level of linkage to post-test care" (2014). Several studies have shown significant increases in HIV testing uptake through HIVST, followed by an increase in frequent testing among the key populations (MSM and sex workers) and the general population (Katz et al., 2012; Krause et al., 2013; Choko et al., 2015; Jamil et al., 2017; Indravudh et al., 2017; De Boni et al., 2018). More interesting were study results showing there was also an increase in HIVST uptake among first-time testers (Krause et al., 2013; Choko et al., 2015; Qin et al., 2017; De Boni et al., 2018).

The HIV self-testing uptake and use at a population level has the potential to increase the number of previously undiagnosed HIV-infected individuals at risk of onward viral transmission who become aware of their infections and practice prevention methods, consequently maximizing the public health benefits of reducing new infections, and lowering HIV incidence rates (Indravudh et al., 2017; Johnson et al., 2017; SANAC, 2017). However, studies have reported sub-optimal linkage to care following HIV self-testing (Krause, et al., 2013; Choko et al., 2015; Ortblad et al., 2017). In an effort to expand and understand HIVST effectiveness, the Self-Testing Africa (STAR) initiative is distributing 4.7 million HIV self-testing kits to sub-Saharan African countries, including, Zimbabwe, Lesotho, Swaziland, Malawi, Zambia, and South Africa (Independent Online, 2017; UNITAID, 2017). This is a bold move towards the realization of an HIV/AIDS-free generation through achieving the UNAIDS 90-90-90 targets (Independent Online, 2017). This study will also be a platform to investigate the linkage to care, as well as any social harms emanating from using an HIVST kit.

5.3 Benefit/Harm Ethical Framework for HIVST

The decision to implement a safe and effective health care intervention is informed by the balance between benefits and harms, and it is justified when the benefits clearly outweigh the harms (Boyd et al., 2012; Puhan et al., 2012; Brett et al., 2013). Furthermore, all major regulatory decisions regarding interventions that are proposed to benefit the public must have the multiple outcomes weighed using a quantitative approach, where outcomes are presented side by side (Puhan et al., 2012). The judgments used when performing a benefit/harm ethical framework are informed by current science and societal concerns (Davies, 2018). This section will determine if the decision taken by the South African government to implement HIVST as an additional HIV testing tool is ethical by performing a benefit/harm analysis.

In medical practice, "ethics deals with choices, decisions/actions based on the choice and the duties and obligations of a doctor, to the best interest of the patient" (Mandal et al., 2016). Having consequences derived from an action of choice determines the morality of an intervention, and it involves a benefit/harm analysis approach (Mandal et al., 2016). Moreover, the action that produces more benefits, such as good health or a reduction in the burden of diseases, is regarded as the right choice (Roberts & Reich, 2002). Hence, Davies suggests that the benefit/ harm analysis

be applied throughout the life span of the new intervention in order to reduce harms and maximize benefits (2018). I believe Davies's suggestion can also be applied throughout the life of the HIVST implementation programme to make sure that benefits always outweigh harms.

In a utilitarian moral judgment, where the action or intervention results in "increased well-being for a larger number of people", cognitive thinking dominates the decision-making process (Conway & Gawronski, 2013). Hence, cognitive processing of decision-making is vital when drafting a public health policy (McCaughey & Bruning, 2010). With regard to HIV testing, the benefits should always outweigh the potential harms to the individual regardless of the testing protocol used (World Health Organization, 2015a). For the implementation and scale-up of HIVST to be ethical and justified, the potential benefits must outweigh the potential harms (UNAIDS, 2013; Youngs & Hooper, 2015). In order to determine if in fact the anticipated benefits outweigh the potential harms, I performed a benefit/harm analysis:

Table 5.1: Comparison of good and bad consequences of using HIVST

BENEFITS	HARMS
Increased access to HIV testing. Test kits are available at pharmacies nationwide. Therefore, HIVST provides an option for those who may not want to use existing HIV testing services, such as some men and some members of key populations. Key populations are individuals at increased risk of HIV infection due to specific higher-risk behaviours, and these include "men who have sex with men (MSM), sex workers, people who inject drugs, and transgender people" (World Health Organization, 2016b).	**Potential for coercion.** Since HIV self-testing is conducted at home or private setting, it provides opportunities for coercive testing to occur. Examples include when adolescents may be forced by their parents to test for HIV; domestic workers are forced to test by their employers; sex workers are forced to test by their clients; and, women or others in lesser positions of power are forced to test by their sexual partners.
Respects the user's autonomy. Self-testing empowers individual users to exercise their	**Linkage to care.** Individuals who are in denial following a positive HIV self-testing result

choice by deciding when, where and how to test for HIV.	may miss out on the benefits of early treatment initiation.
Protects privacy. The user tests for HIV in the privacy and comfort of their own home or another private setting.	**May be used at the point-of-sex decisions**. Since the HIVST may give a false negative test result early in infection when antibodies have not yet reached the detection level, this could result in onward HIV transmission when used as the point-of-sex decision.
Protects confidentiality. The HIVST users have control over the environment in which the test is conducted, where they can test alone or in the company of someone they trust. Therefore, it ensures the protection of confidentiality or minimises room for a breach of confidentiality. However, users will need to be aware that testing with a trusted person may not ensure total protection of confidentiality, as their trust could be breached in the future.	**Potential psychological harm.** This may happen when a first-time tester uses an HIVST and tests HIV-positive in the absence of a face-to-face counselling.
Offers increased convenience. The kits are available over the counter at pharmacies and can be used at any time of the day. A person no longer has to conform to clinic working hours and stand in queues at VCT sites or clinics. The test can be performed whenever a person decides to test.	**Potential physical harm.** Arguments against the use of HIVST include the potential for suicide in the event the person tests HIV-positive in the absence of on-site face-to-face counselling. In addition, due to the possibility of gender-based violence, there is a concern that HIVST may lead to intimate partner violence (IPV) if testing is done with a partner who may react violently if the other partner tests HIV-positive. There may also be a potential for psychological/emotional/verbal abuse in the event the partner's test result is positive.

Encourages men to seek HIV testing. Barriers that prevent some men from seeking HIV testing, including long queues at clinics, and fear of a breach of confidentiality may be eliminated. In addition, men may receive HIVST via a secondary distribution of the kit from their sexual partners, thus allowing for couple testing in a comfortable and controlled environment.	**Potential for inaccurate test results.** There is a potential for inaccurate results due to testing errors in the hands of an untrained user and the difficulty of interpreting results (Krause et al., 2013; Roger, 2014). In addition, a false negative result may occur when used by individuals already on HIV treatment. Moreover, misdiagnosis may result in onward transmission based on a false negative result. In the event that the test kit user tests false-positive, unnecessary stress may occur as a result.
Encourages couples and partner testing. The use of HIVST may encourage couple testing and partner testing. This also provides an opportunity for couples to use HIVST to disclose their HIV status.	**Negative impact on the relationship.** In the event that one or both partners self-test HIV-positive and both are not prepared for the positive test result outcome, the relationship can be put under a lot of strain.
Allows for increased testing frequency. The use of HIVST has been found to increase testing frequency. Individuals who test HIV-negative and are at high risk of infection benefit from regular retesting (World Health Organization, 2015a). Therefore, those who want to frequently test for HIV can do so without feeling stigmatised.	
Allows for early diagnosis. Because HIVST has the potential to increase testing frequency, it may allow for early diagnosis. Early diagnosis can lead to early treatment initiation, which in turn will prolong the person's lifespan and reduce HIV transmission if the individual adheres to treatment.	

Minimises stigma and discrimination. The test is conducted at home or in a controlled environment. No one else will know the person's HIV test result unless the self-tester choses to disclose.	
Realisation of the public health goal. Increasing HIV testing through the implementation of HIVST has the potential to lead to more HIV-positive individuals accessing treatment, thereby potentially reducing the rate of transmission in the population, and may ultimately result in a decreased number of new HIV infections.	
Reduces power imbalances between health care workers and patients. Instead of the health care worker calling in a patient to discuss a reactive test result, the patient makes an appointment with the health care worker to discuss self-test results (Youngs & Hooper 2015). This is beneficial because the user approaches the health facility knowing what questions to ask so s/he can be better informed.	

Based on Mill's theory, an action is ethically justified depending on the welfare of all affected parties, which involves summing up all the positive benefits vs. the negative effects, and having the greatest balance of beneficial consequences (Beauchamp, 2016). The benefit/harm assessment summarised above shows that the implementation of HIVST in South Africa has the potential to produce more benefits than harms, thus making this public health intervention justifiable. In addition, there has been little to no evidence of psychological and physical harms resulting from HIVST; only one study reported 5% of violent incidents, with 35% of the participants reporting

subsequent suicidal thoughts following a positive HIVST result (Choko et al., 2015; Qin et al., 2017).

According to Krause, in addition to making sure that HIVST offers more benefits than harms, the policy makers must ensure that HIVST is accessible and reaches those most at need (2013). Therefore, the success of an HIVST intervention does not only depend on having the best national regulatory system available, but for the policy makers to make sure that these self-test kits are accessible to those who need them the most. In the next chapter I will explore the concepts of distribution and affordability using the principle of justice to determine if the availability of HIVST in South Africa is ethical.

CHAPTER SIX - PRINCIPLE OF JUSTICE AND HIVST

6.1 Health and Social Justice

Beauchamp understands justice to mean, "That each person in society ought to receive his due and that the burdens and benefits of society should be fairly and equitably distributed" (1976; Beauchamp & Childress, 2013). Justice ensures fairness and that the contingency of social circumstances leave no one advantaged or disadvantaged (John Rawls, 2002; Beauchamp & Childress, 2013). In South Africa, inequality in socioeconomic status contributes to inequalities in health (Ataguba et al., 2011). Furthermore, the poor in South Africa suffer more disability and carry the highest burden of HIV and tuberculosis (TB), compared to the individuals with higher socioeconomic status (Ataguba et al., 2011; SANAC, 2017).

Mann in the early years of the HIV/AIDS epidemic realised the necessity of protecting the human rights and dignity of those infected regardless of population group association (Mann, 1988; Fee & Parry, 2008). The HIV/AIDS epidemic does not discriminate against gender, race or socioeconomic status, hence efforts to ending it have always been a global public health imperative. The implementation of HIVST promises to increase people's awareness of their HIV status and consequently reduce HIV transmission (World Health Organization, 2016b; Burke et al., 2017). The distribution of health resources, independent of how other social goods are distributed, can either be justified or unjustified (Wester et al., 2018).

Related to fairness in distribution, "health is but one of several 'currencies' of justice within a pluralist framework, where justice concerns the distribution of more than one good" (Wester et al., 2018). However, Ruger argued that health is not the main variable for assessing social justice; instead, resources and utility are (2010). With regards to HIVST, I would argue that using distributive justice as the focal point in the availability of HIVST kits will ensure that no one is left disadvantaged or advantaged because of social circumstances.

Different societies have different guidelines that they use to distribute health care resources with the goal of reducing inequalities in the health of their populations (Ruger, 2010). Furthermore, in order to know how to allocate resources equitably and efficiently and understand the effectiveness of these resources, it is vital that the impact of resources on health is thoroughly assessed (Ruger, 2010). Therefore, it is imperative that policy makers address the health inequalities in the

population and ensure that access to healthcare services is aligned with the need of the services by the population served (Ataguba et al., 2011). This can be done by shifting resources within existing health budgets and by allocating resources in an efficient way, which can ultimately result in lowered premature mortality and an increase in life expectancy (Ruger, 2010).

Moral philosopher John Rawls devised the notion of the "original position of equality", which ensures that no individual or group is advantaged or disadvantaged based on social circumstances (1971). The original position is understood to be a hypothetical situation where "no one knows his place in society, or social status", which can then lead to justice (Rawls, 1971). Therefore, in order to ensure fairness, that no one is advantaged or disadvantaged by the contingency of social circumstances, the principle of justice is "chosen behind a veil of ignorance" (Rawls, 1971). Hence, when the concept of the "original position of equality" as the principle of justice is employed in social institutions, the agreements reached by role players as equal and free agents will be fair (Rawls, 1971).

Rawls equated the notion of the original position of equality with justice as fairness (1971). And, justice as fairness is relevant to the implementation policy of the HIVST in South Africa. The policies on the implementation of HIVST are set out by different institutions, including the WHO, South African Pharmacy Council, and the National Department of Health. In this chapter I will explore the principle of justice and argue that the national government has a good reason to introduce the use of HIVST in South Africa, but they must ensure that all individuals have a fair chance in accessing this new intervention.

Rawls's notion of the "original position" supports the fair distribution of health resources in ensuring that no one is left disadvantaged or advantaged by the contingency of social circumstances. I think Rawls would also support the notion of making health care resources affordable. Hence, policy makers should therefore make sure that HIVST is distributed fairly and is made affordable so that everyone may benefit from it. Moreover, according to the WHO in the agenda to successfully improve global health access to appropriate medical devices, "availability, accessibility, appropriateness, and affordability" are crucial (World Health Organization, 2010b).

6.2 HIV Self-testing and Distributive Justice

The availability of HIVST has the potential to extend people's choice of which mode of test to use, where one can have a choice of finding out their HIV status without having to go to a health care facility (Allais & Venter, 2014). In my opinion, the national government has done well in increasing access to HIV testing services in an effort to encourage people know their HIV status. However, testing services at health care facilities are met with challenges, which may include inconvenient hours of operation, long queues and breaches of confidentiality (Harris et al., 2011; Koo et al., 2013; Pérez et al., 2016; UNAIDS, 2016b). Because HIVST has the potential to minimise some of these challenges by offering privacy and convenience in testing, I would argue that this new mode of testing, HIVST, if distributed fairly and made accessible to those who need it, recognises Rawls's justice as fairness, which in my opinion equates to distributive justice.

Distributive justice in health care concerns itself with fair, equitable allocation of health care resources, which consequently contribute to societal quality-adjusted life year (QALY) maximisation (Skedgel et al., 2015). This means the distribution of health care resources should be according to the need in a way that maximizes health gains (Juth, 2015; Skedgel et al., 2015). Therefore, in my opinion, the duty to respect the principle of justice related to the distribution of health care resources lies with the national policy makers. They have to ensure that all citizens have equitable access to HIVST; hence, unfair distribution would be regarded as unjust. The Department of Health in its National Strategic Plan promises to monitor access to health care services, identify any inequalities that may arise, and improve access to services (SANAC, 2017).

Accessibility refers to "people's ability to obtain and appropriately use good quality health technologies when they are needed" (World Health Organization, 2010b). Furthermore, Yakob defines access as "the extent to which the health care system fits, inhibits or initiates individual's willingness and ability to enter, receive and benefit from the outcomes of and to gain satisfaction from health services" (2016). Moreover, access to health care services is regarded as a fundamental human right as it is enshrined in the South African Constitution, where Section 27 states: "Everyone has the right to have access to health care services, and that the state must take reasonable legislative and other measures, within its available resources, to achieve the progressive realisation of this right" (Republic of South Africa, 1996). This means everyone has a right to decent, minimum health care services and the right to equal access to health care services (Ruger, 2010).

With regard to HIV infection, South Africa has a generalised HIV epidemic; hence, universal access to treatment and prevention packages is important in making sure that no one is left untreated (SANAC, 2017). The South African National Department of Health uses a rights-based approach in ensuring that the HST programme is available and accessible to all South African citizens (2016). Testing for HIV is regarded as the entry point of care, as it offers individuals the opportunity to know their HIV status and access appropriate care if found to be HIV-positive (South African National Department of Health, 2015). However, a study conducted in South Africa found that long queues, as well as the anticipated disrespectful treatment by health care workers were among the barriers to accessing care at health facilities (Harris et al, 2011).

In order to increase HIV uptake through empowering people and minimising barriers associated with facility-based HTS, the South African government lifted policy restrictions placed on pharmacies that prevented them from selling HIVST kits to the public (van Rooyen et al., 2015; Zanoloini et al., 2018; Lippman et al., 2018). As of December 2016, HIVST kits have been available for distribution via different platforms, which include pharmacies and indirectly via peer-to-peer couples and sex partners (SA HIV Clinicians Society, 2017). Studies conducted in Kenya and South Africa investigating preferred modes of distribution for HIVST kits found that the majority of participants cited pharmacies as their preferred distribution point (van Rooyen et al., 2015; Mugo et al., 2017). This preference was based on the ability of pharmacies to provide potential HIVST kit users with the freedom to access the kits at their convenience (van Rooyen et al., 2015).

To ensure that access to health care resources is not hindered, resources must be located in close proximity to the people that need them (South African National Department of Health, 2016). In terms of geographic distribution of community pharmacies, the WHO recommends that there be a pharmacy per 10,000 residents (Ward et al., 2014). The data presented by Ward et al., showed that there is an uneven distribution of community pharmacies, with the urban provinces (Gauteng and Western Cape) having higher density of pharmacies than the rural provinces (2014). This situation raises concerns over inequitable distribution of community pharmacies in urban and rural provinces (Ward et al., 2014). However, when the community pharmacies were pooled together with community clinic facilities, it resulted in equitable distribution, and all the provinces reached the benchmark set out by the WHO (Ward et al., 2014).

According to the National Health Act, Section 39(d), the national government must develop regulations that "must ensure and promote access to health care services and optimal utilisation of health care resources" (Republic of South Africa, 2004). Therefore, for equitable distribution of HIVST in South Africa, the national policy makers should consider the Ward et al., findings and deliberate on making both clinics and pharmacies the distribution sites for HIVST. Moreover, study participants in Uganda who were concerned about the lack of counselling when self-testing for HIV preferred health care facilities as distribution points; however, those that valued convenience and privacy preferred to obtain HIVST kits outside the health facilities (Burke et al., 2017). Currently, there is a study underway in Malawi investigating feasibility and acceptability of facility-based HIVST among routine out-patients in resource-limited settings (Dovel et al., 2018).

South Africa's national guideline on HIVST stipulates that the distribution of the HIVST kits will be dependent on the population target, and these distribution sites would include healthcare facilities, hospitals and pharmacies (South African National Department of Health, 2018). Based on these proposed distribution sites and considering the Ward et al., data mentioned above, the geographic distribution of HIVST in South Africa would be fair and justified. Other channels of distribution aside from pharmacies and health care facilities will also need to be considered. This need was demonstrated in a study conducted in Brazil among MSM, where there was a low uptake of HIVST in pharmacies (De Boni, 2018). This low uptake in HIVST sparked creative thinking, and the plan is to move towards installing automated HIVST kit dispensers for increased ease of access and to potentially reduce costs (De Boni, 2018). The South African National Department of Health is also considering vending machines as a mode of distribution (2018). Since shops at garages sell pregnancy tests and condoms, I believe it would be advisable to also use them as distribution points for HIVST kits.

Lastly, because access is not only dependent on acceptability, availability, convenience, or quality, affordability to people that require these services also needs to be ensured (South African National Department of Health, 2016). Many studies have shown that the HIVST is acceptable, convenient, and the kits of high quality; however, evidence-based research on accessible pricing is still needed (Zanolini et al., 2018; Lippman et al., 2018). Even though the South African government has made HIV self-testing available to its citizens, if it is not made affordable to those who need it the most, the benefits of implementation of HIVST in South Africa may not be fully realised.

6.3 HIV Self-testing and Affordability

According to the WHO, financial hardship should not prevent one from accessing health care services (World Health Organization, 2010a). It is therefore critical to make medical devices affordable in health care systems, as this access links directly to health equity and service delivery in response to the needs of patients (World Health Organization, 2011). Studies conducted in sub-Saharan Africa have shown an increase in HIV self-testing uptake and acceptability (Choko et al., 2015; Mokgatle & Madiba, 2017; Lippman et al., 2018; van Rooyen et al., 2018; Zanolini et al., 2018). However, the HIVST kits used in these studies were provided for free, whereas in reality potential users will have to purchase them. Considering the current HIVST kit pricing in South Africa, I would argue that the affordability of HIVST kits is an issue of serious concern, as it has the potential to violate the principle of justice.

Affordability refers to "the extent to which the intended client of a health service or product can pay for it", and is positively associated with accessibility (World Health Organization, 2010b; Stellenberg, 2015). Moreover, issues relating to affordability are fundamentally associated with the problem of cost (Stoltzfus & Pollack, 2016). A study evaluating factors that determine a patient's intentions to use self-testing devices found that affordability was an important factor in that the more affordable the device is, the greater the intention to self-test (Ghulam et al., 2013). Furthermore, a study conducted in Zambia showed a positive association of willingness to buy an HIVST with higher income, higher education level, and residence in urban areas (Zanolini et al., 2018). Furthermore, the cost of the medical device was seen by many patients as a barrier to self-testing, especially by those who were unemployed or on low income (Ghulam et al., 2013).

The South African National Health Act, Section 39(f) requires that the national government develop regulations that: "must seek to avoid or prohibit business practices or perverse incentives which adversely affect costs or quality of health care resources or the access of users to health services" (Republic of South Africa, 2004). The HIV self-testing kits in South Africa are priced between 146 - 199 South African Rands, equivalent to $10 - $14 USD. In my opinion, this may be too high of a price for those who need HIV self-testing kits the most. And, this high price may pose a barrier to using HIVST kits, thus hindering accessibility and ultimately defeating the purpose of making HIVST available in the first place. Similar views were echoed in some of the studies conducted in sub-Saharan Africa, where the participants indicated that the price of HIVST

could pose a barrier to testing, as people may not be able to afford to buy the test kits (Indravudh et al., 2017; Mugo et al., 2017; Zanolini et al., 2018).

Affordability was seen as an issue even in high-income countries, where in a study conducted in the USA, only 55% of participants were willing to buy the test kit and of those, only 23% indicated that they were willing to pay the market value of $40 USD for the kit (Nunn et al., 2017). In another study, also conducted in the USA, the price of the kits had a major impact on influencing the participants to test for HIV (Lee et al., 2013). Interestingly, the majority of study participants indicated a willingness to self-test for HIV only if the kits were provided for free or at approximately $5.50 USD (Lee et al., 2013; Nunn et al., 2017; Tun et al., 2018).

In middle- to low-income countries, affordability is no doubt a serious issue, and unaffordability of the kits may prevent many who wish to benefit from the convenience offered by self-testing for HIV. Study participants in a fishing community located in Uganda were willing to pay between $0.29 – $1.47 USD for a self-test kit (Burke et al., 2017). Similarly, study participants in Tanzania were willing to pay between $2 to $9 USD per test kit and cited that unaffordability of self-testing kits may undermine the benefits of self-testing (Jennings et al., 2017). More worrying from this study was the unwillingness to pay for a test kit among those who had never tested for HIV (Jennings et al., 2017).

In South Africa, study participants were willing to buy self-test kits at a price between 10 to 150 South African Rands ($1.00 USD - $15.00 USD) (Knight et al., 2017). However, the majority of study participants together with health care professionals expressed the desire to have free HIVST (Burke et al., 2017; Knight et al., 2017; Zhong et al., 2017). And, when the HIVST kits were priced at $9.80 USD per kit through pharmacies, some study participants refused to buy a kit, citing an inability to afford the test kit (Mugo et al., 2017). Moreover, a study conducted in South Africa found that slightly more males were not willing to buy HIVST kits, as compared to females (Mokgatle & Madiba, 2017).

The empirical studies reviewed above show a variation in willingness to purchase the HIVST. Low- to middle-income countries were willing to purchase the HIVST at a price between $0.29 USD to $9.00 USD, and participants in high-income countries were willing to pay $1.00 USD to $40.00 USD per test kit. However, the majority of study participants expressed willingness to use the HIVST if provided for free. The affordability of the HIVST kits is an issue of concern for both

policy makers and end users (World Health Organization, 2016b). Furthermore, the cost of the kit is likely to prohibit some individuals from being able to purchase and use the kit and thus may pose a significant barrier to HIVST (Lee et al., 2013; Woods et al., 2014; Jennings et al., 2017).

Jennings et al., believe that these HIVST kits should be offered at an affordable price, especially in low-income countries so that the poorest could also self-test (2017). Furthermore, if HIV self-test kits are not appropriately priced, the populations who need to access them the most may not be able to do so (Lee et al., 2013). Moreover, Mugo et al., believes that the government will need to consider offering the kits for free, or at a subsidised price of $1.00 USD per kit at pharmacies in order to cater for those who cannot afford to purchase the kits and would want to test privately (2017). This approach of subsidising the HIVST kit price would ensure that all individuals in South Africa who want to self-test for HIV would not be constrained by the high price and would be able to access the kits whenever needed.

Because of the socioeconomic imbalances in South Africa, individuals that are disadvantaged have been shown to carry the highest burden of HIV, and they might be denied access to benefiting from HIVST on the basis of affordability of the kits. According to Beauchamp and Childress, injustice "involves a wrongful act or omission that denies people benefits to which they have a right or fails to distribute burdens fairly" (2013). Therefore denying the benefits of convenience, testing in privacy, and using HIVST as a "point of sex" decision, which could potentially reduce the transmission of HIV, violates justice.

In summary, this research report has explored the issues surrounding the implementation of HIVST in South Africa and used a principle-based approach to show that the move taken by the national government is ethical, as it does not violate any of the ethical principles of autonomy, beneficence and non-maleficence, including justice. However, the potential for coercion and IPV following HIV self-testing challenges the principle of non-maleficence, and affordability may impede accessibility, thus challenging justice. Furthermore, using a utilitarian approach a benefit/harm analysis was performed in an effort to show that the benefits outweigh the potential harms. The following final chapter will summarise the findings explored in this research report, reach some conclusions and provide recommendations for South African policy makers relating to HIVST.

CHAPTER 7 - CONCLUSION AND RECOMMENDATIONS FOR HIVST USE IN SOUTH AFRICA

7.1 HIV Self-Testing and the Realization of the Public Health Imperative

In light of the high number of new HIV infections in South Africa, currently estimated to be 270,000 annually, the government made the decision to introduce an additional HIV testing tool, HIVST, which allows an individual to conduct an HIV test in the comfort of their own home (UNAIDS, 2018; World Health Organization, 2016b). In an effort to increase HIV testing uptake, especially in populations groups who otherwise would not test and consequently reduce HIV transmission rates, the South African government embraced HIV self-testing in its HIV testing services policy (South African National Department of Health, 2018). This is in line with the South African National Strategic Plan of scaling up HIV testing and "leaving no one behind", and moving towards the goal of reducing new HIV infections from 270,000 to 100,000 by 2022 (SANAC, 2017). This approach is consistent with President Cyril Ramaphosa's State of the Nation Address in 2018, where he mentioned HIV testing scale-up as one of the necessary steps the government promises to take in order to eliminate HIV (State of the Nation Address, 2018).

Self-testing respects the principle of autonomy by empowering HIVST kit users with the freedom to make choices that will affect their own health (van Dyk, 2013; van Rooyen et al., 2015; Mugo et al., 2017). When self-testing for HIV, the individual voluntarily seeks and buys the test kit and makes an informed choice to test based on the pre-meditated desires to self-test (Barilan, 2011; World Health Organization, 2016b). Furthermore, self-testing for HIV provides the user with the new dynamic of the control to initiate and conduct the test at their own convenience (Kumwenda, et al., 2014; Burke et al., 2017; Jennings et al., 2017). In this research report I have argued using a principled-based approach that the implementation of HIVST in South African is ethical.

The HIVST kit users test in private, therefore, ensuring the respect of privacy and protection of confidentiality (van Rooyen et al., 2015; Mugo et al., 2017). The appreciation of privacy and confidentiality afforded by using HIVST was demonstrated in a qualitative study conducted in Myanmar, where one participant was quoted as saying, "I can do it just by myself, no matter what the results are, I will be only one who knows, no one else will know it" (Wirtz et al., 2017). The use of HIVST kits was found to have the potential to eliminate barriers associated with facility-

based HIV testing, such as the violation of privacy and the fear of breaches of confidentiality (Mavedzenge et al., 2013; van Dyk, 2013b; Witzel et al., 2016; Choko, 2017; Knight et al., 2017).

Testing or self-testing for HIV should always be voluntary and be done for the benefit of the individual and to improve health outcomes at the population level (World Health Organization, 2012; South African National Department of Health, 2018). Stigma associated with HIV can have a detrimental effect on health care utilization, where some individuals requiring care, avoid health care services altogether, thus compromising their own health (Chambers et al., 2015). The use of HIV self-testing was found to have the potential to reduce the stigma associated with queuing for testing (DiCarlo et al., 2014; Kumwenda et al., 2014;Wirtz et al., 2017; Moyo, 2018).

Self-testing for HIV is an innovative tool that has the potential to increase HIV testing uptake among men and the general population, increase testing frequency, and potentially reach the undiagnosed HIV-infected individuals who put their sexual partners at risk of viral transmission (Katz et al., 2012; Krause et al., 2013; Choko et al., 2015; Jamil et al., 2017; Johnson et al., 2017; De Boni et al., 2018; Indravudh et al., 2018) And, according to the ethical theory of utilitarianism, an act that produces the maximal overall welfare is the best choice (Beauchamp & Childress, 2013). Since South Africa has the highest number of people on treatment globally, increasing HIV testing uptake through the implementation of HIVST could help the South African public health to reach its goal of lowering the number of new HIV infections without infringing human rights and violating autonomy.

The use of HIVST provides an opportunity for women to introduce the testing kit to their male partners, therefore potentially increasing the uptake in men who would not test otherwise (Kumwenda et al., 2014). This was evident in two studies conducted in South Africa, where there was an increase in HIV testing uptake among men through secondary distribution of HIVST from their sexual partners (Masters et al., 2016; Thirumurthy et al., 2016). Furthermore, HIVST was associated with a reduction in risky sexual behaviour, which included increased condom use and stopping a sexual encounter following a HIVST positive result (Delavande & Kohler, 2012; Katz et al., 2012; Omar et al., 2014; Thirumurthy et al., 2016). Therefore, the use of HIVST kit may provide individuals with more informed sexual decisions and play an important role in point-of-sex decisions (Katz et al., 2012; Thirumurthy et al., 2016; Ong et al., 2018b).

However beneficial HIV self-testing may be, it is not without challenges. The potential harms stemming from the use of HIV self-testing kit raises ethical concerns relating to the principle of non-maleficence. Non-maleficence is one of the four ethical principles cited by Beauchamp and Childress, and this principle obligates one not to intentionally inflict harm (2013). The most compelling argument against the use of HIVST is the potential of a positive self-test result to lead to an individual committing suicide, due to the absence of pre-test counselling and lack of on-site post-test counselling (Youngs & Hooper, 2015; Pando et al., 2017). However, none of the studies conducted thus far have shown evidence of suicide as a potential harm relating to the use of an HIVST kit (Choko et al., 2011; 2015; Youngs & Hooper, 2015; Thirumurthy et al., 2016; Qin et al., 2017).

Self-testing for HIV may also lead to social harms, especially since HIVST is conducted in private settings, where there could be a violation of human rights, including coercion and intimate partner violence (van Dyk, 2013; Wood et al., 2014; Choko et al., 2015; Youngs & Hooper, 2015; Qin et al., 2017; HIV Self-Testing Research and Policy Hub, 2018; Ong et al., 2018). Coercion is a serious human rights violation and a serious concern associated with the use of an HIVST kit (Allais & Venter, 2014). Furthermore, coercive testing may occur during couple or partner testing, between sex workers and their clients, employers testing domestic workers, as well as parents testing their teenage children (van Dyk, 2013; Woods et al., 2014; Qin et al., 2017; Ong et al., 2018; Ong et al., 2018b). Moreover, a study investigating harms related to HIV self-testing found that 8% to 9% of participants were coerced into testing (Qin et al., 2017; Ong et al., 2018b).

Intimate partner violence was also found to be a potential harm that could result from self-testing for HIV (HIV Self-Testing Research and Policy Hub, 2018). The WHO refers to IPV as, "any behaviour within an intimate relationship that causes physical, psychological or sexual harm to those in the relationship" (World Health Organization, 2013). Women bear an overwhelming burden of IPV, and violence against women is regarded as a serious problem to public health and a fundamental violation of human rights (UNAIDS, 2013b; World Health Organization, 2013). Moreover, violence perpetrated against women is a serious problem in South Africa, and the recent national crime statistics reported that 66% of women experienced assault in the year 2016/2017 (South African Government News Agency, 2018; Statistics South Africa, 2018).

The use of an HIVST kit in partner or couple testing, as it can be conducted at home or in other private settings, may perpetuate intimate partner violence (Figueroa et al., 2015; Thirumurthy et

al., 2016; Choko et al., 2017; Johnson et al., 2017; Schaffer et al., 2017;). Consequently, the potential for IPV could have a detrimental effect on the success of the intervention, which aims to increase male partners' HIV testing uptake through secondary distribution of self-testing kits by the female partners (Schaffer et al., 2017). However, there is little or no evidence of coercion and IPV relating to the use of HIVST, and the empirical data does not present convincing evidence of harms, or provide compelling ethical grounds for not allowing use of HIVST in South Africa.

The ethical duty to not cause harm, as associated with the use of a medical device, lies with the medical device manufacturer, policy makers and health care professionals (Youngs & Hooper, 2015). Therefore, manufactures of medical devices have an ethical duty to ensure safety, performance, and to recognize, mitigate and prevent harm to the greatest extent possible (National Research Council, 2010; World Health Organization, 2016c). Policy makers, on the other hand, have an ethical duty to ensure safety and effectiveness of the HIVST kit in the hands of the intended users, as defined by the regulatory systems, thereby ensuring maximisation of the benefits and minimisation of the harms to individuals and to public health (Wong et al., 2014).

The South African National Department of Health requires that all HIVST kits entering the country be approved by the WHO prequalification programme until the national regulatory system is in full operation (South African National Department of Health, 2018). Importantly, to guard against potential violations, the WHO Global Model Regulatory Framework for Medical Devices and Ong et al., advise policy makers and medical device manufactures to put in place channels for timely reporting of adverse events and develop systems to monitor and prevent the occurrence of such violations (2017; 2018).

Due to the limitations of this research report, the effects of the absence of counselling in HIVST were not investigated, as well as the use of HIVST by children. It is important to highlight that the empirical data published thus far does not show any evidence of suicide following an HIVST positive result, due to the lack of pre-and-post counselling. However, the South African government will need to put measures in place to make sure that harms relating to HIVST do not occur and that the rights of all users are protected. Furthermore, it is important that policies and the test kit package inserts include information on all the potential harms resulting from HIVST; and, in order to minimise social harms, it should be stressed that the test kits are only for voluntary testing (South African HIV Clinicians Society, 2017).

Using the ethical theory of utilitarianism, I have shown that HIV self-testing as a new intervention respects human rights and provides more benefits than harms. The ethical theory of utilitarianism states that we ought to choose an act that produces the maximal overall welfare (Beauchamp & Childress, 2013). Hence, in public health, "when choosing between several competing interventions or programmes, states and policy makers ought to opt for those that are likely to produce the greatest aggregate benefit" (Nuffield Council on Bioethics, 2007). Furthermore, when conducting a benefit/harm analysis for a health intervention, "the public health benefits must always outweigh the potential harms or risks" (World Health Organization, 2016b).

For the implementation and scale-up of HIVST to be ethical and justified, the potential benefits must outweigh the potential harms (UNAIDS, 2013; Youngs & Hooper, 2015). The benefit/harm analysis performed for this research report showed that the implementation of HIVST in South Africa has the potential to produce more benefits than harms, thus making this public health intervention justifiable. And according to Wong et al., risk-benefit analysis, and evidence-based studies, including pilot projects, must continue to inform HIVST national policies and the regulatory systems (Wong et al., 2014). Moreover, for the benefits of HIVST to be realised, policy makers must ensure that HIVST is accessible and reaches those most at need (Krause et al., 2013).

This brings me to the issues of distribution and pricing of HIVST, relating to the principle of justice. Distributive justice in health care concerns itself with fair, equitable allocation of health care resources, which should be according to the need and in a way that maximizes health gains (Juth, 2015; Skedgel, et al., 2015). Studies conducted in Kenya and South Africa found that the preferred distribution point of HIVST for the majority of participants was through pharmacies, as pharmacies provide potential HIVST kit users with the freedom to access the kits at their convenience (van Rooyen et al., 2015; Mugo et al., 2017). Vending machines and health facilities are also considered to be distribution points for HIVST kits in South Africa (South African National Department of Health, 2018). In addition, I believe convenience shops in garages would also be ideal distribution points for HIVST kits as they are open all day, which could be convenient for many people who may be interested in self-testing.

Pricing of HIVST kits, as related to the principle of justice, is of serious concern, and the cost of the kit is likely to prohibit some individuals from using it, which may pose a significant barrier to the use of the HIV self-testing kit (Lee et al., 2013; Woods et al., 2014; Jennings et al., 2017). The HIV self-testing kits in South Africa are priced between 146 and 199 South African Rand,

equivalent to $10.00 - $14.00 USD. In my opinion, this may be too expensive of a price for those who need the HIVST kit the most, and the benefits of implementation of HIVST might not be fully realised. Furthermore, Jennings et al. believe that these HIVST kits should be offered at an affordable price, especially in low-income countries, so that the poorest could also self-test (2017).

Because South Africa carries the highest burden of HIV globally, and the country prides itself with the highest number of people on treatment, the move to implement HIVST with the aim of increasing HIV testing uptake was no surprise. This research report supports that move and considers the use of HIVST in South Africa to be ethical, because it: (i) has the potential to empower individuals with more options and choices; (ii) enables individuals to test at their own convenience; (iii) respects the individual's privacy and confidentiality; (iv) contributes to the public health imperative of decreasing annual HIV transmission rates; (v) provides the user with correct, comprehensive health information related to the use of this medical device for home use; and, (vi) provides more benefits than harms to the kit user.

Overall, the implementation of HIVST embraces two ethical principles, respect for autonomy and beneficence. However, non-maleficence and justice are the two ethical principles challenged by the implementation of HIVST. Non-maleficence is challenged when individuals could be coerced into self-testing, and when self-testing may result in intimate partner violence. In addition, non-maleficence is challenged through the lack of pre- and post-test counselling in HIV self-testing, which may lead to suicide. And lastly, non-maleficence is challenged through false negative results for people on ARV. Hence, HIV self-testing is not recommended for people on HIV treatment (South African National Department of Health, 2018).

The empirical studies reviewed in this research report relating to HIVST show little or no evidence of harms, including coercion, IPV and suicide that could potentially challenge the ethical principle of "do no harm". Hence, this situation calls for post-market surveillance and continuous monitoring of these potential social harms by policy makers throughout the implementation phase of the HIVST (Johnson et al., 2014; World Health Organization, 2016b; Indravudh et al., 2018). In addition, for the success of HIV self-testing to be realised, it is important that it is offered in a way that does not violate any of the rights described in the South African Constitution in prioritising quality services, universal health coverage and gender equality (Republic of South Africa, 1996; South African National Department of Health, 2018).

7.2 Recommendations for Policy Consideration

Because the regulatory framework for medical devices in South Africa is still under development, I reviewed the HIVST kit leaflet to try to determine if it is in accordance with the right to have access to correct comprehensive health information for home-use medical devices. My analysis suggests that HIVST users are provided with correct comprehensive information; however, there is room for improvement.

Listed below are the recommendation to policy makers related to a successful implementation of HIVST in South Africa.

- Oral-based HIVST kits are currently not available for purchase in South Africa. The approval process of these test kits must take priority, as the research work on acceptability has been conducted on oral-based kits, which are painless and easy to use. When oral-based HIVST kits are in use, HIV transmission routes must be emphasised to avoid the perpetuation of stigma related to HIV transmission. This may occur as the sample for testing is collected from the mouth, and people may have misconceptions that that HIV can be transmitted via saliva.
- Those responsible for the HIVST hotline services must ensure that counsellors are available 24 hrs, 7 days a week. No call from an HIV self-tester should be left unanswered.
- The HIVST kit may be unaffordable to many, especially those needing frequent testing. The current price stands at R146.00, a price too high for many people in my opinion; the South African government should subsidise the kit price to less than R100, to at least match the market price of other self-test kits such as pregnancy tests, urine tests and diabetes tests, which sell below R100.
- In addition to making HIVST kits available at pharmacies, health care facilities, and vending machines, policy makers should consider making them available through convenience shops at garages.
- Public awareness of HIVST needs to be improved. Since the kits were approved for public use in 2016, there has not been an HIVST television advert broadcast or awareness raising on social media, and coverage on the radio and newspapers. Many people who have no access to the Internet may still not know about the option to self-test for HIV.
- The benefits of testing should be listed in the package insert and encourage those who test HIV-positive to seek a confirmatory test and initiate treatment as soon as possible.

- It would be beneficial to make HIVST kit users aware of all potential harms by having this information available in the instruction insert.
- Research should be conducted on HIVST coercion, especially in the context of vulnerable groups such as adolescents, sex workers, domestic workers and prisoners.
- A warning sign against coercive testing should be displayed on the outside of the package, and should read: “Not For Coercive Testing”.
- South Africa has a very high prevalence of IPV, and recently there has been an increase in women killed by their male partners (South African Government News Agency, 2018; Statistics South Africa, 2018). The occurrence of IPV related to HIVST remains an issue and needs further investigating; any individuals experiencing IPV through HIVST or otherwise should be urged to seek professional assistance immediately.
- Develop a system that enables adverse events reporting related to HIVST use.

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APPENDIX A: WITS RHI HIV Self-testing Brochure

GUIDE TO OFFERING HIV SELF-SCREENING TO YOUR PARTNER

WITS RHI

HIV SELF-SCREENING
1.2.3.SCREEN.KNOW.ACT.

INTRODUCTION

You've been given an HIV Self-Screening (HIVSS) Kit to take home to your partner so he can learn his HIV status.

This booklet will help you understand HIVSS, provide you tips on how to discuss HIVSS with your partner, and give you guidance on how to support your partner with his result.

Index

Introduction to HIV Self-Screening
How to do the HIV Self-Screen
Talking with your partner about HIVSS
Supporting your partner to with the results
Having a different HIV status than your partner
Where to find more information

HIV SELF-SCREENING

Why HIV Self-Screening can work for your partner

The HIV Self screening kit is convenient, comfortable, and confidential. It allows him to learn his HIV status in private and on his own time.

What is HIV Self-Screening?

HIV self-screening is a voluntary process where a person collects and tests their own sample in private. Screening can be done alone or with a partner. With HIV self-screening a person performs the test and reads the results themselves.

How does it work?

The new OraQuick HIV oral self-screening kit looks for HIV antibodies in oral fluid collected from a swab of the gums. Saliva and oral fluids do not contain the HIV virus, but the antibodies your body makes to fight HIV can be detected there. This makes the HIV self-screening kit a good option for people who don't like their blood drawn.

The new OraQuick self-screening Kit

Does it hurt?
Not at all! It is a pain free swab of the gums.

How well does it work?
90% The OraQuick oral HIV self-screening kit is more than 90% accurate.

How long does the test take?
The OraQuick oral self-screening kit takes 20 minutes.

W TO DO THE / SELF-SCREEN

need:
reening kit
ivate, quiet space with table
ay to tell time (phone, clock)

here are detailed instructions inside the reening kit, with pictures of a positive, egative, or invalid result. Please read them oroughly. They explain exactly what to do.

aQuick Screening Kit Results

If HIVSS result is positive, your partner needs to report to the nearest clinic for HIV testing

If HIVSS result is negative, your partner needs to re-test in 3 months. Your partner can also access more information on how to stay HIV negative at the clinic including access to voluntary male medical circumcision

If the HIVSS test result is inconclusive, your partner needs to attend a local clinic for HIV testing

You and your partner can also watch a demonstration video at:

http:www.hivselfscreening.org/

Does your partner need a further HIV test?

Yes, this is a screening test, which means if your partner screens positive they need to have a confirmatory HIV test with a healthcare provider.

Who cannot use this test?

If your partner is already taking ARVs, they should not use the HIV self-screening kits at it may give a FALSE negative result.

TALKING WITH YOUR PARTNER ABOUT HIVSS

Make a plan:

- Many people are afraid of talking to their partner about HIV. It is helpful to make a plan for how and when you want to discuss it with your partner.
- Think about how you would like to be asked to test, if your partner was asking you.
- Chose a day and time when you and your partner will have time to talk. Pick a time when your partner is not stressed or angry, and has not been drinking alcohol.
- Pick a private place where you feel comfortable and safe.

Anticipate Reactions:

Think about how your partner may react, he may:

- Accuse you of not being faithful
- Accuse you of not trusting him
- Be confused or feel angry

WHERE TO FIND MORE INFORMATION

Additional information on HIV prevention, care, and treatment can be found at the following:

AIDS Helpline: 0800 012 322
MomConnect: *134*550#

Watch a demonstration video on the HIV Self Screen Kit at:

http:www.hivselfscreening.org/

WITS RHI

HIV SELF-SCREENING
1.2.3.SCREEN.KNOW.ACT.

Think about how you will respond to these reactions.

Avoid introducing the HIVSS in a way that makes your partner feel like you think he is HIV-positive. Try to make it seem like a special opportunity or convenient way to learn his status.

Highlight that by taking care of his health and knowing his status he is protecting his family, and the health of the new baby.

Start the conversation:

"I went to the clinic for a pregnancy check-up the other day and the doctor/nurse encouraged me to talk to you about HIV testing. They offered me a new kit that I could bring home to you so you can test yourself in private and on your own time."

Share the HIVSS FAQ and Fast Facts flyer with your partner so he can understand better what the HIV screen is. "It's important to know our HIV status so we can ensure the health of our baby."

SUPPORTING YOUR PARTNER WITH THE RESULTS

Encourage your partner to share his status:

- Assure your partner that you will support him.
- Encourage your partner to share his result with the ANC nurse so she can help ensure the best plan is made to protect the baby.
- Encourage attending couples-based HIV counselling for support.

Support for positive result:

Provide comfort and support for your partner. "We will work on this together. I will support you."

Encourage your partner to come with you to the clinic or to a community testing site for a confirmatory HIV test and to discuss his status with the health care provider.

Encourage your partner to come with you to the clinic to support you with preparing for your baby's arrival. Partners appreciate being more involved in the process.

Highlight the importance of protecting the baby and family from HIV and that there are many simple ways this can be done – immediate treatment, medical male circumcision, condom use.

If you are negative and your partner is positive, it is very important that you discuss using condoms to protect you from getting HIV.

Support for a negative result:

The HIV self-screening kits may not screen positive if your partner was recently infected. Schedule your partner to screen/test again after three months to ensure he is negative. Discuss with your partner ways to stay negative: condoms and medical male circumcision.

Encourage your partner to come with you to the clinic to support you with preparing for your baby's arrival. Partners appreciate being more involved in the process.

Highlight the importance of staying negative to protect the baby and family, ensuring healthy parents for your baby's future.

Discussing an "invalid" result:

If your partner cannot determine, or is unsure of his result, encourage him to go with you to the ANC clinic or to a community testing site for an HIV test by a health care provider.

AVING A DIFFERENT HIV STATUS HAN YOUR PARTNER

hat is an HIV discordant couple?

hen one partner is HIV-positive and the other artner is HIV-negative.

he truth about HIV discordance:

ew HIV infection can happen even in HIV scordant couples who have been together for long time:

does not mean that you or your partner is nfaithful

does not mean that one partner is immune HIV



Protecting the health of your baby:

The antenatal clinic nurse needs to know both parents' HIV status to make the best plan for the health of both of you and the baby:

•If you are positive and your partner is negative – you need to start treatment immediately and use condoms.

•If your partner is positive and you are negative your partner needs to start treatment immediately, you need to use condoms every time, and you need to check your HIV status regularly.

•Discuss the importance of taking treatment correctly every day– a person living with HIV that does not have a detectable viral load does not transmit it to their partner or their baby.

