

# CHAPTER 1

## INTRODUCTION

### 1.1 BACKGROUND

The current methods used in the prevention of HIV infections in Zambia have continued to take centre stage in moral discussions that focus on the continued availability and accessibility of these preventive measures to all those infected and affected in the country. In my profession of social work, I have witnessed cases and read literature that confirm that prophylactics are widely used in Zambia and the examples that provide lessons for Pre-exposure Prophylaxis (PrEP) include treatment for prevention of mother-to-child transmission (National AIDS Council 2010a, 48) and Post-exposure Prophylaxis (PEP) as some of the preventive methods being used in Zambia, which are comparable to Pre-exposure Prophylaxis or PrEP. PrEP is a potential HIV preventive method that is yet to be adopted in Zambia and which is at the focus of this paper. Pre-exposure Prophylaxis refers to the use of anti-retroviral (ARV) medication by HIV-negative persons prior to HIV exposure, with the goal of preventing HIV infection.

Before going any further, four questions arise from these statements which need to be answered: (i) What is HIV?, (ii) What are ARVs?, (iii) What is the difference between Pre-exposure Prophylaxis and Post-exposure Prophylaxis in HIV prevention?, and (iv) What is a Prophylaxis? HIV is a virus that is associated with the HIV disease called AIDS, which is an acronym for Acquired Immuno Deficiency Syndrome. This disease is referred to as acquired because it is not a disease that is inherited. It is rather a disease that is caused by a virus (the Human Immunodeficiency Virus or HIV) which enters the body from outside. The term 'immunity' refers to the body's natural inherent ability to defend itself against infections and disease. 'Deficiency' refers to the fact that the body's immune system has been weakened so that it can no longer defend itself against passing infections. 'Syndrome' is a medical term which refers to a set or collection of specific signs and symptoms that occur together and that are characteristic of a particular pathological condition (Alta 2001, 4-5).

There are currently two HI-viruses associated with AIDS namely “HIV-1 and HIV-2. HIV-1 is the cause of the current worldwide pandemic, while HIV-2 is mostly found in West Africa. HIV-2, which is transmitted in the same ways as HIV-1, causes AIDS much more slowly than HIV-1, but clinically the diseases are very similar” (Hunt 2012, 1). The weakening of the body’s immune system due to the HI-virus leads to the body’s inability to fight the pathogens that invade the body, thereby resulting in opportunistic diseases that is, infections and certain cancers that have the ability to cause the death of the infected person in the final stages of AIDS. ARV is an acronym for anti-retroviral. This is the medication being used for the treatment of HIV. It does not cure the infection, but it can prevent people from falling ill for many years. HIV treatment involves the taking of ARV drugs every day, for the rest of a person’s life. Anti-retroviral treatment is aimed at maintaining the amount of HIV in the body of an infected person at a low level in an attempt to stop any weakening of the immune system, thereby allowing it to recover from any damage that HIV could have caused. The drugs are often referred to as anti-retroviral, ARVs, anti-AIDS drugs or anti-HIV drugs.

### **1.1.1 HIV PrEP and HIV PEP**

Pre-exposure Prophylaxis (or PrEP) is a comprehensive HIV prevention method in which HIV negative people, who are at high risk, take anti-retroviral medication daily to try to lower their chances of becoming infected with HIV if they are exposed to it. Clinical trials on PrEP have revealed its effectiveness in men who have sex with men (MSM) and heterosexual men and women as we shall see in later chapters.

Post-exposure Prophylaxis (or PEP) is anti retroviral treatment that is started immediately after someone was exposed to HIV. The aim of Post-exposure Prophylaxis is to give a person’s immune system a chance to provide protection against the virus and to prevent HIV from becoming established in someone’s body. Post-exposure Prophylaxis works only if the medication is taken as soon as possible, and definitely within 72 hours of exposure to HIV. A full course of treatment takes 28 days (National Aids Council 2010b, 48). Post-exposure Prophylaxis (PEP) consists of a month long

dosage of two or three different kinds of anti-retroviral drugs that are also used as treatment for people with HIV.

The common drugs prescribed for Post-exposure Prophylaxis are *Zidovudine*, *Lamivudine* and *Nelfinavir*. Two ARV drugs are currently being used for PrEP, *Tenofovir Disoproxil Fumarate* (TDF) (marketed by the name Viread) and a combination of TDF and *Emitricitabine* (FTC) (marketed by the name Truvada). TDF and TDF/FTC are considered good PrEP candidates as they stay in the bloodstream for a long time and the drugs are taken in one tablet once a day. The two drugs are part of a class of ARVs called nucleoside analogs. A prophylaxis is a measure taken to maintain health and prevent the spread of disease.

### 1.1.2 PrEP Clinical Trials

At present, clinical trials of PrEP have been undertaken in more than 13 countries worldwide, including countries such as the United States, Thailand, Peru, Ecuador, Brazil, Botswana, South Africa, Kenya, Uganda, Malawi, Tanzania, Zambia and Zimbabwe. The trials have enrolled more than 20,000 study subjects and were designed to produce results in various populations, representing different routes of HIV transmission (WHO 2009, 4).

On 23<sup>rd</sup> November, 2010 the American National Institute of Allergy and Infectious Diseases released a report of the iPrEx study, undertaken at 11 sites in Brazil, Ecuador, Peru, South Africa, Thailand and the United States on men who have sex with other men and women who have sex with men. The report shows that the iPrEx study was a randomized, double-blind placebo-controlled Phase III clinical trial, where participants were randomly assigned to receive, on a daily basis, an anti-retroviral tablet that contained a combination of *Emitricitabine* (FTC 200 milligrams) and *Tenofovir* (TDF 300 milligrams), a blend known by the brand name *Truvada*, or a placebo pill. The goal of the study was to find out whether the daily combination of anti-retroviral pills could effectively and safely prevent HIV infection among sexually active gay men and transgendered women who have sex with men. All research participants were assessed for HIV infection monthly for the duration of their participation in the study, which

lasted for about 1 to 2 years. The study enrolled 2,499 participants. All participants were at least 18 years old and HIV-negative at the time of enrolment.

The research report revealed that investigators in the iPrEx study found that study participants who took the daily dose of oral anti-retrovirals experienced an average of 43.8 percent fewer HIV infections than those who received a placebo pill and that a total of 100 cases of HIV infections occurred among participants in the study. Of those, 36 HIV infections occurred among the 1,251 participants who were randomized to receive the study drug compared with 64 HIV infections among the 1,248 participants who were randomized to receive the placebo.

The report also revealed that the reduction in HIV infection risk of 43.8 percent included all research participants even those who did not take the daily pill consistently. It was further revealed that the drug's ability to reduce the risk of HIV acquisition was greater among those volunteers who were more adherent to the daily drug regimen. Participants who took the drug on 50 percent or more days, as measured by pill count, bottle count and self reporting, experienced 50.2 percent fewer HIV infections. Those who took the drug on 90 percent or more days had 72.8 percent fewer HIV infections. The study showed that efficacy was greatest (58%) among participants at particularly high risk for HIV, as measured by self-reports of unprotected receptive anal intercourse at the time of enrolment in the study.

The researchers found that the anti-retroviral drugs proved to be safe and well-tolerated as a prophylaxis method. Side effects were mild and infrequent and included a small number of reports of transient nausea that disappeared after several weeks. Additionally, the report revealed that some participants, who received the active drug, experienced mild elevations of creatinine, a naturally occurring molecule filtered by the kidneys. But these elevations resolved with time or with discontinuation of the pill and no HIV drug resistance occurred among individuals who became HIV-infected during the course of the study. However, the report also showed three cases of *Emitricitabine* resistance, one participant in the placebo group and two participants in the active drug group.

### **1.1.3 Participant Selection in the Clinical Trials**

Men who have sex with men are among the groups that are mostly affected by HIV/AIDS. An article, published on HIV and men who have sex with men in the December 2007 PLoS Medicine, reported that men who have sex with men have a markedly higher risk of contracting HIV than the general population in low and middle-income countries in America, Asia, and Africa. Studies indicate that HIV prevalence among men who have sex with men is 10 percent or higher in each of the countries in which the iPrEx study was conducted. In the United States, 53 percent of new HIV infections occur in this population, according to the 2006 HIV incidence estimates from the Centers for Disease Control and Prevention (Baral et al. 2007).

### **1.1.4 The Use of Tenofovir plus Emtricitabine TDF/FTC (Truvada) as the Study Drug**

The drug *Truvada* was chosen for use in the iPrEx study because it has been proven to be safe and effective and it has few side effects as an HIV treatment drug for HIV-infected persons. The American Food and Drugs Administration approved *Truvada* for the treatment of HIV infected individuals. This drug has the advantage that it is taken orally only once daily and lasts for many hours in the bloodstream. The drug was also shown to be efficacious in trials done on non-humans for the prevention of infection, specifically on primate models of HIV infection. With this success, it was thought that a two-drug anti-retroviral combination would work better than a tablet containing only one anti-retroviral (National Institute of Health, 2010).

### **1.1.5 The AVAC Report on PrEP**

On Wednesday 13<sup>th</sup> July, 2011 a non-profit organization founded in 1995 called AVAC, released a report on Pre-exposure Prophylaxis and the results showed that the use of ARVs in HIV-negative people can reduce risk of infection. The AVAC report on a PrEP study undertaken in Kenya and Uganda, which enrolled 4,758 heterosexual couples in which one partner was HIV-positive and the other HIV-negative showed that *Tenofovir* (TDF) and *Tenofovir plus Emtricitabine* (TDF/FTC) taken daily can reduce the risk of HIV transmission among both men and women. The report shows that daily oral *Tenofovir* reduced the risk of HIV infection by an estimated 62 percent, and daily oral

*Tenofovir* plus *Emitricitabine* reduced HIV risk by an estimated 73 percent when compared to a placebo. Both drugs proved effective in both men and women and there were no significant safety events in the trial.

#### **1.1.6 The TDF2 or Partners Study**

Another clinical trial, called the TDF2 study or Partners Study, was undertaken in Botswana. It enrolled just over 1,200 sexually active men and women. The TDF2 was an expanded safety trial that was not meant to provide information on effectiveness. However, the analysis of TDF2's final data revealed that daily oral *Tenofovir* plus *Emitricitabine* or *Truvada* reduced the risk of HIV infection in both men and women participants by an estimated 62.6 percent, compared to those who received the placebo.

The two studies used oral Pre-exposure Prophylaxis in heterosexual people and showed that oral PrEP can protect women against HIV. At the 6th International AIDS Society Conference that was held in Rome in 2011 additional data from a comparison of two trials of Pre-exposure Prophylaxis in heterosexuals were released. The first study compared *Tenofovir* and *Tenofovir* plus *Emitricitabine* (*Truvada*) versus placebo as PrEP in serodiscordant couples (one person HIV-positive, one negative) in Kenya and Uganda, while the other study called TDF2 compared *Truvada* versus placebo in heterosexual men and women in Botswana. The results from the two studies revealed that *Tenofovir* had an efficacy of 62 percent in preventing HIV infection and that *Truvada* had an efficacy of 73 percent (Warren and Marshal 2011, 1-2).

#### **1.1.7 Efficacy in Men and Women**

In the two PrEP studies discussed above, the HIV-negative partner was female in 38 percent of the 4758 couples. The results showed significant differences in efficacy of either *Tenofovir* or *Truvada* between men and women. The efficacy of *Tenofovir* was 68 percent in women and 58 percent in men versus placebo. The efficacy of *Truvada* was 62 percent in women and 83 percent in men. In the other study, 45 percent of the 1200 participants were women. The efficacy of *Truvada* in men was 80 percent with two HIV infections in men on *Truvada* against ten infections in men on placebo. The results also show that efficacy in women was 49 percent with seven infections on *Truvada* against 14 on placebo. However, the results showed that when only participants who had refilled

their pills at the clinic in the last 30 days were counted, there were three infections in women on *Truvada* against 13 on placebo. According to the researchers, this was an efficacy of 75.5 percent, which was statistically significant. In men in this group there was one infection on *Truvada* versus six on placebo (82 percent efficacy), which was actually not statistically significant, due to the small numbers (Warren and Marshal 2011, 1).

#### **1.1.8 Use of PrEP for Couples hoping to have a Child**

The use of Pre-exposure Prophylaxis in the UK has taken an interesting turn as HIV-positive men and their HIV-negative female partners are now using PrEP in order to have HIV-negative children. In this circumstance, PrEP has been described as an additional tool, which can complement HIV treatment that reduces the HIV-positive partner's infectiousness, thus allowing heterosexual couples to have timed intercourse so as to achieve a pregnancy, with a low risk of HIV transmission.

In order to achieve this, anti-retroviral treatment is used to reduce a partner's viral load to an undetectable level thereby allowing couples to feel more confident about conceiving through "real sex". In the process of achieving a pregnancy, the HIV-negative partner is advised to take one or two doses of *Tenofovir* or *Truvada* (*Tenofovir* and FTC combined in one pill) between 24 and 36 hours before sex and then another dose one to two hours afterwards. Couples are advised to limit unprotected sex to the days during ovulation. At the time of this research on PrEP, results showed that only five couples had gone through the programme so far. There have been four pregnancies, resulting in one live birth, one pregnancy was still ongoing, and two miscarriages. One couple stopped using PrEP when the male partner had a series of viral load blips (all men had an undetectable viral load on entering the programme). Couples had unprotected sex on an average of three times before pregnancy was achieved (minimum one, maximum five). It was revealed that despite participant numbers being far too small to give any reliable data on safety, no HIV transmissions were recorded (Pebody, 2011).

#### **1.1.9 Pre-exposure Prophylaxis in Zambia**

Despite the continued HIV prevention measures that have been put in place, Zambia has one of the world's most devastating HIV and AIDS epidemics. Studies show that more

than one in every seven adults in the country is living with HIV, and life expectancy at birth has fallen to just 39 years (CIA, 2009). Current studies have revealed that HIV prevalence stands at 14.3 percent, while HIV incidence is at 226 daily in Zambia. This was revealed at the Southern African AIDS Trust (SAT) at Mulungushi International Conference Centre by Professor Luo who is a medical practitioner and a researcher (Kalito 2012, 1).

PrEP as a potential method of HIV prevention has not yet been adopted, although trials have been carried out in Zambia in a study called VOICE which stands for Vaginal and Oral Interventions to Control the Epidemic. The VOICE study used the ARV tablets *Tenofovir* and *Truvada*. Around 300 women took part. However, VOICE announced the closure of the trial due to futility, meaning that the trial could not show that the drugs reduced the risk of HIV acquisition. Since then, the World Health Organisation Zambia Country Office has held one consultative meeting with stakeholders on Pre-exposure Prophylaxis in order to discuss the potential role out of the intervention (WHO, 2009). There is, however, currently no plan of action or guidelines on the use of Pre-exposure Prophylaxis as a method of HIV prevention and there has been very little discussion on the matter. It is important to mention that the use of PrEP is still being undertaken on a trial basis in most countries. But based on the results of these trials, on 13<sup>th</sup> February 2012, Gilead the company that manufactures *Truvada*, announced that the American Food and Drugs Administration (FDA) has granted the company a six-month priority review for once-daily *Truvada* (*Tenofovir* plus *Emitricitabine*) for Pre-exposure Prophylaxis in order to reduce the risk of HIV-1 infection among uninfected adults (Gilead 2012, 1).

However, due to the lack of guidelines and further discussions on the matter so far, Zambia is likely to lag behind in the adoption and implementation process of PrEP. This means that the HIV epidemic would continue to spread throughout Zambia and to all parts of its society, and it would adversely affect vulnerable groups, especially children, young women and girls. In Zambia, among young women aged 15-24, HIV prevalence is nearly four times that of men in this age category (UNAIDS, 2008).

For the time being, it has been conclusively proven that condoms are effective at preventing sexual HIV transmission, when used correctly and consistently. Nevertheless,

if PrEP is adopted, as a complement to other HIV prevention measures such as condoms and male circumcision, it is likely to be a subject of prolonged ethical controversy, especially in matters related to the cost of the anti-retroviral drugs and efficacy. The fact that PrEP is being used in other countries and has even been approved by law makers makes it opportune for Zambia to start discussing the matter and work towards formulating policy and guidelines on PrEP. The success of PrEP as a biomedical prevention strategy in Zambia is likely to depend on behavioural and social factors that may determine its appropriate use. In addition, scientific insights from behavioural and social research are crucial to PrEP success should it prove effective in clinical trials and be adopted in Zambia.

## **1.2 LIMITATIONS TO THE STUDY**

This paper is a philosophical work that intends to study oral Pre-exposure Prophylaxis as a potential HIV prevention method in Zambia. The paper shall not deal with legal issues or with factors that make law pertaining to the adoption of Pre-exposure Prophylaxis as an HIV prevention method in Zambia. It is a philosophical work that investigates whether Pre-exposure Prophylaxis should be adopted as an HIV prevention method in Zambia.

This implies that it is not an empirical research on attitudes or feelings of Zambians on Pre-exposure Prophylaxis. The empirical data that were collected are, however, needed as a basis for the ethical assessment as only data that were needed for the ethical assessment have been collected. Notwithstanding the fact that data was collected in Lusaka district only, the results of this study can, to some extent, be generalized to the whole of Zambia. This is so partly because of the centralization of the health policy at the Ministry of Health in Zambia.

## **1.3 STATEMENT OF THE PROBLEM**

When compared to existing prevention strategies such as condoms, male circumcision, voluntary counselling and testing, PrEP is a continuous biomedical intervention which has shown partial efficacy in protecting against HIV infection. Therefore, issues of PrEP such as its cost, adherence to PrEP regimens, reduced perceptions of HIV risk and HIV complacency and the potential detrimental effects of PrEP adoption on other sexual risk

reduction practices call for an ethical assessment of the adoption of PrEP as a prevention method for HIV in Zambia.

#### **1.4 OBJECTIVES**

The objectives of the study are:

- a) To explain the methods aimed at preventing HIV infections.
- b) To investigate the current situation in Zambia on Pre-exposure Prophylaxis.
- c) To assess from an ethical point of view whether Pre-exposure Prophylaxis should be adopted in Zambia.

#### **1.5 RESEARCH QUESTIONS**

The research questions are:

- a) What are the methods aimed at preventing HIV infections?
- b) What is the current situation regarding Pre-exposure Prophylaxis in Zambia?
- c) Ethically seen, should Pre-exposure Prophylaxis be adopted in Zambia?

#### **1.6 SIGNIFICANCE OF THE STUDY**

This study is intended to investigate ethical issues of Pre-exposure Prophylaxis prior to its adoption as a possible HIV preventive method. The study's significance further lies in adding to efforts in curbing the spread and the rise in HIV infections as well as the detrimental effects of HIV and AIDS in Zambia.

This research is intended to add to the body of knowledge on medical ethics in the Zambian context. Further, it is hoped that it will elicit more research and wider consultation before the adoption of Pre-exposure Prophylaxis in Zambia.

#### **1.7 METHODOLOGY**

This research employs two different methods, an empirical method that is used in Chapter 4 and an ethical method that will be employed in the ethical assessment. I shall outline here these methods only briefly and will describe them in more detail in Chapters 4 and 5.

In the empirical part of this dissertation, data have been collected using primary sources (informal interviews) and secondary sources (documentary research). Interviews

have been conducted with some professionals, who were selected purposively at the World Health Organization (WHO) Country Office in Zambia, the Centre for Infectious Diseases and Research in Zambia, the Ministry of Health in Lusaka, National AIDS Council in Zambia, physicians at the University Teaching Hospital in Lusaka, lecturers at the school of Medicine at the University of Zambia, persons from the Zambia Medical Association and officials of non-governmental organizations. The interview schedule that was used to interview the research participants consists of questions on types of HIV prevention methods in Zambia and some general questions on the current situation of Pre-exposure Prophylaxis as a potential HIV preventive method in Zambia. The data collected from primary sources will be used as background for the ethical analysis part. The research also used secondary sources that included books from the University of Zambia Library, the Philosophy Department and journal articles from the Internet.

In the ethical evaluation, philosophical research was conducted which was partly based on the Precautionary Principle. This principle holds that “when human activities may lead to morally unacceptable harm that is scientifically plausible but uncertain, actions shall be taken to avoid or diminish that harm” (UNESCO 2005, 14). In addition, this research employed Utilitarianism, which, in short, holds that “what makes an action morally right or wrong is the total good or evil produced by the act, not the mere act in itself” (Beauchamp 1982, 73). This theory together with the Precautionary Principle, have been used to critically assess whether Pre-exposure Prophylaxis is morally permissible or morally impermissible as an HIV prevention method in Zambia.

## CHAPTER 2

# LITERATURE REVIEW

### 2.1 INTRODUCTION

This chapter reviews the literature on the adoption of Pre-exposure Prophylaxis as a method aimed at preventing HIV infections. Pre-exposure Prophylaxis (PrEP) is a method of HIV prevention in which HIV negative people take anti-retroviral medication used to treat HIV infections. Taking anti-retroviral drugs enables them to lower the risk of HIV infection if they are exposed to the virus. This review gives an overview of different methods aimed at preventing HIV infections in order to show that there is still need for the new method called PrEP. This chapter addresses the first objective of the study by outlining and discussing empirical studies that have been conducted on methods aimed at preventing HIV infections, including studies done on Pre-exposure Prophylaxis, which is the newest HIV prevention method that has shown partial effectiveness in preventing the transmission of HIV.

#### 2.1.1 Condoms

Condoms are a component of the HIV prevention strategy referred to as ABC (Abstain, be Faithful to one sexual partner, or use a Condom). They are made of thin latex or plastic sheaths that are worn on the penis during sexual intercourse to prevent sexually transmitted infections. Sometimes they are called rubbers, safes, or jimmies. They reduce the risk of sexually transmitted infections, including the infections caused by HIV, by covering the penis and keeping semen out of the vagina, anus or mouth. Like other HIV prevention methods, condoms are more effective when used correctly. Condoms protect both sexual partners from contracting the HI-virus. Condoms also reduce the risk of other sexually transmitted infections, including cheamydia, gonorrhoea, hepatitis B, herpes, and syphilis. Some people are allergic to latex. Those who are allergic can try using plastic condoms.

Like the male condom, the female condom is a plastic pouch that is used during sexual intercourse to reduce the risk of contracting the HI-virus and other sexually transmitted infections. Just before vaginal intercourse, it is inserted deep into the vagina

or anus and by covering the inside of the vagina or anus and preventing contact with blood and other fluids that may contain the virus from infected persons, these condoms can prevent HIV infection.

The use of the condom is part of the prevention strategy of AIDS in Zambia and many other countries. However, low levels of condom use have been prevalent among women. In the year 2000, about 40 percent of males reported using condoms as compared to 33 percent females in the same year in Zambia, and five years later in 2005, about 38 percent males reported using condoms as compared to 28.6 percent of females. In addition, there are also persistent myths about condom use, for instance that HIV can pass through small pores in the condom and that condoms are deliberately infected with HIV so that using them actually increases the risk of contracting the HIV virus (National AIDS Council 2009, 9).

Condoms are distributed through many channels, among them are family planning clinics, social marketing and private physicians. This is done in order to make condoms available to as many outlets as possible. According to studies on condom use, indicators of their use are calculated by estimating the average number of condoms available per person who are aged 15-49 in the past 12 months divided by the population of people aged 15 to 49 years old (UNAIDS 2001b, 1). These indicators are a reflection of the overall capacity of condom supply. They do not reflect the effectiveness of condom distributions nor do they reflect the condom need or demand that is met by the supply.

Latex condoms have been available for a long time, but to date only a small percentage of individuals use them in sexual relationships to prevent HIV infection. The HI-virus has led to the promotion of condom use in high risk sexual relationships. This has resulted in the marketing of condoms to both men and women. The HI-virus has also led to a number of studies focusing on social influences, community norms, and interpersonal communication skills involving condoms.

When the first manufactured condoms were introduced, the focus was on the technical aspects of how to use them. Of secondary importance was how the condoms would affect sexual behaviour, and how to negotiate condom use with one's sexual partner. A third focus was on distribution, with the aim of providing unlimited numbers

of free condoms, which could be retrieved from any local community business. In a study that was carried out in the early days of condom use in Los Angeles (California), of the 903 subjects who took part in a condom trial study to assess effectiveness and whose medical records were retrieved after exposure to the intervention programme, there was evidence of continued unsafe sexual behaviour. This was revealed by subsequent treatment for new sexually transmitted diseases, which was 12.6 percent for women and 19.9 percent for men (Deborah et al. 1992, 245).

Other research has shown that the biggest perceived benefit of using condoms among college students was protection from pregnancy. On the other hand the benefit for prostitutes, who are at high risk, is protection from diseases including HIV. However, college students and prostitutes agree that having to rely on a partner's cooperation is a disadvantage of using condoms. Currently, condoms are either sold at a minimal cost or given free of charge in almost every supermarket, petrol station, pharmacy, bar, youth club, music festival, and you can even find them in public toilets (Deborah et al. 1992, 245).

In campaigns promoted by health authorities worldwide, the condom has been described as safe, easy to use and comfortable. In a study that involved heterosexual couples aged 30 years with experience in condom use, 20 to 60 percent felt that condoms reduced the sensitivity of the penis, depending on the type of condom used, and that the loss of this sensitivity was less with lubricated condoms. Seventeen percent of the women did not like the appearance of the penis with a condom on it and 22 percent found it less exciting to touch a penis with a condom.

It is apparent that condoms deteriorate over time. In order to address the issue of deterioration, researchers subject condoms to tests and major buyers of condoms, such as WHO and USAID, have added a packaging integrity test to their specification to ensure that the product they buy is stable and can withstand intense heat, humidity or moisture, all of which could accelerate the deterioration process of condoms. In the 1980s, this test tended to subject the package to stress under a vacuum seal. In addition WHO and USAID require that all condoms be packaged with aluminium foil laminate (Family Health International 1998, 49).

In general condoms protect against HIV infection. Especially high quality latex condoms are impervious to HIV and other organisms. The ineffectiveness of condoms can be a result of manufacture errors, distribution, storage, and user failure, which can diminish effectiveness to different degrees.

### **2.1.2 Male Circumcision**

Male circumcision is an operation that has come a long way in the history and tradition of man kind. Its practice is documented in Jewish and Muslim societies in which all males are circumcised as part of their faith. Male circumcision is an operation which involves the cutting off of the foreskin from the penis, thereby leaving the glans (knob) exposed. Zambia is one of the countries in the southern African region where male circumcision is practised. The country has recognised a significant HIV protection from male circumcision, and based on information from randomized control trials in Zambia, more than a hundred doctors have been trained in conducting male circumcision and more than 15000 men have been circumcised.

There are three methods that are widely used in male circumcision. These are the dorsal slit method, the forceps-guided method and the sleeve resection method. In the dorsal-slit method, after the patient is anaesthetized the foreskin is retracted and adhesions are removed. The surgeon marks the line of incision by either using a pen or a scalpel. This enables the surgeon to easily identify the exact parts for surgery. The marking is important to ensure that the surgeon does not cut too deeply and divide the blood vessels. Thereafter, two artery forceps are used to grasp the foreskin and using dissection scissors the surgeon cuts the foreskin.

The forceps guided method of circumcision is a seemingly simple procedure for surgeons and assistant surgeons. The patient is given an anaesthetic after which the foreskin is retracted and adhesions are removed. The intended line of incision is marked, and the foreskin is then grasped by two artery forceps which are placed at the apex of the foreskin in order to avoid leaving too much mucosal skin or remove too much shaft skin. By applying sufficient tension the marked area on the foreskin is pulled to position just below the glans allowing long straight forceps to be applied across the foreskin. When the forceps is in position the surgeon feels the glans to ensure that it is not accidentally

caught in the forceps. When this is done, the foreskin flush is cut away using the outer aspect of the forceps and the skin is then pulled back to expose the raw area. The bleeding vessels are then clipped and tied off. However, this method cannot be used with men who have phimosis, a narrowing of the opening of the foreskin that prevents that it can be drawn back over the penis.

The sleeve resection method is better suited to a hospital than a clinic as it requires exceptional surgical skill. This procedure requires an assistant to reduce the risk of surgical error. In this method the patient is first anaesthetized, this is then followed by the retraction of the foreskin and the removal of adhesions. A V-shaped line of incision is marked, pointing towards the frenulum on the underside of the penis. This is followed by the retraction of the foreskin and the mucosal incision line is then marked proximal to the corona. As the assistant retracts the foreskin with a moist gauze swab, incisions are made by using a scalpel along the marked lines (WHO/UNAIDS, 2008).

The Zambia National AIDS Council report of 2009 reveals on page 6 that only 15 percent of the males in Zambia are circumcised. According to the report, acceptability studies indicate that male circumcision is acceptable to communities if it is made safe, affordable and available.

In a study on male circumcision in Lusaka (Kabwe 2012, 42-43) it was revealed that the dorsal slit method is the only method of male circumcision that is practised in all the circumcising centres in Lusaka urban. The researcher of the study reports that the advantage of male circumcision is that it is a one-off procedure, with no ongoing costs or supply issues to worry about. The person who undergoes circumcision will benefit from it for the rest of his life. The researcher also reported that there is a benefit of the reduction in the risk of infection of HIV, which seems to be around 60-70 percent. Further, the procedure reduces the risk of contracting other STIs including syphilis, chancroid and infections caused by the human papilloma virus (HPV). Among the disadvantages which the researcher reported are the fact that the procedure leads to a loss of the foreskin, which is a protective covering for the penis, causes pain and disfigurement and that it is less effective than the condom in preventing HIV transmission.

In the same study the researcher found that from the 150 research participants who took part in his research, most men viewed male circumcision as 100 percent effective in preventing HIV infection. About 17.5 percent of the participants indicated that once married, most men tend to become complacent and lose interest in male circumcision. The study also revealed that 90.7 percent of the research participants decided to go for male circumcision on their own. About 93.3 percent of the circumcised males indicated that there was a difference between circumcised males and uncircumcised males in relation to HIV contraction. Of the 150 participants, 68 percent indicated that people go for male circumcision with the view of HIV prevention, as compared to 30 percent who did not think that to be the case. In the same report, 54 percent of the participants thought that male circumcision is an effective means of HIV prevention, while 46 percent did not think so.

In other parts of Africa, studies have been done on male circumcision and 188 developing countries were analysed with the goal of investigating possible association between male circumcision and the prevalence of HIV. The findings revealed that in sub-Saharan Africa, HIV prevalence was at 16.5 percent higher in countries that had low male circumcision as compared to 3.0 percent among those nations that had higher male circumcision thereby showing that male circumcision can affect HIV prevalence. Male circumcision is believed to reduce HIV infection by 50-60 percent. This was revealed in a trial that was conducted in South Africa, Kenya, and Uganda (Wawer et al. 2009). The situation in Uganda was televised in a British Broadcasting television programme in November 2000, showing the disparity in HIV infection among two tribes across a valley. The tribe that practised circumcision showed fewer HIV infections as compared to the other tribe that did not practise circumcision.

There are at least three reasons why male circumcision works. First, about 70 percent of men infected with HIV have acquired the virus through vaginal sex. This supports the claim that most men have acquired the virus via the penis. It also raises the question of how HIV enters the penis and why men who are uncircumcised are more susceptible to becoming infected with HIV. Research shows that the inner mucosal surface of the foreskin is rich in Langerhans cells, thus making it susceptible to the virus because these cells have CD4 receptors on their surface. In men who are circumcised the

foreskin is removed. This reduces the risk of infection. The second reason is that after circumcision the newly exposed skin on the knob of the penis becomes covered with a protective layer of keratin. The keratinisation of the skin decreases a man's risk of acquiring HIV during sexual intercourse. The third reason is that the removal of the foreskin reduces the risk of genital ulcers. HIV can enter the body through genital ulcers on or near the penis.

According to another report on male circumcision, a randomized controlled trial on the efficacy of male circumcision in reducing the risk of HIV transmission revealed that male circumcision reduced the risk of HIV infection by 60 percent. This result is consistent with other observational studies conducted on male circumcision. The benefits of male circumcision include protection from HIV and other sexually transmitted infections. This HIV prevention measure can be significant, especially in situations where other methods of prevention, such as condoms, are not available or fail to effectively protect against sexual infections during sexual intercourse, due to deterioration or breakage (Auvert et al. 2009).

Male circumcision can also reduce the complication that arises from prostate or bladder gland problems among older men, which is an important aspect that anti-retroviral drugs cannot achieve. It is clinically known that older men who undergo treatment for prostate gland or bladder problems may sometimes develop difficulties with their foreskins because of their surgeon's handling, cleaning, and using instruments. Male circumcision can also reduce the chances of developing cancer of the penis among some older men. Circumcising infants and young adults could give a large degree of protection from these complications. Male circumcision can protect women from cancer of the cervix which can be caused by the Human Papilloma Virus (HPV). The Human Papilloma Virus thrives under and on the foreskin from where it can be transmitted during intercourse. Research supports that if all the males were circumcised this would reduce cancer of the cervix by 20 percent.

Apart from protection from HIV and other sexually transmitted infections, those who have undergone male circumcision have indicated that they prefer the appearance of their penis after circumcision. The penis is odour-free, feels cleaner, and their partners have acknowledged enjoying better sex. Male circumcision can also prevent a condition

called *Balanitis*, which is a recurring inflammation of the glans (knob). Circumcision in babies makes it 10 times less likely that infants will develop urinary tract infections, which can sometimes be serious (David, 2012).

In a study undertaken on male circumcision, among those 18 years of age and above in Mufulila district of the Copperbelt Province of Zambia, 72.2 percent of the respondents taken from non-circumcising tribes, revealed that they did not believe that the practice could threaten their cultural identity or would result in the loss of a particular tribe's cultural identity (Chiwele 2011, 59).

Research has shown that there is some consistency in arguments for and against male circumcision in a number of countries which have adopted the practice as a method aimed at preventing HIV. Studies conducted in some African countries indicated that the main barriers to male circumcision in non-circumcising areas were cost of the operation, the fear of pain and the concern for safety. In the same vein, the advantages that people see in promoting male circumcision in these countries are improved hygiene and reduction in sexually transmitted infections (Rennie et al. 2007).

A report about a focus group discussion on assessing male circumcision practices and opinions and acceptability in Zambia's urban and rural areas revealed that there is limited interest in male circumcision among tribes that do not practice male circumcision. This information was collected from a group of married and unmarried men aged 18-39 years. The report also reveals that some men are interested in the practice if it is true that men who are circumcised are preferred by women (USAID/JHPIEGO, 2007). Another study on male circumcision revealed that there is generally high acceptability of male circumcision as indicated in a report on the practice at the Urological Department of the University Teaching Hospital in Zambia. This was confirmed in an acceptability study that was done prior to the commencement of the male circumcision services at this hospital (Bowa and Lukobo, 2006).

In a report on factors inhibiting male circumcision uptake, involving a sample of 360 youths in Zambia, it was revealed that 48.8 percent of the respondents who had taken part in a study believed that the main reason for choosing not to undergo circumcision was the belief that the procedure reduces sexual pleasure. In addition, 47.8 percent of the respondents believed that the operation can cause health problems. In the

study other reasons were given as well. For instance, the procedure was painful (46.5 percent of the respondents) and 21.3 percent of the respondents believed the procedure was costly (Phiri 2011, 31).

### **2.1.3 Microbicides**

Microbicides are products that are intended for vaginal or rectal administration. These products may decrease the transmission of HIV. Microbicides are compounds that can be applied inside the vagina and rectum to protect against Sexually Transmitted Infections (STIs) including HIV. They can be used as a measure of protection against HIV infection for women whose partners refuse to wear condoms or take anti-retroviral drugs. They can be produced as gels, creams, films, or suppositories. The vaginal gel has been reported to significantly cut the risk of HIV infection in a trial in South Africa. The trial results revealed that the gel containing the ARV *Tenofovir* cut the rate of infection by 50 percent among the 889 participants over a two year period. Many scientists, however, have questioned the effectiveness of microbicides. Some scientists have suggested that there is a 1 in 10 chance that the effectiveness of the microbicide gel in the South African trial was due to chance. In a trial in Montreal, scientists revealed that the gel was effective in 30 percent of women who used it for the prevention of HIV (Brenda, 2009).

The results of the South African trial were replicated by using a larger sample size, but results were very disappointing. This led to a situation where microbicides were declared as less effective and unreliable. However, between 1994 and 1996 the microbicides in clinical trials increased from 12 to 20 and those that were in early development increased from 9 to 13. To date, there have been many clinical trials on microbicides. These range from the CAPRISA 004 trial, which is a trial that assessed the safety and effectiveness of *Tenofovir* gel. This is used before and after vaginal sex. The results of this trial, reported in 2010, showed that it was 6 to 60 percent effective. There is also the VOICE which stands for Vaginal and Oral Intervention to Control the Epidemic. The review of the VOICE results, released in 2011, indicate that the tablets used were not more effective than a placebo in preventing HIV. However, more results are expected for this prevention measure using the drug *Truvada* in 2013. The trial

called FACT 001 used the same testing regimen as CAPRISA 004, where women use *Tenofovir* before and after sex. The trial enrolled 2,200 women in South Africa and the results of this study are expected in 2014. There is also the CAPRISA 008 trial, which is a follow up of the CAPRISA 004. This trial is aimed at testing the feasibility and effectiveness of *Tenofovir* gel in family planning clinics.

The development of microbicides which are effective at preventing the transmission of HIV would empower women to contribute more to the fight against HIV (UNAIDS 1998, 2). If microbicides are effective in preventing HIV infection, they can offer a better chance of protection for women, considering the fact that some women have fewer options for protection and that they have little power to refuse sex or demand for safer sex with their partners. One advantage of microbicides is that women may not require consent and cooperation from the male sexual partner. This makes microbicides an important factor in the fight against HIV transmission because women can easily control the use of microbicides.

In Zambia microbicide trials were undertaken in Mazabuka district. The case of a Mazabuka man who sued his wife for divorce after she had taken part in the trial raises concern. The man was claiming that his wife had been infected with HIV after sleeping with another man during the microbicide trials that were undertaken in the district. This case raised concern about the efficacy of microbicides as a prevention method. The trials were undertaken by the Microbicide Development Program (MDP), a non profit partnership funded by the UK government, through the Department for International Development (DFID) and the Medical Research Council (ZARAN 2010, 3).

#### **2.1.4 Prevention of Mother-to-Child Transmission**

HIV can pass from the mother to her unborn baby. In this situation HIV is thought to be transmitted during pregnancy, delivery or by breast-feeding the baby. This is usually called Mother-to-Child Transmission (MTCT) of HIV. According to a study by WHO, every day over 1700 infants get infected with HIV and about 90 percent of the infants are infected through mother-to-child transmission. Medically this is referred to as perinatal transmission which occurs during labour, breast feeding and during pregnancy. The WHO report of a recent study also revealed that if HIV positive women take anti-

retroviral drugs during pregnancy and six months into breast feeding they can reduce the risk of their babies getting infected with the virus by at least 40 percent (WHO, 2012b).

Prevention of Mother-to-Child Transmission (PMTCT) plays a vital part in combating paediatric AIDS, which is currently a matter of concern in Africa, especially in southern Africa where about 90 percent of the world's 800000 children who are infected with HIV are found. Today, there is a range of different things that can be done to prevent MTCT. For instance, the risk of Mother-to-Child-Transmission can be reduced with anti-retroviral treatment and caesarean section. The recent clinical study report by WHO (released on 30<sup>th</sup> November, 2009) calls on all HIV positive women to begin ARVs at 14 weeks of pregnancy and continue until they stop breast-feeding. The infant will receive treatment with AZT syrup for four weeks after it is born. According to new guidelines, HIV positive mothers taking ARVs are encouraged to exclusively breast feed their infants for the first twelve months of the baby's life.

There are a number of challenges involving PMTCT as an HIV prevention strategy in Zambia and other developing countries. To start with, the majority of health facilities that provide the PMTCT service are located in distant places which are not easily accessible to rural families. The other challenge is the non-availability of HIV test kits. This is compounded by the lack of preventive drugs and other necessary supplies. There is also a shortage of staff and a lack of motivation for existing staff who implement PMTCT services. In addition, there is also the challenge of access to drugs and adherence. A report by ZARAN revealed that the non-nucleoside HIV drug *Nevirapine*, which is used for PMTCT, is sometimes given in one dose each to the mother and to the child. This can only reduce the transmission of HIV from mother to child by 50 percent and it can also lead to HIV drug resistance. A study conducted on adherence revealed that non-adherence to *Nevirapine* tablet was 32 percent. These challenges limit the effectiveness of PMTCT programs (ZARAN 2011, 3).

In a study that was conducted to determine the effectiveness of counselling in PMTCT programs in Lusaka Province, results showed that 66.7 percent of the respondents did not know that an elective caesarean section delivery could also reduce the risk of transmission of HIV from the mother to the child. This raises concern about the dependence on PMTCT as an HIV prevention strategy. A study conducted at six

clinics in Lusaka revealed that PMTCT programs do not provide caesarean section as an alternative. Generally, studies done in sub-Saharan Africa have revealed that despite the extensive scale up of Prevention of Mother-to-Child Transmission services, results show that pregnant women who are HIV positive and their HIV exposed infants are not accessing the complete package of preventive and treatment services that can lower the risk of Mother-to-Child Transmission of HIV to less than 2 percent. Ineffective PMTCT intervention poses a risk of 5-20 percent of MTCT of HIV during breast feeding and a risk of 15-50 percent during pregnancy and at birth (Peter 2005, 19).

In 2009, a World Health Organization study revealed that only 51 percent of the 1.4 million HIV positive women had been clinically assessed in sub-Saharan Africa and among those eligible, only 15 percent were provided with Highly Active Antiretroviral Treatment (HAART). Further studies indicated that of the 1.4 million HIV positive women, 90 percent were in sub-Saharan Africa, and only 53 percent had received anti-retroviral to reduce the risk of Mother-to-Child-Transmission. Researchers have further raised concern about the plight of HIV exposed children, who are in a similar situation in the southern part of Africa. One of the concerns raised is the diagnosis of infants at an early stage in life, using DNA Polymerase Chain Reaction (PCR) testing to determine infant HIV status in infancy. In 2009 it was reported that only 15 percent of the infants, who were exposed to the virus, were tested within the first two months of life (Dillabough et al. 2012).

Voluntary counselling and testing also plays a vital role in the successful delivery of PMTCT, especially for those mothers who attend antenatal clinics. The success of PMTCT also depends on a range of successful steps that are undertaken, such as the already mentioned HIV counselling and testing, assessment of HAART eligibility through CD4 testing and clinical staging, Post-exposure Prophylaxis and now Pre-exposure Prophylaxis provision, infant testing, and HAART provision for HIV-positive infants.

There are numerous other challenges in the implementation of PMTCT delivery, particularly with respect to HAART uptake for qualifying women and infants. These challenges include health systems infrastructure limitations, such as inconsistent commodity supply for essential lab services or drugs, inefficient laboratories, poor

provider knowledge, low stakeholder involvement, poor integration of services, and ineffective referrals. These challenges are compounded by inadequate PMTCT knowledge by the patient, the partner and by social stigma. Fear and denial can prevent women from accessing or following through with the HIV care and treatment they need. These challenges make provision of PMTCT services at each step difficult and lead to an ineffective and compromised PMTCT quality of care that leaves much to be desired in terms of meeting the expectations of those who need the service and those who provide it (Dillabough et al. 2012).

### **2.1.5 Caesarean Section**

A Caesarean section, also known as C-section, is the surgical delivery of a baby. This procedure is conducted by doctors who care for the woman before, during and after she delivers. To perform a C-section, a doctor inserts a needle into the woman's spine and injects morphine. This causes numbness from the waist down, allowing the doctor or obstetrician to make a long incision in the mother's abdominal wall and uterus to remove the baby. Mostly it is carried out at 38 weeks.

A study has revealed that in Zambia, from the month of January to June 2005, about 6367 patients were referred from 24 clinics in Lusaka for Caesarean section, out of which 1358 (or 21.3 percent) delivered at the University Teaching Hospital. According to the study, Prevention of Mother-to-Child Transmission of HIV accounted for about 5 percent of the indication for Caesarean deliveries, among other reasons, such as hypertension, cephalopelvic disproportion and foetal distress. These studies have shown that children get infected with HIV at the time of delivery and that caesarean section is able to lower the rate of infection (Ndumba 2005, 8-12).

Caesarean section can reduce the risk of HIV infection, but it has disadvantages to the mother and to the child. For instance, the mother has to stay in hospital for at least 3 to 5 days after the operation and it may take up to six weeks for the mother to fully recover and resume performing her normal activities. In worst cases, death can occur due to loss of blood as a result of the operation. Because of these challenges, many women who are HIV positive and have been faced with the prospect of undergoing a C-section, have tended to wonder whether combination anti-HIV treatment such as

HAART, which is proven to reduce the risk of mother-to-child HIV transmission to as low as 1 percent is a better option, comparatively. However, studies have shown that C-section, when done before the mother's water breaks, is able to reduce the risk of HIV transmission, as it minimizes the baby's contact with the mother's blood. This type of C-section is referred to as Elective or Planned C-section. To reduce the risk of infection, the operation should be carried out before the mother goes into labour. However, C-sections done after the mother's water has already broken, pose a greater chance of transmitting HIV infection to the child. The introduction of Highly Active Anti-retroviral Treatment (HAART) as a preventive method for Mother-to-Child Transmission has led to a reduction in transmission rates. But C-sections before HAART was introduced lowered transmission rates and were preferred by HIV pregnant women.

Recent research has shown that HIV positive women who are taking ARVs and have undetectable viral loads can reduce the risk of HIV transmission to at least 1 percent or less for vaginal births without undergoing a C-section. Because C-sections require surgery, they pose a greater risk to the health of the woman, compared to vaginal births where a woman can recover quicker after delivery. It is likely that the baby, if delivered at 38 weeks using this procedure, could be delivered before its lungs are fully developed. In addition, because of the surgical operation involved in C-sections, women are more prone to infections than those who give birth vaginally. Studies have revealed that a woman on HAART with a low viral load is not likely to further reduce the risk of transmitting HIV to her child. In contrast, a viral load over 1,000 could increase the risk of transmission of HIV during vaginal delivery (Highleyman, 2003).

Comparative studies that ascertain the effectiveness of ART and C-section in reducing transmission of HIV from mother to child could save the lives of many babies lives. Such studies could indicate whether taking a powerful HIV drug combination would be more effective than C-sections in reducing the risk of Mother-to-Child Transmission of HIV. Caesarean sections are used to deliver babies for a variety of reasons. Beyond reducing the risk of mother-to-child HIV transmission, there are other reasons that may require HIV-positive pregnant women to have a C-section. These may range from diabetes, problems that arise during delivery, such as failure to progress in

labour, foetal distress, breech births, low-lying placenta or a placenta that has prematurely detached from the uterus (Highlyman, 2003).

A report by an organization called AIDSMEDS reveals that some experts do not recommend C-sections aimed at reducing the risk of mother-to-child HIV transmission. Because C-section involves surgical operations, there is an increased risk of infections and other complications. Research has shown that HIV-positive women who undergo C-sections face a higher risk for infection or other complications than HIV-negative women undergoing C-section delivery. Some experts have hoped that ART can show greater efficacy in preventing infection during pregnancy than C-sections. Research has shown a reduction of 2 percent in risk of transmitting HIV for HIV-positive pregnant women with an undetectable viral load at the time of giving birth. In America, C-sections to reduce perinatal HIV-1 transmissions are only recommended when the mother has a viral load that is over 1,000 copies. Research has indicated that this is usually done at week 36 of pregnancy and the surgical operation, should be carried out at week 38 of pregnancy. The ARV drug *Retrovir* is recommended for the mother beginning three hours before surgery and her infant receives six weeks of *Retrovir* after birth (AIDSMEDS, 2011).

### **2.1.6 Voluntary Counselling and Testing**

In Voluntary Counselling and Testing (VCT) people undergo counselling to enable them make an informed choice about being tested for HIV. VCT is seen as a critical strategy in the comprehensive primary prevention campaign against HIV/AIDS. Studies have revealed that the potential benefits of VCT include improved health status through good nutritional advice and earlier access to treatment and prevention for HIV related infections. The other benefits of VCT include emotional support and better ability to cope with HIV related anxiety. There are also other benefits such as safer blood donations (Chishimba 2005, 1).

UNAIDS acknowledges that VCT has a very important role to play within a comprehensive range of measures for HIV prevention and support and that it should be encouraged. Despite this acknowledgement, studies have shown that people view VCT in a negative way, namely as a means of collecting information on the prevalence of

HIV infections when they go to test for the virus and not as a means of preventing HIV. Studies also indicate that in many high HIV prevalence areas, young people, especially women, are at risk of HIV infection, but they often have no access to VCT (UNAIDS 2003, 3).

Clinical trials that were carried out in Tanzania and Kenya to examine the effectiveness of VCT in preventing HIV infection showed that VCT is effective in reducing sexual risk behaviour when both members of a couple participate. The counsellors involved in VCT provide HIV related information and correct some misconceptions, including support for those that are already infected with HIV. The counsellors also prepare the client for testing and to receive the test results, no matter what the result will be. They also help the client in behaviour change, to avoid infection or infecting others. VCT is very important, especially in reducing Mother-to-Child HIV Transmission and it should be included in pregnancy care programmes where women and their partners can be provided with information about reducing their own and their partner's exposure to HIV (UNAIDS 2000, 35-38).

The assessment of the benefits of VCT indicates that unless women and their partners know the benefits of an HIV test, most of them will not choose to undergo testing. Studies have revealed that VCT is crucial in giving advice to individuals who test HIV negative. The advice given at VCT centres allows such individuals to take preventive measures that would avoid or reduce the risk of acquiring HIV infection.

Research has also revealed that VCT is very important to women who are breast feeding. The advice given at VCT centres is vital in boosting the confidence of breast feeding women, thereby enabling them to breast feed freely. In contrast, a person who tests positive will depend on the intervention available at VCT centres. These interventions can enable an individual to reduce the transmission of the HI-virus to other persons, such as the transmission from a positive mother to her children. Research has revealed that VCT interventions can reduce HIV transmission of mother-to-child by at least 10 percent. However, VCT guidelines indicate that such interventions cannot be made available to women whose HIV status is not known. The downside of VCT is that in cases where breast feeding is universal, every mother is expected to breast feed her baby. Because women are expected to breast feed their babies, not doing so, may raise

suspicions of HIV infection. Some women may not be able to use alternatives to breast feeding due to non-availability of alternative interventions and high cost of intervention measures (UNAIDS 2001a, 9).

In Zambia, voluntary counselling and testing services have been provided by Non-Governmental Organizations (NGOs) since the late 1980s. VCT services have faced a number of challenges in implementation. Within a period of ten years, from 1980 to 1990 with about 20 percent of antenatal clinic attendants testing HIV positive, studies have revealed that with close to 500 new HIV infections resulting into 200-300 deaths per day, there arose a need for government involvement in providing VCT services (Chiboola et al. 2001).

The Zambian government involvement in VCT led to the integration and establishment of joint work plans on VCT with local NGOs, Zambia Counselling Council (ZCC), District Health Management Teams (DHMT), as well as other stakeholders, who joined to provide logistical support in establishing VCT services. These initiatives resulted in better VCT services being provided and better coordination which encouraged joint training programmes for counsellors and laboratory technicians. In a study conducted to determine the effectiveness of VCT in HIV prevention, it was shown that for VCT to be effective in preventing HIV among young people, there was need to take into account the emotional and social contexts of the lives of common people. These included the influence of peer pressure and the development of social and sexual identities. In order to be effective, VCT services must be user friendly, and the counselling should be offered in safe, easily accessible, non-threatening environments that are able to utilize age appropriate and familiar examples of situations that are relevant to the youths, with language that is non technical and easy to understand (Sangiwe, 2000).

In a study conducted in 2005 in higher learning institutions in Zambia to determine the levels of awareness and the perceptions of VCT as an HIV prevention strategy, only 16.3 percent, from a sample of 280 respondents, reported using VCT services. According to this study, factors that led to low utilization of VCT services ranged from fear of being identified as an HIV positive individual to low psychological preparedness to undertake HIV tests. In the same study, some respondents attributed low

VCT use to the location of VCT centres within the institution and poor knowledge of HIV/AIDS among counsellors, with 44.8 percent describing their counsellors as not being knowledgeable. These reasons were also compounded by suspicions of lack of confidentiality at VCT centres, coupled with the fear of being stigmatized by colleagues (Chishimba 2005, 47).

Over the years some factors that lead to ineffective VCT delivery have been addressed by stakeholders. However, for VCT to remain an important aspect of HIV intervention there is need to update the guidelines and to include new HIV prevention measures such as Pre-exposure Prophylaxis.

### **2.1.7 HIV Sperm Washing**

Sperm washing is a procedure that has been developed to reduce the risk of infection for couples who wish to have a child. In developed countries, this process is carried out in serodiscordant couples, where the male is HIV-positive and the female is HIV-negative. The procedure reduces the risk of transmission of HIV to the female partner and also to the unborn child. Research has shown that sperm washing can reduce the risk of HIV infection by 96 percent. This means there is only a 4 percent risk of HIV transmission which some couples may find unacceptable (Carter, 2011).

Sperm washing was first developed in Italy. The concept is founded on the fact that HIV is prominent in the seminal fluid of an HIV-positive male. Sperm washing is a procedure that is used to help couples trying to conceive without passing on diseases or genes for disease. Sperms are concentrated and separated from the surrounding seminal fluid by a centrifuge, a device that separates components of a liquid as it spins at high speed. The separated sperm is then washed twice in a solution in order to remove the undesirable materials which include the HIV virus. Polymerase Chain Reaction (PCR), the same technology that is behind viral load testing, is then employed to test the sperm sample for HIV. The woman is then artificially inseminated with the washed sperm, in order to fertilize the ovum. This reduces the chances of vertical transmission of HIV from mother to child. The washed sperm, after it has been tested, can also be frozen and stored until the HIV test results come back. It may also be stored for use during the

woman's next fertility cycle if she is past ovulation by the time the results come back (Vasquez, 2003).

In order to fertilize the ovum, various methods are employed, one way of fertilization is by In-Vitro Fertilization (IVF). In this procedure, the woman is given a reproductive hormone to cause ova to ripen. Eggs are then removed from the woman's ovary and fertilized with sperm in a petri dish, resulting in zygotes that are placed in the woman's uterus or stored for later use.

IVF is considered the safest method for conceiving with HIV. The other way of fertilization is by Intra Cytoplasmic Sperm Injection (ICSI). This is when a single sperm cell is used to fertilize the egg. It is an additional step that can be taken following IVF which makes it expensive. It also increases the level of safety. It is especially useful with a low sperm count when fertilization otherwise would not occur.

Intra-Uterine Insemination (IUI) is another option, where washed sperm is placed directly into the cervix or the uterus itself. Sperm washing with IUI may be just as safe and less expensive than other insemination methods. There is also the Cervical Cup Method of fertilization. An apparatus, referred to as an oligospermic cup that contains washed sperm is inserted over the cervix by a doctor. This allows the washed sperm to travel into the uterus. To reduce the risk of transmission further, Pre-exposure Prophylaxis or anti-HIV medication is given at the time of insertion.

There is still no guarantee of safety in preventing the transmission of HIV as there might be the potential for microscopic tears of the vagina mixing with the sperm. In such cases, Post-exposure Prophylaxis can be used to prevent transmission following exposure. Post-exposure Prophylaxis is used to prevent infection following exposure to the virus, while Pre-exposure Prophylaxis is used to reduce the risk of infection *before* one is exposed to the virus.

The effects of PrEP or Pre-exposure Prophylaxis on foetuses and children born to women who used either Post-exposure Prophylaxis or PrEP are currently unknown. Researchers have indicated that even after sperm washing, there is no 100 percent guarantee that HIV will not be transmitted. Although sperm does not seem to be infected by HIV, the virus may be present in the seminal fluid surrounding the sperm and separating them may not be so easy in developing countries with poor laboratory

instruments and other necessary health facilities. In addition, while sperm washing and testing may be relatively simple and inexpensive in developed countries, the processes and procedures involved with in-vitro fertilization, zygote implantation, and clinical insemination are complex and expensive. They are, however, the safest ways to conceive (Vazquez, 2003).

As a result of effective HIV medications people who are HIV positive are able to have families and improve their wellbeing. Today, being HIV positive and conceiving is no longer impossible. However, the attempt by an HIV negative woman and HIV positive man to engage in normal sexual intercourse in order to conceive increases the risk of infecting the negative woman. Therefore, sperm washing is in developed countries one option that is being used to prevent HIV transmission to an HIV negative woman and her baby. This procedure is however not available in most developing countries, including Zambia. In Italy, there were 567 serodiscordant couples who underwent sperm washing, out of which 298 pregnancies occurred. Statistics on pregnancies that resulted from sperm washing indicate that 26.2 percent were artificially inseminated and 37.2 percent were from conventional in-vitro fertilization and intracytoplasmic sperm injection. The study undertaken in Italy showed that there were no HIV seroconversions, either in the women or in the child (Cichocki, 2009a).

#### **2.1.8 Harm Reduction for Injecting Drug Users**

This HIV prevention measure can be very useful, especially in prisons where HIV can be transmitted by using needles, razors and tattooing. Many men and women may be already infected with the virus when they are imprisoned. The HI-virus can then be transmitted by sharing razors and tattooing in prison (Fidgen, 2010). People who inject drugs can take precautions against becoming infected with HIV by sterilizing injecting equipment, including needles and syringes, for each injection. Prevention and treatment packages for those who inject drugs can include strategies that aim at opioid substitution therapy for drug users, such as drug dependence treatment, HIV testing and counselling, HIV treatment and care, and access to condoms and management of STIs, tuberculosis and viral hepatitis (WHO, 2012c).

### **2.1.9 Anti-Retroviral Treatment**

Research results have revealed that if an HIV-positive person adheres to an effective anti-retroviral therapy treatment, the risk of transmitting the virus to their uninfected sexual partner can be reduced by 96 percent. For serodiscordant couples in which one partner is HIV-positive and the other HIV-negative, WHO recommends anti-retroviral treatment for the HIV-positive partner regardless of his or her immune status. This can help to reduce the risk of transmission of HIV to the uninfected partner and reduce the spread of the virus (WHO, 2012).

### **2.1.10 Post-exposure Prophylaxis**

Post-exposure Prophylaxis (PEP) refers to using antiretroviral medication in an attempt to reduce the risk of HIV infection, especially of healthcare workers, following an exposure to the blood or body fluids of a patient who is infected with the HI-virus. Studies have shown that nearly one million healthcare workers worldwide have suffered needle stick injuries each year. This has resulted in hundreds of healthcare workers being infected with HIV. Studies done on Post-exposure Prophylaxis, involving occupation exposure have shown that in June 2000 there were a total of 56 healthcare workers who occupationally got infected with HIV in the United States of America. These included 23 nurses, 20 laboratory technicians, and 6 physicians. The transmissions involved blood and blood body fluid, except for three laboratory workers who were exposed to HIV viral cultures while working in the laboratory. A case control study of needle stick injuries from an infected source showed 33 cases that seroconverted. Further studies on occupational exposure to HIV have indicated that the risk for HIV infection was high when it involved deep injury, visible blood on the device, needle placement in the vein, and when it resulted from a source which had late stage HIV infection, especially that which had a high viral load. There was evidence that Post-exposure Prophylaxis, using the drug *Zidovudine* (AZT), reduced transmission rates from these sources by 79 percent (Bartlet and Gallant 2003, 106-110).

In Post-exposure Prophylaxis anti-retroviral drugs are given immediately after exposure to an infectious organism, in an attempt to prevent infection from taking hold in the body. The recommended regimens for a 3-drug-combination are 2 nucleosides

plus *Indinavir*, *Nelfinavir*, *Efavirenz*. The use of *Zidovudine* (or AZT) is recommended because it has been used extensively and it has established merits for preventing against HIV transmission. In some studies, two-drug-PEP has been recommended for certain instances, such as needle stick with any type needle and any amount, especially if the source has an unknown HIV status but has HIV risk factors. It is also recommended for a mucous membrane exposure to any volume of blood in which the source of HIV is not known but it is in a setting where HIV exposure could take place (Cichoki, 2009b).

Like most medication, PEP is not without risk. Hence, it should only be given to those people that really need it, especially those that have being exposed to the virus. That being said, a closer look at PEP raises concern when it comes to issues of adherence and the problem of resistance to drugs. A known fact about HIV medications is that it has some unpleasant side effects, which have made it difficult for people, who are exposed to HIV to adhere to their PEP treatment as prescribed, and even to complete the recommended four week course. These PEP side effects have led to poor adherence. For those who are infected with the HIV virus and who are on medication, poor adherence leads to viral resistance and poor control of HIV. PEP is a viable option for occupational exposures to HIV and people who are exposed to the virus, such as women who have been raped, and for persons who had sex with an HIV positive person who used a condom that ruptured. PEP can reduce the risk of HIV infection from a needle stick and make infection from other sources of the virus less likely but not impossible (Cichoki, 2009b).

In a study conducted on PEP attitudes and awareness among nurses in Chipata district of Zambia, of the 50 respondents that took part in the study, 47 percent agreed that Post-exposure Prophylaxis reduces the risk of HIV infection after exposure to the virus, one person disagreed, and two did not know about how PEP can reduce HIV infection risk. This raises concerns about how PEP information has been disseminated to avoid occupational infection of HIV. The fact that some do not know that PEP can reduce the risk of infection, could hamper the efforts to provide and access treatment after exposure, as some exposed nurses may not take precautions or follow the guidelines outlined for the administration of PEP. The same study revealed that most nurses had not being trained or oriented on PEP despite having been in the service for a

considerable long period. According to the study undertaken in Chipata the PEP scale up plan was inadequate to effectively and efficiently manage the work place exposure to HIV. The study also revealed that nurses had a negative attitude towards PEP. This was due to lack of information, training and in-house mentoring to motivate the nurses to seek knowledge and PEP service on their own (Banda 2008, 62).

#### **2.1.11 Pre-exposure Prophylaxis**

The newest HIV prevention strategy of providing oral anti-retroviral drugs to uninfected individuals is called Pre-exposure Prophylaxis (PrEP). Pre-exposure Prophylaxis is the latest addition to the methods aimed at HIV prevention. It is especially important for preventing transmission of HIV in women.

As shown in this chapter, there are a number of methods aimed at preventing HIV transmission, including male and female condoms, male circumcision, prevention of mother-to-child HIV transmission (PMTCT) and harm reduction strategies such as provision of sterile injecting equipment and opiate substitution therapy for people who inject drugs. They have contributed to a levelling of the rate of new infections in some countries. In recent years, a promising new approach has emerged, the use of anti-retroviral drugs for HIV prevention, both for the uninfected and for those already living with HIV. This approach is called Pre-exposure Prophylaxis. Research shows the efficacy of this new HIV prevention method in men and transgender women who have sex with men and serodiscordant heterosexual couples.

The clinical trials on PrEP began in 2005. These trials were undertaken to demonstrate the effectiveness of Pre-exposure Prophylaxis. They revealed partial efficacy, which led to anxiety among stakeholders who called for more clinical trials before the implementation of PrEP on a wider scale. A clinical trial in Botswana called the CDC TDF2 study, which was the third clinical trial conducted in partnership with the Botswana Ministry of Health, revealed that a once-daily tablet containing *Tenofovir Disoproxil Fumarate* and *Emitricitabine* (TDF/FTC, known by the brand name *Truvada*) was able to reduce the risk of acquiring HIV infection by roughly 63 percent. This study was conducted in a population of uninfected heterosexual men and women (WHO 2012a, 3).

According to a report released by the University of Washington on the Partners study, which was the fourth clinical trial on Pre-exposure Prophylaxis, study results show that taking PrEP daily reduced HIV transmission among heterosexual couples in Kenya and Uganda. In this study, the two drug regimens, *Tenofovir (Viread)* and *Tenofovir plus Emtricitabine (Truvada)*, were found to be able to significantly reduce HIV transmission in situations in which one partner is infected with HIV and the other is not. The findings were released after it became evident that the two drugs had proved efficacious in reducing the risk of HIV transmission. At this point, an interim review of the trial data went ahead to recommend that the placebo arm of the study be discontinued early (University of Washington, 2011).

When these results were released, a previous study, called the iPrEx study, had already shown that PrEP reduced HIV transmission among men who have sex with men (MSM). But the iPrEx study did not show that PrEP could also prevent HIV infection among heterosexuals. However, the iPrEx trial found an overall reduction in HIV acquisition of 44 percent, with higher effectiveness in the most adherent users. In participants with measurable drug levels at clinic visits, effectiveness in preventing HIV acquisition reached 90 percent. The iPrEx trial was followed by a second trial of daily oral TDF/FTC (*Truvada*) that involved African women at higher risk of HIV in Kenya, South Africa and Tanzania. This trial was however terminated early due to futility.

The trials results by the Centre for Disease Control (CDC) and the University of Washington on PrEP were a follow up on preliminary findings from other studies conducted in the year 2011, such as the Female-PrEP (or FEM-PrEP) trial. The Female-PrEP trial failed to demonstrate a protective effect of PrEP among heterosexual women. This situation led researchers from the FEM-PrEP study to engage in further analysis of the study that raised issues of adherence after a close examination among the participants of the trial, who were mostly women. The close examination of the results indicated that non-adherence could have been the reason for the negative outcome of the TDF/FTC study.

After finding out that PrEP reduced the risk of HIV infection by roughly 63 percent in the study population overall, other studies were conducted to further analyse and determine the effectiveness of PrEP. One such study was referred to as the CDC

TDF2 study whose aim was to analyse the results of the first trials and to better understand the level of effectiveness of PrEP among trial participants believed to be taking study medications. The study revealed that TDF/FTC, which is a drug combination of *Tenofovir* and *Emitricitabine* marketed by the brand name *Truvada*, was able to reduce the risk of infection by 78 percent. The analysis excluded any HIV infections that occurred more than 30 days after a participant's last reported drug dose because it was assumed that such individuals could not have been taking study pills at the time of infection.

The TDF2 study undertaken in Botswana enrolled a total of 1,219 HIV-uninfected heterosexual male and female participants in the age range of 18 to 39 years. These individuals were randomly assigned to take a daily TDF/FTC (*Truvada*) pill or a placebo pill. The study participants were provided with comprehensive HIV prevention, services which included testing and treatment for sexually transmitted infections that could make them susceptible to the virus. The other prevention measures included male and female condoms and intensive risk-reduction behavioural counselling. HIV testing was conducted on all participants before they were enrolled, and it was determined that three participants were HIV-infected at the time of enrolment. Other reasons led to the exclusion of 16 of the participants. This meant that the study participants who were HIV negative and who enrolled in the trial analysis were reduced to 1,200 of which 54.7 percent were male and 45.3 percent were female.

In the study, the drug *Truvada* was given to 601 participants. From this number nine became infected with the HIV during the study. At the same time, of the 599 participants that were put on a placebo pill, 24 became infected with the virus. This statistically represented a 62.6 percent reduction in risk of HIV infection. For those participants who consistently adhered to the medication and were known to have a supply of study drugs, the risk of HIV infection was reduced to 77.9 percent. Following this improved result, further analysis that needed to determine the level of adherence and the amount of detectable drugs in the blood was needed in order to ascertain effectiveness.

The use of *Truvada* in reducing the risk of HIV infection did not present any significant safety concerns, as participants only reported vomiting, nausea and dizziness

during the study. This was consistent with other PrEP studies. The researchers acknowledged that participants assigned to receive the study drug, were more likely than those assigned to the placebo arm to report nausea, vomiting, and dizziness.

The drug *Truvada*, which is a combination of *Tenofovir* and *Emitricitabine*, has meanwhile been approved by the American Food and Drugs Agency and it has been allowed for use in combination with other anti-retrovirals for the treatment of HIV-1 infection in adults and paediatric patients 12 years of age and older. *Truvada* is also approved for the prevention of HIV infection. The findings of the two studies Partners PrEP and the CDC TDF indicated that *Tenofovir* alone was as effective as *Truvada* for prevention of heterosexual transmission. This may, however, not be the case with men who have sex with other men (MSM). The WHO recommends that a combination of *Tenofovir* and *Truvada* be used for same sex serodiscordant couples as evidence of effectiveness and safety exists for male to male penetrative sexual relationship of this nature (WHO 2012, 6).

In order to implement PrEP and scale it up to the entire population in a country, a number of factors have to be put into consideration. PrEP should only be used among individuals who have been tested for HIV and have been confirmed to be HIV-negative. Due to factors associated with HIV testing like the so-called window period, it will be necessary to conduct regular HIV testing for those considering to use PrEP. In addition, individuals who will be considering PrEP use must also be evaluated for other health conditions that may impact PrEP use. As a warning to the general population, PrEP has only showed partial efficacy and should not be seen as the first line defence against HIV. The effectiveness that was shown in clinical trials was partly due to other measures that were put in place, such as regular HIV testing, condoms, and other methods of prevention that have already been proven. The would-be user of PrEP should also be aware that the strategy does currently not have an approved and recommended dosage and that taking PrEP daily is critical for the prevention of infection. In most PrEP trials, only a daily dosage was evaluated. PrEP should only be administered with consultation from medical doctors, and taking into consideration the doctor per patient ratio in most developing countries which indicate a shortage of doctors in most hospitals, implementing PrEP would present a challenge, especially due to the fact that it must be

obtained and used in close collaboration with health care providers who must ensure regular HIV testing, risk reduction, adherence counselling, and careful safety monitoring.

The clinical trials on PrEP, to determine its effectiveness in reducing HIV, have mostly been carried out among heterosexual men and women and among men who have sex with men. Recent studies indicate that there are no data available on its benefits or risks among injection drug users. In the PrEP trials mentioned in this chapter, pregnant and breastfeeding women were excluded from participation in PrEP trials. This has left a gap and has made it difficult to recommend the use of PrEP for women during conception, pregnancy, or breastfeeding.

Research on determining resources that are required for PrEP implementation revealed that the cost of PrEP is high, but the cost per infection averted was significantly offset by future savings in lifelong treatment for couples who have multiple partners who are likely to spend less on condoms and other prevention methods. Some studies have revealed that PrEP could be cost-saving overall. The Partners in their analysis of the cost of PrEP implementation indicated that it was between US\$6000 and \$66000 per HIV infection averted. The savings per quality-adjusted life year (QALY), which is a standard measure of cost-benefit, was between \$260 and \$4900. The cost analysis of PrEP on less risky sexual behaviour indicated that the cost per HIV infection averted was between \$0 and \$26000. The cost per QALY gained was between minus \$200 (cost-saving) and \$1900 (WHO 2012a, 7).

Matters dealing with feasibility may also be an important consideration in the decision to implement PrEP in certain settings. A 2012 WHO report shows that oral PrEP for heterosexual HIV serodiscordant couples has proved feasible in various trial setting. But issues concerning adherence to daily oral medication may prove challenging over longer periods of time. Adherence remains a challenging aspect of ART treatment worldwide. The decision to recommend PrEP as an HIV prevention method was made due to the positive balance of benefits and harms based on high quality evidence and acceptability in the values and preferences review, feasibility in trial settings, and potential cost-effectiveness. As a new initiative to prevent HIV infection, PrEP trials have not adequately addressed the issues of resource use and feasibility in non-trial

settings. The long term health effects of *Truvada* in HIV-uninfected individuals or among those who become HIV-infected while on PrEP are still unclear. The factors that may determine the effective implementation of PrEP are compounded by other matters concerning sexual risk behaviour and adherence to PrEP medications that might be different outside a trial setting. These reasons make the recommendation for PrEP implementation ethically controversial, in particular in the Zambian context.

## **2.2 CONCLUSION**

The methods of HIV prevention mentioned in this chapter, are part of a global effort to fight the deadly disease referred to as AIDS that result from the HI-virus. Reviewing the available methods of HIV prevention as it has been done in this chapter, provides an insight into the best policy to take regarding the adoption of PrEP. The earlier barrier methods of prevention, such as the condom have proved to be partly successful in reducing HIV infections. Though not 100 percent effective, these methods have remained a very important prevention measure, even though their use has raised worldwide controversy, especially with conservative religious groups.

The condom, so to speak, has bought some time for the HIV researchers and other stakeholders to fashion other methods of prevention that have existed without recognition. Take, for example, male circumcision. It has been a practise for a long time, but it is only recently that researchers have been able to unmask its potential of preventing not only HIV but also other sexually transmitted infections, such as HPV. If the potential for male circumcision had been known earlier, there would probably have been fewer HIV infections and fewer cervical cancer cases in the world. This scenario should invite serious consideration by would-be PrEP implementers, who should begin to ponder on the potential of PrEP in preventing HIV infections and what actions to take regarding its adoption, with serious consideration of possible benefits and harms to the Zambian society.

## CHAPTER 3

# THEORETICAL FRAMEWORK

### 3.1 INTRODUCTION

This chapter explains the theory and principle that was used in the ethical assessment and that guided the collection of data in this study. The ethical assessment of the adoption of Pre-Exposure Prophylaxis (PrEP) will employ Utilitarianism and the Precautionary Principle. The decision to use Utilitarianism and the Precautionary Principle emanated from existing research in which this theory and this principle have been used in the field of public health ethics, as shall be highlighted in this chapter. In the following, I shall outline the Utilitarian theory and the Precautionary Principle.

### 3.2 UTILITARIANISM

Utilitarianism is a type of consequentialism. Consequentialism holds that the rightness or wrongness of an action is a function of its results or outcomes. According to consequentialism, it is not an actions intrinsic nature that determines its rightness or wrongness. The classic origins of utilitarianism are found in the writings of Jeremy Bentham during the period 1748 to 1832, as well as in the writings of John Stuart Mill during the period 1806 to 1873 (Beauchamp and Childress 2009, 337). Bentham is the one who coined the term 'utilitarianism'. He is the first person to have plainly used the word 'utility' for describing the feature that makes an action right, and subsequently Bentham used the term 'Principle of Utility' or the phrase 'Principle of the Greatest Happiness' in order to characterise his views. John Stuart Mill, who was the godson of Bentham, made utilitarianism popular. He used the doctrine to champion individual freedoms as well as to push for the emancipation of women, and like Bentham, Mill associated happiness with pleasure and unhappiness with pain. After Mill, another philosopher who lived during the period 1838 to 1900 by the name of Henry Sidgwick, the last of the nineteenth century utilitarians, developed and refined utilitarianism as a moral philosophy and consequently brought it to full intellectual development (Shaw 1999, 8-9).

The basic idea of utilitarianism is that an action is morally right if it has better or at least not worse consequences than any other alternative that is available to the agent. Utilitarianism is therefore the most outstanding of consequentialist theories. The utilitarian theory proposes that an action or policy is right if and only if it produces at least as much good as anything else the agent could have done in the circumstances, otherwise it is wrong. Utilitarian assumptions and arguments have played a very influential role in politics and economics. The utilitarian tradition has also been very influential especially in shaping public policy (Mulgan 2007, 2). There are two basic forms of utilitarianism, the first form, *act utilitarianism*, is concerned with individual actions and takes them to be right if they maximize the good. The second form, *rule utilitarianism*, deals with rules or moral principles that will maximize the good (Pratt 1993, 219, 234). In this dissertation, a contemporary version of act utilitarianism will be used.

In what follows, I shall explain the main components of the contemporary version of utilitarianism that will be employed in the study: welfarism, universal consequentialism, equal consideration, expected consequentialism, direct consequentialism, aggregate consequentialism, total consequentialism, and maximizing consequentialism (Sinnott-Armstrong, 2011).

### **3.2.1 Welfarism**

Utilitarianism focuses on the value of well-being which is analysed in terms of happiness, pleasure, welfare, and preference satisfaction. In welfarism, whether an action is right or wrong depends only on the contribution to the well-being of those affected by them. The understanding in this statement is that in order to know whether an act is right or wrong one must try to find out whether it makes the lives of those affected better or worse.

Well-being is therefore the only thing that is to be valued for its own sake. Other things are to be valued only because they are means to it and therefore they have only instrumental value. Take, for example, health. It is usually valued because it is a means to well-being (Shaw 1999, 36-37). Applying utilitarianism to the adoption of PrEP, the

question that should be asked is whether the consequences of the adoption of PrEP make the lives of all affected better or worse.

### **3.2.2 Universal Consequentialism**

This second element asserts that moral rightness depends on the consequences for all people or sentient beings. The understanding is that one has to take into consideration the consequences of actions on every one affected and therefore what should be promoted is the well-being of everyone affected.

Utilitarianism, when considered in PrEP adoption, should be seen to be universalistic in the sense that it considers the consequences of PrEP on the well-being of everyone who will be affected by this policy. For instance, if PrEP adoption would affect all the 13 million people in Zambia, then the effects of PrEP should be considered on each of the 13 million people in Zambia. The total effect of the adoption of PrEP should be considered on all whose well-being will be affected.

### **3.2.3 Equal Consideration**

In determining moral rightness, the well-being of one person matter just as much as the well-being of any other person. In short all who count should count equally. This aspect of utilitarianism stresses the need for impartiality, implying that using the utilitarian approach in the ethical assessment of the adoption of PrEP, all those affected by the implementation of PrEP must receive impartial consideration.

Impartiality requires treating equal cases equally regardless of the individuals involved. This means that everyone should be treated with the same degree of respect without regard to individual characteristics. Based on this aspect, moral judgment should be formed without regard to personal preference and interests. Applying utilitarianism in PrEP adoption should therefore emphasise on an unbiased evaluation, without regard to a person's race, sex, nationality, and economic circumstances (Beauchamp et al. 2008, 14).

### **3.2.4 Expected Consequentialism**

The rightness of an action depends only on its reasonably expected consequences, as opposed to actual consequences. In order for utilitarianism to be used in the ethical assessment of the adoption of PrEP, there is need to base ethical decision making on the reasonably expected consequences of PrEP instead of actual consequences of PrEP adoption because the later are not known when the decision must be made.

Based on the actual consequences perspective, the adoption of PrEP could turn out to be a wrong action because of some unforeseen disastrous consequences. On the other hand, the adoption of PrEP could turn out to be the right action if the decision to adopt PrEP is based on the reasonable expected consequences.

### **3.2.5 Direct Consequentialism**

According to the version of utilitarianism used in this study, the moral rightness of an action depends only on the consequences of that act itself, not for instance on the agent's motive. Therefore, only the consequences of adopting PrEP determine whether the decision to adopt PrEP is morally right, as opposed to the consequences of the agent's motive of adopting PrEP. The agent in this case is the Government or other implementing agents, such as private clinics and NGOs.

### **3.2.6 Total Consequentialism**

The moral rightness of an action depends only on the total net good in its consequences, as opposed to the average net good or goods per person. Utilitarianism says that the right action is the one with the best effects. In order to choose the right action, one must consider all effects of all possible actions. Therefore, direct and indirect effects, immediate and remote consequences, and positive and negative effects must be considered. Consequently, the net effect of the adoption or the non-adoption of PrEP on the well-being of those affected should be considered and will determine what the morally right policy is.

### **3.2.7 Aggregate Consequentialism**

Utilitarianism requires taking together the values of the consequences of each affected party to an overall value for all affected. One way of aggregation is adding, but this is

unrealistic in this study because it requires numbers. Therefore, a holistic approach that will consider all factors will be employed in this study.

In considering the adoption of PrEP, aggregation in the sense of adding would be unrealistic, therefore ranking the total sets of consequences created by the adoption of PrEP without breaking them down into numerical parts will be used; for instance, by comparing the consequences that would result from adopting PrEP and the consequences of not adopting PrEP. If the consequences of adopting PrEP are, taken together, better than the consequences of not adopting PrEP, then it follows that the action of adopting PrEP is the morally better action to take.

### **3.2.8 Maximizing Consequentialism**

The Utility Principle emphasises that an ethical decision should maximize the well-being of the affected parties. That is to say, an action is morally right if there is no alternative that has better consequences. For instance, if one has the choice between options A, B, C and A is better than the other options in terms of maximizing the good and will thus result in more well-being than B and C, then A should be chosen as the right action.

In the field of HIV prevention, if the adoption of PrEP would result in more well-being to the society as compared to the non-adoption of PrEP then PrEP should be adopted. Therefore, in this research, the well-being of stakeholders that will be affected by the adoption of PrEP and the alternative policies need to be systematically identified.

After considering the different elements of utilitarianism, the Utility Principle, which states in brief the utilitarian view, can be stated as follows: “An act is morally right if and only if there is no other possible act that has, overall seen, better consequences”. In other words, the decision to adopt PrEP would be morally right if and only if there is no other possible action that has, overall seen, better consequences. Therefore, the application of utilitarianism requires that data on the positive and negative effects that would result from the adoption of PrEP in Zambia must be collected.

An example of how utilitarianism has been used to make an ethical decision can be drawn from the 2009 crisis in the food industry in the United States of America, where close to 4000 products of the Peanut Corporation of America (PCA) were recalled due to an outbreak that resulted in illness and deaths, following a contamination of the

products by a bacteria called Salmonella which causes diarrhoea, fever, and abdominal cramps 12 to 72 hours after infection. On January 13, 2009 PCA issued a recall of the products made over the past six months, after the first five deaths and 400 illnesses were linked to Salmonella poisoning. The company had on several occasions identified the Salmonella in its products during its own testing programs but decided to release the product anyway even though there existed a chance of contamination.

The failure of PCA to inform the authorities and the public about the possible contamination of its products resulted in legal and ethical dilemmas. Ethical dilemmas have the potential to result in someone or something being hurt as was the case in the Salmonella poisoning, which resulted in deaths and illnesses thereby affecting the well-being of not only those affected and infected individuals but also the entire food industry in America, which suffered financially.

An ethical theory that can be used to analyse this peanut butter recall crisis is utilitarianism, which emphasises the end result of an action. The end result being the halting of further deaths and illnesses resulting from recalling the Salmonella contaminated products, which resulted in the greatest good and therefore justified the action to do so. In simpler terms, the end justified the means (Roman and Moore 2012, 318).

### **3.3 THE PRECAUTIONARY PRINCIPLE**

General ethical principles play a pivotal role in certain processes of moral reasoning and ethical decision making in bioethics and public health. Research shows the beginning of the Precautionary Principle emanated from raising concern on the sustainability of the environment that led to national and international environmental policies that were characterized by a curative model towards the natural environment.

#### **3.3.1 Historical Background**

The term “Precautionary Principle” is a translation of the German word “Vorsorgeprinzip”. The word “Vorsorge” means forecaring. When translated further, forecaring does not only mean caution, but it also raises the aspect of foresight and preparation when the principle is applied to human health and the environment. The

growth in populations and the subsequent effects of industrialization resulted in increased human activities that consequently led to a rise in environmental impacts which caused damage to the environment. This situation meant that the environment required some help in repairing the damage that arose, as it could not cure itself. Governments responded to these environmental impacts by putting in place measures aimed at protecting, preserving, and restoring the global ecosystem by requiring polluters to pay the cost of pollution. The Polluter Pays Principle led to another preventive policy that aimed at limiting the damage to what could be repaired. However, the emergence of increasingly unpredictable, uncertain, and unquantifiable but possibly calamitous risks like those linked to Genetically Modified Organisms, led to another model of protecting humans, referred to as the Precautionary Principle (PP). The Precautionary Principle is a scheme aimed at dealing with scientific uncertainties (UNESCO 2005, 7).

The Precautionary Principle was developed from an environmental consideration. Today the principle has matured to cater for a variety of ethical concerns with a far broader scope that is capable of providing a policy guide even in the field of public health. Research has shown that ethical decision making in public health requires more than just calling for ethical principles and rules. Therefore, the Precautionary Principle must be taken into account when dealing with problems concerning feasibility, effectiveness, efficiency, uncertainty about benefits and risk, cultural pluralism, and political procedures that are involved in public health. Studies have shown that this can be done by specifying rules and principles that are enshrined in the Precautionary Principle model of prevention (Coughin, 2012).

The Precautionary Principle falls under the wings of the United Nations Educational Scientific and Cultural Organization (UNESCO). The Precautionary Principle is also part of the 1992 Rio Declaration on Environment and Development, the United Nations Framework Convention on Climate Change and the World Trade Organization's (WTO) Agreement on Sanitary and Phytosanitary Measures (SPS Agreement) of 1994. Today, the Precautionary Principle is incorporated into the Biosafety Protocol established in January 2000 in Montreal (UNESCO 2005, 7)

According to a report by UNESCO, the Biosafety Protocol gave shape to the legal framework of the Precautionary Principle and subsequently UNESCO integrated the role of the World Commission on the Ethics of Scientific Knowledge and Technology (COMEST). Together they focus on matters concerning the impact of complexity and on the development of scenarios for decision making (UNESCO 2005, 8).

### **3.3.2 The Precautionary Principle Explained**

This study shall employ the version of the Precautionary Principle that has been defined by the Commission on the Ethics of Scientific Knowledge and Technology (COMEST). According to this definition, the Precautionary Principle is comprised of five parts as follows: When (i) human activities may lead to morally unacceptable harm that is (ii) scientifically plausible but (iii) uncertain, there is (iv) a need to act now, and it is (v) currently impossible to reduce the uncertainties, proportional actions shall be taken to avoid or diminish that harm (UNESCO 2005, 14, 31, 34)

In what follows, I shall explain the definition. According to COMEST “Morally unacceptable harm refers to harm to humans or the environment that is threatening to human life or health, or serious and effectively irreversible or inequitable to present or future generations, or imposed on without adequate considerations of the human rights of those affected”. The determination of plausibility in this case should be “based on scientific analysis which should be ongoing so that chosen actions can be subject to review”. In the definition, “Uncertainty may not be limited to causality but may apply to it or to the bounds of possible harm”. “Actions are interventions that are undertaken before harm occurs, actions also seek to avoid or diminish the harm. Actions should be chosen that are proportional to the seriousness of the potential harm with consideration of their possible positive and negative consequences and with an appraisal of the moral implications of both action and inaction. A participatory process should therefore lead to the choice of an action to be taken” (UNESCO 2005, 14).

The Precautionary Principle is therefore activated by the reasonable proof of possible harm, in cases where it is not possible to adequately describe and quantify the risk due to scientific uncertainty and ignorance (Beauchamp and Childress 2009, 229).

Other factors that need to be considered are whether there exist considerable scientific uncertainties or even ignorance about the anticipated harm, for instance the harm that may result from the lack of sustained and effective counselling which is important in maintaining ARV adherence.

The levels of counselling to non-experimental PrEP participants, if PrEP is adopted in Zambia, will definitely be different when compared to the intense counselling that was undertaken in PrEP clinical trials. Counselling patients on PrEP could strain the already overburdened capacity of the HIV related delivery system in a low income country such as Zambia, which depends on donor funding for the current ARV supply. The other factor that needs to be considered is that the drug *Truvada* that has been used in PrEP poses a risk of liver toxicity. This is evident in those who have been on this HIV treatment drug, and results of liver tests have revealed scenarios of possible harm that are scientifically reasonable. Other factors to be considered are whether there is capacity for active surveillance for resistant viral strains that may develop and undermine the current treatment strategies that are employing *Truvada* and *Tenofovir*, the two drugs used in PrEP.

Other relevant factors for applying the Precautionary Principle in this research are whether it could be impossible to reduce the uncertainties posed by the adoption of PrEP in Zambia, without at the same time increasing the ignorance of other relevant factors by higher levels of generalization and idealization. The potential harm for PrEP use could indeed be sufficiently serious or even irreversible for present or future generations or otherwise morally unacceptable in that PrEP is not 100 percent effective in preventing HIV infection and it is not a replacement for other HIV prevention measures (Arleen et al. 2011, 3-4). However, regardless of the challenges posed by the impending implementation of PrEP such as the high cost involved, there is a need to act now since effective counter-action later will be made significantly more difficult or costly at any later stage.

An example of the use of the Precautionary Principle to a public health issue is the case of the denial by the Food and Drug Administration (FDA) of *Thalidomide*, which is a hypnotic drug used to prevent morning sickness during pregnancy. The drug *Thalidomide* was found to be metabolized to an oxide that causes severe birth defects

and can also result in nerve damage. The action by the FDA of not allowing *Thalidomide* is seen as an example of the success of the Precautionary Principle (Nelson, 2012). Another example of the use of the Precautionary Principle is on modified tobacco products by the Food and Drugs Administration (FDA) and the United States Department of Health and Human Services. A workshop focused on how the FDA should act towards legislation aimed at authorizing tobacco products and claims of modified risks in tobacco products (Gross 2011, 5).

### **3.4 CONCLUSION**

In conclusion, the theory of Utilitarianism and the Precautionary Principle that have been outlined in this chapter will be used for ethical evaluation of the adoption of Pre-exposure Prophylaxis as an HIV prevention method. They will also guide the data collection for this study. What data are relevant to this study is determined by the respective theory and principle. Part of the data needed for the application of Utilitarianism and the Precautionary Principle were collected from secondary sources because of the scientific nature of Utilitarianism and the Precautionary Principle and their defining components.

## CHAPTER 4

# FINDINGS, DISCUSSION AND ANALYSIS

### 4.1 INTRODUCTION

The present chapter addresses the second objective of the study, that is, it investigates the current situation of oral Pre-exposure Prophylaxis in Zambia. The chapter provides information collected by using semi-structured interview schedules that were administered to health workers and NGO representatives in the field of HIV/AIDS in government and non-government organisations in Lusaka. Pre-exposure Prophylaxis is the newest HIV prevention method, where HIV negative individuals take anti-retroviral drugs to prevent HIV infection. On 12 July, 2012 the anti-retroviral drug *Truvada* was approved for prevention of HIV infection by the American Food and Drugs Agency (FDA). At the time of writing this dissertation, Zambia had only conducted one consultative meeting with stakeholders to discuss PrEP. Therefore, information as well as informants for this study were scanty. Regardless of this factor, the researcher managed to collect raw data by purposively choosing and interviewing 20 HIV/AIDS experts who included doctors and clinic officers involved in anti-retroviral therapy.

In the attempt to interview more people on PrEP, the researcher was told by officials of some organizations, which were chosen as research sites, that there were no credible respondents who could be interviewed on PrEP in their organizations because Zambia had not yet adopted PrEP as a means of preventing HIV infection for HIV negative individuals and that their organizations did not have any PrEP programmes or experts who could confidently discuss issues involving PrEP. This situation caused the researcher to focus on the expertise of the respondents, rather than focusing on the quantity of interview respondents for the study. The data that was subsequently collected proved to be sufficient for an ethical assessment of PrEP.

### 4.2 MATERIALS AND METHODS

The present study was conducted in Lusaka District. Face-to-face interviews were conducted in the months of October and November 2012 with representatives from government and non-government organizations. The interviewees included doctors,

clinic officers, a nurse and other officers working in the HIV prevention sector. Before the interviews were conducted, a pilot study was conducted to clarify the interview schedule. At the commencement of the interviews, the participants were informed that their responses would be treated with confidentiality.

The respondents who were interviewed were from organizations such as the University Teaching Hospital in Zambia, Ministry of Health, Centre for Infectious Diseases in Zambia, National AIDS Council, Kabwata ART clinic, Kara Counselling Centre, Churches Health Association of Zambia, Zambia Medical Association, ZAMBART, Corridors of Hope, Treatment Advocacy and Literacy Campaign (TALC), and Zambia Led Prevention Initiative. Because PrEP is very new and it has not yet been adopted in Zambia, twenty face to face interviews were conducted with twenty experts in HIV/AIDS prevention, using a semi-structured interview schedule and a recorder.

In the interview schedule (see Appendix) the questions on descriptive characteristics of the respondents were followed by questions on PrEP. The participants were first asked about their professional qualifications, position in the organization and their involvement in HIV prevention. All interviews were conducted in English. The data that was collected using the interview schedule was the data needed for ethical evaluation. The same interview schedule was administered to respondents in government organisations and to non-governmental organizations.

#### **4.3 FINDINGS**

The researcher interviewed 20 people. They included doctors, clinic officers, a nurse and other experts. Of the 20 persons, 12 respondents had Master's degree qualifications, five respondents had Bachelor's degrees in medicine only, two respondents had Diplomas in medicine and one had a Certificate in nursing.

These respondents provided the primary data for the study. A semi-structured interview schedule was administered to those in government and non-governmental organizations. A recorder was also used to record the interviews. Table 1 shows the descriptive characteristics of the respondents in terms of qualifications.

This purposively chosen sample consisted of ten males and ten females. In terms of qualifications, of the 12 respondents who had a Master's degree in either public health

or infectious diseases, only two respondents were not qualified medical doctors. In fact, one of the two had a Master's degree in business administration with over ten years of experience in HIV prevention and she was in charge of HIV prevention in the organization. Three respondents had Bachelor's degree qualification only. Four respondents had a Diploma in clinical medicine. One respondent had a Certificate in nursing and was in charge of anti-retroviral treatment in the respective organization with extensive experience in ART.

<b>Gender</b>	<b>N</b>	<b>%</b>
Male	10	50
Female	10	50
<b>Qualification</b>	<b>N</b>	<b>%</b>
Master's degree	12	60
Bachelor's degree only	3	15
Diploma in clinical medicine	4	20
Certificate in nursing	1	5

Table 1: Descriptive characteristics of respondents

In order to clearly present the findings and discussion of the research, seven themes were used: PrEP knowledge, PrEP side effects, PrEP benefits, and PrEP programme concerns, early against late adoption, general harms and PrEP versus other options.

#### **4.3.1 PrEP Knowledge**

Of the 20 respondents, two (10%) responded that they have never heard of Pre-exposure Prophylaxis (PrEP) being used as an HIV prevention method for HIV negative individuals, while eighteen (90 %) of the respondents stated that they have heard of PrEP being used as an HIV prevention method for HIV negative individuals. When asked what medication is used for PrEP, 65 percent mentioned *Truvada*, 15 percent mentioned *Nevirapine* and ten percent of the respondents mentioned *Zidovudine* as the medication being used for PrEP. Ten percent did not know what medication is used for PrEP (see Chart 1 below).

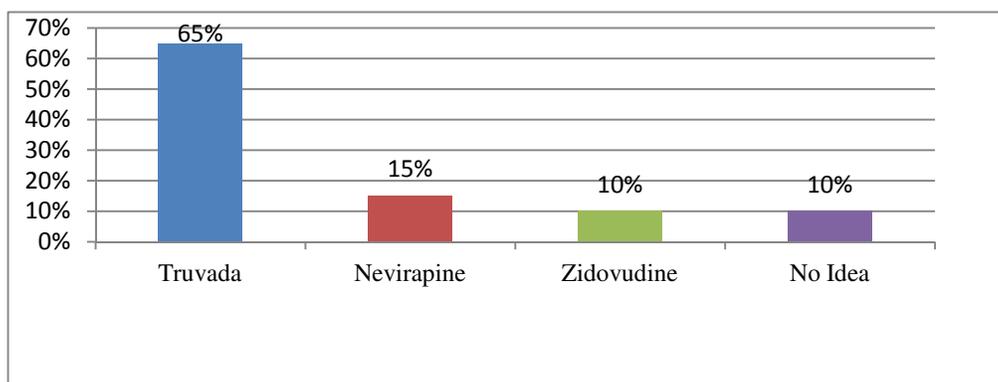


Chart 1

Of the 20 individuals from different organizations who were interviewed, eighteen (90%) respondents stated that they did not know any organization that has already adopted PrEP in Zambia. However, two respondents, both medical doctors who are directly involved in HIV/AIDS at a very high level in Zambia, said that they know some organizations which are implementing PrEP in Zambia, but neither of the two respondents could mention the names of the organizations.

The 20 participants were asked which institutions should be allowed to implement PrEP. Eight interviewees from different organizations responded that all ART centres which operate in accordance with the PrEP guidelines should be allowed to implement PrEP. Nine respondents said that only government ART centres should be allowed to implement PrEP and they put forth reasons such as the following; the government is directly responsible for the health of its citizens; this would avoid prescription errors; to see to it that there is no misuse of drugs; and that the government would be able to better control the PrEP programme in terms of monitoring.

Responding to the same question, two respondents said that only organizations that deal with high risk groups such as men who have sex with men, or organizations that deal with sex workers should be allowed to implement PrEP. One respondent preferred non-governmental organizations, citing the reason that non-governmental organizations deal with fewer people on anti-retroviral treatment. This would provide an opportunity for other organizations to learn from their experiences with PrEP

implementation and it would help in the sensitization process of PrEP (see Table 2 that summarises these findings).

Response	N	%
All ART centres with PrEP guidelines	8	40
Only government ART centres	9	45
Organizations which deal with high risk groups	2	10
Non-governmental organization	1	5

Table 2: Responses of interviewees on who should implement PrEP

The information in Table 2 has been presented in Chart 2 to clearly show the variations in responses by the interviewees who took part in this study.

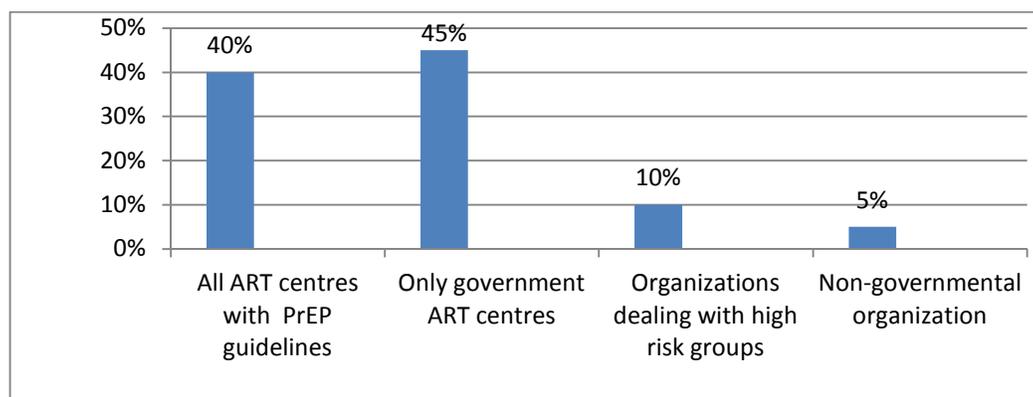


Chart 2: Summary of responses on who should implement PrEP

In the interviews, the respondents were asked to state the rate of effectiveness of PrEP medication (*Truvada*) in preventing HIV infection. Of the 15 respondents who gave an answer to the question, one respondent estimated PrEP effectiveness to be between 60 to 80 percent. Another respondent stated that PrEP is 47 percent effective, and one respondent said PrEP is 80 percent effective. Two (13.3%) respondents stated that PrEP is 50 percent effective. Of the 15 respondents, four (26.6%) respondents estimated PrEP effectiveness to be at 70 percent. Out of the 15 respondents, one respondent stated that PrEP is 75 percent effective. Two respondents stated that PrEP is 90 percent effective when *Truvada* is used with strict adherence, and three (20%) respondents estimated PrEP effectiveness to be between 60 to 62 percent.

The remaining five (33.3%) respondents opted not to give an estimate of PrEP effectiveness, although two respondents, out of the five remaining respondents, mentioned that PrEP is not 100 percent effective. The remaining three respondents said they did not know the exact rate of effectiveness.

In a follow-up question, all the 20 respondents were asked on the impact that PrEP effectiveness would have on HIV infections in Zambia. Of the 15 persons who gave estimated responses, fourteen (93.3%) said that it would lead to reduced HIV infections. Only one respondent said that it may worsen the HIV pandemic because it is not 100 percent effective.

Only two participants from the five subjects who did not give an estimate of PrEP effectiveness, said that there is no data for the Zambia population on PrEP. This represented ten percent of the 20 respondents in the study. One respondent from the five participants who did not give an estimate of PrEP effectiveness said that it will complement other HIV preventive methods, thereby representing five percent of the total number of respondents. Only one respondent out of the 20 said that there is need for research on PrEP in the Zambian population in order to determine how the rate of effectiveness would affect HIV in Zambia. One respondent stated that at 70 percent effectiveness of PrEP, there is a chance of reaching zero HIV infection rate.

#### **4.3.2 PrEP Side Effects**

When the participants were asked whether the medications used for PrEP had any harmful effects on the human body, 13 (65%) respondents said “yes”, while seven (35%) said “no”.

Regarding the harmful effects of PrEP medication, those who responded in the affirmative to PrEP having harmful effects, referred to the harmful side effects of *Truvada*. Of the 13 respondents who said “yes”, 11 participants cited renal toxicity or kidney failure, six cited edema or accumulation of excess fluid between body tissues cells. Of the 13 respondents who answered affirmatively, two mentioned confusion and one mentioned lung problems. Four said reduced bone density and another four mentioned liver toxicity, while three said nausea and vomiting. Five respondents cited gastral intestinal disturbances. Of the 13 respondents one mentioned loss of appetite and

two mentioned rash, again two cited anaemia, while one respondent mentioned skin discoloration (yellowing of skin). Bone pains, elevated creatinine levels, mood changes, flushes or feeling of discomfort, lactic acidosis, abnormal skin sensations such as burning sensations on the skin and weight loss were each mentioned by one respondent. Abnormal body fat distributions, diarrhoea, rash, and resistance of HIV to *Truvada* when infection occurs while one is on PrEP, were each mentioned by two respondents. Table 3 below shows the types of harms that are associated with the use of *Truvada* in PrEP. The tabulation in percentages is based on the 13 (65%) who responded in the affirmative to harms of PrEP.

<b>Types of effects</b>	<b>N</b>	<b>%</b>
Renal toxicity or kidney failure (increased creatinine levels)	11	84.6
Edema or accumulation of excess fluid between body tissue cells	6	46.2
Confusion	2	15.4
Lung problems	1	7.7
Reduced bone density	4	30.8
Liver toxicity	4	30.8
Nausea and vomiting	3	23.1
Gastral intestinal disturbances	5	38.5
Loss of appetite	1	7.7
Rash	2	15.4
Anaemia	2	15.4
Skin discoloration ( yellowing of skin)	1	7.7
Bone pains	1	7.7
Abnormal skin sensations such as burning sensations on the skin	1	7.7
Weight loss	1	7.7
Abnormal body fat distributions	2	15.4

Table 3: Summary of responses on harms of PrEP based on the use of *Truvada*

#### 4.3.3 PrEP Programme Concerns

The third theme is a presentation of data that concerns PrEP with regard to programme implementation by the stakeholders. With regard to the cost of the anti-retroviral treatment, the interviewees were asked whether they thought the implementation of

PrEP can affect the cost of anti-retroviral treatment in Zambia. Of the 20 respondents interviewed, 18 (90%) respondents said “yes”, while two (10%) respondents said “no”. This is presented in Chart 3 below.

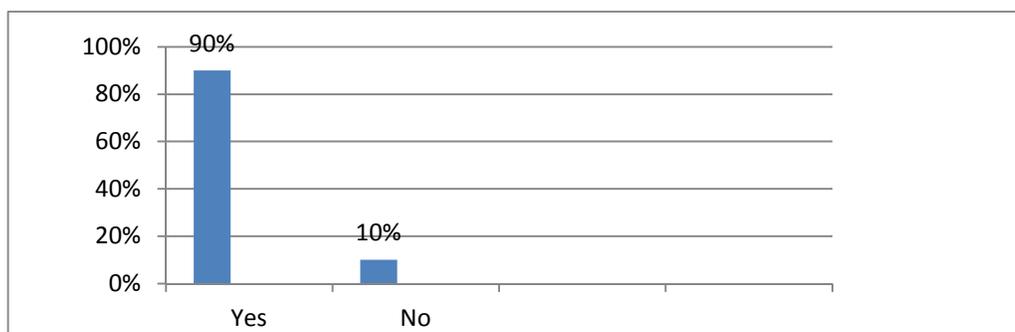


Chart 3

In a follow-up question, those who responded affirmatively to the preceding question were asked to state how adopting PrEP would affect the cost of anti-retroviral treatment in Zambia. All 18 respondents gave a similar response, declaring that there will be a cost variation on *Truvada* depending on the circumstances.

Of the 18 participants, one respondent (representing 5.6 percent of the total number of respondents) said that ART will be costly as those who will be screened for HIV before being put on PrEP might be found HIV positive and will have to be put on full anti-retroviral treatment. Of the 18 participants, two (11.1%) respondents, a nurse and a clinic officer from different ART clinics, asserted that the cost of *Truvada* would go up because adopting PrEP would lead to an increased demand for the drug. One of the respondents stated in a quite similar response, “nearly everyone would want to take *Truvada* to reduce the chances of contracting HIV, so the cost of the drug would go up and so will the cost of HIV test kits.”<sup>1</sup>

Of the 18 respondents, one respondent stated that the cost of *Truvada* might go down in the long run as fewer people would get infected with HIV, and therefore they may not need to be put on treatment. Two respondents declared that the cost of *Truvada* will rise and this would lead to the drug being found on the black market. One of them said, “The drug *Truvada* might become expensive in private clinics which might have a

<sup>1</sup> The respondent preferred that his name be withheld.

profit motive towards PrEP and this would lead to shortages in the public clinics. If this happens, the drug would only be accessible to the rich”.<sup>2</sup>

A total number of three (16.7%) respondents, out of the 18 persons, said that the cost of *Truvada* will go up in the short term, but in the long term, the cost of *Truvada* will go down because there will be fewer HIV infections and therefore, less need for the drug. As one of the 3 respondents put it, “In the short term, PrEP would lead to more HIV infections, hence there will be need for more resources for HIV testing and adherence support services.”<sup>3</sup>

Referring to the Zambian population, one respondent said that the number of HIV negative individuals is high. Therefore, there would be more requests for the PrEP drug, and this would make the drug more expensive. Another respondent, who is a medical doctor and is involved in anti-retroviral treatment of HIV positive individuals, said “The adoption of PrEP would mean that Zambia would have to budget for HIV negative people also. Therefore, this would raise the cost of ART in Zambia”.<sup>4</sup>

Of the 18 respondents, one respondent said that the cost of *Truvada* would depend on where the drug is purchased. If it is purchased from India as a generic then it would be less expensive. Another respondent, who is a medical doctor with extensive experience in HIV treatment at a clinic in Lusaka, said “PrEP would lead to increased promiscuity. Hence this would lead to more people acquiring HIV and undergoing anti-retroviral treatment, which would then increase the cost of ART”.<sup>5</sup>

Of the 18 respondents who responded affirmatively, two respondents declared that implementing PrEP would lead to a situation where *Truvada* would be sold on the black market as the drug might become expensive. Two medical doctors, both of whom are specialists in disease control, said very bluntly that adopting PrEP would increase the cost of anti-retroviral therapy. Another clinician, who is in charge of anti-retroviral therapy at Kara Counselling Centre in Lusaka, stated that adopting PrEP might be costly because this would probably lead to an adjustment to the price of *Truvada* by manufacturers.

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<sup>2</sup> The respondent preferred that his name be withheld.

<sup>3</sup> The respondent preferred that his name be withheld.

<sup>4</sup> The respondent preferred that his name be withheld.

<sup>5</sup> Personal communication by Dr. Lendy Kasanda (Kabwata ART Clinic).

In a different question, the interview participants were asked whether the implementation of PrEP would result in social and economic (non-medical) harms in Zambia. Eighteen (90%) out of 20 respondents responded affirmatively, while two participants responded negatively (see Chart 4 below).

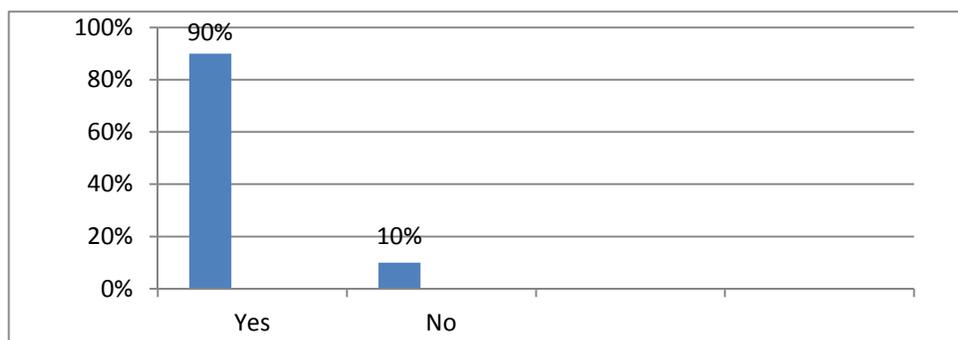


Chart 4

The twenty respondents were then asked to specify the social and economic (non-medical) harms of PrEP. Eleven (55%) respondents stated that the adoption of PrEP would change risk behaviour in a negative way and people would indulge in more risky behaviour.

Again, the cost of implementing PrEP was mentioned when ten (50%) of the 20 respondents said that PrEP would be very costly to the country because it would require more human resource and money to purchase the drugs. Seven (35%) respondents stated that the supply of *Truvada* may not be adequate to implement PrEP because the country depends on donors for the supply of anti-retroviral drugs and those donors might not support the implementation. One respondent stated that if PrEP was adopted this could lead to an increase in other sexually transmitted diseases, which may be expensive to manage. Another respondent, who conducts male circumcision at Chilenje Clinic in Lusaka, said that adopting PrEP may lead to misuse of anti-retroviral drugs. According to this respondent, “People might start using Truvada and other ant-retroviral drugs to boost the growth of their chickens and other poultry at home”.<sup>6</sup>

The misuse of anti-retroviral drugs, if PrEP was to be adopted, was also mentioned by two other respondents, in different interviews and at different sites. One

<sup>6</sup> Personal communication by Linly Mudenda (Chilenje Clinic).

respondent said that adopting PrEP might lead to an increase in serodiscordant couples (where one partner is HIV positive and the other partner is HIV negative) and this, in turn, would lead to more psychological problems in cases where these relationships fail and couples end up separating. Moreover, people might still get infected with HIV because PrEP is not 100 percent effective in preventing HIV infection.

Seven (35%) respondents stated that adopting PrEP would lead to difficulties in monitoring those on PrEP. This would cause drug adherence problems for *Truvada*, and therefore the risk that people would stop or not adhere to treatment was very high. Regarding the issue of adherence, one of the respondents, who did not wish to be named, said, “If people cannot consistently use condoms whenever they have sex why would they take PrEP medication, which has side effects, and this is considering the fact that these people are not even HIV positive.”

One respondent, who is involved in anti-retroviral treatment at the University Teaching Hospital in Lusaka, said “High risk groups who could benefit from PrEP, such as sex workers and men who have sex with men, are not legal in Zambia and there are no well defined risk groups for the implementation of PrEP in Zambia. Therefore it would be difficult to effectively implement PrEP”.<sup>7</sup>

Another respondent stated that adopting PrEP would increase mortality rates in Zambia. Four (20%) respondents from different organizations stated that if PrEP is adopted people might stop using other preventive methods of HIV such as the ABC method. Two (10%) respondents said that adopting PrEP might lead to stigmatization of those who will be put on PrEP. Table 4 below summarizes the numbers of respondents who gave a particular response which is also presented in percentages. The number of respondents per particular response is calculated out of 20 (100%).

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<sup>7</sup> Personal communication by Dr. Royd Mulenga (UTH, Adult Infectious Diseases Centre).

Types of harms	N	%
Increased risk behaviour	11	55
Implementing PrEP would be very costly	10	50
Monitoring/adherence	7	35
Truvada shortage due to dependence on donors	6	30
Increase in other sexually transmitted diseases	1	5
PrEP may lead to misuse of anti-retroviral drugs	3	15
PrEP might lead to an increase in serodiscordant couples	1	5
High risk groups are not legal in Zambia	1	5
PrEP will increase mortality rates in Zambia	1	5
People might stop using the ABC strategy	4	20
PrEP might lead to stigma for those on PrEP	2	10

Table 4: Summary of social and economic (non-medical) harms of PrEP

The social and economic (non-medical) harms of PrEP, presented in Table 4 above, have also been presented in Chart 5 below, which shows the particular responses from the 20 participants who took part in the study.

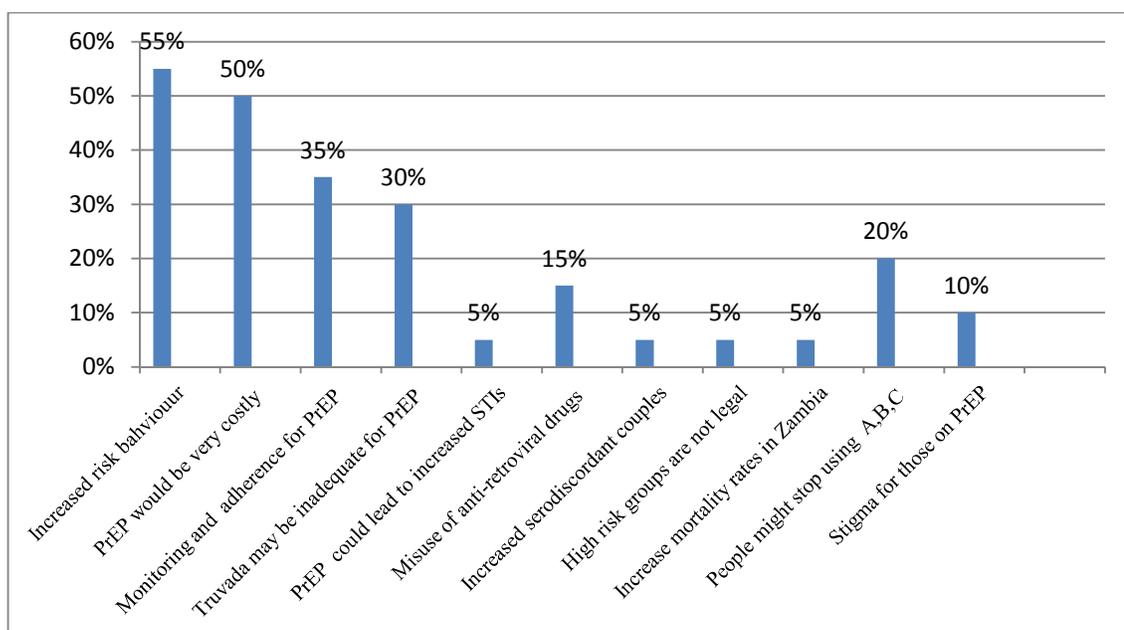


Chart 5: Responses on social and economic (non-medical) harms of PrEP

As the interviews progressed with the 20 individuals that took part in the study, all interviewees were asked whether they thought Zambia is capable of conducting effective adherence counselling for PrEP. Of the 20 respondents who were asked this question 14 (70%) responded in the affirmative. However, six (30%) respondents did not think Zambia can conduct effective adherence counselling for PrEP. They gave reasons such as the lack of manpower, infrastructure and training for health workers. For instance, one of these respondents, who is the officer in-charge of ART at Kanyama ART Centre in Lusaka, said “There is currently a challenge of manpower and bringing in PrEP would strain the already over stretched manpower at the Centre. For instance, there are just three of us dealing with ART at the centre serving the whole Kanyama community.”<sup>8</sup> Another respondent, who said “no” to this question and who is a medical doctor said,

There is too much work for the health workers for them to have an additional responsibility of adherence counselling for PrEP, and the numbers that would want to be on PrEP would be too much, such that it would be hard to even conceive how adherence services will be provided. If Truvada is used the side effects of this drug may be a draw back and the chances that people may develop kidney problems may lead to difficulties in adherence. Also the chances that people will not follow what they are told at the PrEP treatment centre are very high, that is, considering that most people still fail to adhere to condoms.

With regard to HIV risk perception, all 20 interviewees assented when they were asked if they thought PrEP would affect HIV risk perception. The majority, eighteen subjects, explained that if PrEP is adopted people would feel that they are at a low risk of contracting HIV and they will no longer observe the ABC strategies of HIV prevention. One respondent said that there will be positive thinking towards HIV, which will reduce stigma. However, another respondent did not give a clear reason for his view (see Chart 6 below which shows a summary of responses in percentages).

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<sup>8</sup> The respondent preferred that his name be withheld

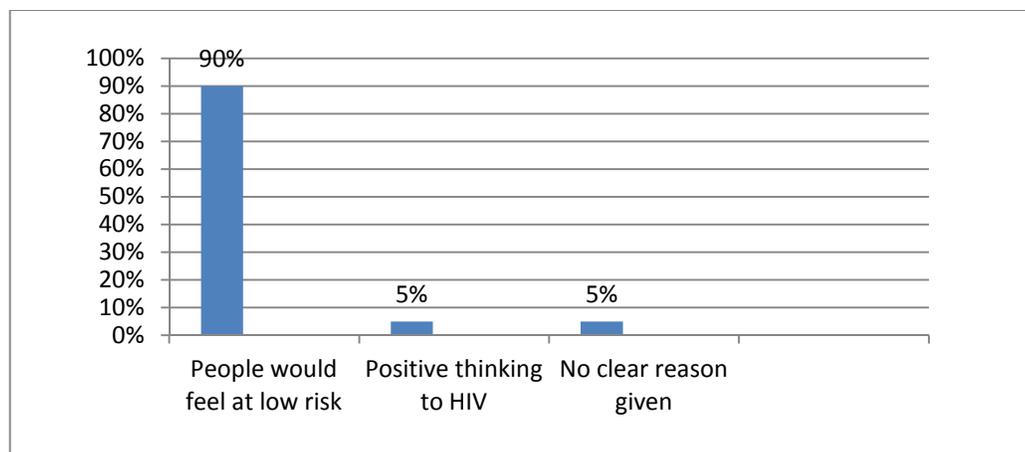


Chart 6: Summary of responses for HIV risk perception

In response to a different question, seven (35%) participants in the study did not think that the adoption of PrEP would affect the provision of anti-retroviral treatment to those who are HIV positive in Zambia. Four out of the seven are medical doctors who had taken part in a consultative meeting on PrEP in Zambia. However, fourteen (70%) respondents said “yes“, that PrEP would affect the provision of anti-retroviral treatment to those who are HIV positive.

Of the 14 participants that responded affirmatively, six (43%) explained that adopting PrEP would lead to a shortage in the provision of the *Truvada* for HIV positive individuals who are on anti-retroviral treatment. One of the six respondents said, “Because the cost may go up at the beginning of PrEP, ethical issues may also arise in the sense that ART will be provided to HIV negative individuals when those who are positive have not been fully attended to.”<sup>9</sup>

Another one of the six respondents, who is a medical doctor specialized in the treatment of HIV and tuberculosis, said:

Those who are not eligible for ART may be taking the ARVs such that those who are eligible may eventually have a problem with access to treatment hence leading to an issue of availability of the drugs. Secondly the pattern of taking HIV drugs may change among those who are HIV positive and are eligible for treatment, as they may start to behave like those who are HIV

<sup>9</sup> The respondent preferred that his name be withheld.

negative and not eligible for treatment but are taking PrEP, which may lead to challenges in adherence to the HIV drugs. For example, in a house which has two people, one HIV positive and another HIV negative and both are taking HIV drugs, one for treatment and the other for prevention, the one taking PrEP may take the drugs at any time and this would influence the one who is positive and who should take the drug at specific times.<sup>10</sup>

The remaining eight respondents (57%) gave similar responses that emphasized the non-availability of *Truvada* and manpower constraints in the health sector, which will be needed for effective treatment of those who are HIV positive and those who are HIV negative, if PrEP is adopted. As one of the eight respondents put it, “there will be a competing need for anti-retroviral treatment, considering the fact that only about 72 percent of HIV infected individuals is accessing anti-retroviral treatment in Zambia. Therefore, adopting PrEP would widen the gap between those accessing treatment and those who are not.”

Regarding the effectiveness of *Truvada* in the treatment of HIV, the 20 interviewees were asked whether they thought adopting PrEP would affect the effectiveness of *Truvada* in the treatment of HIV/AIDS in Zambia. Of the 20 respondents interviewed, four (25%) respondents said “no”. However, there were variations in the explanations from the fifteen (75%), who said “yes” when they were asked how PrEP would affect *Truvada* effectiveness. The majority of the 15 respondents, thirteen persons explained that PrEP would lead to HIV resistance to the drug *Truvada*. However, two of the 15 respondents said that PrEP would affect adherence to *Truvada* if it is not properly implemented. Table 5 and Chart 7 below show a summary of the responses.

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<sup>10</sup> The respondent preferred that his name be withheld.

PrEP affects effectiveness of <i>Truvada</i> in HIV treatment?	N	%
Yes	15	75
No	5	25
Total	20	100

Table 5

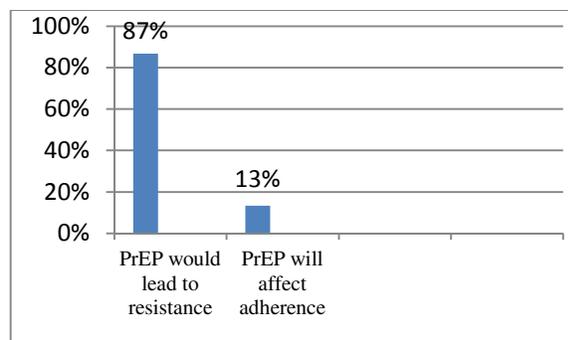


Chart 7

As the interview progressed, the interviewees were asked whether they thought Zambia can conduct effective HIV testing for PrEP, considering the issues that surround the HIV testing, such as the so called window period. Of the 20 respondents, eleven (55%) said that it would. However, nine interviewees (45%) did not think Zambia can conduct effective HIV testing. Of the nine interviewees, four cited reasons concerning the testing procedures, like the non-availability and high cost of the nuclear HIV test and the PCR test which can catch HIV as early as two weeks. Another reason cited was the non availability of the P24 test, which can detect HIV as early as six days after infection. According to one respondent who is a medical doctor in-charge of ART at the University Teaching Hospital in Lusaka,

Right now, the HIV test which is used is just on antibodies, which is only reactive six weeks to three months after someone is exposed, but still some people get a false negative result. Therefore, we don't have the proper mechanisms of identifying the HIV virus as early as possible for PrEP. Besides, what we are currently using, which is the anti-bodies test, does not give results as early as possible.<sup>11</sup>

In responding to the question on HIV testing for PrEP, five other participants put forth reasons such as inadequate human resource to conduct effective tests for PrEP, poor monitoring and inadequate HIV testing centres for PrEP. One respondent from Mutendere ART centre in Lusaka said, "There are currently limited HIV testing centres in Lusaka, most of the urban ART centres take their CD4, full blood count, renal

<sup>11</sup> Personal communication by Dr. Royd Mulenga (Adult Infectious Diseases Department, UTH).

function tests, hepatitis and viral load tests to Kalingalinga ART Centre. This is the situation for over fifteen ART Centres which are under the Lusaka District Health Management Team.”<sup>12</sup>

In another interview question, the interviewees were asked whether adopting PrEP would affect the existing HIV prevention strategy in Zambia, which puts emphasis on abstinence, being faithful to one sexual partner, and the use of condoms. Of the 20 respondents interviewed, fourteen (70%) respondents said “yes”, while six respondents said “no” but they did not give any reasons for their response.

In a follow-up question, the respondents were asked whether PrEP can affect the HIV prevention strategy in Zambia. The respondents, who responded affirmatively to this question, were further asked to state their reasons. Of the 14 respondents, who said “yes”, seven respondents (50%) said that people would stop using condoms if PrEP is adopted. One of the seven respondents was concerned about how PrEP would affect condom promotion, citing the reason that people would have an alternative prevention method and they might say condoms are no longer needed. One respondent said that people would start having sex at a very early age in life if PrEP is adopted. Regarding male circumcision, three respondents stated that PrEP would affect negatively the implementation of male circumcision. Only two respondents (14%) said that PrEP would strengthen all the other HIV prevention methods if it was adopted.

Only two respondents stated that people will opt for PrEP and do away with the other HIV preventive methods if PrEP was adopted. One respondent declared that it would increase the number of couples testing together at the same time and that there could be an increase in the number of serodiscordant couples. Of the 14 respondents who gave an affirmative response, three (21.4%) stated that adopting PrEP would lead to a reduction in the success trends of other HIV preventive methods.

Regarding abstinence, only one respondent said that people would stop abstaining if PrEP was adopted, and seven respondents stated that the adoption of PrEP is likely to lead to an increase in number of sexual partners that people have (see Table 6 below).

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<sup>12</sup> Personal communication by Zozi Racheal (Mutendere Clinic, Lusaka).

Responses	N	%
People would stop using condoms	7	50
People will start having sex at a very early age	1	7.1
PrEP will have negative impact on male circumcision	3	21.4
PrEP will strengthen all the other HIV prevention methods	2	14.3
People will not use other HIV prevention methods	2	14.3
It will increase couples testing together	1	7.1
PrEP will reduce the successes achieved by other HIV prevention	3	21.4
People would stop abstaining	1	7.1
Number of sexual partners per person will increase	7	50

Table 6: Responses on how PrEP would affect other preventive methods

The data presented in Table 6 is also presented in Chart 8 below in order to clearly show the particular responses per person. This data is also presented in percentages to make understanding easy.

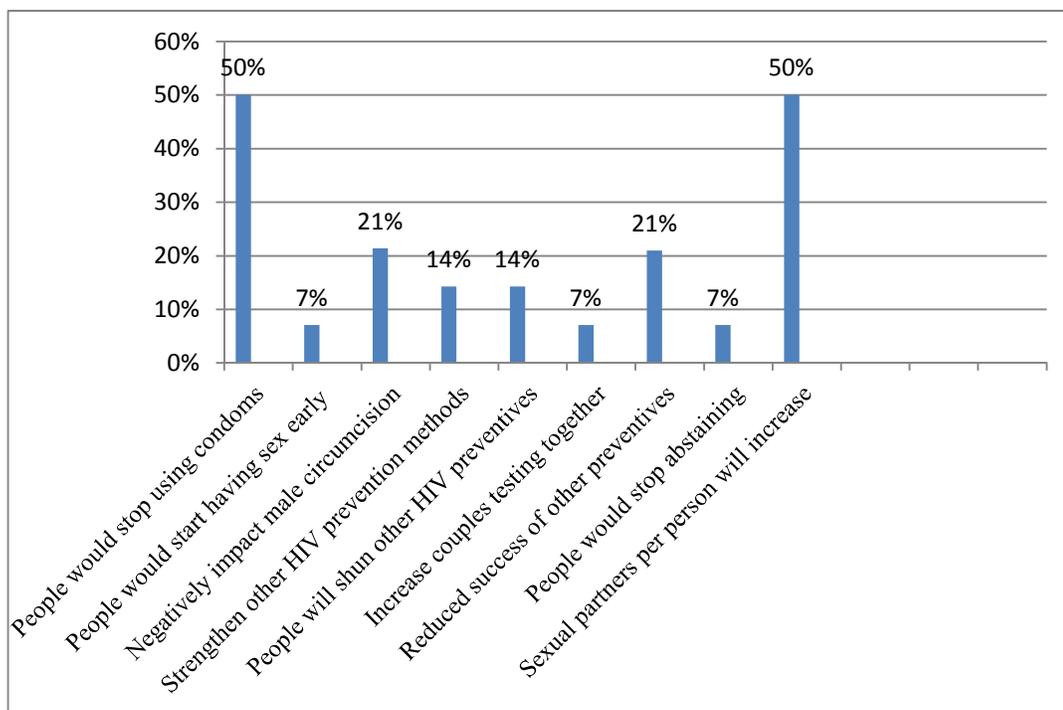


Chart 8: Responses on how PrEP would affect other methods

#### 4.3.4 PrEP Benefits

The fourth theme focuses on the responses on the perceived benefits that were collected using the interview schedules in the study. When the respondents were asked whether

the medication used for PrEP had any beneficial effects, twenty (100%) respondents answered affirmatively.

Regarding the beneficial effects of PrEP medication (*Truvada*) on human body health, 40 percent of the respondents mentioned that the medication is beneficial as an anti-retroviral drug, 30 percent responded that it reduces HIV viral load, 45 percent responded that it enables the body to build white blood cells and improve the body's immune system, 30 percent responded that it increases the body's CD4 count, 35 percent responded that it is also used as treatment for hepatitis B, 55 percent responded that it prevents HIV infection, 40 percent responded that it reduces transmission of HIV to other persons, ten percent responded that it increases appetite, ten percent responded that it prevents opportunistic infections such as Candida, ten percent responded that it prevents the HI-virus from replicating, five percent responded that it improves general well-being. Another five percent responded that it prevents mother-to-child transmission of HIV, five percent responded that it improves confidence levels by treating and preventing HIV infection and five percent responded that because *Truvada* is taken only once a day it is easy to adhere to treatment. One respondent who is directly involved in anti-retroviral treatment of HIV positive individuals at Kalingalinga ART Clinic, revealed that the drug *Truvada* increases the susceptibility of HIV to other drugs such as Kaletra.

Table 7 below summarises the responses of the interviewees on the benefits of PrEP medication specifically *Truvada*. The percentage of each response is calculated from a total number of respondents.

Responses	N	%
Anti-retroviral drug	8	40
Reduces HIV viral load	6	30
Builds white blood cells by improving immune system	9	45
Increases CD4 count	6	30
Treatment of hepatitis B	7	35
Prevention of HIV infection	11	55
Reduces transmission of HIV virus to other persons	8	40
Increases appetite	2	10
Prevents opportunistic infections such as candida	2	10
Prevents HI-virus from replicating	2	10
Improves general well-being	1	5
Prevents mother-to- child transmission of HIV	1	5
Improves confidence levels	1	5
It is easy to adhere to treatment	1	5
PrEP increases susceptibility of HIV to other HIV drugs	1	5

Table 7: Summary of responses on benefits of PrEP medication on the human body

When the respondents were asked whether the adoption of PrEP would have any social and economic (non-medical) benefits in Zambia, seventeen (85%) responded affirmatively, while three (15 percent) respondents said “no” (see Chart 9 below).

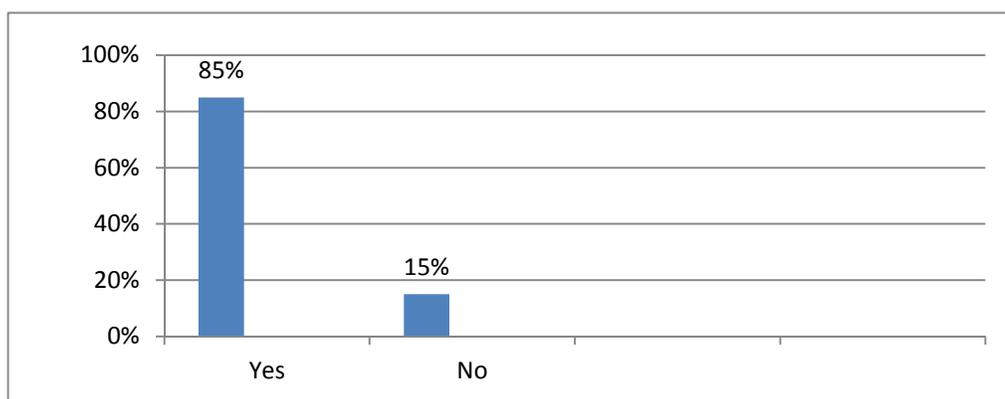


Chart 9

Those who gave an affirmative response to the question on social and economic (non-medical) benefits of PrEP were asked to mention the social and economic benefits. Of the 17 respondents, one respondent said that the adoption of PrEP would help planners to plan for PrEP in the national health budget. Another respondent stated that adopting PrEP would make people know that *Truvada* can also be used to reduce the chances of contracting HIV. Three respondents, from different organizations, said that the adoption of PrEP would reduce the number of orphans and street children because fewer people would become infected with HIV and die from AIDS.

Of the 17 respondents who gave an affirmative response, three (17.6%) stated that hospital admissions will be reduced, thereby leading to a reduced disease burden on medical staff, which will, in turn, result in effective provision of health services. Seven respondents, from different organizations, stated that adopting PrEP would lead to more productivity in the economy because of the subsequent decrease in disease burden. Only one respondent said that adopting PrEP would lead to a rise in life expectancy, because of low death rates and better quality of health care, which would be partly due to medical personnel dealing with fewer chronically ill people in hospitals.

Regarding the reduction in transmission of HIV, 14 respondents stated that PrEP would reduce the transmission of HIV and that this would lead to a healthy population that will be economically productive. Only seven respondents stated that adopting PrEP would reduce the cost of managing HIV in the society and that in the long run, HIV prevalence would also be reduced, thereby leading to reduced costs of treatment for HIV in families. The study findings showed that eight respondents stated that adopting PrEP might result in reduced death rates of household heads, as such families would be maintained and would have improved economic statuses.

Regarding the issue of stigma, only two respondents said that adopting PrEP would reduce HIV stigma in the society. Only one respondent said that PrEP offers an option that can lead to an increase in risk reduction awareness in the society. Two respondents, from different organizations, stated that adopting PrEP would reduce absenteeism in work places, because fewer people would fall sick (see Table 8 below).

Responses of benefits	N	%
Adopting PrEP would help planners budget for PrEP	1	5.9
<i>Truvada</i> reduces the chances of contracting HIV	1	5.9
Number of orphans and street children will reduce	3	17.6
Hospital admissions will be reduced	3	17.6
PrEP will lead to more productivity in the economy	7	41.2
Adopting PrEP would lead to a raise in life expectance	1	5.9
PrEP will lead to a reduction in transmission rate	14	82.4
PrEP will reduce the cost of managing HIV	7	41.2
Families will be maintained due to reduced death rates of household heads	8	47.1
PrEP would reduce HIV stigma in the society	2	11.8
Absenteeism would reduce in work places	2	11.8

Table 8: Responses for social and economic (non-medical) benefits of PrEP

The responses, presented in Table 8, are also shown in Chart 10 to clearly indicate the disparities. The responses shown in the Chart are representative of the number of respondents who gave a particular response as presented by percentages, which were calculated from the total number of 17 respondents who answered affirmatively to the question on social and economic (non-medical) benefits of the adoption of PrEP.

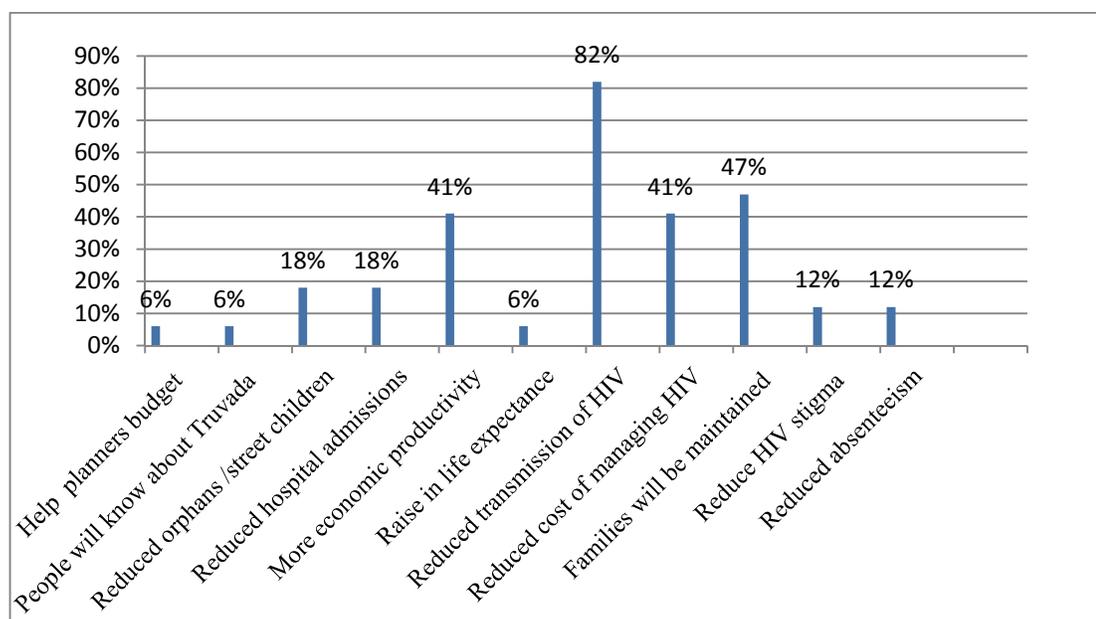


Chart 10: Response to social and economic benefits of PrEP

Regarding HIV transmission rates, the interviewees were asked how PrEP would affect the rate of HIV transmissions in Zambia. The proportion of individuals who stated that PrEP would lead to reduced HIV transmissions was sixteen (80%) out of the 20 respondents. Only four (20%) stated that it would lead to increased HIV transmission rates. None of the interviewees responded that it would not lead to any changes in the HIV transmission rates (see Chart 11 below).

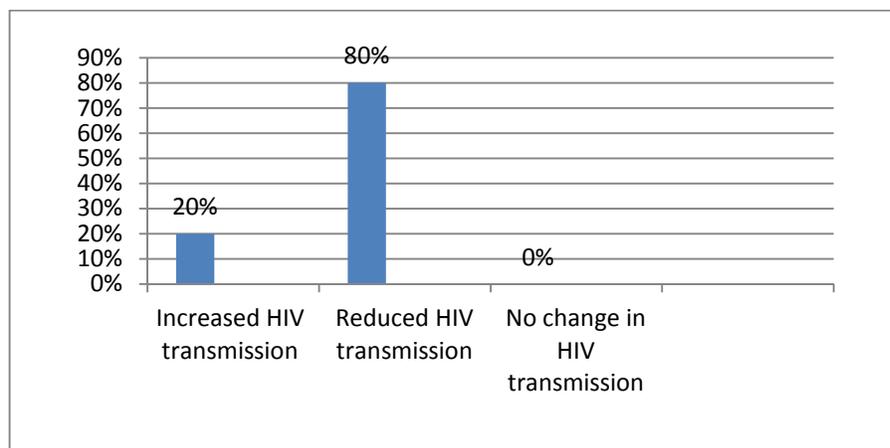


Chart 11: Summary of responses on HIV transmission rates

#### 4.3.5 Early versus Late PrEP Adoption

The fifth theme involved questions regarding the opinions on the perceived best time to adopt PrEP, if it should be adopted at all. Of the 20 respondents interviewed, twelve (60%) responded that they would support an early adoption of PrEP, and eight of them gave explanations for their answers. For example, some said that they would support an early adoption only on demonstration projects or pilot projects in some districts so that the country can learn from these projects and this would reduce the chances of unforeseen harm. In a separate interview, one nurse at an ART treatment centre in Lusaka stated that she would support an early adoption because there are more than ten HIV positive individuals who are enrolled on anti-retroviral treatment every working day at the clinic, which shows that the rate of transmission of HIV is constantly increasing, hence the need for early adoption. Another health worker said that early adoption would lead to a new generation of HIV free individuals. One respondent stated that adopting PrEP early would result in more benefits in terms of fighting HIV

infections. And another respondent stated that early adoption should first begin with small groups, such as discordant couples.

In contrast, of the seven (35%) respondents who responded that they would support late adoption, five (71%) cited the cost of implementing PrEP as the main reason for supporting late adoption. One of the seven respondents stated that information on PrEP efficacy is still not enough to warrant the adoption of PrEP. Another interviewee said that we do not have well defined high risk groups for the implementation of PrEP and that priority should be given to those who are already HIV infected, before we start dealing with those who are HIV negative. However, one respondent out of the entire sample did not support early or late adoption of PrEP for the reason that the health sector in Zambia is still not ready for that kind of HIV prevention measure. A summary of the responses is shown in Chart 12 below which clearly presents the responses using percentages.

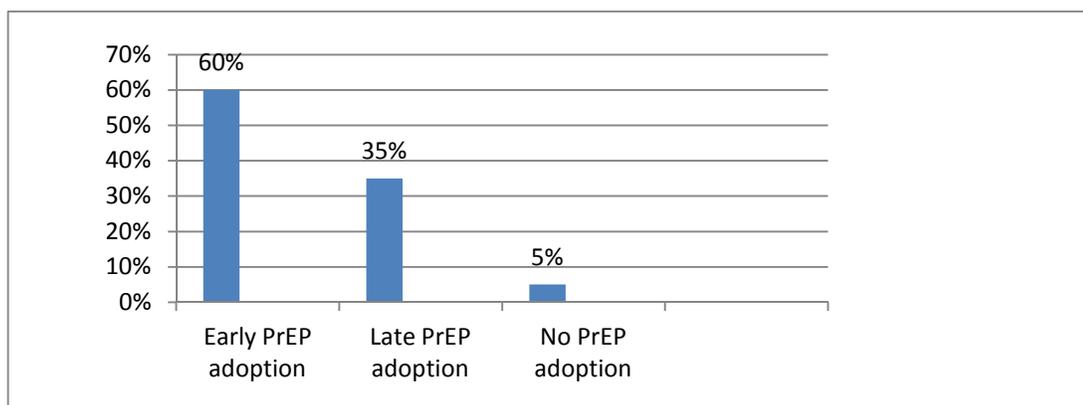


Chart 12: Summary of responses for adoption of PrEP

#### 4.3.6 General Harms of PrEP

Towards the end of the interviews, the 20 respondents were asked whether they thought that the adoption of PrEP would generally lead to more harms than benefits. The responses make up the sixth theme. The majority, 13 respondents, said “yes”, while a proportion of seven respondents said “no”. The variation in responses to the question is presented in Chart 13 below.

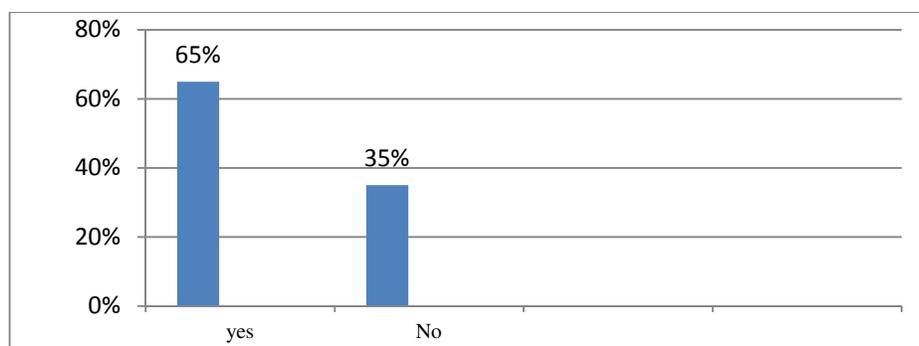


Chart 13

In a follow-up question, the interviewees who answered the question affirmatively were asked to mention the general harms that would result from the adoption of PrEP. Of the 13 respondents, four mentioned resistance, again four mentioned monitoring and another four mentioned high costs of PrEP.

Of the 13 interviewees who gave an affirmative response, two said that people may still get infected after taking PrEP, another two said it would lead to increased risk behaviour, while three respondents said that people may stop using the ABC prevention strategy. Only one person said it would affect male circumcision and another respondent said that people would start sharing ARVs. Table 9 below shows the number of people and the number of times a particular harm was mentioned in percentages.

General harms	N	%
Resistance	4	30.8
Monitoring	4	30.8
High cost of PrEP	4	30.8
People may still get infected	2	15.4
Increased risk behaviour	2	15.4
People will stop using ABC strategy	3	23.1
PrEP would affect male circumcision	1	7.7
People would start sharing ARVs	1	7.7

Table 9: Showing general harms of PrEP

The information presented in Table 9 has also been presented in Chart 14 below. This was done in order to clearly show the disparities in responses and to make understanding

of the harms simpler. The chart shows the number of times a particular harm was mentioned in percentages. Remember that these percentages were calculated from the total of 13 respondents who gave an affirmative response to the question on general harms of PrEP.

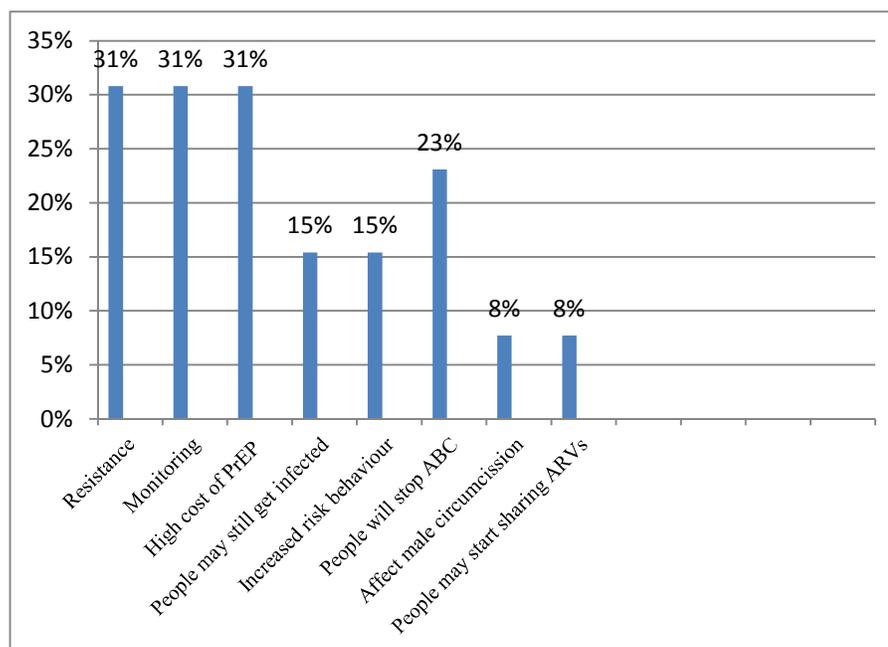


Chart 14: Showing the general harms of adopting PrEP

#### 4.3.7 PrEP versus Other Options

The final theme addressed the last question in the interview, which asked the 20 respondents what proportionate actions they thought should be taken to avoid or reduce the harms that would result from the adoption of PrEP in an effort to prevent HIV infections. Of the 20 interviewees, five groups of responses emerged from the question.

The first group consisted of seven respondents who said that to avoid or reduce the harms that would result from a general adoption of PrEP, the implementation of PrEP should be limited to specific groups of people who are at high risk, such as serodiscordant couples, sex workers and men who have sex with men (MSM). The second group consisted of six respondents who said that PrEP should be part of a comprehensive HIV prevention strategy, which should include all the other methods of prevention, including condoms and male circumcision. The third group consisted of two

respondents. They said that every drug has harms or side effects, therefore the harms of PrEP should be dealt with accordingly after adoption. The fourth group, which also consisted of two respondents, declared that the priority should be to first conduct an HIV test on everyone in the country and treat those who will be found positive before PrEP is even considered as a prevention method in Zambia. The fifth group also consisted of three respondents. They said that as a country we should emphasize on condoms and not PrEP. One respondent from the fifth group said:

How are you going to get people to use PrEP when they don't even use condoms consistently? Condoms are cheap, have no side effects. Condoms work 100 percent almost, with condoms you do not need testing and they can even stop the infection of other STIs. You don't have to use condoms every day but only when you have sex and you don't have to go to an ART centre to get condoms as it would be with PrEP. Therefore, in my opinion, condoms are the best option for preventing HIV infections.<sup>13</sup>

Groups of responses	N	%
1. PrEP should be limited to high risk groups	7	35
2. PrEP should be part of a comprehensive HIV prevention strategy	6	30
3. PrEP side effects should be dealt with accordingly	2	10
4. First conduct an HIV test and treat everyone then consider PrEP	2	10
5. Emphasize on condoms and not PrEP	3	30

Table 10: Showing the groups of respondents who answered the question

#### 4.4 DISCUSSION AND ANALYSIS

This is the first study on PrEP in Zambia. The findings of the study show the current situation of PrEP in Zambia by means of conducting an investigation into PrEP attributes in a purposively chosen sample, consisting of those who work in the field of HIV/AIDS in Zambia. Interestingly, all participants that took part in this study gave

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<sup>13</sup> Personal communication by Dr. Carolyn Bolton (Centre for Infectious Diseases in Zambia).

detailed responses to some of the questions in the interview schedule. However, there were differences in the perceived harms and benefits of adopting PrEP based on social, economic and medical contexts. Like in the previous section, seven themes are used in the discussion of the findings.

#### **4.4.1 PrEP Knowledge**

In the first theme, the findings show that the majority of the respondents (90%) said that they had heard of the newest HIV prevention method (for HIV negative individuals) called PrEP. A similar study by Wheelock et al. (2012, 4) found that 55 percent of the respondents had heard of PrEP. Those who took part in their study on PrEP awareness included healthcare workers, policymakers and non-governmental organization representatives who are specialized in HIV/AIDS in Peru, Ukraine, India, Kenya, Uganda, Botswana, and South Africa. In Zambia, PrEP has currently not yet been adopted. Therefore, I think that the majority of the 90 percent who said they had heard about PrEP in the present study did not have first hand experience in PrEP. The majority has only heard of PrEP in the media. Remember that in the findings it was revealed that only four of the respondents attended the consultative meeting on PrEP in Zambia, which included participants from the World Health Organization and the Ministry of Health.

When the respondents were asked to mention the medication being used for PrEP, 65 percent mentioned the correct drug, which is called *Truvada*. The remaining 15 percent and ten percent who mentioned *Nevirapine* and *Zidovudine*, could not make a clear distinction between Pre-exposure Prophylaxis and Post-exposure Prophylaxis. This is probably because they have had first hand experience with Post-exposure Prophylaxis, which is implemented in Zambia, but not with Pre-exposure Prophylaxis, which has not yet been adopted in the country.

Of the 20 respondents, 18 persons stated that they did not know any organization that had already adopted PrEP in Zambia. This response by the majority of respondents confirms to some extent that indeed most organizations in Zambia are not implementing PrEP. There are currently no guidelines from the government of Zambia on PrEP, even though two high placed and reliable respondents mentioned that some unnamed non-

governmental organizations are already implementing PrEP in Zambia. If this is true, it probably means that some people in the Zambian society are already embracing this kind of HIV prevention.

In the same vein, one can ask questions such as, “Which institutions should be allowed to implement PrEP before it is given a green light by the government of a country?” and “Who has the authority to give this permission?” And “when it is given, do they wait for more people to fall ill and die?” This could be referred to as the wait and see approach of doing things.

In trying to understand the current situation of PrEP in Zambia, an evaluation of the responses reveals the current situation of PrEP in Zambia. This evaluation was done by matching the percentages of PrEP effectiveness that were reported in scientific experiments about PrEP with the responses given in the findings of the present study. The two PrEP drug trials referred to as the iPrEx study and the TDF2 study revealed that the drug *Truvada* or TDF/FTC offered 44 percent protection and 92 percent protection when calculated for subjects with detectable drug concentrations for the iPrEx trial and 63 percent protection for the TDF2 trial.

Looking at the findings of the present study, the majority estimated that PrEP offered an effective rate, which ranged from 47 percent to 90 percent, with 47 percent being the lowest estimate given by one of the 15 respondents. Another hint that would show that the respondents could have ample knowledge of PrEP is that two of the five respondents in the present study who said that they did not know the rate of effectiveness, mentioned that PrEP is not 100 percent effective when they were probed. Therefore, 17 respondents (85%) gave an estimate which is similar to percentages indicated in the two clinical trials that show an overall range of 44 to 92 percent PrEP effective rate. That is to say, 85 percent of the respondents in the present study were aware of and had knowledge of PrEP in Zambia.

But the question that could be asked is, could this knowledge and awareness be enough to warrant the adoption of PrEP in Zambia? In an attempt to answer this question, the respondents were asked what impact the rate of effectiveness PrEP would have on HIV infections. The majority, 70 percent, responded that it would lead to

reduced HIV infections, which is the aim of PrEP, based on the concept on which it was developed.

#### **4.4.2 PrEP Side Effects**

The second theme in the findings addressed responses on the perceived harms or side effects of PrEP adoption. The study encompassed questions on the harmful effects of PrEP on the human body. The 13 respondents, who responded affirmatively to the question, were asked to mention the harmful effects of PrEP medication. In the present study, the harms frequently mentioned by the respondents, which would be of concern in the adoption of PrEP, were renal or kidney failure mentioned by 84.6 percent of the respondents, edema or accumulation of fluid between the body tissues cells (46.2%), 38.5 percent mentioned gastral intestinal disturbances, 30.8 percent mentioned reduced bone density and 30.8 percent mentioned liver toxicity.

In a similar study (Underhill et al. 2010), it was reported that a study in West Africa identified possible side effects of PrEP medication, which include renal effects, loss of bone density, gastral intestinal effects and flares of hepatitis B. In the present study, side effects such as nausea and vomiting, lung problems, diarrhoea, abnormal body fat distribution, resistance, anaemia, rash, weight loss, lactic acidosis, bone pains and other side effects seemed to be of less concern to most of the respondents. I make this assertion based on the low frequency of responses for some side effects, which in most cases were mentioned by only one or two respondents, as can be seen in the findings.

In the mentioned West African study, resistance was seen to be more of a potential risk in the implementation of PrEP. But in the present study, resistance seemed to be a minor concern of the respondents. It was mentioned by only two respondents out of the 13. The similarities in the side effects, mentioned in the West African study and the present study, shows that most of the respondents interviewed in the present study were aware of PrEP. I think, however, that the responses in the present study on harmful or side effects were based on the experiences they have had with *Truvada* in the treatment of HIV positive individuals in their respective organizations and not on the effects of PrEP on HIV negative individuals. But it still provides an insight into the

expected side effects of PrEP on HIV negative individuals. To be sure, the harms mentioned in the present study are related to the side effects of *Truvada*, which is the drug recommended for PrEP

#### **4.4.3 PrEP Programme Concerns**

The implementation of PrEP in Zambia is a matter that would involve the country's policy on HIV/AIDS, and this third theme addresses this policy aspect by discussing the concerns that would affect the adoption of PrEP. Regarding the social and economic harms of PrEP, the findings of the present study show that 50 percent of the 18 respondents, who said PrEP would result in social and economic harms, mentioned the high cost of implementing PrEP. In comparison, a report of a study conducted in the United States of America revealed that the entire cost of medicinal PrEP therapy is approximately \$900 per month (Leibowitz et al. 2011, 2). This is equivalent to 4500 Kwacha in Zambia, when calculated according to the prevailing currency exchange rate of \$1=K5. This takes into consideration that the drugs are manufactured in America, thereby making them easy to access. The cost would be much higher in Zambia because the ARV drugs for PrEP are not manufactured locally and currently the country mostly depends on donors for the funding of the supply of ARVs.

In addition, costs would also include the price for on-going counselling and testing, monitoring for side effects and the possible resistant viral strains, as well as the increased costs that would result from the development of other STIs which PrEP cannot prevent. In America these indirect costs were estimated to be more than \$1 billion annually for about 100 000 persons. In Zambia this cost would be much higher and could possibly reach five million Kwacha for the same number of persons. This is roughly 14 percent of the 2013 Zambian national budget, which was around 36 million Kwacha. The question that can be asked is where the money would come from.

The first theme in the findings addressed a question regarding which organizations should be allowed to implement PrEP. It was revealed that the majority, 45 percent of the respondents, preferred that government ART centres should implement PrEP. For this response, the participants gave the reason that government ART centres would reduce prescription errors and would be able to properly monitor and report the

PrEP side effects or harms, despite the inadequate human resources and infrastructure necessary to effectively implement PrEP. Similar findings were reported in a PrEP study conducted in a population of at-risk Peruvians, which showed that most respondents preferred PrEP being distributed in health care centres as opposed to pharmacies, citing high costs and the potential for drug misuse (Galea et al. 2011, 5).

Some of the respondents in the present study raised the issue of drug misuse. In contrast to these findings, a study that was conducted in America (among gay men and transgender women) showed that PrEP should be offered in neutral clinics that are not entirely specialized in HIV treatment. This raises another concern of PrEP, which is stigma.

In the present study, surprisingly only two respondents mentioned that PrEP would lead to stigma for those on PrEP. A similar outcome was reported in a study conducted in China, where sex workers were concerned about safety (81%), efficacy (81%), cost (51.2%), convenience (19.2%) and (16.6%) accessibility of the drugs (Peng et al. 2012, 154). There was no mention of stigma in the China study, too. I think stigma is an aspect of PrEP that has been down-played by many stakeholders, even though it could be a matter of concern when considering the adoption of the PrEP.

In the present study, the majority, 55 percent of the respondents, were more concerned that PrEP would lead to an increase in risk behaviour than about the cost of PrEP. In contrast, a similar report of a PrEP study conducted with Peruvian participants, revealed that the interviewees did not feel that PrEP would alter sexual risk-taking behaviour because it would only reduce the risk of contracting HIV and not other sexually transmitted diseases (Galea et al. 2011, 5). Similarly, a study conducted on attitudes of PrEP providers revealed that none of the providers was concerned about risk compensation by patients on PrEP (Arnold et al. 2012, 5).

There was an interesting response in the findings of the present study, although only stated by 20 percent. They said that adopting PrEP would lead to low utilization of the ABC strategy of HIV prevention. I think this finding on the ABC strategy ought to be taken seriously when considering the adoption of PrEP. Based on the literature in the present study, PrEP offers only partial efficacy in preventing HIV. Therefore, it is

important that all stake holders in HIV prevention acknowledge the potential negative effects of PrEP on the other HIV prevention strategies.

#### **4.4.4 PrEP Benefits**

The research findings reveal in the fourth theme that the respondents felt that implementing PrEP would lead to more productivity in the economy and would improve general well-being for the users. Similar findings were reported in another study on PrEP, where it was revealed that PrEP would have a positive impact on a country's economy and that it would improve the user's well-being and reduce the disease burden (Wheelock et al. 2012). In the present study, only three respondents, out of the 17 who gave an affirmative response to the question on PrEP benefits, mentioned that PrEP could lead to reduced hospital admissions and that this would result in reduced disease burden on medical staff. This would also result in the effective provision of medical services, thereby lead to a reduction in HIV related death rates. They said that PrEP has the potential to address the problem of increased street children and orphaned children in the society.

A study conducted to determine the motivators of PrEP adoption revealed that PrEP can protect against HIV infection, both for those who are HIV positive and those who are HIV negative, and that PrEP has the ability to provide greater sexual freedom by offering users a feeling of protection (Brooks et al. 2011). Five percent of respondents in the present study referred to this as improved confidence levels. In the same report, it was revealed that PrEP decreases the stress that results from having sexual relationships with an HIV serodiscordant partner. In the present study, similar findings have been presented with the majority (55%) of the respondents stating that PrEP has the ability to prevent HIV infection, improve general well-being (5%) and improve confidence levels for those who have sexual relationships with HIV positive persons by reducing the chances of transmission of HIV to other persons.

In the present study, the respondents mentioned a variety of benefits which can be regarded as motivators of PrEP use. For example, its ability to prevent mother-to-child transmission of HIV. A woman who uses PrEP before having sex with an HIV positive male partner may not get infected with HIV, but she may become pregnant with

an HIV negative child. In another study on attitudes of respondents working in the HIV field, it was reported that a PrEP trial conducted on serodiscordant couples found that a positive partner, who was virally suppressed, has a 96 percent reduction in risk of HIV transmission to the uninfected partner (Arnold et al. 2012, 5). Similar results were found in the present study, where a majority of 55 percent mentioned prevention of HIV infection as a benefit of PrEP.

Another important aspect of PrEP, mentioned in the findings of the present study, was the ability of PrEP medication (*Truvada*) to also treat hepatitis B. In the present study, 35 percent of the respondents mentioned treatment of hepatitis B as a benefit of PrEP. This was also found in another report that revealed that *Tenofovir* (one of the drug combinations in *Truvada*) was well tolerated and did not lead to hepatitis B flare-ups in PrEP clinical trials (Underhill et al. 2010, 3).

I think that the other benefits, mentioned in the present study, were considered as minor by the respondents. They were mentioned by few respondents, mostly by one or two respondents, and some responses could be considered as mere repetitions or translations of what other respondents had already mentioned. For instance, responses such as, “PrEP is beneficial as an anti-retroviral drug and it reduces HIV viral load and builds white blood cells which in turn increases CD4 count”, can all fall into one response, which is “PrEP is beneficial as an anti-retroviral drug.”

#### **4.4.5 Early against Late PrEP Adoption**

In the present study, a majority (60%) said they would support an early implementation of PrEP. In contrast, a similar study on PrEP awareness revealed that 47.3 percent of participants would support early implementation of PrEP. This study on PrEP awareness included three participants in Peru, five in Ukraine, three in India, seven in Kenya, six in Uganda, eight in Botswana and 11 in South Africa (Wheelock et al. 2012). The majority in the present study cited the ability of PrEP to reduce HIV infection as the main reason for their response.

#### **4.4.6 General Harms**

A study conducted on gay and bisexual men in America revealed that the cost of PrEP, the side effects of PrEP medications, and the possible inconsistent use of PrEP by users could be a barrier to the adoption of PrEP (Brooks et al. 2011, 4). In the present study, 65 percent of the respondents thought that PrEP would generally lead to more harms than benefits. The most frequently mentioned harms were resistance and monitoring and 31 percent mentioned the high cost of PrEP. These results show some similarities in the responses and they indicate to some extent that the respondents who took part in the present study know about PrEP, even though it has not yet been adopted in Zambia.

There was another interesting response in the present study. One respondent mentioned that people might start sharing ARV drugs if PrEP was adopted. The other harms mentioned in this theme, such as increased risk behaviour and effects of PrEP on other HIV prevention methods, were addressed in the preceding themes of this discussion.

#### **4.4.7 PrEP Compared to other Options**

The final theme covers the last question of the interview. It required the respondents to state the proportionate action that should be taken to avoid or reduce the harms that would result from adopting PrEP. The question elicited responses that fell into five groups. A majority of 35 percent, who belong to the first group, stated that in order to reduce or diminish the harms, PrEP should be implemented only for high risk groups, such as serodiscordant couples or sex workers. In the second group, 30 percent preferred that PrEP be adopted only as part of a comprehensive HIV prevention strategy that should include condoms, male circumcision and other HIV prevention methods. These two responses reflect the intended scheme of PrEP and they are similar to the findings in a 2009 report of a consultation on PrEP by WHO, which alerts to the fact that PrEP can complement other HIV prevention strategies and that it can be most useful to those who are at high risk of infection, such as sex workers, men who have sex with men and those who inject drugs (WHO 2009, 3).

Two other interesting responses were captured in this study. Thirty percent of the respondents emphasized that condoms are a better option than PrEP and therefore one

should stick to condoms because they are less complicated. Another respondent stated that everyone in the country should be tested first and treated if they are found HIV positive. Only then PrEP should be considered in Zambia. This latter response is supported by a report on ethics guidance where it is stated that the current HIV prevention research should be conducted within the sphere of a test-and-treat approach in which everyone is tested for HIV and those who are found HIV positive are put on anti-retroviral treatment, regardless of viral load (Rennie and Sugerman 2010, 7).

#### **4.5 CONCLUSION**

The findings of the present study are the result of a qualitative method research that was conducted by purposively choosing participants who work in the field of HIV/AIDS in Zambia. The aim of this chapter was to explore the current situation on PrEP in Zambia, which is the second objective of this dissertation. The findings reveal that the respondents were aware of PrEP, since the majority mentioned *Truvada* as the drug recommended for PrEP, even though PrEP was partly confused with PEP. The majority preferred PrEP being offered in government clinics because of the threat of side effects and monitoring for resistance strains.

A majority mentioned that PrEP would lead to reduced HIV infections if adopted, but they were mainly concerned with renal toxicity or kidney failure for those who may be put on PrEP. The cost of PrEP was raised as a major concern regarding the adoption of PrEP. This cost involved monitoring, adherence, resistance, human resource infrastructure and the cost of drugs. Most respondents stated that PrEP would affect other HIV prevention strategies. However, they believed that in the long run, PrEP would be more beneficial, even though it would result in more harms in the short term. Despite the shortcomings of PrEP, the majority preferred its early adoption to reduce HIV infections. They also preferred using PrEP on high risk groups, despite the fact that the country has no legal approval for some high risk groups such as sex workers and men who have sex with men. Most of the responses in the present study were based on what the respondents have heard and read in the media on PrEP. None of the respondents mentioned that they have had first hand experience in the use of PrEP.

## CHAPTER 5

# ETHICAL ASSESSMENT

### 5.1 INTRODUCTION

This chapter applies the Precautionary Principle and Utilitarianism to evaluate the adoption of Pre-exposure Prophylaxis (PrEP) as a potential HIV prevention method in Zambia. This ethical assessment is based on the data contained in the literature review and the findings of the study that have been reported in the previous chapter.

### 5.2 METHODS

There are different methods used in Applied Ethics (see Beauchamp 2003). Some of them are purely descriptive, for example, when researchers investigate the actual behaviour of a group of people with regard to a morally relevant issue such as abortion or genetic engineering. But most studies in applied ethics are normative. Their goal is to investigate how an ethical issue should be resolved. However, there is also a variety of methods used in normative ethical studies. Some favour “Case based Methods”, which involve a “bottom up”, inductive approach to ethical justification. For example, casuistry is a case based approach which has been defined as a method for arriving at justifiable decisions about what to do in specific cases by means of analogical case analysis (Childress 2007, 29). Other researchers choose the “Method of Reflective Equilibrium”, developed by John Rawls. This method involves “the attempt to bring our most confident ethical judgements, our ethical principles, and our background social psychological and philosophical theories into a state of harmony or equilibrium” (Arras 2007, 47). Recently, different approaches to an “empirical turn” in Applied Ethics have been suggested all of which attempt to integrate empirical and normative research.

This dissertation employs the “Principle-based Method” of Applied Ethics, which is, according to Beauchamp’s (1984, 514) definition, the application of an ethical theory to some particular moral problem or set of problems. The Principle based Method does this in a direct and straightforward way. It “consists in the application of ethical theories or ethical principles to a certain problem with the aim to answer the ethical question of what ought to be done in connection with this problem” (Spielthener 2009,

29). When the idea of Applied Ethics gained a foothold in philosophy, it was widely alleged that general ethical theories were to be applied to particular moral problems or cases. In fact, it is this approach that gave Applied Ethics its name. It is still one of the established methods in Applied Ethics, even though it has, as any method, limits and dangers (Beauchamp 2003, 7-8).

According to this method, the ethical theory (or ethical principle) is the starting point and we apply the theory (or principle) to the case at hand in order to reach a conclusion about what should be done. On this view, an ethical evaluation of a case is equated with deductive reasoning that starts from ethical principles. This requires (i) a careful investigation of the case under consideration (one needs to be sensitive to the complex and particular characteristics that make up the situation), (ii) a clear definition of an ethical principle that is intended to be applied in order to see whether it is applicable to the issue, (iii) collection of empirical data that is required for applying the principle and (iv) the correct deductive reasoning to make sure that the principle together with the empirical data entail a judgement about what ought to be done in the case under investigation. As I have already mentioned, the principle and the theory that I have applied in this study are the Precautionary Principle and Utilitarianism.

### **5.3 APPLICATION OF THE PRECAUTIONARY PRINCIPLE**

The Precautionary Principle has already been outlined in the chapter on the theoretical framework. However, the principle shall be stated here again before it is applied to the issue of adopting PrEP. As explained in Chapter 3, I shall employ the version of the Precautionary Principle that has been defined by the Commission on the Ethics of Scientific Knowledge and Technology (COMEST). According to this definition, the Precautionary Principle states: When (i) human activities may lead to morally unacceptable harm that is (ii) scientifically plausible but (iii) uncertain, there is (iv) a need to act now, and it is (v) currently impossible to reduce the uncertainties, proportional actions shall be taken to avoid or diminish that harm (UNESCO 2005, 14, 31, 49). That is to say, the principle is only applicable to an ethical issue when all five conditions are met. If the five conditions are met the principle states that proportional actions should be taken to avoid or diminish the morally unacceptable harm.

In what follows, I shall apply the principle by first showing that all five conditions have been met in the study. Then I shall propose a proportional policy that can avoid or diminish the morally unacceptable harm.

### 5.3.1 Conditions of the Precautionary Principle

(i) The first condition of the principle requires specifying that human activity which may lead to the morally unacceptable harm. The “morally unacceptable harm refers to harm to humans or the environment that is threatening to human life or health or serious and effectively irreversible, or inequitable to present or future generations or imposed without adequate considerations of the human rights of those affected” (UNESCO 2005, 14). This requires that I specify the activity that may lead to the morally unacceptable harm. In the study, this activity is not adopting PrEP in Zambia (or the *status quo option*), in short, the option “no PrEP”.

The morally unacceptable harm that would result from the option “no PrEP” is that more new HIV infections will occur. Studies show that new HIV infection rate is high among young people especially among women in sub-Saharan Africa (e.g., Wheelock 2012, 3). In Zambia, there are 226 new HIV infections daily, this was revealed at the Southern African AIDS Trust (SAT) at Mulungushi International Conference Centre, and HIV incidence currently stands at 14.3 percent (Kalito 2012, 1).

As shown in the findings of the study (see 4.3.4), 80 percent of the participants responded that PrEP would lead to reduced HIV transmission. From this, one can conclude that not implementing PrEP would lead to an increased number of HIV infections. That is, it is plausible to hold that the option “no PrEP” (or the *status quo*) would lead to the “morally unacceptable harm” of more new HIV infections.

(ii) The second condition requires showing that the harm of more new HIV infections is scientifically plausible. According to the COMEST report, the “judgement of plausibility should be grounded in scientific analysis and this analysis should be ongoing so that chosen actions are subject to review” (UNESCO 2005, 14). In what follows I shall show that the harm of more new HIV infections is scientifically plausible.

A study by Okwundu and his colleagues revealed that there was an increase in new HIV infections for those who received a placebo and a reduction in new HIV infections by 95 percent for those who received the drug *Truvada* (TDF+FTC). The same study showed that there was a reduction in new HIV infections for those who received the drug *Tenofovir* (TDF) alone and an increase in new HIV infections for those who received a placebo (Okwundu et al. 2012, 11). The infection rates that resulted from the placebo represent the option “no PrEP”. It is clear from this that the option “no PrEP” would lead to more new HIV infections.

Further, a clinical trial in Botswana, called the CDC TDF2 study, which was conducted in partnership with the Botswana Ministry of Health, revealed that a once-daily tablet containing *Tenofovir Disoproxil Fumarate* and *Emitricitabine* (TDF/FTC, known by the brand name *Truvada*) was able to reduce the risk of acquiring HIV infection by roughly 63 percent. In other words, the “no PrEP” option resulted in the harm of more new HIV infections, which were subsequently reduced by 63 percent. This study was conducted in a population of uninfected heterosexual men and women (WHO 2012, 3).

The Literature Review of this study reveals that another PrEP clinical trial, called iPrEx, showed that PrEP reduced the risk of new HIV infection by 44 percent and even reached 90 percent for some individuals. The TDF 2 study also showed a 78 percent HIV risk reduction (see 2.1.11). Therefore, the clinical trials mentioned in the Literature Review, and the findings of this study show that the harm I have specified (more new HIV infections) is scientifically plausible.

(iii) The third condition of the principle requires showing that the “morally unacceptable harm” of no implementation of PrEP is uncertain. According to the COMEST report, “uncertainty may apply to, but need not be limited to, causality or the bounds of the possible harm” (UNESCO 2005, 14).

The Literature Review of the study shows that, based on the scientific clinical trials in the month of July 2012, the drug *Truvada* used in PrEP was approved by the American Food and Drugs Agency (FDA) for prevention of HIV infection, even though PrEP did not show 100 percent effectiveness in preventing HIV infection. Therefore,

one cannot say for certain that the option “no PrEP” will lead to more new HIV infections than the option of implementing PrEP. In addition, there are no studies which have been undertaken to compare or show that the option of not implementing PrEP would lead to more new HIV infections, neither in Zambia or anywhere in the world. Therefore, one must conclude that it is likely but not certain that the option “no PrEP” leads to more new HIV infections than any other available option.

(iv) The fourth condition requires showing that the action needs to be taken now, “since counter-action later will be more difficult and costly at any later time” (UNESCO 2005, 49). According to the Precautionary Principle, actions are interventions that are carried out before the harm takes place. If no decision is made about the implementation of PrEP then there will be more new HIV infections, which would have a negative effect on the fight against AIDS and could lead to higher mortality rate in Zambia. Concerning the adoption of PrEP, waiting is therefore not an option because it will lead to more new HIV infections and more deaths among Zambians.

(v) Regarding the fifth condition of the principle, the option “no PrEP” could have the effect of more new HIV infections. Therefore, the uncertainty that “no PrEP” will lead to more HIV infections can at the moment not be reduced because there is first little research on the problem, and second, research would take long to conclude and results would only be available after years. Thus, the uncertainty whether no implementation of PrEP will indeed lead to more HIV infections can currently not be reduced.

### **5.3.2 A Proportional Policy**

So far I have only shown that the conditions for applying the Precautionary Principle are met. As I have already stated, if these conditions are met, the principle requires that a proportional action shall be taken to avoid or diminish the morally unacceptable harm, which is “more new HIV infections”. I go now on to suggesting a policy that can avoid or diminish this harm. This policy is the adoption of “PrEP for high risk groups”, such as serodiscordant couples (where one partner is HIV positive and the other is HIV

negative). In what follows, I shall argue that adopting PrEP for high risk groups would avoid or diminish the harmful effects of “no PrEP”.

This study has shown that the policy of not adopting PrEP is likely to result in harmful effects such as more new HIV infections. In contrast, based on the results that have been reported in Chapter 2 and Chapter 4, it is very likely that the proportional action of adopting PrEP for high risk groups would reduce new HIV infections of HIV negative partners in high risk sexual relationships such as serodiscordant couples. PrEP for high risk groups will therefore avoid or diminish the “morally unacceptable harm” of an increased number of new HIV infections. HIV negative persons in high risk groups should be targeted for PrEP as they are likely to be a small group and monitoring them during PrEP treatment for HIV infection and adherence to treatment would be less difficult and PrEP treatment for such groups of people would be less costly. In cases where the HIV negative partner becomes infected during PrEP treatment, it would be less difficult to also monitor them for drug resistance to anti-retroviral HIV treatment. According to this analysis, the policy that would avoid or diminish the harmful effects of not implementing PrEP, is the adoption of “PrEP for high risk groups”. That is, mainly people in serodiscordant relationships.

#### **5.4 APPLICATION OF UTILITARIANISM**

Utilitarianism has already been outlined in Chapter 3. As stated in that chapter, utilitarianism assesses and compares the consequences of available options in terms of the well-being they produce. In order to apply utilitarianism in this study, I shall first state the so-called “Utility Principle”. According to this principle, an action is morally right if and only if there is no other possible act that has, overall seen, better consequences. That is to say, an option is morally right, according to utilitarianism, if no other option has better effects on the lives of the affected parties than this option. However, my aim is not to find the right treatment option because this would require determining that treatment option which is better than all other possible treatments, which goes beyond the scope of this dissertation. My aim is more moderate. I want to find a PrEP treatment option which is better than the current situation (the *status quo*). By doing this, I will have shown an alternative to the current situation that is, according

to utilitarianism, morally better than the *status quo*. My strategy in applying utilitarianism is therefore as follows: I will compare the policy of “PrEP for high risk groups” to the current situation, which is “no PrEP”, and I shall try to show that PrEP for high risk groups has overall seen better consequences on the well-being of all affected than the *status quo*. If I am successful in doing this then I have shown that PrEP for high risk groups is morally better on utilitarian standards than the current situation.

#### **5.4.1 Evaluation of the Two Options**

Let us first consider the consequences of the two options “no PrEP” and “PrEP for high risk groups” by specifying the affected parties and determining in which way they are affected, either positively or negatively.

##### **(i) Advantages of “no PrEP”**

With regard to the *advantages for HIV positive individuals*, this section assesses the advantages of the option “no PrEP”. The findings of the study (see 4.3.2) indicate that the option “no PrEP” would lead to a reduction in ailments such as renal problems, cases of edema and liver toxicity. The option “no PrEP” would also lead to better monitoring and adherence service provision for those who are HIV positive. The cost of managing HIV in households would not go up, as household income would be spent on other household needs and not on *Truvada*.

Regarding the *advantages to HIV negative individuals*, my research shows the following advantages of the option no PrEP (see 4.3.2). The advantages would include a reduction in ailments such as renal problems, cases of edema or accumulation of fluids in body tissue cells. The option “no PrEP” would lead to a reduction in cases of liver toxicity. There would also be no need for monitoring and adherence service provision, and this would result in cost-cutting because there would be no need to buy the drug *Truvada* and spend money on counselling and other services. There may also be a possible reduction in sexually transmitted infections such as syphilis, gonorrhoea and other STIs, which PrEP can not prevent. The action “no PrEP” would also not affect negatively the other prevention strategies, e.g, male circumcision.

**(ii) Disadvantages of “no PrEP”**

Regarding the disadvantages of no PrEP to *HIV positive individuals*, the findings of the study show the following disadvantages of the option “no PrEP”. The findings of the study indicate (see 4.3.3) that there would be an increase in HIV incidence rates, increased cost of treating new HIV infection as the cost would involve that for monitoring and adherence to HIV medication and other illnesses, caused by HIV, such as tuberculosis. The disadvantages of “no PrEP” would also include an increased risk of HIV re-infection. This option would lead to higher death rates from AIDS because of re-infection and infection with new HIV viral strains that would be difficult to treat.

The disadvantages of “no PrEP” to individuals who are *HIV negative* stem from an assessment of the findings of the study which indicate that “no PrEP” would lead to an increase in HIV incidence rates. The option no PrEP would also result in an increase in the cost of treating new HIV infections. In addition, there would be an increased risk of HIV infection. The option “no PrEP” would also result in less people testing for HIV infection, since the adoption of PrEP would require that people get tested before they take PrEP. There would also be higher death rates from AIDS because of lack of HIV prevention.

**(iii) Advantages of “PrEP for High Risk Groups”**

The study findings indicate that to those who are *HIV positive*, the option “PrEP for high risk groups” (mainly serodiscordant couples where one partner is HIV positive and the other is negative) would have advantages that would include reduction of risk of HIV re-infection. There would also be a reduction in risk of transmitting HIV to the negative partner and to other people, for instance, in cases of mother-to-child transmission. The drug *Truvada* is also used in treatment of HIV as anti-retroviral medication that reduces the viral load in an HIV positive person. The drug can be used as an anti-retroviral in cases where HIV infection occurs to those who are HIV negative. With regard to a serodiscordant couple, this option would reduce the cost of managing HIV as it would prevent HIV infection to the negative partner and the couple would not spend most of their money on treatment and other services. The option “PrEP for high risk groups” would also lead to economic productivity because fewer people would get infected with

HIV and become unproductive. Furthermore, families would be maintained because of reduced death rates from AIDS. The results of this study show that hospital admissions would be reduced thereby improving service delivery by medical staff. In addition, there would be an increase in couples testing for HIV together.

Regarding the group of those who are *HIV negative*, the option “PrEP for high risk groups” would have advantages such as reduction in risk of HIV infection. To HIV negative individuals in high risk groups, PrEP can reduce risk of HIV infection and it can be used as an anti-retroviral treatment in case HIV infection occurs to the negative partner. The option PrEP for high risk groups would also lead to reduced cost of managing HIV. This cost would include the cost of purchasing medication, adherence, monitoring as well as counselling services. The findings of the study indicate that there would also be more economic productivity because fewer people would fall sick if PrEP is adopted. The adoption of PrEP for high risk groups would lower death rates in household heads, thereby maintaining families. Due to reduced infection rates, hospital admissions would also be reduced because fewer people would fall sick. This option would also lead to an increase in HIV testing for those who are negative, since this would be a requirement for PrEP enrolment.

#### **(iv) Disadvantages of “PrEP for High Risk Groups”**

With regard to people who are *HIV positive*, the Literature Review of this study supports that there is a small risk that the adoption of “PrEP for high risk groups” could result in new HIV infections that could introduce new strains of the virus in the HIV positive individual. This could occur because PrEP is not 100 percent effective in preventing HIV infection. The findings also indicate that people could stop using other prevention methods such as the ABC strategy and it would affect negatively male circumcision. There could also be an increase in the cost of monitoring and adherence services for HIV treatment, and the cost of treating HIV could also increase because of possible new HIV viral strains that would require more expensive drugs to treat. In addition, there could be HIV resistance because of the adoption of PrEP, since those who are positive may stop adhering to treatment and start taking the drugs like those who are negative. The findings of the study also indicate that PrEP could lead to increased risk behaviour.

With regard to the group of those who are *HIV negative*, the adoption of PrEP for high risk groups could lead to more HIV infections of those who are negative because PrEP is not 100 percent effective in preventing infection. The adoption of PrEP could affect the other HIV prevention strategies (see Table 4) such as the ABC strategy. To those who are negative, HIV resistance may occur in case of infection and this would lead also to increased cost of managing HIV overall. This cost would involve the cost of treating HIV infection, monitoring and counselling services before and after testing. It is also likely that there would be an increase in sexual risk behaviour. The drugs for PrEP (*Truvada*) may be inadequate to cater for both HIV positive and negative individuals, thereby leading to cases of HIV resistance. Table 11 summarises the positive and negative outcomes of the two treatment options that I have considered in this research.

#### **5.4.2 Comparison of the Two Options**

In order to compare the two options, vital information about the options “no PrEP” and “PrEP for high risk groups” has been shown in the decision table (Table 11). The table shows that the option “PrEP for high risk groups” has more advantages and fewer disadvantages to those who are HIV positive and to those who are HIV negative than the option “no PrEP”. The table shows that the option “PrEP for high risk groups” has nine advantages compared to five for the option “no PrEP” for HIV positive and negative individuals. The nine advantages include reduced risk of HIV infection and re-infection. This first advantage would address the problem of increased HIV incidence rate and the increased risk of HIV infections as well as HIV re-infection that has been presented as a disadvantage for the option “no PrEP”. The option “PrEP for high risk groups” can also lead to reduced cost of managing HIV by reducing infection rates, thereby addressing the disadvantage of increased cost of treating new HIV infections that would result from the option “no PrEP”. The advantages for the option “no PrEP”, such as better monitoring and adherence service provision can be determined by the costs involved in the services. Therefore, the reduced cost of managing HIV, indicated as an advantage of adopting “PrEP for high risk groups”, also addresses the matter of costs involved in adherence and monitoring in that the reduced HIV infection and re-infection, due to

Affected Options	HIV Positive Individuals	HIV Negative Individuals
<b>No PrEP</b>	<p><b>Advantages</b></p> <ol style="list-style-type: none"> <li>1. Renal problems would be avoided</li> <li>2. Cases of edema would not increase</li> <li>3. Cases of liver toxicity would not increase</li> <li>4. Better monitoring and adherence services provided</li> <li>5. Cost-cutting because people would not need to buy <i>Truvada</i></li> </ol> <p><b>Disadvantages</b></p> <ol style="list-style-type: none"> <li>1. HIV incidence rate would increase</li> <li>2. Increased cost of treating new HIV infections</li> <li>3. Increased risk of HIV re-infection</li> <li>4. Fewer people would test for HIV</li> <li>5. Higher death rates from AIDS</li> </ol>	<p><b>Advantages</b></p> <ol style="list-style-type: none"> <li>1. Renal problems would be avoided</li> <li>2. Cases of edema would not increase</li> <li>3. Cases of liver toxicity would not increase</li> <li>4. No need for monitoring and adherence service provision</li> <li>5. Cost-cutting because people would not need to buy <i>Truvada</i></li> </ol> <p><b>Disadvantages</b></p> <ol style="list-style-type: none"> <li>1. HIV incidence rate would increase</li> <li>2. Increased cost of treating new HIV infections</li> <li>3. Increased risk of HIV infection</li> <li>4. Fewer people would test for HIV</li> <li>5. Higher death rate from AIDS</li> </ol>
<b>PrEP for High Risk Groups</b>	<p><b>Advantages</b></p> <ol style="list-style-type: none"> <li>1. Reduced risk of HIV re-infection</li> <li>2. Treatment of hepatitis B</li> <li>3. Reduced risk of transmitting HIV</li> <li>4. It can be used for anti-retroviral treatment of HIV</li> <li>5. Reduced cost of managing HIV</li> <li>6. More economic productivity</li> <li>7. Families would be maintained because of reduced death rates.</li> <li>8. Hospital admissions would be reduced</li> <li>9. Increased testing for HIV</li> </ol> <p><b>Disadvantages</b></p> <ol style="list-style-type: none"> <li>1. HIV re-infection can occur</li> <li>2. People could stop using ABC and engage in risky behaviour</li> <li>3. HIV resistance could occur</li> <li>4. Increased cost of managing HIV</li> </ol>	<p><b>Advantages</b></p> <ol style="list-style-type: none"> <li>1. Reduced risk of HIV infection</li> <li>2. Treatment of hepatitis B</li> <li>3. Reduced risk of HIV infection</li> <li>4. It can be used as anti-retroviral treatment of HIV</li> <li>5. Reduced cost of managing HIV</li> <li>6. More economic productivity</li> <li>7. Families would be maintained due to reduced death rates from AIDS</li> <li>8. Hospital admissions would be reduced</li> <li>9. Increased testing for HIV</li> </ol> <p><b>Disadvantages</b></p> <ol style="list-style-type: none"> <li>1. HIV infection can occur</li> <li>2. People would stop using ABC and engage in risky behaviour</li> <li>3. HIV resistance could occur</li> <li>4. Increased cost of managing HIV</li> </ol>

Table 11: Summary of advantages and disadvantages of the two options

adoption of “PrEP for high risk groups”, would also lead to reduced costs of adherence and monitoring service provision. Cases of edema and liver toxicity, which are presented as advantages of the option “no PrEP” and are a result of using anti-retroviral drugs, rarely occur in HIV treatment. Therefore they can be considered as lesser factors in deciding the better option.

Based on this comparison of the two options, I think that it is plausible to hold that the option “PrEP for high risk groups” has overall seen better consequences than the option “no PrEP”. If I am right in this, then implementing “PrEP for high risk groups” is morally better than not implementing PrEP, according to utilitarianism.

## 5.5 CONCLUSION

The ethical evaluation conducted in this chapter by using the Precautionary Principle and Utilitarianism, has shown the advantages and disadvantages of the two options under consideration, which are “no PrEP” and “PrEP for high risk groups”. In the application of the Precautionary Principle, the option “PrEP for high risk groups” was found to be a proportionate policy that can diminish or even avoid the “morally unacceptable harm” of not implementing PrEP. The two options were further evaluated by using utilitarianism, to determine what effects they would have on the well-being of the affected individuals-that is, HIV positive and HIV negative individuals. The evaluation using utilitarianism has shown that adopting “PrEP for high risk groups” is a better option than the *status quo* (or no PrEP option). By comparing the two options, I have therefore also given a utilitarian reason for adopting PrEP for high risk groups. As a result, given the *Zambian* situation, it seems to be morally better to implement PrEP for high risk groups rather than maintaining the status quo of not implementing PrEP. In short, in this chapter I have argued that adopting “PrEP for high risk groups” is a morally better policy than no PrEP implementation according to the Precautionary Principle, and the same result was achieved by using utilitarianism.

## CHAPTER 6

# SUMMARY, CONCLUSION AND RECOMMENDATIONS

### 6.1 SUMMARY AND CONCLUSION

This study began with a presentation of the background of PrEP. It explained the various clinical trials that have been undertaken to prove the efficacy of PrEP, with the most prominent trials being the iPrEx and TDF2 study trials that have been conducted in more than 13 countries worldwide. The introduction to the study also explained how the participants were selected in the clinical trials. It showed that at the beginning of the PrEP trials, the trial participants included men who have sex with men. The introduction showed that HIV incidence was ten percent or higher in each of the countries where the iPrEx study was conducted. The introduction also explained the reasons why the drug *Truvada* was chosen as the study drug. It is only taken once daily and remains in the blood stream for many hours. The introduction has also presented the statement of the problem, the specific objectives and the research questions of the study. The limitations of the study, including an analysis of the current situation on PrEP in Zambia, were also explained in the first chapter. The final part of the introduction introduced the two methodologies, the empirical and ethical that have been applied in this study.

The dissertation includes a Literature Review of the various HIV prevention methods, which are part of a global effort to fight the AIDS pandemic. The chapter on the Literature Review addressed the first objective of the study. It has described methods of preventing HIV infections such as the condom. Even though condoms are not 100 percent effective, they are still a very important prevention measure, despite the controversy that surrounds them. The controversies that surround condom use are based on the opinions of conservative religious groups. The other HIV prevention methods, mentioned in this chapter, include male circumcision, which is a practice that has been around for a long time, even though it has only currently been recognized as a vital HIV prevention measure. Male circumcision also reduces the chances of contracting other sexually transmitted infections.

Chapter 2 also discussed the other methods of HIV prevention such as the caesarean section, microbicides and prevention of mother-to-child transmission of HIV.

The chapter has also presented HIV prevention measures which are based on behaviour change such as voluntary counselling and testing and methods based on technology such as HIV sperm washing, where sperms are concentrated and separated from the surrounding seminal fluid by a centrifuge (a device that separates components of a liquid as it spins at high speed).

The Literature Review also discussed methods aimed at harm reduction for people who Inject Drugs. People who inject drugs can take precautions against becoming infected with HIV by sterilizing injecting equipment, including needles and syringes. The final part of Chapter 2 presented further methods that use anti-retroviral drugs, such as Post-exposure Prophylaxis and now Pre-exposure Prophylaxis, which Zambia is considering to implement for the prevention of HIV for those who are HIV negative. The methods of HIV prevention, mentioned in Chapter 2, are all part of a global effort to fight the deadly disease referred to as AIDS that results from the HIV-virus. Reviewing all the available methods of HIV prevention as it has been done in the Literature Review provides the background for understanding what policy to adopt regarding the implementation of PrEP. The Literature Review was necessary to identify the gaps that would consequently be filled by the latest HIV prevention method called Pre-exposure Prophylaxis.

In the Chapter on the Theoretical Framework, Utilitarianism and the Precautionary Principle were outlined. Utilitarianism was explained in this chapter and it was used as a guide to the data collection for this study. It was explained as a type of consequentialism whose classic origins are found in the writings of Jeremy Bentham (1748-1832) and John Stuart Mill (1806-1873). The summary of utilitarianism, referred to as the 'Utility Principle', was stated as follows: "An action is morally right if and only if there is no other possible act that has, overall seen better consequences".

The Precautionary Principle was also explained in Chapter 3. The version of the Precautionary Principle that was used in this chapter was defined by the Commission on the Ethics of Scientific Knowledge and Technology (COMEST), which falls under the wings of the United Nations Educational Scientific and Cultural Organization (UNESCO). According to this definition, the Precautionary Principle has five conditions that must be met for its application. They are (i) human activities may lead to morally

unacceptable harm that is (ii) scientifically plausible but (iii) uncertain, there is (iv) a need to act now, and it is (v) currently impossible to reduce the uncertainties. If the conditions are met the principle states that proportional actions shall be taken to avoid or diminish that harm.

Utilitarianism and the Precautionary Principle ensured that data collection was relevant to the study. In the case of the Precautionary Principle, there was consideration of the scientific plausibility of the use of PrEP to prevent HIV transmission to those who are not yet infected by the HI-virus. In the case of Utilitarianism, as a guide to data collection, the well-being of all those affected by the implementation of PrEP was considered. Part of the data needed for Utilitarianism and the Precautionary Principle was collected from secondary sources.

The fourth chapter of this study was a presentation of the findings of the research. It showed the results of a qualitative method of research conducted by purposively choosing ten males and ten female participants who work in the field of HIV/AIDS in Zambia. The chapter presented data on the current situation on PrEP in Zambia, which is the second objective of the study. Among the findings of the present study is the fact that a majority of 90 percent of the participants are aware of the new HIV prevention method called PrEP. Concerning the medications used for Pre-exposure Prophylaxis, 65 percent of the participants mentioned *Truvada* as the drug recommended for PrEP, but to some extent Pre-exposure Prophylaxis was confused with Post-exposure Prophylaxis. The participants of the study prefer Government anti-retroviral treatment centres as implementers of PrEP because of the reported possibility of the threat of side effects and monitoring for HIV resistant strains.

In Chapter 4, it was reported that a majority of the participants held that PrEP would lead to reduced HIV infections if adopted. But the concern was more on renal toxicity or kidney failure for those who may be put on PrEP. Among the major concerns of PrEP was the issue of cost. This cost involved monitoring, adherence, HIV resistance, human resource infrastructure and the cost of ARV drugs. The chapter also showed that most respondents said that PrEP would affect other HIV prevention strategies such as condoms and male circumcision. However, in the long run, PrEP would be beneficial, even though it would result in more harm in the short term. The chapter revealed also

that most of the participants preferred early adoption of PrEP, so as to reduce new HIV infections. Most of the responses in the present study were based on what the respondents have heard and read in the media on PrEP

The fifth chapter of the study presented the ethical assessment. The Precautionary Principle and Utilitarianism were applied. The chapter addressed the final objective of the study. The application of the Precautionary Principle showed that adopting Pre-exposure Prophylaxis for high risk groups of people (such as serodiscordant couples) would diminish the harm of an increased number of HIV infections. According to the Precautionary Principle, the option “PrEP for high risk groups” was shown to be a proportionate policy that can diminish or avoid the morally unacceptable harm of more new HIV infections that would result from the option “no PrEP”. This policy should therefore be adopted according to the Precautionary Principle.

The same result was achieved by using utilitarianism, which assessed the advantages and disadvantages of the two options, namely the *status quo* and PrEP for high risk groups. The two options were evaluated using utilitarianism in order to determine their effects on the well-being of the affected individuals, both the HIV positive and the HIV negative. Utilitarianism showed that “PrEP for high risk groups” had more advantages and fewer disadvantages than the option “no PrEP”. Therefore, PrEP for high risk groups should be considered for adoption. The comparison of the two options gives a utilitarian reason for adopting PrEP for high risk groups. The chapter on ethical evaluation showed that, in the Zambian situation, it would be morally better to implement PrEP for high risk groups rather than not implementing PrEP.

## 6.2 RECOMMENDATIONS

- The present study supports adopting PrEP for high risk groups in Zambia. This is necessary in order to reduce the number of new HIV infections. As I have tried to show in the ethical assessment using the Precautionary Principle and Utilitarianism. Based on the results of the Precautionary Principle and Utilitarianism, I therefore recommend that the adoption of PrEP should be limited to high risk groups of people such as serodiscordant couples and sex workers.

- There is need to first conduct a social awareness campaign of PrEP before it is adopted in Zambia. This campaign would make it easy for people to understand the intended use of PrEP. This sensitization campaign should involve members of the community who should work with health workers to educate the public about PrEP. Involving the community would lead to a better understanding of the messages that would be communicated and would also demystify the use of anti-retroviral drugs to prevent HIV infections of those who are HIV negative.
- The majority of the participants preferred adopting PrEP earlier rather than later, in order to reduce new HIV infections. The risk of more new HIV infections has been reported as a harm of the option “no PrEP”, which is the *status quo*. This brings to light the fact that there still exists the harm of more new HIV infections to the Zambian society that results in alarming death rates from the HIV disease called AIDS. Based on the responses from the participants, I therefore recommend that PrEP for high risk groups should be adopted earlier rather than later in order to reduce new HIV infection in Zambia.
- There is need to effectively deal with the issue of HIV monitoring and adherence to HIV medication if PrEP is to succeed. Zambia still has problems dealing with the issue of monitoring and adherence to HIV drugs for people who are already infected with HIV. Therefore, PrEP for high risk groups could have a negative impact on efforts to deal with the issue of monitoring and adherence as more people would be added to the current anti-retroviral treatment that requires these services, thereby over-burdening the service provision.
- The present study shows that anti-retroviral treatment for HIV requires adherence and monitoring for those on PrEP. The participants of the study mentioned that adherence and monitoring for PrEP would be a challenge. Therefore, I recommend that anti-retroviral treatment for PrEP for high risk groups should be conducted only by those who are trained in providing HIV treatment using ARVs. This would reduce or diminish the harm of more new HIV infections. This recommendation is also supported by the finding of this study that most participants prefer that PrEP should be implemented in Government ART centres because there are trained personnel.

- This study also recommends that all ART centres should be allowed to implement PrEP for high risk groups, as long as they abide by the PrEP guidelines set by the Ministry of Health. This would decongest Government ART centres and complement the Governments efforts to prevent HIV infections.
- In order to deal with the problem of new HIV infections, there is need to test for HIV all those who would be considered for PrEP for high risk groups. There could be more new HIV infections if the issue of HIV testing is not considered seriously in implementing PrEP for high risk groups. If there is little regard to HIV testing before someone is put on PrEP, new HIV resistant strains could arise which would subsequently be very costly. This measure of HIV testing is a desirable tool that can be used to fight the HI-virus. Those who would be found to be HIV positive after testing should be treated with anti-retroviral drugs and counselled in order to prevent new HIV infections.
- Participants in the study raised concerns about the poor HIV test kits that are currently available in Zambia. As a prerequisite to an effective HIV prevention measure for high risk groups, there is need to improve HIV test kits in all ART treatment centres, in order to reduce the risk of new HIV infections that are associated with the implementation of PrEP. Therefore, for an effective implementation of PrEP for high risk groups, HIV test kits, which include the nuclear test, polymerase chain reaction and the P24 test, should be made available and affordable in ART clinics in Zambia.
- There is also need to address the high cost of PrEP by properly budgeting and finding new ways of addressing the cost. This would ensure continued availability of anti-retroviral drugs that are needed for HIV treatment and prevention. This can be done by developing a plan for the supply of ARVs meant for PrEP for high risk groups and ARVs meant for treating those who are already infected, especially for high risk groups. The cost of managing HIV is currently a matter of concern in Zambia, since most of the funding for the current ARV supply is donated. Therefore, measures should be put in place now to enable the country to provide sustainable funding towards the purchase of

ARVs and ensure that the drugs are available for treatment of those who are HIV positive and those who are negative.

- PrEP should not be implemented as a stand along prevention measure, but as a complement to all the other HIV prevention methods that are available in Zambia. Implementing PrEP for high risk groups cannot prevent all new HIV infections. Therefore, it should be implemented as a complement to condoms, male circumcision and the other HIV prevention methods that are available in Zambia.

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## APPENDIX

### SEMI-STRUCTURED INTERVIEW SCHEDULE

**DEPARTMENT OF PHILOSOPHY AND APPLIED ETHICS  
THE UNIVERSITY OF ZAMBIA**

Interview schedule identification number.....  
 Date of interview...../...../..... (Month/Day/Year)  
 Name of organization.....  
 Name of interviewee.....

Good morning/ afternoon, how are you?

My name is Martin Chilukwa. I am a student pursuing a Master of Arts Degree in Applied Ethics in the School of Humanities and Social Sciences at the University of Zambia. This interview schedule is intended for the collection of data for my Master's dissertation in Applied Ethics.

My research topic is entitled "An Ethical Assessment of the Adoption of Pre-exposure Prophylaxis as a potential HIV prevention method in Zambia." Pre-exposure Prophylaxis (PrEP) refers to the use of anti-retroviral (ARV) medication by HIV-negative persons prior to HIV exposure, with the goal of preventing HIV infection. By using this interview schedule, I want to investigate the current situation in Zambia on Pre-exposure Prophylaxis.

This interview schedule is targeted at professionals in Government and Non-Governmental organizations who work in the field of HIV/AIDS in Zambia, and you have been selected purposively to take part in this study. I would be grateful if you could allow me to interview you. Please be assured that your responses shall be confidential and will only be used for academic purposes. (Is it ok, if I quote you and use your name?)

<b>No</b>	<b>Questions/statements (circle the responses and fill in the blank spaces)</b>
Q.1	Department in which you work?
Q.2	What is your official position?
Q.3	What is your highest level of education?
Q.4	Have you ever heard about PrEP? (a) Yes (b) No
Q.5	If the answer to A.4 is Yes. What are the medications being used for PrEP?..... ..... .....
Q.6	Does the medication used for PrEP have any harmful effects on the human body health? (a) Yes (b) No
Q.7	If the answer to A.6 is Yes. Can you mention any side effects of PrEP medication on human body health? ..... ..... ..... ..... .....
Q.8	Does the medication used for PrEP have any beneficial effects? (a) Yes (b) No
Q.9	If the answer to A.8 is Yes. Can you mention any beneficial effects of PrEP medication on the human body health? ..... ..... ..... .....
Q.10	Can the implementation of PrEP have any social and economic (non-medical) benefits in Zambia? (a) Yes (b) No

<p>Q.11</p>	<p>If the answer to A.10 is Yes. Can you mention any social and economic (non-medical) benefits of PrEP?                  .....                  .....                  .....                  .....                  .....</p>
<p>Q.12</p>	<p>Can the implementation of PrEP result in social and economic (non-medical) harms in Zambia?                  (a) Yes (b) No</p>
<p>Q.13</p>	<p>If the answer to A.12 is Yes. Can you mention any social and economic harms?.....                  .....                  .....                  .....                  .....</p>
<p>Q.14</p>	<p>Do you think implementing PrEP would affect sexual behaviour in Zambia?                  (a) Yes (b) No</p>
<p>Q.15</p>	<p>If the answer to A.14 is Yes. Can you mention the ways in which you think sexual behaviour would be affected by adopting PrEP in Zambia?                  .....                  .....                  .....</p>
<p>Q.16</p>	<p>Do you think adopting PrEP would affect the existing HIV prevention strategies in Zambia, e.g, Abstinence, condoms, be faithful to one sexual partner, male circumcision etc? (a) Yes (b) No</p>
<p>Q.17</p>	<p>If the answer to A.16 is Yes. In what way would PrEP affect the existing HIV prevention strategies in Zambia?.....                  .....                  .....</p>
<p>Q.18</p>	<p>What is the rate of effectiveness of PrEP in preventing HIV infections?                  .....</p>
<p>Q.19</p>	<p>From question A.18, What impact will this rate of effectiveness have on HIV infections in Zambia?                  .....</p>

	..... ..... ..... ..... .....
Q.20	Do you think the implementation of PrEP can affect the cost of ART in Zambia? (a)Yes (b) No?
Q.21	If the answer to A.20 is Yes. Can you mention the reasons, how PrEP will affect cost of ART in Zambia? ..... ..... ..... ..... ..... ..... ..... ..... ..... .....
Q.22	Do you think PrEP can have an impact on the rate of HIV transmission in Zambia, which is currently at 14 percent? (a) Yes (b) No
Q.23	How do you think PrEP can impact the rate of HIV transmission in Zambia? (a) Increased HIV transmission rate (b) Reduced HIV transmissions rate (c) No change in HIV transmission rate.
Q.24	Would you support an early or late implementation of PrEP in Zambia? (a) Late implementation (b) Early implementation
Q.25	What in your opinion would be the reason for your answer to A.24?..... ..... ..... .....
Q.26	Do you know of any non-government or government organisation which has already adopted PrEP in Zambia? (a) Yes (b) No
Q.27	In your opinion, which institutions should be allowed to implement PrEP in Zambia? (a) Government ART centres only (b) Non-Government ART centres only (c) Others (specify).....





	..... ..... ..... ..... .....
Q.41	To prevent HIV infections, what proportional action do you think should be taken to avoid or reduce the harms mentioned in A.40? ..... ..... ..... ..... ..... ..... ..... .....

**Thank you very much for your time and for allowing me to interview you.**