An exploration of young women's perceptions and experiences of participating in HIV prevention vaccine clinical trials in Nyanga Township in the Western Cape, South Africa

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COMPULSORY DECLARATION

This work has not been previously submitted in whole, or in part, for the award of any degree. It is my own work. Each significant contribution to, and quotation in, this dissertation from the work, or works, of other people has been attributed, and has been cited and referenced.

Signature:_____ Date:_____

Research Topic: An exploration of young women's perceptions and experiences of participating in HIV prevention vaccine clinical trials in Nyanga Township in the Western Cape, South Africa

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ABSTRACT

HIV and AIDS has severely inflicted suffering on the global population and reported to be the worst killer disease in sub-Saharan Africa. Preventive measures such as condom use among young people is still low and less effective in preventing the spread of the disease, it was recommended by the United Nations General Assembly Special Session on HIV and AIDS (2001) to accelerate the development of HIV vaccine aimed at curbing the disease. This study sought to explore young women's experiences and perceptions about HIV prevention vaccine clinical trials so as to inform the design and implementation of vaccine trials in Africa. The study employed purposive sampling to interview 27 participants using semi-structured interview schedule. A tape recorder was used to capture data and coding procedures were used to analyze data.

Findings drawn from participants' responses and compared with literature from previous studies on vaccine trials and social development theories indicate that participants decide

to join HIV prevention vaccine clinical trials because they hope to be protected from HIV infection. Most importantly participants hope to get access to medical care and treatment, meanwhile some participants perceived HIV vaccines harmful to humans hence they usually decline to participate. The study also identified study participation challenges related to socio-cultural and historical aspects.

Although vaccines have had some success stories in the prevention and control of infectious diseases such as the eradication of polio, smallpox and measles, prevailing challenges need to be addressed if vaccine development is to be feasible. Providing more information, reinforcement of community awareness and mobilization around issues of HIV vaccine clinical trials at all levels of vaccine design and implementation is required to ensure appropriateness and acceptability of vaccine trial participation.

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TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

CHAPTER ONE

INTRODUCTION

This chapter introduces the topic of the study being the exploration of the perception and experiences of young women about participating in HIV prevention vaccine clinical in Nyanga Township, Cape Town, South Africa. The chapter presents the background of the problem under study and the rationale for undertaking the study. The main research questions and objectives have been outlined, key concepts have been clarified and ethical considerations have also been discussed.

1.1 Background and Context

This study sought to explore the perceptions and experiences that young women have about participating in HIV and AIDS prevention vaccine clinical trials in Nyanga Township Cape Town in the Western Cape, South Africa.

It is estimated that globally 34 million people were living with HIV by the end of 2010 (UNAIDS, 2011) and sub-Saharan Africa remains the region most heavily affected by HIV and where it is still the major cause of deaths (UNAIDS, 2011). Accordingly, in 2009, over 40% of new adult infections with HIV occurred in young people between the ages of 15 and 24, amounting to 890,000 new infections in that age group during that year (UNICEF, 2010). Basically, HIV and AIDS scourge has had adverse implications on public health, public policy and social development aspects of human nature.

The Southern Africa sub-region, particularly, experiences the most severe HIV epidemics in the world, with one third (34 per cent) of all people living with HIV globally residing in the 10 countries of Southern Africa (UNAIDS, 2010).

According to UNAIDS (2011) the AIDS epidemic has had a unique impact on women, which has been exacerbated by their role within society and their biological vulnerability to HIV infection. Research has also found that women are at a greater risk of heterosexual transmission of HIV and biologically women are twice more likely to become infected with HIV through unprotected heterosexual intercourse than men. In many countries women are less likely to be able to negotiate condom use and are more likely to be subjected to non-consensual sex (UNAIDS, 2011). The Bill of Human Rights contained in the South African Constitution (1996) gives every South African citizen a right to access to health care and health related services such as water. But the reality on the ground is that people are still faced with constraints such as poor access to decent basic health care services.

The American Association for the Advancement of Science and Physicians for Human Rights and Health (1988) reports on the apartheid regime in South Africa indicate that laws and policies at the time affected all aspects of the people's lives, the health sector not being an exception. The South African health care system not only limited access to health care for Blacks and often ignored quality-of-care guidelines, which caused major disparities in health care. During apartheid, most of the national health expenditure was allocated to building a medical infrastructure that would be used by urban inhabitants and

the privately insured. It was noticed that privately insured patients pay a highly subsidized fee for medical care and receive tax benefits for their contributions to the private health sector (Zeida and Nuha, 2008).

Based on such reports, in the generally resource-poor settings where HIV prevention trials are being conducted, it is critically important to recognize the historical backdrop of apartheid and racism, and on-going challenges of poverty and exploitation.

Across the sub-Saharan Africa, some countries have achieved notable reductions in HIV prevalence among young people (15–24 years), notably, HIV prevalence among young women and men fell by 42% from 2001 to 2012. However, despite these advances, still too many people are acquiring HIV infection, too many people are getting sick and too many people are dying from HIV and prevalence among young women remains more than twice as high as among young men throughout sub-Saharan Africa (UNAIDS, 2011).

In response to the global outcry the United Nations General Assembly Special Session on HIV and AIDS (2001) recommended that increase in investment HIV vaccine development be accelerated (United Nations General Assembly Special Session on HIV and AIDS, 2001). The UNAIDS (2010) published evidence from clinical trials confirmed the powerful impact antiretroviral drugs have on the epidemic as part of an effective package of options for HIV prevention. The report shows that for first time, the prospect of a microbicide that contains antiretroviral medicine is providing additional hope to women in sub-Saharan Africa who continue to disproportionately bear burden of the HIV

epidemic in this region. This confirms the findings in the UNAIDS (2011) report that suggests that there is a remarkable decline in the number of people being infected. It is further stated that a total of 2.7 million people acquired HIV infection in 2010, down from 3.1 million in 2001, contributing to the total number of 34 million people living with HIV in 2010 (UNAIDS, 2011).

According to Ethics in Health Research report (UNAIDS, 2012), the purpose of an HIV preventive vaccine is to induce an immunological response to counteract the HIV virus if it enters the human body, or to prevent it from entering at all. Since HIV prevention vaccine trials require that several injections be given over months or years, this sometimes result in pain, occasional skin disorders and possibly other adverse events, such as fever may be sustained due to clinical procedures related during the course of the clinical trials.

1.2 Statement of the Research Problem

Although HIV prevalence is stabilizing and declining in some countries, Southern Africa still experiences higher incidences of HIV infections estimated at 31% of new infections and 34% of AIDS deaths (UNAIDS, 2010). Reports indicate that not only is HIV epidemic a global crisis, but also has also had adverse effects on the development and social progress of the global economy. Not only does HIV present a tragedy at human level but it also heavily affects the economic development of countries, many of which are already severely strained for resources (UNDP, 2011).

As the HIV and AIDS epidemic rages globally, it is becoming increasingly clear that treatment such as antiretroviral therapy cannot control the worldwide spread of HIV, nor will HIV transmission be stopped through behavioral interventions alone. First, safe and effective vaccines to prevent HIV infection and AIDS are necessary to control the spread of the disease (de Zoysa, Elias & Bentley, 1998). Second, although some notable achievements have been made in HIV management, including substantial improvements in access to condoms, expansion of tuberculosis control efforts and scale-up of free antiretroviral therapy, an HIV and AIDS vaccine would have a number of key advantages over the existing HIV prevention options. These arguments are based on the fact that protection offered by a vaccine during sex would not depend on the consent of both partners, unlike the use of condoms or adherence to abstinence which would require behaviour change (Abdool Karim, 2005; UNAIDS, 2010).

1.3 Rationale of the Study

Various studies have shown that there is little information about factors that motivate young people who had gone to participate in HIV vaccine clinical trials to do. For example a report on a study conducted by Starac et al., (2006) in 72 high public high schools in Soweto (2005) on adolescents and HIV vaccine trials shows that participants have little knowledge about HIV clinical trials. Findings from the study show that participants had inadequate information communicated to them at enrolment. These studies hence highlight the importance of clear identification of motivations and incentives that may facilitate participation in vaccine clinical. Various studies have identified numerous common factors that motivate participation and adherence to

participation in clinical trials. These factors are, in general, linked to altruistic feelings, the perception of personal benefits and satisfactory interaction with the study staff (Celentano, 1995; Jenkins, 1995; MacQueen, 1999; Pe´risse´, 2000; &Strauss, 2001 cited in Starac, 2006).

This study focused on young women aged 18-24 years perceptions and experiences about participating in HIV prevention vaccine clinical trials. The fact that young women accept to participate in clinical trials should not compromise their rights in the long-run. For that matter, identification and consideration of potential barriers is paramount when designing procedures and guidelines to be followed in the recruitment into vaccine trial studies.

International AIDS Vaccine Initiative (IAVI) and International Centre for Research on Women (ICRW) (2008) highlight some of the barriers to vaccine trial participation. These include a collection of psychological and social factors that may discourage someone from participating in a vaccine trial. Although this study is focusing on young women, it is recognized that men also get affected either directly as participants or indirectly as relatives to the clinical trial participants (IAVI and ICRW, 2008).

The overall aim and objective of this study was to explore young women's experiences and perceptions about HIV prevention clinical trials. Information gathered from this study may be used to inform the design and implementation of HIV vaccines trial processes in Africa.

1.4 Specific Objectives of the Study

The main research objectives are:

- To find out the reasons why young people participate in HIV prevention vaccine clinical trials
- To explore young women's perceptions about of HIV prevention vaccine clinical trials
- To explore young women's experiences regarding their participation in HIV prevention vaccine clinical trials
- To explore young women's attitudes about in HIV prevention vaccine clinical trials
- To identify factors that influence women's decision to participate or not to participate in HIV prevention vaccine clinical trials
- To identify the challenges and barriers that participants encounter while participating in HIV prevention vaccine clinical trials
- To identify whether study participants are knowledgeable about the risks, benefits and rights related to participating in HIV prevention vaccine clinical trials
- To assess whether study participants are aware of the policies that relates to HIV prevention clinical trials

1.5 Main Research Questions

The main research questions are:

- What are the reasons and motivations that inspire young women to participate in HIV prevention vaccine clinical trials?
- What are the young women's perceptions and experiences of HIV prevention vaccine clinical trials?
- What are the young women's attitudes towards participating in HIV prevention vaccine clinical trials?
- What are the subjective norms that influence women's decision to participate or not to participate in HIV prevention vaccine clinical trials?
- What are the young women's challenges and barriers related to participating in HIV prevention vaccine clinical trials?
- Are young women aware of the risks, benefits and rights related to participating in HIV prevention vaccine clinical trials?
- Are young women aware of the policies that relate to HIV prevention clinical trials?

1.6 Significance of the Study

Sub-Saharan Africa remains the region most heavily affected by HIV, accounting to 70% of new HIV infections in 2010 (UNAIDS, 2011). In sub-Saharan Africa, the epidemic continues to be most severe in southern Africa, with South Africa having more people living with HIV (estimated at 5.6 million) than any other country in the world. And of the people living with AIDS, 518 000 are children under 15 years while 2.95 million were females over the age of 15 years and worse still, almost half of the deaths from AIDS-related illnesses in 2010 occurred in southern Africa (UNAIDS, 2011).

Since as many as 34 million people are infected with HIV worldwide (UNAIDS, 2011) the vaccine is still the best hope for eradicating AIDS (International AIDS Vaccine Conference, 2012). A report by International AIDS Vaccine Initiative (IAVI) (2006) explains that even a partially effective HIV vaccine could save millions of lives. Experts have calculated that a vaccine that is 50 percent effective, given to just 30 percent of the population could reduce the number of HIV infections in the developing world by more than half over 15 years (IAVI, 2006).

Accordingly, studies have found that an HIV and AIDS vaccine would have a number of key advantages over today's HIV prevention options. International AIDS Vaccine Initiative (IAVI) reports show that once found, an HIV vaccine would be invaluable for couples wishing to conceive a child while minimizing the risk of HIV transmission, and children could be given an HIV and AIDS vaccine before ever being exposed to HIV to protect them from all routes of HIV transmission. And it is also hoped that, vaccinating

large numbers of people would probably require relatively little equipment and expertise, and would be much simpler and cheaper than providing antiretroviral treatment for those already infected (IAVI, 2006).

Based on the above statements, therefore, the search for an effective AIDS vaccine needs to be one of the highest priorities for scientific research.

1.7 The Research Topic

The research topic is "An exploration of young women's perceptions and experiences of participating in HIV prevention vaccine clinical trials in Nyanga Township in the Western Cape, South Africa". The research topic clarifies what the researcher intends to study and it explains whether the research explores new ideas or describes existing phenomena and the practical significance of the study (Babbie & Mouton, 2001). The proposed study is exploratory and of a contextual design. The researcher expects the study to contribute findings that will contribute to useful information about young women decisions to participate in HIV vaccine clinical trials.

1.8 Concept Clarification/Definition of Terms

The following terms will be used repeatedly in this study. For the purposes of further understanding of the topic in this study key concepts have been clarified.

AIDS. According to the dominant and current definition of AIDS offered by the by the Centers for Disease Control (CDC) in the United States, AIDS stands for acquired immunodeficiency syndrome, a cluster of medical conditions, often referred to as

opportunistic infections and cancers and for which, to date, there is no cure (Harold, 1995)

Clinical Research: This is a health related research conducted on human beings or on specimens collected from specific patients, but not on human tissues, where the identity of the people from whom the cells or tissues are derived is unknown (Harold, 1995)

Clinical Trials: These are organized experiments in which outcomes in participants who are assigned active treatment are compared with those receiving an alternative active treatment, a placebo (inactive treatment) or no treatment (Harold, 1995).

The *Human Immunodeficiency Virus* (HIV): This is a retrovirus that infects cells of the immune system, destroying or impairing their function. As the infection progresses, the immune system becomes weaker, and the person becomes more susceptible to infections. The most advanced stage of HIV infection is the acquired immunodeficiency syndrome (AIDS) (WHO, 2006).

HIV Vaccines: These stimulate the body's immune system to provide protection against infection or disease. Vaccines against HIV are being developed, and they are in various stages of clinical trial but at present none have proven effective (WHO, 2009).

Township: According to the South African meaning of township (often underdeveloped), this refers to urban residential area in which the non-white inhabitants used to live during times of the apartheid. However, the term township also has a precise legal meaning, and is used on land titles (in all areas, not only traditionally non-white areas) (Pettman, 1913).

Young Women (youth): The National Youth Policy (NYP) 2009 – 2014, defines the youth as the youth people falling within the age group of 14 to 35 years. While "the youth" or "young people" are defined as the 14–35 age cohort in South Africa, taking into account both historical as well as present-day conditions, this study will focus on the 15–24 age group with its very specific characteristics and needs in terms of the school-to-work transition.

1.9 Structure of the Report

The research report has been structured as follows:

Chapter One: Introduction. This chapter introduces the research problem. A brief background of the research problem has been given, followed by the statement of the problem, rational and aim for the study, ethical considerations, research topic, main research objectives, research questions, definition of key terms, list of abbreviations and layout of the research report.

Chapter Two: Literature Review. This chapter presents a review of the literature relating to the research topic, the theoretical frameworks to be used for conceptualization and analysis of the data. This chapter is structured around the research themes namely HIV prevention clinical vaccine trials from a global perspective, the South African context and specially Cape Town in Nyanga Township.

Chapter Three: Methodology. This chapter presents the research methodology by discussing the research design, sampling considerations, data collection methods, data analysis and limitations of the study.

Chapter Four: Findings. This chapter presents the research findings. Firstly a profile of the participants is presented, followed by framework of analysis, discussion of the findings placed under headings, which relate to the main themes and categories in the framework of analysis.

Chapter Five: Conclusions and Recommendations. The chapter uses the research objectives to discuss the conclusions that emanated from the findings. The chapter also presents the recommendations by the researcher based on the findings.

CHAPTER TWO

LITERATURE REVIEW

In order to determine what has already been done that relates to the research topic, it is significant for the researcher to review the existing literature that is related to the topic being researched. This knowledge helps the researcher from intentionally duplicating another person's research as well as providing the researcher with an understanding and insight needed to ascertain what has been and what needs to be done and identify knowledge gaps. According De Vos (2011) literature review sheds light into the nature and meaning of the problem that has been identified. In order to understand the concept of HIV vaccine clinical trials the researcher has drawn on various theoretical frameworks as will be explained later in the subsequent paragraphs.

2.1 Global HIV and AIDS Responses

At the end of 2010, it was estimated that out of the 34 million adults worldwide living with HIV and AIDS, half are women (UNAIDS, 2011). The AIDS epidemic has had a unique impact on women, which has been exacerbated by their role within society and their biological vulnerability to HIV infection (UNAIDS, 2013). Women are at a greater risk of heterosexual transmission of HIV and biologically women are twice more likely to become infected with HIV through unprotected heterosexual intercourse than men (Dworkin, 2005 and Zierler, Krieger, 1997). In some countries, women are less likely to be able to negotiate condom use and are more likely to be subjected to non-consensual sex (UNAIDS, 2009).

The UNAIDS (2009) report adds that millions of women have been indirectly affected by the HIV and AIDS epidemic. Women's childbearing role means that they have to contend with issues such as mother-to-child transmission of HIV. The responsibility of caring for people living with AIDS and taking care of orphans is an emerging challenge for women. Based on the above arguments, a number of things need to be done that in order to reduce the burden of the epidemic among women. These include promoting and protecting women's human rights, increasing education and awareness among women and encouraging the development of new preventative technologies such as post-exposure prophylaxis and microbicides (UNAIDS, 2009).

2.2 HIV and AIDS Strategies and Interventions

Because of the formidable and persistently unique threat and challenge the HIV and AIDS poses globally, the UNAIDS (2011) report highlights unprecedented global response to further fight against the scourge. These innovative interventions include the Political Declaration on HIV and AIDS, adopted in June 2011 by the United Nations General Assembly, which sets ambitious targets aimed at achieving universal access and the health-related Millennium Development Goals by 2015; The World Health Organization (WHO) Global Health Sector Strategy on HIV and AIDS, 2011-2015, the UNAIDS 2011-2015 Strategy: Getting to Zero, and the UNICEF's strategic and programmatic focus on equity aimed at helping to guide national and global efforts to respond to the epidemic and move from an emergency response to a long-term, sustainable model of delivering HIV services. These strategies emphasize the need to better tailor national HIV responses to the local epidemics, to decentralize programmes to

bring them closer to people in need and to integrate with other health and community services to achieve the greatest impact (UNAIDS, 2011).

2.3 Global HIV and AIDS Vaccine Clinical trials as New Prevention Tools

As the AIDS epidemic continues to expand, especially in sub-Saharan Africa initiatives to reduce HIV incidence are also being accelerated, reference give to the endorsement of the 2011 UN Political Declaration on HIV/AIDS, which set forth a series of ambitious targets and elimination commitments for 2015 (UNAIDS, 2013). Although prevention campaigns that promote Abstinence, Being faithful and using Condoms (ABC), male circumcision and the testing of microbicides are being emphasized as some of the current measures towards the fighting of the HIV and AIDS epidemic, studies have shown that the best hope to end the AIDS epidemic is the development and distribution of effective vaccines (IAVI, 2006).

In 2000, the Security Council of the United Nations began to address the possibility that by devastating a country's entire population of young adults, AIDS now threatens the world's security. Besides the immediate crisis that HIV presents, it also undermines global development, nullifying or even reversing decades of progress that most likely lead to deepening poverty, reducing life expectancy, contributing to economic and political instability, exacerbating food shortages and increasing the divide between the rich and the poor (Kahn, 2005).

Against this background, response to curtail HIV prevalence has become a critical and contentious issue that needs global concerted efforts. For example, one of the world's

renowned leaders, Bill Clinton, pointed out that despite recent developments in averting the HIV scourge, control of AIDS still awaits a vaccine. In 1997, President Bill Clinton challenged scientists to provide an effective vaccine and as a result a national HIV Vaccine Trials Network was established to develop and test possible compounds (Kent et al., 2001). This development, however, was associated with challenges to researchers such as establishing viral heterogeneity, uncertainty about how to achieve optimal immunogenicity, the lack of a practical animal model, and the ethical dilemmas involved in conducting primary prevention trials in the United States and abroad (Kent et al., 2001). AIDS Vaccine Advocacy Coalition also warned that though the HIV vaccine remains the world's best chance to reverse this relentless epidemic, the search a vaccine must not come at the expense of our immediate response (Kahn, 2005).

Testing vaccines requires that efforts be directed towards delivering the best possible risk-reduction counselling and prevention tools, ensuring confidential voluntary counselling and testing, providing referral to comprehensive treatment. Additionally, in order to marshal and sustain public involvement in global AIDS efforts, communities need information that not only educates but also suggests how people can play an active role (Kahn, 2005).

In response to the escalation of the HIV epidemic, the UNAIDS (2008) reports that in 2000, global leaders embraced a series of Millennium Development Goals (MDG) that reflected new found resolve to make the world safer, healthier, and more equitable. Millennium Development Goal 6 states that, by 2015, the world will have halted and

begun to reverse the global HIV epidemic. By making the HIV response one of the overriding international priorities for the 21st century, world leaders acknowledged the centrality of the HIV response to the future health and well-being of our increasingly interconnected planet (UNAIDS, 2008). While national programmes work to bring available HIV prevention strategies to scale and to improve their strategic application, the search continues for additional tools to strengthen prevention efforts. In particular, new prevention technologies are urgently needed, more especially for women who currently lack access to female-initiated prevention methods (UNAIDS, 2008).

The HIV and AIDS vaccine agenda is increasingly part of some larger agenda that agenda includes alleviating poverty and promoting development and economic growth; and promotion of social equity (Kahn, 2005). However, much as vaccine discovery seems to be a desired direction against HIV prevention, enough efforts have not been made to make it work. This is evidenced in AVAC's remarks that AIDS vaccine development has not received enough attention or funding since the discovery of HIV and rarely gets government action or support (Kahn, 2005). Scientific uncertainties over what is likely to work, plus doubts about the profitability of an AIDS vaccine, have discouraged the involvement of pharmaceutical companies, which traditionally led the way in making new vaccines (Kahn, 2005). Vaccine developers cannot predict what strategy will work or even whether they are going in the right direction or heading down to a dead end. The only way to find out is to test vaccines in populations of HIV negative people exposed to HIV through different routes, for example, gay men exposed through anal sex and injecting drug users sharing needles (Kahn, 2005). However, the testing of HIV vaccines

is ethically complex because HIV prevention clinical trials involve international collaborations, potentially vulnerable communities and participants, and high levels of discrimination and stigma surrounding HIV (Slack et al., 2000).

Since HIV vaccine testing also raises significant human rights issues, it is critical the International Ethical Guidelines developed by UNAIDS be adhered to. The publication of the Nuremberg Code 6 in 1947 and the subsequent to the Declaration of Helsinki in 1964 recognize that research should be regulated by some type of ethical-legal framework. However, the nature and extent of regulation varies from country to country (Strode, Slack & Mushariwa, 2005). In South Africa, National Health Research Committee (NHRC), established in terms of Section 69 of the National Health Act is a policy-formulating body that advises the Minister of Health on the nature and focus of health research within South Africa and co-ordinate such efforts (Department of Health, 2003). The HIV and AIDS Vaccines Ethics Group research the ethical aspects of HIV vaccine trials and develop guidelines to assist in the practice of ethically sound HIV vaccine trials (Slack et al., 2000).

2.4. Reasons why Young People Participate in HIV Vaccine Clinical Trials

Vaccine trial participation is a complex process that involves barriers and motivators. To gain a comprehensive understanding of potential and actual trial participants, we need to build on Mills et al, (2005) work on barriers and examine the related literature on motivators. For example, altruism and health insurance (Sahay, Mehendale &Sane et al., 2005), and provision of high quality HIV treatment, personal protection against HIV

infection, making a contribution towards the fight against HIV and AIDS, the hope to receive free medical attention and financial incentives (McGrath, Mafigiri, & Kamya et al., 2001) and to get protection from HIV infection (Mills, Cooper & Guyatt, et al., 2004) are often identified as a motivators. These findings further show that the design and implementation of vaccine trials benefit from a better understanding of these motivators, and efforts to engage these motivators ethically.

The Medical Research Council outlines ethical guidelines for potential benefits that participants in HIV preventive vaccine trials should receive as a result of their participation. These include facilitating regular and supportive contact with health-care workers and counsellors throughout the course of the trial; receiving comprehensive information regarding HIV transmission and how it can be prevented, and access to appropriate HIV prevention methods, accessibility to treatment and care for HIV and AIDS if they become HIV infected while enrolled in clinical trial studies and getting compensation for travel, time and inconvenience relating to trial participation (Slack, C. and Kruger, M. (2005).

2.5 Perceptions of HIV and AIDS Vaccine Clinical Trials

In South Africa, differences exist in status, knowledge and power between investigators and research participants, especially where participating individuals and communities are vulnerable because of socio-economic and other factors (UNAIDS, 2000). Meaningful involvement of communities in research can serve to offset the vulnerability of communities and promote their rights and welfare and those communities have the right

and responsibility to take decisions regarding the nature of their participation in HIV vaccine research (UNAIDS, 2000). There should be community participation in all relevant aspects of HIV vaccine research and investigators must clearly justify and explain those aspects of research that are essential to a scientifically valid and ethically sound research design (UNAIDS, 2000). For that matter, the social context of a proposed research population that creates conditions for possible exploitation or increased vulnerability among potential research participants should be assessed and where this is applicable, steps must be taken to overcome these conditions with the aim of promoting and protecting the dignity, safety and welfare of participants. In South Africa, like other developing nations, many individuals at high risk of HIV infection may be simultaneously vulnerable to exploitation because of socio-historical factors, such as oppression and economic impoverishment (UNAIDS, 2000).

Research in developing countries about clinical research has found that due to the risk of inadvertent or deliberate exploitation, a cautionary approach should be followed when conducting research with human participants in developing countries. According to Glantz (2001) cited in Starac (2006) citizens of developing countries are often in vulnerable situations because of their lack of political power, lack of education, unfamiliarity with medical interventions, extreme poverty, or need for health care health care and nutrition. It is the dire need of these populations that make them both appropriate participants of research, especially those vulnerable to exploitation (Glantz, 2001, cited in Starac, 2006).

This combination of need and vulnerability has led to the development of specific guidelines for health research in developing countries. Despite codes of ethics and regulations, there is on-going evidence of unethical recruitment and research practice. (LaFraniere, Flaherty & Stephens et al (2000) cited in Starac (2006).This malpractice generally violates the autonomy of research participants and targets the vulnerable subgroups of a given population as is evidenced with the legacy of apartheid in South Africa which is marred with reports of unethical research conducted and may have impacted negatively on public perceptions of the voluntariness of research participants. Specific ethical guidelines for HIV vaccine trials were published by UNAIDS (2000), and were revised and adapted for South Africa (Slack and Kruger, 2005). Special attention needs to be paid to the protection of participants' autonomy in particular as noted by Jenkins (1985) who emphasizes that simple justice requires that each socio-economic group bears a proportionate share of research risk, but many researchers fall into the trap of recruiting participants from dependent and less privileged populations. Developing countries, and particular communities within developing countries, arguably fall within this category (Jenkins et al., 1985).

Studies conducted on volunteerism in clinical trials in South Africa suggest that community preparedness campaigns conducted prior to recruitment for clinical trials such as HIV prevention vaccine trials need to emphasize the voluntariness of enrolment in the trial and the freedom to withdraw at any time. These studies further point out that informed consent procedure should also highlight the voluntary component of trial participation. This is underscored by findings from microbicide trials in South Africa and

elsewhere that found that very few participants recalled or understood key elements of the trial design (Ramjee, Morar & Alary et al., 2000).

Merck and the US National Institute of Allergy and Infectious Diseases, part of the National Institutes of Health (NIH), the pharmaceutical company Merck & Co. Inc., and the NIAID-funded HIV Vaccine Trials Network (HVTN) announced that immunizations in the HIV vaccine clinical trial known as the STEP study, also referred to as the HVTN 502 or Merck V520-023 study was discontinued basing on the decision made by an independent Data and Safety Monitoring Board (DSMB). This was because of the findings that the vaccine did not prevent HIV infection nor reduce the amount of virus in those who became infected with HIV (Kristen, 2005).

2.6 Barriers and Challenges to Participation in Vaccine Clinical Trials

Historically studies have shown that immunizations have not always been universally accepted and this is based on resistance to mandatory smallpox vaccination began in the 1850s in the UK and towards the end of the 19th Century in the USA in response to enforcement of existing laws or creation of new ones (Wolfe & Sharp, 2003). It is further argued that after decades of relative acceptance of new vaccines, a strong anti-vaccination movement began in the 1970s owing to adverse events from the whole-cell pertussis vaccine and this anti-vaccination sentiment continued into the subsequent decades (Poland et al., 2001).

Based on the mentioned anti-vaccine movements it has been suggested that the importance of risks and costs be put into consideration and refers to it as a hallmark of

the health belief model which can be used to predict decisions such as willingness to participate (WTP) in a trial (Poland, et al. 2001. Studies on HIV and AIDS vaccine trials have examined several barriers that may hinder people considering participation in HIV clinical trials. It is important that barriers are clearly understood from the onset of clinical trials for purposes of planning. Mills et al., (2004) points out that if researchers understand what factors could hinder potential participants in clinical studies, then it is possible for them to attend to those hindrances to avoid shortcomings in HIV prevention vaccine research processes. Mills et al., (2004) mentions that researchers, for example, can attend to potential harms and misconceptions related to participation in HIV vaccine trials, help eliminate these barriers, and enroll sufficient numbers of participants willing to participate. Emphasis should be given to the identification of potential barriers when designing informed consent procedures (Mills et al., 2004). For example, potential participants must understand that there may be side effects from the vaccine being tested, some participants becoming HIV sero-positive secondary to the HIV vaccine and that the vaccine efficacy is unknown (Lindegger & Richter, 2000).

For example, a study on Organization for Economic Co-operation and Development (OECD) countries and the non-OECD countries, it was found that barriers to participation in HIV vaccine trials included personal risks, social risks, personal costs, social costs, and misconceptions. Concerns regarding adverse effects and vaccine-induced sero-positivity were cited as outstanding barriers in both types of countries in various populations. In the OECD countries, men who have sex with men (MSM) cited discrimination, HIV infection from the vaccine and distrust of research institutions as

common fears and hence barriers to participate in HIV clinical trials (Mills et al., 2004). Other examples include experiences based on the first Phase 1 HIV vaccine trial in Africa, which indicated a number of perceived barriers to participation and misconceptions about trial participation, including fears of deliberate infection with HIV (Mugerwa, Kaleebu, & Mugyenyi et al., 2002).

Another potential barrier cited is mistrust of information about HIV vaccine provided by the government and researchers. In their findings, Newman et al., (2006) suggest that lack of transparency and false information has fostered mistrust of the government, science and health care in South Africa, posing potential barriers to participation in HIV vaccine clinical trials.

The importance of ethics, communication and attending to societal concerns in health science research and ethical guidelines should therefore be emphasized. Since HIV vaccines are important long-term preventive measures aimed at combating the epidemic that has overwhelmed the world, it is imperative therefore, that vaccine trials in search of suitable and effective vaccines be designed and conducted according to high ethical standards. Additionally, HIV vaccine development should ensure that the vaccines are appropriate for use among such populations and Good Clinical Laboratory Practice (GCLP) should be adhered to for guidance (Slack and Kruger, 2005). On the international level, international guidance documents on research ethics such as the Declaration of Helsinki and guidelines (1964) and the guidelines of the Council for International Organizations of Medical Science (CIOMS) provide a broad framework for participants'

rights such as the right to bodily integrity or to have access to interventions which prove effective, and other rights (Slack and Kruger, 2005).

2.7 Rights to Participation in HIV Prevention Vaccine Clinical Trials

In clinical research, trial participants are entitled to legal rights that must be adhered to by researchers. Independent and informed consent for participation, based on complete, accurate, and appropriately conveyed and understood information as well as its consequences, should be obtained from each individual who is legally competent to give consent (Slack and Kruger, 2005).

Throughout the trial efforts must be made to ensure that participants continue to understand the consequences of participation and that they participate freely as the trial progresses. Some of the rights include empowering participants to make decisions that are consistent with their values and preferences. And before starting research a process of consultation between community representatives, investigators, research ethics committees, regulatory bodies, and sponsor(s) should be undertaken to design for effective implementation processes (Slack and Kruger, 2005).

2.8 Benefits of Participating in HIV Prevention Vaccine Clinical Trials

The ethical considerations in biomedical HIV prevention trials emphasize the importance of research protocol providing anticipated benefits of the procedures and interventions of clinical trials to anticipating trial participants (Slack and Kruger, 2005). It is re-enforced that the trial protocol outlines the expected services and other supplementary interventions that may benefit those participating in the clinical trials. The benefits may

be in terms of support, care and treatment to participants and the community involved in HIV prevention clinical trials (UNAIDS 2000).

Benefits to trials participants include regular contact with health care workers and counsellors throughout the course of the trial; participants receive comprehensive information regarding HIV transmission and how it can be prevented; have access to HIV testing and prevention methods (UNAIDS, 2000).

2.9 Policies and Legislative Framework on HIV and AIDS Clinical Trials

Although there is no specific policy in regard to HIV and AIDS vaccine clinical trials, the government has put in place general policy guidelines such as the National Strategic Plan (NSP, 2012-2016), whose strategic objectives among other include addressing social and structural barriers that increase vulnerability to HIV, STI and TB infection. The main goal of research on HIV, STIs and TB in South Africa in the new NSP is to provide scientific evidence to guide policy and enhance the country's response to these diseases (NSP, 2012-2016). The Health Research Policy in South Africa has been developed to promote practice and conduct of research that contributes towards the improvement of the human health and welfare of the South African population (NSP, 2012-2016).

At a macro level, the 2009–2014 Medium Term Strategic Framework (MTSF) sets to identify strategic priorities and targets that serve as the basis for determining the government's implementation plans, while the National Planning Commission is a broad government framework for addressing the major developmental challenges in South Africa (NSP, 2012-2014).

At the international level, the Millennium Development Goals s have specific targets that all countries are striving to achieve by 2015. By situating the response to HIV, STIs and TB within the broader development agenda and integrating the human rights and gender dimensions, countries are in a better position to accelerate progress across an array of MDGs (NSP, 2012-2016).

The strength of the various policies and legislation has however not always translated into enhanced or improved delivery on the ground. This phenomenon is more as a result of a lack of capacity at Local Government level than a deficiency in the policy environment. The National Youth Policy (2009) thus emphasizes the need for holistic intervention for the youth in South Africa which must target challenges of poverty, health and education. However, despite amplified attention on national and global policy agenda, few countries have been able to systematically reduce socially determined inequities in health (WHO, 2008). Further findings in the National Health Act, Act No. 63 of (2003) show that although South Africa has a functioning ethical-legal system that has recently been strengthened through the implementation of the National Health Act, the ethical-legal framework, it does not have many of the laws needed to protect and promote the rights of persons participating in research, including HIV prevention vaccine trials (Government Gazette, 2004). The researcher, therefore, suggests that future effort must be directed at enhancing the ability of the South African ethical-legal system to respond to the complexities of clinical research including vaccine trials.

2.10 Theoretical Framework

HIV and AIDS prevalence poses a challenge to the South African health sector and communities. It is of paramount importance for the health sector to design interventions aimed at alleviating this scourge. These interventions should be derived from well-tested theories. To try and understand how health behaviours act as catalysts towards the way individuals preserve or enhance their health, the researcher will use commonly known and relevant theories to help us understand health behaviour. These Reasoned Action (TRA) and Planned Behaviour (TPB) (Ajzen, 1988; Fishbein & Ajzen, 1975). The researcher has chosen the TRA and TPB for this study since they are some of the most cited theories in HIV and AIDS research.

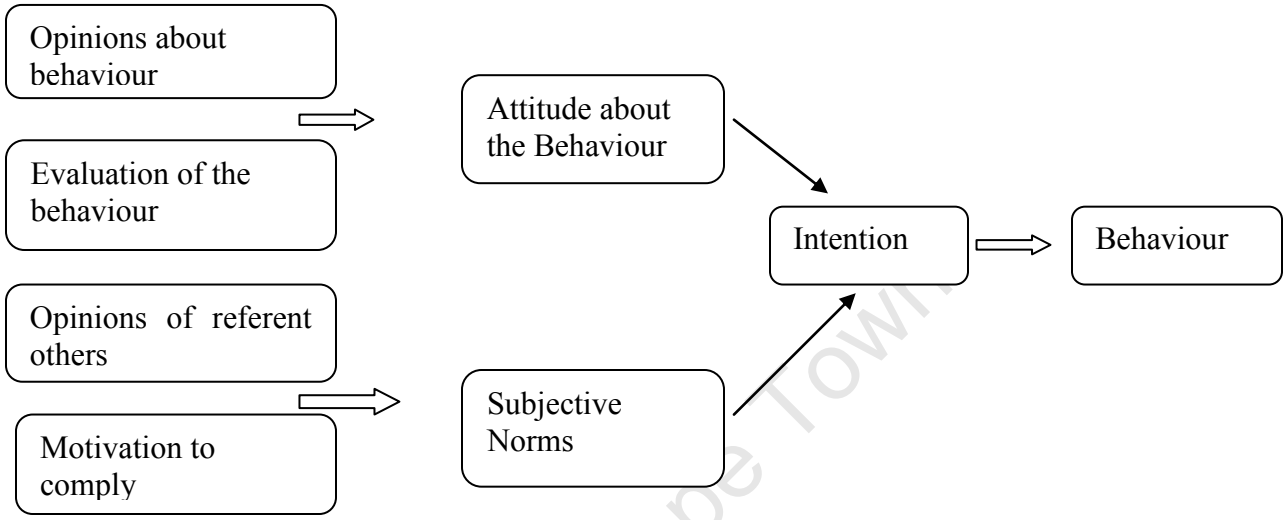
These theories are more reliable in predicting HIV and AIDS health behaviour than other models (Fishbein, 1993). This particular study is about HIV prevention vaccine trials, the researcher finds it relevant to apply the TRA and TPB theories.

2.10.1 Overview of Theory of Reasoned Action (TRA)

The Theory of Reasoned Action was first introduced in 1967 by Fishbein in an effort to understand the relationship between attitude and behaviour (Fishbein & Ajzen, 1975). The Theory of Reasoned Action was based on the premise that humans are rational and that the behaviours being explored are under volitional control (Fishbein & Ajzen, 1975). The TRA attempts to explain the relationship between beliefs, attitudes, intentions and behaviour. In the work that led to the development of the TRA, Fishbein (1980)

distinguished between attitude towards an object and attitude towards behaviour with respect to that object.

Figure 1: Diagrammatic Representation of Theory of Reasoned Action



Adapted from Fishbein & Ajzen (1975)

As shown in figure 1 above, there are three determinants of behavioural intentions, namely the personal or attitudinal component and the social or normative component. Ajzen and Fishbein (1980) defined underlying beliefs (behavioural, normative, intentions and normative leading to behaviour and their measurement. Ajzen and Fishbein (1980) have shown that it is critical to have a high degree of correspondence between measures of attitude; norm, perceived control, intention, and behaviour. A change in any of these factors results in a different behaviour being explained (Ajzen & Fishbein & 1980).

2.10.2 Assumptions of the Theory of Reasoned Action

According to Ajzen and Fishbein (1980), the theory of reasoned action assumes that a person's behaviour is determined by his/her intention to perform the behaviour and that this intention is, in turn, a function of his/her attitude toward the behaviour and his/her subjective norm. The best predictor of behaviour is intention. Intention is the cognitive representation of a person's readiness to perform a given behaviour and it is considered the immediate precursor of behaviour. This intention is determined by three factors: their attitude toward the specific behaviour, their subjective norms and their perceived behavioural control. However, it is not clear that the TRA components are sufficient to predict behaviours in which volitional control is reduced (Ajzen, 1991).

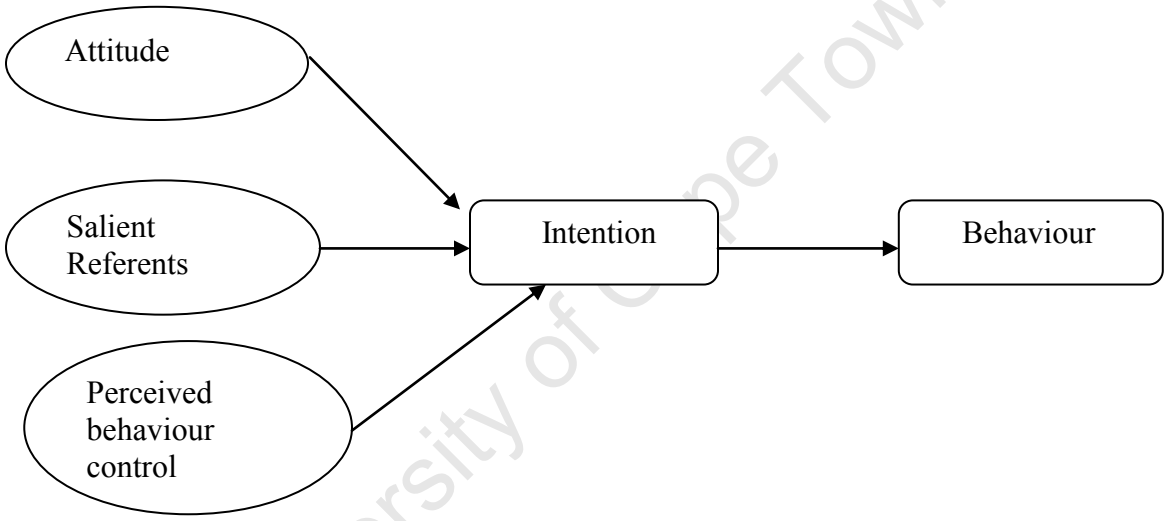
2.10.3 The Theory of Planned Behaviour (TPB)

The Theory of Planned Behaviour (Ajzen, 1991), used to predict an array of behaviours including HIV clinical research is built further on the Theory of Reasoned Action (Werner, 2004). The TPB is determined by behavioural intentions which are largely influenced by an individual's attitude toward behaviour and the subjective norms influencing the execution of the behaviour, and the individual's perception of their control over the behaviour (Ajzen, 1991). The TPB adds perceived control over the behaviour, taking into account situations where one may not have complete volitional control over behavior (Smith et al., 2007 cited in Lutz, 2011).

For example, the perception of whether HIV prevention vaccine trial participation constitutes a health-promoting behaviour or not appears to depend on the lens through

which it is viewed, that is, of the researcher or the trial participant. Whilst researchers recognize that trial participants have a crucial role to play in the development of an effective HIV prevention vaccine, this role primarily concerns a contribution to the scientific process. For the individual for whom the risk of HIV infection is constantly made salient, however, trial participation may appear to offer the direct benefit of protection from HIV infection.

Figure 2: Illustration of Theory of Planned Behaviour



Adapted from Ajzen (1991)

A person's intentions are a good predictor of their behaviour. The stronger the intention to perform a particular behaviour, the more likely the person is to perform that behaviour. This, however, is not especially illuminating to say that people do what they intend to do is not particularly instructive. It is important to consider the determinants of behavioral intentions and from observing the figure above, intentions are a function of three

determinants, namely, beliefs, salient referents and perceived behavioral control (Ajzen, 1988).

2.10.4 Application of the Theories of Reasoned Action and Planned Behaviour

Both TRA and TPB were designed to provide explanations of informational and motivational influences on behaviour and both models can be considered as deliberative processing models, as they imply that individuals make behavioural decisions based on careful consideration of available information (Conner & Armitage, 2001). Both models were designed to provide explanations of informational and motivational influences on behaviour.

A study conducted by Sheeran and Orbell (1998), cited in Rammule (2009) to examine the extent to which behavioural intentions are associated with condom use in heterosexual and gay men. A moderate relationship exists between intention and condom use behaviour. This suggests that intentions to use a condom do not always translate into condom use behaviour. Similarly, a finding was made by Bogart, Cecil and Pinkerton (2000) cited in Rammule (2009) in a study examining the use of female condoms among African-American adults. The only difference Bogart and colleagues found was that self-efficacy in men showed a marginally significant relationship to intention to use a female condom with casual partners, but not with steady partners (Bogart et al., 2000 cited in Rammule, 2009). For both men and women, self-efficacy showed weak correlations with intention to use a female condom, and did not add to the explanatory power of the theory, suggesting that self-efficacy may be a weaker predictor of female condom use for both

men and women. For both men and women, self-efficacy showed weak correlations with intention to use a female condom, and did not add to the explanatory power of the theory. This finding suggests that self-efficacy may be a weaker predictor of female condom use for both men and women

Although there seems to be exposure to some information in regard to HIV and AIDS, and how it can be prevented, it is also important to move towards behaviour change. As attitudes and beliefs have been shown to be significant in people's choice of action, the theories of reasoned action and planned behaviour are relevant to behaviour change. The theory of reasoned action and the theory of planned behaviour were chosen for this study as they are the theories most cited in HIV and AIDS research, and have been found to be better analysts of HIV and AIDS health behavioural than other models (Fishbein, 1993; Warwick et al., 1993, cited in Rammule, 2009).

The TRA and TPB have been applied in this study based on the assumption that if people's attitudes towards specific HIV-preventive behaviours are shaped in particular directions and if their beliefs about the expectations of their significant others are reinforced, it is most likely that behaviour will change. Since attitudes and beliefs have proved to be significant in people's choice of action, the researcher chose the theories of reasoned action and planned behaviour since they have been proved to be relevant to behaviour change.

This study explored the perceptions and experiences of young people in participating in HIV prevention vaccine clinical trials and examined the use of the TRA model for

behaviour of interest in making decisions to participate in HIV vaccine trials. By applying the TRA and TPB theories to examine the correlates of trial participation, researchers may be afforded insights that offer more nuanced understandings and explanations that appropriately reflect and incorporate the complexities of HIV vaccine trial participation.

2.10.5 Critique of the Theories of Reasoned Action and Planned Behaviour

The theories of reasoned action and planned behaviour which fall within the realm of cognitive theories are based on the assumption that humans are endowed with the ability to reason, and that reason is the primary psychological process involved in decision-making (Leviton, 1989 cited in Rammule, 2009). A major criticism of the TRA (which, in my view, should also apply to the TPB, since TPB is an extension of the TRA), is that its strong cognitive orientation tends to preclude the affective nature of humans, which also plays a role in decision-making processes (Dutta-Bergman, 2005, cited in Rammule, 2009). The Theory of Reasoned Action was criticized for neglecting the importance of social factors that in real life could be a determinant for individual behaviour (Werner, 2004).

Using sexual behaviour change as an example, the theory of reasoned action suggests that for behaviour change to occur, the individual must systematically identify and weigh the outcomes of his/her sexual behaviour to form attitudes towards the specific behaviour that must be learned. This assumes that behaviour change can be induced by adding a new belief, increasing or decreasing the favorability of an existing belief, and increasing

or decreasing the belief strength associated with the intended behaviour. While the individual may satisfy the requirements for behaviour change in this paradigm, they may not be able to enact the behaviour in a situation where they initiate sexual intercourse on the spur of the moment (Dutta-Bergman, 2005; Rammule, 2009).

Another criticism is based on the focus of the theory of reasoned action on the individual as opposed to the group of which they are a member (Dutta-Bergman, 2005; Kashima, Gallois & McCamish, 1993, cited in Rammule, 2009)). This is particularly significant in HIV and AIDS research as Van Dyk (2001) cited in Rammule (2009) referring to the African context in which she writes, recommends that the community be involved in AIDS education, prevention and counselling. Emphasis is put on the significance of health care interventions in view of the collective existence that is a norm in traditional African contexts. The theory of reasoned action and the theory of planned behaviour, on the other hand, ignore the collective context in which individuals exist, and place emphasis solely on the individual actor (Van-Dyk, 2001, cited in Rammule, 2009)).

Dutta-Bergman (2005) cited in Rammule (2009) suggests that although proponents of the theory of reasoned action might argue that a subjective norm explains the role of the collective in an individual's decision-making, it is still driven by an individual motive orientation, thus keeping the locus of decision-making with the individual. Although subjective norm taps into the individual actor's evaluation of significant others, it does not tap into the complexity of the social fabric that constitutes the health behaviour in question. Social influence, according to Dutta-Bergman (2005) cited in Rammule (2009)

moves beyond the realm of a few significant others to the broader socio-cultural context of the community. Using the African collective context that Van-Dyk (2001) cited in Rammule (2009) referred to, it could happen that while the significant others closest to a person may discourage participation in HIV vaccine clinical trials the broader sub-culture to which a person belongs may consider such behaviour a norm. Such a strong emphasis on the individual ensures that the theory lacks a social-ecological approach that can be used to influence social policy. The social-ecological approach assumes that the community is super ordination to the individual, and transforming individual behaviour is therefore a consequence of transformation at a community level (Van-Dyk (2001), 2009 cited in Rammule, 2009).

The theory of planned behaviour holds that only specific attitudes toward the behaviour in question can be expected to predict that behaviour. In addition to measuring attitudes toward the behaviour, we also need to measure people's subjective norms and beliefs about how people they care about will view the behaviour in question (Fishbein & Ajzen, 1975).

Based on the above arguments, the researcher is of the view that TRA and TPB cannot themselves be used to address questions relating to how beliefs and attitudes underpinning behavioural intentions can be changed. The sufficiency of the TRA and the TPB has been questioned and thus suggestions made for an extension of these theories because the variables of attitude, subjective norm and perceived behavioural control may not offer sufficient explanation (Conner & Armitage, 2001).

CHAPTER THREE

METHODOLOGY

Chapter three presents the research setting, research design; population and sample, piloting the study; data collection; data analysis; data apparatus, data verification, ethical considerations, reflexivity and limitations of the study.

Research methodology focuses on the research process, tools, and objective procedures to be undertaken, as well as specific tasks to be used (Babbie & Mouton, 2001). Included research design is the approach, type and purpose of the research. The methodology discussed the sampling procedures, data collection methods, tools and data analysis.

3.1 Research Design

Mouton & Marais (1993) cited in De Vos (2011) define a research design as a plan or blue print of the study. This plan includes who, what, where, when and the how of the topic under study. The research design is a guideline on which a choice of data collection methods can be made. For the purpose of this study, the researcher will follow an exploratory design approach and explore the perceptions and experiences of young women about HIV prevention vaccine clinical trials.

This design is considered useful when the researcher has limited knowledge about the subject. Fouche & Delport (2002) cited in De Vos (2011) explain how qualitative research helps the researcher make use of multiple methods such as interviews and observations in to understand the context of what is being researched. More to that qualitative design will enable the researcher to explore the participants' views with regard

to the phenomenon under investigation. Qualitative approach will allow the researcher to explore the circumstances and perceptions that the young people have towards participating in HIV prevention vaccine clinical trials (Fouche & Delport, 2002 cited in De Vos, 2011)

3.2 The Research Setting

To gain further insight into the study, focus area reference was made to Statistics South Africa (StatSA), (2011) Census data, to examine the basic socio-economic data of the township. The population is predominantly Black African (99%), 31% of those aged 20 years and older has completed Grade 12 or higher. 55% of the labour force (aged 15 to 64) is employed and 74% households have a monthly income of R3 200 or less. 67% of households live in formal dwellings, 79% of households have access to piped water in their dwelling. 81% of households have access to a flush toilet connected to the public sewer system, 92% of households have their refuse removed at least once a week, and 95% of households use electricity for lighting in their dwelling (StatSA, 2011).

According to South African History, Nyanga Township is one of the oldest and largest black townships. It lies about 26 kilometers from the city centre, along the N2 close to the Cape Town International Airport. Like most of townships in the country, Nyanga originated as a result of the migrant labour system (Marais, 1998). The United Nation's Development Index Report (2010) explains that in Nyanga HIV prevalence rates tend to be at their highest in these spaces due to the failure of economic growth to trickle down

to the poor and the persistent set of economic and spatial dynamics has helped to fuel HIV in the township (Hunter, 2006).

3.3 Population and Sample

A population is defined as the totality of all subjects that conform to a set of specifications, comprising the entire group of persons that are of interest to the researcher and to whom the research results can be generalized (Polit & Hungler, 1999). A sample is a sub-set to of a population selected to participate in a study (Polit & Hungler, 1999). The population sampled consisted of young women between the ages of 18-24 years, some of whom were also participants in on-going vaccine studies. Also included in the population sample were key informant participants either from the Nyanga township communities or from community based organization, Non-governmental organization (NGOs) and staff from local clinics.

3.3.1 Sampling Procedure

A purposive sample of 27 participants was interviewed. These include young women who are participants in the ongoing clinical trials, women or are not participating/have not participated in HIV prevention vaccine clinical trials, plus five other participants either from community-based organizations or from the wider Nyanga Township community. The research purposively targeted fifty five respondents but eventually a total sum of twenty seven was interviewed. When using this type of sampling, the sample is mostly selected on ease of access and is based on the judgment of the researcher (De Vos et al., 2001). This particular sample was chosen because they have special

knowledge about the study topic and they are important to the research topic. The sampling method used in this study was purposeful sampling. This is because purposeful sampling seeks information which can be studied in-depth (De Vos, 2001).

The eligibility criteria used in this study include:

- Young women who are participants in the on-going clinical trials;
- Women or are not participating/have not participated in HIV prevention vaccine clinical trials;
- Representatives from the community-based research organization;
- Representatives from community based NGOs;
- Representatives from the local clinic, and who were willing to participate in the study;
- Participants from the wider community; and
- One student from the community school

Eligibility criteria are specifications used by the researcher that designate the specific attributes of the target population determining which subjects are selected to participate in a study (Polit & Hungler, 1999). The inclusion criteria used in this study was people who meet the criteria such as participants in clinical trials.

According to De Vos (2011), the most useful strategy for the naturalistic approach is maximum variation sampling. This strategy aims at capturing and describing the central themes or principal outcomes that cut across a great deal of participant or program variation (Lincoln & Guba, 1985, cited in De Vos, 2011).

3.3.2 Recruitment of Participants

Recruitment of study participants was done using convenience sampling. The researcher identified participants by approaching young women who are currently enrolled in vaccine trials and have designated visit schedules for their clinic visits. Before identification of participants the researcher sought permission from the site manager to conduct this study. The same method was applied while identifying subjects from the wider community by seeking permission from community leaders and leaders in other community-based NGOs. Efforts were made by the researcher to interview young women in the ages of 18-24 years. Some young men were interviewed to ensure that all categories that are either directly or indirectly involved in participating in HIV vaccine trials were represented.

3.3.3 Pre-testing of the Interview Guide

Pre-test is a trial run to determine, as far as possible, the clarity, adequacy and freedom from bias of the research. Pre-test was done with individuals who have similar characteristics with those who were to be interviewed in the study (Polit & Hungler, 1999). A draft interview guide was discussed with my supervisor who is knowledgeable about the construction and substantive content of semi-structured interview schedules.

This was done to ensure that all important steps and details have been taken care of before pre-testing is done. The final draft was then pre-tested among young women who meet the set eligibility criteria. The pretested participants were not to participate in the main research study because of the concern that they would have already been exposed to an intervention and therefore may respond differently from those who were previously not exposed.

3.4 Data Collection

In this section data collection strategies have been discussed.

3.4.1 Data Collection Approach

To obtain information from participants, the researcher used a semi-structured interview schedule to collect data from participants. The participants comprised of young women aged 18-24 years (See Table 1). The advantage of a semi-structured interview schedule is that it can be pretested on a suitable participant and also allows the researcher to refine the wording, ordering and layout of the questions (De Vos et al., 2011). Interviewing is the predominant mode of data collection in qualitative research (De Vos, 2011). The researcher chose the above-mentioned approach because it facilitates interaction between the researcher and the participants and also enables the researcher to gain a detailed picture of the participant's beliefs, perceptions and accounts of a particular topic under investigation (De Vos, 2011).

3.4.2 Data Collection Apparatus

Before interviews were conducted, the researcher first explained to the participants that she was going to use unstructured interview guide and also sought permission to record the interview (De Vos, 2011). The study used a tape recorder to record the interviews as it allows the researcher to concentrate on exploring the topic while also noting the non-verbal cues. The tape recorder was preferred because it allows for verbatim recording hence facilitating more accurate data collection and analysis (Saunders & Thornhill, 2003 cited in De Vos 2011). Smith et al., (1995) cited in De Vos (2011) mention that a tape recorded allows a much fuller record than notes taken during the interview. It also means that the researcher can concentrate on how the interview is proceeding while following up interesting points being made, prompting and probing where necessary, drawing and paying attention to any inconsistencies in the interviewee's responses. Care was taken so that the voice recorder was modest during the interview in order to avoid unnerving the participant and the researcher (De Vos et al., 2001).

3.5 Data Analysis and Verification

Data analysis is the process of bringing order, structure and meaning to the mass of collected data (De Vos, 2011). Data analysis is the activity of making sense of, interpreting and theorizing data (Schwandt 2007cited in De Vos 2011). Gibbs (2007) cited in De Vos (2011) states that the idea of analysis implies some kind of transformation. One starts with some (often voluminous) collection of qualitative data and then processes it, through analytic procedures, into a clear, understandable, insightful, trustworthy and even original analysis (Gibbs, 2007:1 cited in De Vos, 2011).

Using the data collected through interviews, the researcher transcribed the data from the tape recorder and written notes, and an adaptation of Tesch (1990) cited in De Vos (2011) steps were as outlined below:

- The researcher read through all the transcriptions and then selected one interview at a time, tried to understand what the respondent was saying in relation to the objectives of the research
- The researcher jotted down some words (phrases) on the margins that capture the participants' meaning/perceptions. In the margin of the transcript, the researcher assigned labels to those meanings;
- All the transcriptions were subjected to the process of assigning labels;
- The researcher then grouped the labels into categories of the main themes;
- The researcher then revisited the main themes and categories in order to make sure that these themes and categories encapsulated the fullness of the data. All categories had sub-categories;
- The categories were reworked to make sure that they are mutually exclusive;
- A coding framework was developed;
- The findings were written up using the coding framework as a guide. Actual quotes were used to illustrate the themes/categories and for subcategories/sub-categories. The findings were cross-linked to previous studies done (literature

review) thereby validating or contradicting the findings; and developed critical arguments

3.5.1 Data Verification

The researcher verified the collected data using Guba's approach (Lincoln & Guba cited in De Vos, 2001). This was aimed at ensuring accountability to ward off biases and errors in the results of a qualitative data analysis. The four constructs central to this approach include credibility, transferability, dependability and confirmability (De Vos, 2001).

- Credibility demonstrates that the study was conducted in such a manner as to ensure that the phenomenon is accurately described.
- Transferability is the burden of demonstrating the applicability of one set of findings to another context.
- Dependability is any attempt to account for reliability of the study; and
- Conformability focuses on whether the results of the study could be confirmed by another (De Vos, 2001).

3.6 Ethical Considerations

When conducting research, there are ethical guidelines that should be followed. Ethics is typically associated with morality as it deals with matters of right and wrong. In social research, there are general agreements among researchers about what is proper and improper in the conduct of scientific inquiry (Babbie & Mouton, 2001).

Ethics is defined as a set of moral principles which is suggested by an individual or group is, subsequently widely accepted, and which offers rules and behavioural expectations about the most correct conduct towards experimental subjects and respondents, employers, sponsors, other researchers, assistants and students (De Vos, 2011). Anyone in research needs to be aware of the general agreement about what is proper and Improper in scientific research (Babbie 2001, cited in De Vos, 2011). Based on this fact, researchers need to ensure that the rights of study subjects are safeguarded. In this study, ethical issues were taken into consideration especially realizing that HIV clinical trials is a sensitive issue and that HIV is a human rights issue.

In carrying out the study, the researcher was bound by the following ethical issues as outlined by De Vos (2011) and Babbie and Mouton (2007).

3.6.1 Informed Consent

Before interviews were conducted, the researcher obtained informed consent from the participants based on the rights to self-determination to participate in the study (Appendix 1). In this study, the researcher informed the participants about the purpose, potential benefits, pledge for confidentiality, right to withdraw and that participation was voluntary. Informed consent form contains information about the goal of the study, procedures that are to be followed during the study, the possible advantages, and disadvantages and credibility of the researcher (De Vos, 2011). The informed consent process was conducted to ensure that participants are fully informed of the study before

they agree to participate and also to know the advantages and disadvantages and dangers that they may be exposed to as a result of their participation.

3.6.2 Human Subjects' Protection

In order to protect participants the researcher obtained ethical approval from the University of Cape Town, Department of Social Development. This was aimed at protecting participants from harm, exploitation and knowledge of potential benefits. This principle encompasses the maxim of above all do not harm (Polit & Hungler, 1999). The researcher included these dimensions to ensure that the participants know the benefits of the study and have full details about the study as well as providing a clear explanation regarding the purpose, objectives as well as the potential benefits of the study without raising any unrealistic expectations.

3.6.3 Confidentiality and Anonymity

Confidentiality means that no information that the participant divulges is made public or available to others and the anonymity of a person or an institution is protected by making it impossible to link aspects of data to a specific person or institution (Polit & Hungler, 1999). In this study, the researcher guaranteed confidentiality and anonymity assuring participants that the data obtained from them will be used in such a way that no one other than the researcher knows the source. The researcher ensured that information collected from the study participants was not divulged or publicly reported and that no the participants' identifiers would be attached to the data provided. The researcher also assured the participants that information obtained will be locked up and password

protected to avoid access by 'outsiders' and that all documents containing raw data will be destroyed after the dissertation has been accepted by the university.

3.6.4 Privacy

According to De Vos (2011), privacy in its most basic meaning refers to keeping to oneself that which is normally not intended for others to observe or analyze. The researcher maintained privacy in this study by conducting interviews in private and secure places where nobody else could have access except the researcher herself. The right to privacy was also respected in this by ensuring that no intrusion is made during interviews with participants.

3.6.5 Rights and Benefits to the Participants

The protection of the rights of the participants was a priority in this study. The researcher informed the participants about the purpose of the study (Appendix I). The researcher informed participants that their participation was voluntary and that they could choose to discontinue participating at any point should they wish to without incurring ill effects whatsoever. This was meant to ensure the participants' rights to self-determination and full disclosure. The right to self-determinations means that participants have the right to voluntary decide whether to or not participate in the study without incurring penalties or the risk of prejudicial judgment (Polit & Hungler, 1999). Benefits to participants include acquiring knowledge about vaccines.

3.6.6 Debriefing

The researcher ensured to incorporate a debriefing section after the interview. Debriefing is a session after the study in which participants get the opportunity to work through their experience of the study and its aftermath (De Vos, 2011). Debriefing interviews encourage the researcher to monitor the degree to which participants and stakeholders are empowered to act on the increased understanding that emerged from the study (Onwuegbuzie et al., 2008). It constitutes one possible way in which the researcher can assist participants and minimize harm. In this section, the researcher asked participants to talk about their feelings of doing the interviews and if they had encountered any problems in taking part in the study thereof. This session was meant to help the researcher rectify any misconceptions that may have arisen in the minds of participants. The researcher conducted debriefing interviews in a private place and these were tape recorded. The session helped the researcher get to understand concerns regarding the impact of the study on the participants and also to establish if any, problems that could have stemmed from the interviews.

3.7 Limitations of the Study

Limitations in research are those aspects that may negatively influence the results but over which the researcher has no control (Mugenda & Mugenda, 1999). Various limitations were encountered during the study and these are related to the research design, the data collection method, the data collection tool, and data analysis and language limitations

The qualitative research design is highly subjective in nature and the sampling technique of non-probability sampling used is generally small and cannot be generalized to a larger population (Mugenda and Mugenda, 1999; De Vos, 2007). Because the researcher used semi-structured interviews there is a possibility that inferences were made based on her subjective experiences. The researcher overcame this limitation by 'bracketing' her own feelings. Nevertheless, the researcher found this design appropriate to explore the perceptions and experiences of participants in HIV prevention vaccine clinical trials in order to gain a deeper understanding of the meaning participants gave to their situation.

The research used a semi-structured interview schedule. The use of a semi-structured interview schedule can be misused as a novice researcher could stick too rigidly and not allow for the free flow of communication. However, the researcher was aware of this and tried to allow for maximum information through probing.

The use of a tape recorder to capture data made it likely for some participants to be reluctant to give information as they knew they were being taped and some participants declined to be tape recorded. However, the researcher used the tape recorder for most participants who consented to it since verbatim recordings allow for all the verbal details to be captured and analyzed (Saunders & Thornhill, 2003 cited in De Vos, 2011). In this study, some participants declined to be tape-recorded because they felt that nobody else should hear them talk about the HIV related issues. In that case the researcher resorted to writing down the participants' responses. This may have affected the outcome of the

research since the researcher may not have written everything down during the interviews.

An adaptation of Tesch (1990) cited in De Vos (2011) used to analyze data requires the researcher to identify themes and categories. Since procedure allows the data to be analyzed in a subjective manner, it may be wrongly interpreted and biased as some categories may be either overlooked or overemphasized. As a result, this can affect the accuracy of the research findings. Nevertheless, the approach was used as it allows data to be analyzed using empathetic understanding to make sense and to draw meaningful conclusions (Mugenda & Mugenda, 1999).

Some participants felt comfortable speaking in their local language but since the researcher is not well-conversant with the Xhosa language which the majority of the participants speak. , she resorted to those participants that understand and speak English. As a result the chosen sample had a language bias. Nonetheless, the researcher chose participants who have the capacity of providing responses to the questions being asked.

CHAPTER FOUR

PRESENTATION AND DISCUSSION OF FINDINGS

This chapter presents findings from the interviews following a comparison and an analysis of findings from literature review. The chapter is structured as follows: demographics of participants, framework of analysis and a discussion of the findings from the interviews using a framework of analysis. The research findings are divided into themes, categories, and subcategories adopted from Tesch (2011).

4.1 Introduction

The aim of the research was to explore the perceptions and experiences of young women on their participation in HIV vaccine clinical trials in Nyanga. The study followed a qualitative research design in explorative and descriptive nature. The study anticipated to use in-depth interviews with 33 respondents, but ended up getting only 27 because some of these were either not available or too busy to participate in the interview. Findings have been summarized in the last section of this chapter.

4.2 Socio-Demographics Characteristics of Participants

This section provides a profile of participants and this gives the background information of the participants in terms of demographic categories. The profile is categorized according to education level and employment status. Also explained are sex, race, family background, and occupation, area of residence and area of origin.

Table 1 below presents the demographic profile of main study participants that comprises of 12 young women, all between the ages of 18-24.

Table 1: Socio-Demographics of the Study Participants

	Education		Employment status	
	Primary	Matric	Employed	unemployed
Number of participants	12	0	2	10

The participants chosen were from various backgrounds and they range between the ages of 18-24 years. All the participants in this study do not have matric certificates. Ten of the participants out of twelve were unemployed, which reflects the state of youth employment in South Africa (National Treasury, 2011).

4.2.1 Key Informants' Profile

Table 2 below presents key informants' profile.

Table 2: Key Informants' Profiles

Category	Number	Description
HIV research-based organization centre	4	These organizations conduct projects that support HIV positive youth, provide clinical support to HIV positive counselors, conduct community outreach to vulnerable groups such as men who have sex with men, provide anti-retroviral services to the vulnerable communities, HIV Mobile testing services and conduct HIV prevention clinical trials
Community based Organizations	3	Advocacy for increased access to treatment, care and support services for people living with HIV and campaigns to reduce new HIV infections; advocates of human rights, gender equality and equity; and creating HIV awareness and support to HIV positive women
Local clinics	1	Provide health care to the communities
Community Advisory Board (CAB) members	2	The CAB provides the opportunity for community to understand clinical research and purposes. It is the forum to voice concerns regarding specific clinical studies, their development, implementation and outcome
Community members	4	From the Nyanga township
Students	1	Scholar from the community school
Total	15	

The 15 key informant participants interviewed include 4 representatives from a research based organization, 2 Community Advisory Board (CAB) members, 3 from Community Based Organization (CBOs), 1 student, 1 participant from the local clinic and 4 community members. It should also be noted that due to issues around privacy 1 participant from a CBO and 1 research participant declined to be tape recorded hence the researcher had to take notes.

4.3 Framework for Discussion of Findings

In order to identify themes and categories, the researcher used an adaptation of Tesch (1990) cited in De Vos (2011) and reference made to Chapter Three, Section 3.7 of Tesch's Approach to Analysis. Identified were nine major themes linked to the research objectives and thirty two categories. The categories of these themes emerged from an analysis of the findings (see Table 3).

Table 3: Framework for discussion of research findings

Themes	Categories
Motivations to participate in clinical trials	• Protection from HIV • Financial incentives • Free medical care and treatment • Altruism • Receiving information about HIV
Perceptions and experiences about clinical trials	• Vaccines good for the community • Vaccines make people sick • Inadequate knowledge about vaccines • Community perceptions and misconceptions about vaccines
Attitudes towards participation	• Mistrust of researchers • Safety of the vaccine • Vulnerability of getting infected • Inadequate knowledge about scientific concepts
Subjective norms to participation	• Behavioural beliefs • Normative beliefs • Motivation to comply
Risks	• Potential physiological risks • Potential psychosocial risks
Barriers	• Vaccination side effects • Sero-positivity due to vaccine inducement • Uncertainty about vaccine efficacy

	• Perceived risk of HIV infection from the vaccine
Challenges and barriers	• Time commitments to attending study visits • Stigmatization and discrimination • Community misconception that the vaccine contain an HIV virus • Being afraid of needles • Perception that some people may never be affected or infected by HIV
Benefits	• Improved knowledge on HIV • Access to health services • Financial benefits
Rights	• Right to participate or decline to participate
Knowledge of policies and legal framework	• Inadequate knowledge about HIV vaccine related policies

The findings will be discussed logically as presented in the framework above.

4.4 Motivating factors for Participation in HIV Clinical Trials

The findings in this section are linked to the first research objective which investigated the reasons which motivate young women to participate in HIV prevention clinical trials. Various reasons emerged about the theme motivations to participate in clinical trials.

4.4.1 Protection from HIV

Most participants indicated that the most important reason they participated in HIV vaccine clinical trials is because they wanted to be protected from getting infected with HIV, as illustrated below:

> Yah, yah, but my boyfriend says as long as it is for HIV prevention he does not mind me taking part... [*22 year old vaccine trial participant*]

Some participants were hopeful that if the cure for HIV is found, then the world will be safe from dying from HIV and AIDS but add that some people in the community are sure that vaccine trials are a real cure for HIV as illustrated below:

> It gives me hope that one day HIV will be a forgotten thing; but they said it being tried to see if it works – I think some of my friends think they are safe and protected with the vaccine. Some of them do not use condoms with their boyfriends because they are protected [*18 year old vaccine trial participant]*.

Some participants had a mixed range of arguments for joining the trials. Among them is getting money, getting free medical care and getting protection from HIV, as evidenced from the following remarks:

> I joined because my friend also said if you get the vaccine injection you get protection from HIV infection and get paid at the clinic … [*19 year old vaccine trial participant*]

Protection from HIV as a motivator may be a consequence of high perceived risk of acquiring HIV and based on this argument, desire for protection as a motivator would need to be addressed in a clinical trial. The vaccine may be protective, enhance the risk of HIV infection, or have no effect (Bartholow, et al., 1997 cited in Shayesta & Gary, 2011).

According to some participants' responses there seems to be an enhancement of behaviour since there is a perceived belief that the vaccine can protect them from contracting HIV.

4.4.2 Financial Incentive Gains

Almost all participants confessed that their willingness to volunteers in HIV prevention vaccine clinical trials was because of the monetary reimbursements provided to them at the research centre. Most young women participants reported to have children and they are single mothers who are unemployed. By participating in HIV vaccine clinical trials, they expect money in return for their participation. Participants' explanations in regard to monetary incentives are as explained below:

> I am unemployed and life becomes very hard but now I am assured of money at every visit; I heard of the bad things about vaccines but I have no choice ... [*22 year old vaccine trials participant*]

Another participant adds:

> … this money helps me to buy food for my child … [*20 year old vaccine trials participant*]

This participant appreciates the fact that they get re-imbursed for their transport fare, a rare opportunity not found in the local clinics as she expresses herself below:

> ...in the local clinic nobody gives money for the transport used meanwhile here I get money for my transport … [20 year old *vaccine trial participant*]

Similar concerns about the role of financial incentives as a stimulant to participate in HIV vaccine clinical trials were expressed in studies conducted in other low-and middle-income country sites in Africa and among marginalized populations in the United States

of America. Findings reveal that many men who have sex with men (MSMs) expressed willingness to participate based on contingent on clinical trials providing health insurance coverage and financial compensation for family members in the event they are injured in a trial (Moodley, et al., 2002).

Most participants are unemployed, so getting a financial incentive boosts their financial income and facilitates access to basic life requirements. However, as regards monetary incentives, some people have varying perceptions about participants being paid. Some participants expressed their concerns as follows:

> People in the community asked me why I get paid if the vaccine is meant to help get a cure for HIV [*22 year old vaccine trial participant]*

Some participants had a feeling that clinical trials are good because they are trying to find a cure against HIV but they are not happy about how they are introduced in poor communities. The choice of trial sites leaves some people to be suspicious as illustrated here below:

> I think there is something good in it but I wonder why in Cape Town the trials are conducted in only black communities – is it because we are black or poor so we cannot question anything... *[Key informant, local clinic*]

Bearing in mind the complex past of South Africa and especially black South Africans, such socially derived fears and frustrations can easily be seen as underlying reasons behind the participants' fears and concerns regarding the choice of HIV vaccine clinical trial sites. Responses from participants coincide with media reports which made the headlines by claiming that European-manufactured condoms were deliberately infected

with HIV in order to wipe out the African people (McGreal, 2007). Taylor (2012) reports condoms infected with HIV also aimed at killing the blacks.

4.4.3 Access to Medical Care and Treatment

Almost all participants confessed that participating in HIV prevention vaccine clinical enabled them to access free medical care. Below are some of the illustrations about the health situation:

> I wanted to know my health condition. Here at the centre they check everything in the body … for free [*19 year old vaccine trial participant*]

Relatedly, the other participants were attracted to medical care and attention offered at the vaccine centre as explained here under:

> I get free medical check-ups and knowing my HIV status… [*19 year old vaccine trial participant*]

Similarly this participant was appreciative of the of health gains from the researcher centre, as explained below:

> Until I joined this research centre I had never had a full health screening. It involves a lot of money to get this done in a private clinic… [*20 year old vaccine trial participant*]

One key informant also reiterated that researchers have given women preference because they are the most affected and infected with HIV than men as illustrated below:

> We at this facility focus on women because they are the most affected. In our communities not much has been done for women in terms of primary health care; when they come here they receive quality services [*key informant, vaccine research centre*]

Similar concerns about the role of financial incentives as a stimulant to participate in HIV vaccine clinical trials were expressed in studies conducted in other low-and middle-income country sites in Africa and among marginalized populations in the United States of America. Findings reveal that many men who have sex with men (MSMs) expressed willingness to participate based on contingent on clinical trials providing health insurance coverage and financial compensation for family members in the event they are injured in a trial (Moodley, et al., 2002).

4.4.4 Altruism towards community wellness

Some participants indicated that they volunteered to participate for the sake of those who are vulnerable to getting infected in their communities and also being part of the global campaign against the killer disease. This is manifested in the responses illustrated below:

> I feel good to be part of the study; I want to make a difference in other people's *lives* [*22 year old vaccine trial participant*].

The desire to help find prevention as well as a cure for HIV has driven some participants into the vaccine trials:

> I just wanted to be part of the research work; and if they find a cure for HIV I will be among the heroes who gave their lives for... [*23 year old vaccine trial participant*].

Some participants have lost their loved ones and now feel it is time they contributed towards finding a cure for HIV:

> I remember my cousin who died of HIV if prevention had been in existence she would not have contracted HIV... [*18 year old vaccine trials participant*]

For some participants they do not have a specific reason but just to be part of the studies:

> I just wanted to be part of the research work [23 year old *vaccine trial participant*]

These above statements were reiterated by key informant from an HIV vaccine centre:

> According to my recollection and observation, these young people are brave, full of enthusiasm… families need their support; most families been affected by losing loved ones; they want to see HIV come to an end; … [*key participant from a vaccine trial centre*]

The above responses collaborate with findings from which identified altruism as a common motivator for clinical trial participation. The studies indicate that some people participate in HIV vaccine clinical trials to make a contribution towards the fight against HIV and AIDS (Sahay, et al., 2005). According to the voices of the young people in this study, they seem to be optimistic that the future lies in their hands so their contribution as clinical trial participants is of paramount importance.

4.4.5 Receive Information about HIV

Almost all participants were happy about health education they receive on HIV as being one of the major reasons to volunteering in HIV prevention vaccine clinical trials.

All clinical trial participants agreed that whenever they attend their study visits risk reduction counselling is reinforced as a reminder to them to practice safe sex.

> I think this routine counselling is good. I used to sleep with my boyfriends without minding about using condoms but now I insist on using a condom [*20 year old vaccine trial participant]*

Another participant stated:

> … you get reminded of risky behaviour that can put you at risk of getting HIV [*19 year old vaccine trial participant*]

Some participants seemed not to be sure of issues around HIV and vaccine trials so to them it was an opportunity to gain clear understanding as explained below:

> I wanted to get more knowledge about HIV ... [*24 year old vaccine trial participant]*

Some other participants who are not enrolled on clinical trial volunteers yearn to get information about vaccines because of what they hear in the communities about vaccines:

> I hear they give women things to protect them from HIV but I do not know whether it is true [*community member*]

One key informant from a vaccine centre listed a number of services offered at the clinic to include the following: talks about diet, exercise, Family planning, where she insists participants have limited knowledge about clinical trials so health education provided to them is meant to empower the vulnerable township young women.

Potential trial participants should be made to understand that the effectiveness of the HIV vaccine to be tested is not known. Based on required ethical considerations in HIV vaccine clinical trial, vaccine trial volunteers should receive regular risk-reduction

counselling, HIV testing, male and female condoms, and treatment for sexually transmitted infections. Nonetheless, not all participants seemed to agree that the idea of risk reduction was easily applicable.

One young woman expressed her fear that as sex worker she may not decide when a condom should be used with a male client as explains here below:

> How can I use condoms regularly when my clients demand that if I am to be paid some 'good' money they decide either to use condoms or not because he is paying for a service [*19 year old vaccine trial participant*].

Women's ability to control their sex lives has been discussed by Kahn (2005) who argued that lack of economic power for women make them vulnerable to accepting certain conditions that may jeopardize their health. For instance, it is common to find a woman who may willingly continue living with a man whose behaviour puts her at risk on HIV infection for the sake of financial dependence.

The study participants shared with the researcher the social, economic and cultural issues and possibly faced risks of HIV infection. Yet, in contradiction, their statements concerning HIV and AIDS and sexual relationships with men were typical and reflected a greater sense of individual agency. Based on their arguments, the study participant in HIV vaccine trials appeared more knowledgeable about the possibilities of contracting HIV and this was attributed to the fact that these participants had acquired some relevant information and knowledge during their clinic visit and they seemed empowered to make decisions regarding their health.

Below are some of their views:

> After testing and knowing my HIV status (negative) I have vowed never to get involved in risky behaviour [*19 year old vaccine trial participant*]

Another participant adds:

> My partner and I have now stuck together … and now using condoms always, thanks to the study counsellors", [*24 year old vaccine trial participant*]

This is an indication that participation in the HIV prevention vaccine trial procedures and in particular the regular HIV counselling and testing is informative and transformative. According to the medical ethical guidelines, efforts must be made to maximise the potential benefits of HIV preventive vaccine research. The research protocol should outline the benefits that participants in HIV vaccine trials should receive as a result of their participation and ensure that the risks undertaken by the participants from that population should be balanced by the potential benefits (Slack and Kruger, 2003).

4.5 Perceptions in participating in HIV Prevention Vaccine Clinical Trials

How women and men perceive their participation in HIV vaccine prevention clinical trials is an important issue for HIV prevention trial research and an important component of study design. However, reports show that in South Africa, HIV is perceived as a 'black disease', due in part to popular media representations of AIDS, that project an image of HIV and AIDS as young, black, and female (McNeil and Donald,1999). Furthermore, women who reside in South African Townships are faced with socio-economic and cultural challenges. Some of these challenges include sexual violence and rape, which intensify their risk of exposure to HIV (Jewkes et al., 2003). Similarly, the

study participants in this study cited social, economic and cultural environment as some of the contributing factors to the possible increase of their vulnerability to HIV infection. Participants' perceptions vary. Most of the participants described the comprehension of the study procedures as being fairly good while some of the participants expressed considerable anxieties about the procedures.

4.5.1 Vaccines are good for the Community and the World

Participants who expressed satisfaction regarding their participation in vaccine clinical trials pointed out their appreciation regarding clinic procedures such as the regular pap smears for cervical cancer, the screening for sexually transmitted diseases (STIs), counselling and HIV testing, information given about HIV and AIDS. To some participants, vaccines give them hope of prevention from being infected with HIV. And most importantly there is hope that if vaccines are found to be effective, then their children will have an HIV free future world. Additionally, participants were reimbursed for their time and travel and to most of them the reimbursement is entirely their source of income for the general household consumption given the socio-economic situation of most trial participants who are unemployed and hence have no source of income.

Most importantly, majority of the participants mentioned that the vaccine centre was the only place where they had been treated with dignity and respect unlike the public health centres. Most participants described the research staff as caring and friendly.

Responses from almost all participants indicated, as explained by some of the participants:

> It is a good thing, for sure if what they [study staff] told me is correct then there is hope for discovering a cure for HIV ... [*19 year old vaccine trial participant*]

Another participant had similar views as stated below:

> It is a good thing, I support the idea. People have died of HIV it is high time a cure is found to stop this dreadful killer of our young people!! [*22 year old, vaccine trial participant*]

A representative from community NGOs also emphasized that vaccine trials are for the good cause as explained below:

> People in our communities have responded to the call to fight the dreaded disease and that is the reason why you see mostly young women flocking to the research centre... [*Key informant, community NGO*]

As one of the routine processes all young women participants mentioned that it was mandatory for them to go through Voluntary Counselling and Testing (VCT) a process that came with mixed feelings. Participants revealed they had gained knowledge regarding their sexual and reproductive health. This is true given the fact that the researchers emphasize that all young people who are legible and accept to participate and in HIV vaccine prevention clinical trials are obliged to go through a range of medical examination and treatment STIs, HIV testing and condom counselling and use and adherence. The HIV test and its influence on how enrolled women felt about their current relationships and risk of HIV acquisition were most prominent in interviews with the

study participants. A clinical trial participant narrated how having tested for STIs and HIV had had a significant impact on her sexual behaviour. She emphasized her commitment to using condoms always, in order to avoid infection.

The following quotation explains a young women study participant's response to sexual behavioural change:

> I used to have multiple partners but now I have changed and I now know which friends I hang out with…. I tell you what: before I did not know my status I for sure did not really care who to go out (sleep) with... [*18 year old clinical trial participant*]

Some participants acknowledged that risk reduction counseling has helped them shape not only their own sexual behaviour but also for their partners as illustrated below:

> … I decided to join the vaccine clinical trials because I wanted to know my HIV my status. I have since stuck to my main boyfriend who I have also convinced to use condoms always [*22 year old vaccine trial participant*]

The mere fact that this particular not only talk of using condoms but also of being committed to a monogamous relationship with emphasis to use condoms always is regarded by the clinical researchers as a resource that she draws on to reaffirm her commitment to avoid being exposed to HIV. The study participants not only give attention to HIV infection, but also the importance of knowing one's status, regardless of the outcome.

This particular participant who openly testified to be living with HIV also had a relatively optimistic outlook, emphasizing the importance of knowing her status:

> The thing that makes me return to the clinic is that my eyes are now open. It is correct to know your status… [*18 year old vaccine trial participant*]

Participants' commentaries about their involvement in HIV prevention vaccine clinical trials seems to reflect the emergence of a powerful discourse that stresses their need to take control over the circumstances and relationships that may place them at risk of being infected with HIV.

4.6 Experiences in participating in HIV Vaccine Clinical Trials

Participants have different opinions and experiences about their participation in HIV vaccine clinical trials. Some participants expressed positive views about the vaccine trials, while others had negative thinking.

4.6.1 Vaccines are good for the community

Some participants appreciated HIV prevention vaccines because as the word 'prevention' is used they assume that they prevent them from getting infected with HIV. Below are some of the responses:

> I am now happy that I and my boyfriend can stop using condoms because of the protection by the vaccine [*20 year old vaccine trial study participant*]

Another participant adds:

> …I was told that I would get family planning services, and also the "protection" from get HIV [*19 year old vaccine trial study participant*]

This particular participant feels good to be a participant but has made some observations especially about her friends' behavioural change as she explains here under:

> I have realized that this vaccine has made some of my friends change their life styles. Girls are now saying that there is no use for condoms after being injected [vaccinated] with a vaccine which protects them from getting infected with HIV. They want to try and 'see' if it works… [*22 year old, vaccine trial participant*]

Overall, participants' experiences in HIV vaccine trial seem to involve multiple factors. These factors could have important implications for promotion of participation in HIV prevention vaccine clinical trials.

4.6.2 Vaccines are not Good for the Community

Some had bad experiences and while others expressed mixed feelings and uncertainties about HIV vaccine clinical trials, some of which portray a negative picture. Some participants think vaccines cause sickness as illustrated here below:

> My first experience was not good, after being vaccinated I went home feeling weak, dizzy and nauseas …[*19 year old vaccine trial participant*]

Another participant explained how she got sick after vaccination:

> … Every time I get an injection I fall sick of headache, joint pains and last month. I had virginal bleeding for almost two weeks. This made me worried and up to now I do not feel well. But I was given a letter which I took to the local clinic and I was given treatment [*23 year old vaccine trial participant*]

Some participants have a feeling that researchers are using them as guinea pig to test strange medications that have not yet been tested on humans. Some of the illustrations manifest such feelings:

> To be honest this vaccine 'thing' is quite new and not everybody fully understands it. We heard that in America they tested it on monkeys and rabbits but here they test it on 'us – it is strange nay [*20 year old vaccine trial participant*]

Some participants were concerned and worried that vaccines contain an HIV virus that infects people with HIV. Below are some of the responses in relation to their worries:

> Testing HIV positive because of the vaccine is quite daunting! … the vaccine staying in the body for an unknown number of years – who knows the long-time effects of the vaccine on our health [*23 year old vaccine trial participant*].

Some participants indicated that they sometimes get neglected or even stigmatized at local clinics because they participate in vaccine clinical trials. Below is an explanation:

> I reported to the research centre that I am sick and I was given a referral letter to get treatment from a local … At the clinic some nurses do not understand how vaccine work and they ask a lot of questions? [*18 year old vaccine trial participant*]

Community feelings about the vaccine centre and its services were also expressed by a key informant from the local clinic:

> … people in our community think that the research centre buys blood and inject blood with an HIV virus or some people think you get vaccinated and then told to have sex with an HIV positive person to test if a vaccine works... This makes our community angry … they use our people as 'guinea pigs' to test a thing that is not well known to them [*key informant, local clinic*]

The same sentiments were echoed by a vaccine trial participant who feels scared that may be it is true the vaccine contains a virus that might wipe out the black community by infecting them with HIV virus:

> I fell sick with fever and my husband thought I was pregnant again. But I kept it to myself and when I went back to the vaccine centre I was told it was just the side effect of the vaccine that would soon disappear [*20 year old vaccine trial participant*]

Some participants appeared to be nervous when talking about clinic procedures as expressed here below:

> Injections are very painful; I feel uncomfortable sometimes I get sick with headache and my friends in class think I am HIV positive so I go to the clinic for ARVs … [*18 year old vaccine trial participant*]

Participants continued to express their fears for clinical procedures are expressed below:

> When the doctor asked me to enter the examination room I imagined going through this huge machine and seeing other scary operating instruments such as cutting blades ..." [*22 year old vaccine trial participant*]

This particular participant was scared of injections during vaccination and blood draws, as illustrated below:

> Painful injections and scary blood draws. They draw a lot of blood and I am worried this may ruin my health... [*19 year old vaccine trial participant*]

The discomfort about clinic procedures and vaccine side effects was a common concern among the vaccine trial participants. But according to the response from one key informant from a research centre, these side effects occur for a short while and prospective study participants are made aware beforehand and it is documented in the consent document that some participants may experience some side effects such as pain at the vaccination site, feeling dizzy after blood draw, and so on.

Psychosocial risks ensuing as a result of stress related to participation in HIV vaccine trials include complicated, lengthy trial involving intensely intimate matters, and repeated HIV testing. Additionally, anxiety related to exposure to culturally different scientific and medical concepts; stress that may result between partners in a relationship as a result of the participation of one partner in a trial; stigma and discrimination that may result if volunteers' participation becomes publicly known, and they are perceived to be HIV-infected or at high risk of HIV infection and worse still, some participants may develop a

positive HIV test after receiving a candidate vaccine (Newman, Duan, Kathleen, et al., 2006).

4.6.3 Inadequate of Knowledge about HIV Vaccines

Very few participants had knowledge about HIV vaccines trials but had some knowledge about previous vaccines such as small pox and influenza. Some participants tried to explain how far they understand HIV vaccines:

> I think vaccines are drugs or medicines that are given to prevent a certain disease from infecting a person… [*19 year old vaccine trial participant*]

Meanwhile other participants seemed uncertain about HIV vaccines as explained below:

> I do not know what I can call it; I think it is scientific medicine tested to see if it prevents HIV infection [*23 year old vaccine trial participant*]

Some participants wondered why it was important for HIV negative people to be injected with an HIV vaccine yet there are other preventive measures such as condoms that can prevent people from getting HIV virus. Below are some of the concerns raised:

> Condoms are very perfect why must we be injected with something that contains HIV virus, commented [*Key informant from the community*]

Inadequate of knowledge about HIV vaccine trials may be due in part due to the fact that some key clinical trial concepts do not directly translate into the local language. This cannot easily be understood by most participants whose level of education is lower than matric certificate and hence they find it hard to understand scientific terms.

Words such as “placebo” and “vaccine” seemed to confuse most participants who were enrolled in HIV clinical studies, as expressed below:

> To be honest this vaccine ‘thing’ is quite new and not everybody I know of fully understands it. We heard that in America they tested it on monkeys and rabbits but here they test it on ‘us – it is strange nay and for sure some of this stuff is hard … Some words [such as placebo] which I cannot even explain [*20 year old vaccine trial participant*]

The study noted that although it is not certain to assess from the research outcomes based on these commentaries about the young women’s involvement in HIV vaccine prevention clinical trials, there is evidence that it has contributed to their transformations in sexual behaviour. On the other hand such commentaries reflect the rise of a new and powerful discussion that stresses women's need to take control over the circumstances that tend to place them at risk of HIV acquisition.

Community concerns are around the issues such as the vaccine containing some particles of the HIV virus, as explained below:

> Since we all know that HIV and AIDS are incurable, why then does the vaccine containing a virus gets injected into healthy human beings? (*Kei informant from the community*]

Other participants added:

> Young people want to try things I believe they heard about vaccines that prevent HIV infection and they rushed to join they want to be on the spot light [*key participant, local clinic*]

Some participants reckon that HIV vaccines contain a virus that causes AIDS, as illustrated below:

> ... I also hear that the vaccine contains HIV, is it true? [*20 year old vaccine trial participant*]

Most participants were concerned that the vaccine is too risky to be injected into the blood system:

> In polio it [vaccines] worked – but this is risky. Once you get HIV you cannot reverse it and this thing is done in such a hurry especially here in Africa people do not know much about it [vaccines*]* [*key informant, community member*]

Most participants expressed fear regarding security issues as they get targeted by community drug dealers who use ARVs to manufacture illicit drugs:

> I have a lot of worries because the neighbour's son now knows that I am a participant at the research centre; recently … recently a girl was robbed immediately after leaving the research centre!! [*19 year old vaccine trial participant*]

Some participants have a feeling that compensation is not sufficient compared to the risks they incur while participating in the studies:

> Compensation to trials participants is not worth it; they must be given a lot of money though money is never enough to buy life; the volunteers are like soldiers who have sacrificed their life – a vaccine is like a bomb on their bodies – I will never participate – I am scared [*Key informant, local clinic*].

Some participants expressed fears based on the past experience from previous studies that turned out not to be effective and are hence scared to participate in HIV prevention vaccine clinical trials. Below are some of the responses:

> I have also heard people say that the vaccine has made people get HIV – I know of a girl who tested positive after taking that thing [vaccine]; I have also heard people say that women who receive that vaccine may never have children; I also heard of a vaccine that infected people with a virus [Phambili]. Why don't people learn from this experience, especially women? [*Key informant, community member*]

Participants' fears especially those related to a vaccine that was believed to have increased the number of infections among the participants concur with findings in the South African AIDS Vaccine Initiative news release where immunizations in the HIV vaccine clinical trial known as the STEP (in South Africa, commonly known as Phambili) study was discontinued after Data and Safety Monitoring Board (DSMB) findings that the vaccine did not prevent HIV infection nor reduce the amount of virus in those who became infected with HIV (Kristen, 2005).

Due to the uncomplimentary outcome of the Phambili and STEP trials it is likely that young people and the general population in South Africa may hesitate to participate in HIV prevention vaccine clinical trials. The way in which a vaccine trial is presented can vary considerably with differing emphases on risks, benefits, and the burden of trial participation. In addition, South Africa is an extremely diverse country and different community norms may critically influence participation in HIV vaccine clinical trials (Adler, 2012).

4.7 Attitudes Towards Participating in HIV Prevention Vaccine Trials

4.7.1 Mistrust of Researchers

Mistrust of researchers was consistently mentioned by the participants. While most participants were clear about the causes of HIV and how it is passed on to people, all the participants seemed not to understand the reason why clinical trial sites are based in poor neighborhoods such as Nyanga.

> I do not at all trust white people when it comes to their relationship with us. Why don't they test the vaccine on themselves first; I heard they want to wipe the black community by experimenting on us [*20 year old vaccine trial participant*]

Some people think that because they are blacks, the whites still continue to abuse them as was during the apartheid era:

> … in my community there is a thinking that the white people are using us [blacks] to do experiments ... [*CAB member*]

Cultural beliefs affect the way some people perceive scientific research and this sometimes affect the level of participation in clinical research. Fears surrounding cultural beliefs were cited as below:

> I have heard people say that white people practice cultism and they use our [black people] … why do they use the poor townships for clinical trials*?* [*22 year old vaccine trial participant*]

This particular participant does not understand the concept of clinical trials as expressed below:

> How do you know that the vaccine is working if they use condoms as well? For a study to be accurate they must test to ascertain if it works … *ayi ayi* I will never put myself at risk being vaccinated with drugs *[Key informant, local clinic*]

A participant who also said is living with HIV positive thought otherwise about HIV vaccine clinical trials. She wondered why researchers should not focus on finding the cure and help the already sick from dying.

Below is the illustration:

> Some people think it is a good idea to help find a vaccine that may prevent HIV infection; meanwhile others feel it is a waste of money instead that money must be used to treat people who already have the virus than waste the money on people who are not sick … [*Community outreach worker*]

Some participants had a feeling researchers are taking advantage of the fact that they are disadvantaged so they use them for their scientific experiments, as pointed below:

> The government should get involved in these clinical trials because it is the government's constitutional duty to look after its citizens. But research has been left in the private sector and international NGOs who aim at profiteering from the poor people. The poor people are being exploited so government must protect its people… [*Key informant, community NGO]*.

4.7.2 Safety of the vaccine

Some participants think the vaccine may contain an HIV virus and hence risky for human, as explained below:

> …where was the vaccine tested? Tested in monkeys…? It would be fair if they tested in other people in the US before they test in our ignorant people here in the township. I know in the polio epidemic it worked, but this HIV one is risky … once you get HIV you cannot reverse … [*Key informant, local clinic*].

Participants displayed the lack of or limited knowledge about HIV vaccines by asking questions such as:

> "Is it true that Americans manufactured the HIV disease and have now put it in a vaccine to kill blacks [*18 year old vaccine trial participant*].

A point of concern to the researcher was that despite the research centre being in their community most participants seemed not to understand what was being done in that clinic. Most of the community members live by guesses as expressed here under:

> This vaccine centre has been in our community for a number of years but we as the community do not understand why they are here. That is why we do not trust anything to do with the vaccine centre [*key informant, community member*]

Some participants feel there is wide information gap between the community and the researchers because even though a research centre exists in their community, most people have limited knowledge about what is being done.

This participant expressed herself as follows:

> … Researchers must tell us about HIV prevention to make us understand how it works and how it can help us in our community... I think they are up to "something" [*key informant, community member*]

The issue of mistrust and using blacks coincides with sentiments from studies by Jenkins (1985) who emphasizes that researchers tend to recruit participants from less privileged populations. In developing countries some communities, arguably fall within this category. It is important to ascertain whether individuals or communities trust the source of information to represent the risk accurately, and this trust is influenced by whether an individual or group has had a history of positive or negative experiences with the health system, with law enforcement, with research institutions, or with government. In resource-poor settings where HIV prevention trials are being conducted, it is critically important to recognize the historical backdrop of colonialism and racism, and on-going challenges of poverty and exploitation. In this light, building and maintaining trust among researchers, communities, and participants can be a critical element of informed consent (Shapiro & Benatar, 2005).

Despite these concerns, participants were in support of finding HIV prevention measures but suggested effective communication strategies between the community and researchers regarding the implementation of clinical trial studies.

4.7.3 Inadequate Knowledge About Vaccines

Some participants were concerned that information about vaccines has not reached everybody and this leaves gaps in information dissemination. Even those who seem to have received some information about HIV prevention vaccine trials still feel they do not understand some concepts.

> Some of this stuff is hard; sometimes the medical researchers give us things to read I just listen because I want to be part of the study. Some words [placebo] which I cannot even explain [*19 vaccine trial participant*].

Another participant adds:

> I would support the idea if I am told what vaccines are and the importance of HIV vaccines to our people. I do not accept things just because they are here in the community … [*key informant, community member*]

Some participants suggested that researchers develop a video to present basic trial information and explain difficult concepts because they felt that a video would be more engaging and informative than print material which may not be easily understood by most people in the community, most of whom with low literacy levels.

4.8 Normative Beliefs Influencing Participation Vaccine Clinical Trials

In this research, I have utilized renowned behavioural theories, the Theory of Reasoned Action (TRA) and Theory of Planned Behaviour to explain the connection between people making a decision to participate in clinical trials and how other people influence their decision to participate.

4.8.1 Behavioural Beliefs

Perceived "social pressure" (Ajzen & Fishbein, 1980, p. 246) to perform behaviour or forego it, is reflected in the "subjective norm" construct. In this research, participants were asked if they thought people, including family and boyfriends, neighbours or community friends, might influence their participation in clinical trials. Responses include:

> The community sometimes negatively judges those who participate in HIV vaccine clinical trials [*23 year old, vaccine trial participant*]

Some participants are influenced by people closer to them to make decisions to either participate or decline to participate in HIV prevention vaccine clinical trials as illustrated below:

> My boyfriend and my mother family were bitter because I was risking my life to get injected with the unknown drug [*19 year old vaccine trial participant*].

While some participant reported being discouraged by their partners some reported that their partners were supportive to their participation in HIV vaccine clinical trials:

> Some young women say partners are supportive while some women report to have been dumped by their partners after discovering that they are participants in clinical trials; [*key informant, vaccine research centre*]

The researcher found out that there are some influential people in the community that participants seek advice from before they make decisions, as illustrated here:

> The pastor is preaching about people who do not trust in God and they keep trying other things [vaccines] [*20 year old vaccine trial participant*]

And because they trust their people they fear losing them due to their participation in HIV prevention vaccine trials. Some of these may be bread winners:

> My boyfriend does not approve of my participation and I am afraid if he finds out that I am still visiting the research centre he might leave me… [*20 year old vaccine trial participant*]

The issue of boyfriends influence in decision making ……

> It is my boyfriend, how do I tell him that I am a participant in a vaccine trial and yet he believes it is risky [injecting people with HIV vaccines … [*22 year old vaccine trial participant*]

4.8.2 Beliefs about HIV Vaccines

Participants were also asked what their own intentions were on deciding to volunteer in the HIV prevention vaccine trials. Several questions measured volunteers' salient beliefs about their role in HIV vaccine research. Most of their responses were basically due to their self-motivation and interest. The illustrations below show some of these responses:

> I want my community to benefit from modern science so my participation is a contribution to achieve this *[20 year old* vaccine trial participant]

Another participant adds:

> I decided on my own but later I also asked a friend just to make sure I was making the right decision… [*18 year old vaccine trial participant*]

4.8.3 Normative Beliefs

Other participants highly applauded their parents, spouses and community leaders to have supported them to participate in HIV prevention vaccine clinical trials as explained below:

> My ward councillor approved of my participation and he asked if I could talk to other youths in our community [*20 year old vaccine trial participant*]

Some participant felt motivated by their parents and siblings to participate, as illustrated below:

> My mother has been supportive all the way, the same to my brother so I feel encouraged [*19 year old vaccine trial participant*]

While some participants were being discouraged to participate:

> Yes my mum. She was very bitter that I could make such a crazy decision. She even shared this with my boyfriend and they turned against me [*22 year old vaccine trial participant*]

Beliefs that vaccines make participants barren is yet another issues mentioned:

> My boyfriend wants me to get another child but I was told that once enrolled I must not conceive until such a time that I will be told to do so. This worries me so much and makes me think I am doing a wrong thing *[23 year old vaccine trial participant*]

Some participants think that if they had enough resources they would not participate in 'risky' HIV vaccine clinical trials.

Below is an illustration:

> … I told you that because of poverty our people especially the young ones go into things without even knowing what they are going into. How many of the young people in Nyanga here are employed…? [*Key participant, local clinic*]

4.8.4 Motivation to Comply

In some cases individuals might declare a willingness to participate or reluctance to get involved due to general compliance with referent opinion. The theorized influence of family, friends, and others on behavioral performance sometimes exerts social pressure to act or engage in avoidance. Some of the items measuring this domain include responses such as:

> I always pay attention to what people expect of me, even if I don't know them, "I just want to obey my family and act as it pleases them, they always trust in me *[19 year old vaccine trial participant];*

According to the Theory of Reasoned Action, formation of individual attitude is affected by behavioural beliefs and evaluation of behavioural outcome (Montano & Kasprzyk 2002). The salience of these beliefs combines with the social factors and normative beliefs and motivation to comply and is weighted in relation to each other. The addition of the social component is useful for prediction of health behaviour outcomes, particularly as the approval or disapproval of referent others and importance accorded to these opinions can be important influential factors in decision making (Ajzen *et al*. 1980).

4.9 Risks, Challenges and Barriers for Participation in Vaccine Clinical Trials

Numerous factors such as ethnicity, socio-economic status, and sense of agency, usually influence how individuals assess risk and the actions they take as a result of their participation in HIV vaccine clinical trials. An essential effect to risk assessment is whether individuals or communities trust the source of information to represent the risk accurately. This trust is influenced by whether an individual or group has had a history of positive or negative experiences with the health system, with law enforcement, with research institutions, or with government.

4.9.1 Potential Physiological Risks

Some participants are not only worried about vaccine, but also using contraception for more than 2 years as expressed below:

> Taking a vaccine for two years is risky because I was not told how it works while inside the body. Using contraceptives puts me at risk of not getting pregnant and this may affect my relationship with my boyfriend… *[18 year old vaccine trial participant*]

Some young people participants were concerned about these risks as explained here under:

> When I received a vaccine injection for the first time, I suffered from body pains, I lost appetite and my boyfriend was worried [*22 year vaccine trial participant*]

A feeling of uncertainty about not knowing how long the vaccine can stay in the blood system makes some participants worry, as explained below:

> My biggest fear is living with a vaccine in my body system because when I asked the doctors at the vaccine centre they told me they are not sure when my blood will be free from the vaccine. I am afraid it might affect my fertility [*22 year old, vaccine trial participant*]

The community has their own interpretation of people who participate in clinical trials as explained below:

> The thinking of the community that if you visit a research centre you are HIV positive and a 'danger' to community … [*23 year old vaccine trial participant*]

Even in the local clinics there is limited understanding of vaccine clinical trials as illustrated below:

> Some of them come to this clinic with complications such smelly vaginal discharges, over bleeding, diarrhea etc … The biggest risk is that nobody knows whether it is safe for participants to accept vaccines in their bodies and nobody knows what long term effects could be!! [*Key informant, local clinic*]

Similar fears were expressed by another participant as shown below:

> Rumour is going around about the negative intentions of researchers [white people] to use black people to test their drugs and later sell them at very high prices to get profit… *[Key informant, local clinic*]

Some participants felt that with the use of vaccine trials the youth behavior has worsened because they no longer care to practice safe sex:

> Some people have become more irresponsible after their partners receiving the vaccine; some men believe that the vaccine works so why should they use condoms to 'kill' their sexual pleasure? [*Key informant, community member*].

Some community members' understanding of how the vaccine works is by trying unprotected sex:

> They go and try if it works and they stop using condoms; my neighbour friends are now experimenting with HIV positive girls to see if the vaccine they was injected into them works [K*ey informant, community member*]

These findings are consistent with UNAIDS (1998 & 2000) reports cited in Slack C *et al.,* (2000) that highlight potential psychosocial and physiological risks emanating as a result of participating in HIV clinical trials. Physiological risks include rapidly progressing or established infection if a vaccine is subsequently exposed to HIV (Slack et al*.,* 2000). Psychosocial risks include inconvenience and participation fatigue associated with lengthy research; anxiety induced by repeated HIV testing; stress caused by exposure to culturally unusual medical and research concepts; vaccine-induced sero-positivity in conventional screening methods and associated negative consequences, such as the potential for discrimination in employment, and a false sense of security leading to increase in risky behavior; and stress between partners as a result of the participation of one partner in a vaccine trial (UNAIDS, 2000 cited in Slack, et al., 2000).

4.9.3 Barriers and Challenges for Participation in HIV Vaccine Clinical Trials

Noticeably, several stigma-related barriers to participation emerged among all participants and these include the notion that volunteers are often labeled by family and community members to be HIV positive because of their participation in HIV vaccine clinical trials. There is also public perception about pharmaceutical companies whose interest is about profiteering from HIV vaccines at the expense of the vulnerable populations. A major concern that featured in almost all the responses was vaccine-induced sero-positivity as explained in the respondents' explanations below:

> I am also worried that may be it is true that the vaccine contains a virus that causes HIV … Why is it that some people turn positive – I am worried if I am one of them my husband will not believe that I did not cheat on him [*20 year old vaccine trial participant*]

Similarly, another participant had this to say:

> What I have heard from the community is that the vaccine contains an HIV virus how they can do that to our community [*24 year old vaccine clinical trial*]

Some participants complained about the risk of getting anemic because of too much blood draws as illustrated here:

> Most of them complain about time and the amount of blood. At every visit approximately 10 tubes of blood is drawn; vaccine trials require a lot of blood …. … [*Key informant, research centre*]

Another participant said that acceptability of vaccine trials has been negatively publicized by the media. Below is his explanation:

> During the microbicide studies African women were portrayed as being used 'guinea pigs' by the media" *[Key informant, local NGO*].

Some participants suggested that the media send out good messages to the community if it is going to limit the success in solving the issue of vaccine trials. It was also mentioned that there exists some form of disengagement between researchers and the community they serve and that in most instances researchers feel they have all the answers and disregard community views and concerns. Further still, it was mentioned that certain categories of people such as men who have sex with men (MSMs) get discriminated and worse still, raping lesbians help escalate the spread of HIV. Below are related comments:

> We all have fundamental human rights have a right to choose … evangelicals think gay is 'evil' [*Key informant, local NGO*]

4.9.3 Benefits Related to Participating in HIV Prevention Vaccine Clinical Trials

The most common benefits mentioned by the participants include reimbursement and clinical care, as illustrated below:

> Before I joined the vaccine trials I did not know my HIV status and blood pressure. After joining the trials I was tested for "everything" in my body. … I get money to me it is income; [*18 year old vaccine trial participant*]

To some participants, the financial re-imbursement received supplements their family meager incomes, as explained below:

> My husband earns little money as a security guard so I also get my own money to buy my own ladies stuff which he cannot buy for me [*20 year old vaccine trial participant*].

Most participants were happy to mention that they have access free medical services as explained below:

> I am given from free medical examinations and advice in case of any sickness… [*23 year old vaccine trial participan*t]

Some participants thought that participants benefit in terms of accessing knowledge about HIV prevention, as illustrated below:

> Benefits may be there but indirect. Participants are equipped with general knowledge about HIV and how to take precautions about protecting themselves from getting infected; the services such as risk reduction helps shape the young women's behaviour especially when it comes to sexual issues… [Key *informant, research centre*]

However, some respondents have a feeling that the poor communities are being taken advantage of and they do not see any benefit for participants, as explained in the quotation below:

> If there are any benefits I do not know. What I know is that the researchers benefit from the participants. If the vaccines are found to be effective, of course the researchers will benefit by selling the vaccines… [*Key informant, local clinic*]

To some participants it is just the question of being poor so they participate to earn a living as explained below:

> … if I am poor and I am earning some cash study every visit I am participating for sake of survival; they are actually not empowered with all the information. Communities do not understand the science... [*Key informant from local NGO*]

Worth noting was the way young people appreciated the power and ability to control their lives. Studies indicate that originally HIV was perceived as an uncontrollable and inevitable epidemic, without hope (LeClerc-Madlala, 1997). However, based on the study findings conducted among the in among some youth in South Africa showed change in perception about getting infected with HIV. A study conducted among university students revealed that about 37 per cent of Durban university students saw reason to change their sexual practices in order to avoid AIDS, and only 17 per cent considered themselves at risk for HIV infection (Naidoo et al., 1991 cited in Varga, 1998).

Nearly two-thirds of youth people stated they wanted to make some behavioral change, such as abstinence, monogamy or condom use, to decrease the risk of HIV infection. Relatedly, some participants confessed to be in charge issues regarding making sexual. This was attributed the fact that they are empowered with knowledge from researchers. A young woman testifies:

> Every visit at the clinic the counsellor talks to me about the dangers of having sex without a condom, sex under the influence of alcohol ... [*20 year old a vaccine trial participant*].

4.9.4 Knowledge of Rights to Participation in HIV Prevention Vaccine Clinical Trials

The following responses exhibit some of the legal rights that the participants highlighted in the interviews with the researcher:

> I have a right to participate or decline if I want to … trials [*23 year old clinical trial participant*]
>
> *I can say no to certain things such as injections and blood withdrawals; I have a right to privacy …* [*18 year old clinical trial participant*]

Community Advisory Board (CAB) members are the link between researchers and the community and are expected to inform the potential about research procedures. These are some of the expectations:

> **…** *I presume the CAB and community out-reach team inform them of their rights but as nurse I am quite aware that volunteers can terminate their participation anytime they so wish …* [*Key informant, research centre*]

Some community members appear to be informed about the participants' rights, as explained below:

> What I know is that they have a right make choice whether to participate or not … [*Key informant, community member*]

But knowing their rights is directly linked the way messaging is communicated to the communities, as explained below:

> It depends on what kind of messaging goes out there to the communities … [*key informant, community NGO*]

Most participants admitted to have been told about their rights as participants. However, given the low literacy levels and the socio-economic background, they are easily

compromised even on their own rights because they cannot make independent decisions. The researcher also found that participants were not familiar with the concept of vaccination and this is a clear manifestation that due to low literacy levels of the participants they do not understand the language used in the consent document in which rights and obligations of the trial participants are outlined. Responses in this regard are illustrated below:

> I was told that I can decide to leave whenever I want to. But I do not know whether they meant that it will not affect my life because I have already taken two injections; how about if I fall sick afterwards because of the vaccine will they help me get medical treatment [*20 year old vaccine participant*]

Another key informant thinks it is the right of the community in which HIV vaccine trials are conducted to take full participation in the trial process and also to have the government respond to structural barriers that contribute to the HIV prevalence in communities:

> There is need for active participation at grass level, localized campaigns, in communities major concerns include food, water; only one in 8 in a family is employed, TB in the house without windows… mass voices, accountability civil society to hold government to accountable and mobilization of all sectors is required [*key informant, local NGO*]

4.10 Policies and Legislative Framework on HIV Vaccine Clinical Trials

Most participants indicated that they have no or inadequate knowledge about policies that are concerned with the development and administering of HIV vaccines in the country. Below are some of the responses:

> I know nothing about policies [*20 year old vaccine trial participant*]

Similarly this participant explained:

> I even do not know what policies is I do not know [*19 year old clinical trial participant*]

This particular had at least head about ARVs as explained below:

> I heard about HIV law of giving people ARVs but this one of vaccines I do not know [*22 year old clinical trial participant*]

Participants from well-established institutions also seemed to have limited knowledge about existing policies on HIV vaccine trials as shown below:

> I only know that the government has put in place the National Strategic Plan (NSP) (2012-2016 that guides the national response to HIV, STIs and TB; the Health Research Policy in South Africa promotes practice and conduct of research [*key informant, research centre*]

Community Advisory members (CABs) who happen to be the link between the community and the researchers were not quite sure whether participants have knowledge about policies governing clinical trials as illustrated below:

> *... No. But I doubt whether the participants know about this policy or law* [*CAB member*]

Policies create frameworks for identifying objectives and setting priorities and define the roles of different stakeholders in achieving those purposes. With the encouragement of

organizations such as UNAIDS and the Global Fund, national HIV programs and committees throughout the world have developed HIV and AIDS frameworks that establish national priorities in responding to the epidemic. These frameworks include goals for national prevention programs and provide the basis for coordinating the work of all partners.

The government has put in place general policy guidelines such as the National Strategic Plan (NSP) (2012-2016), whose strategic objectives include addressing social and structural barriers that increase vulnerability to HIV, STI and TB infection. The Health Research Policy in South Africa has been developed to promote practice and conduct of research that contributes towards the improvement of the human health and welfare of the South African population. At a macro level, the 2009–2014 Medium Term Strategic Framework (MTSF) sets out the strategic mandate of government. In addition, the National Planning Commission is currently developing a broad government framework for addressing the major developmental challenges in South Africa, while at the international level the MDGs have specific targets that all countries are striving to achieve by 2015.

It was noted, however, that although the various policies exist on national and global levels the participants do not seem to understand and even have knowledge of such laws. Studies have also shown that although South Africa has a functioning ethical-legal system with the necessary institutions and some of the guidelines, but does not have many of the laws needed to protect and promote the rights of persons participating in

research, including HIV vaccine trials (Strode, et al., 2005). On that basis, the researcher adds that policy documents should be communicated to various constituencies in the simplest language possible for them to understand. It is worth noting weak policies may lead to the increase of vulnerability to exploitation of HIV clinical trials participants and communities in South Africa and elsewhere in the world where HIV prevention vaccine clinical trials are being conducted.

CHAPTER FIVE

CONCLUSION AND RECOMMENDATIONS

Chapter five presents the conclusions and recommendations from the research findings. The conclusions drawn from the research findings will be presented in relation to the research objectives.

5.1 Behavioural Beliefs, Motivations and Benefits

To understand subjective norms that influence young women's participation in HIV vaccine clinical trials, the study utilized renowned behavioural Theory of Reasoned Action (TRA) and Theory of Planned Behaviour (TPB) to explain the connection between people making a decision to participate in clinical trials and how other people influence their decision to participate.

The major conclusions drawn from the findings regarding reasons that motivate young women to participate in HIV prevention clinical trials include getting protection from getting infected with HIV. Most participants' responses indicated that their motivation was derived from the urge to get protected from HIV infection. Most of the young people were of the view that getting an HIV vaccination gives them protection from HIV. This is contrary to the information from some key informants who were of the view that that young people should not only participate in HIV vaccine clinical trials to get protected from contracting HIV but they must also practice safe and protected sex because there is no effective vaccine yet on the market.

5.2 Monetary Gains from Participation in HIV Vaccine Clinical Trials

Another aspect that participants consider in order to join clinical trials is because of the monetary re-imbursement. Majority of the respondents were in agreement that most HIV prevention vaccine clinical trials participants get attracted to join because of they get some financial re-imbursement for their time and transport. Key informants were equally in agreement saying that due to the socio-economic conditions in which the participants find themselves they rely on the money that they receive to meet some of their basic requirements.

5.3 Access to Medical Care

Most participants in this study admitted that it is easy to get medical care from the research centre than in the public local clinics. Most key informants were in agreement with the young people saying getting medical care from the public clinics and hospitals is quite frustrating so people turn to private health providers if they have money. But most of the participants reported to be unemployed so they get free health care services from the vaccine research centre. Similarly some key informant participants agreed that their focus in the vaccine centre is mainly on health issues such treatment of STIs, giving family planning contraceptives, etc. The researcher found out that women who attend the vaccine clinical trials have been somehow empowered to control their health issues by regularly getting educated on how to address specific health issues without compromise.

5.4 Altruism to the Community

The responses by the young people also concur with some of those from the key informants who admit that some women have taken a firm stand against HIV and they have demonstrated this partially by volunteering in HIV prevention vaccine clinical trials to help find an effective vaccine.

5.5 Getting Access to Information about HIV

Almost all respondents admitted that the information they get at the vaccine centre has helped them change their behaviour regarding getting involved in risky behaviour that may expose them to getting HIV. Some key informants also agree to that effect although one key informant had different views, "*when your girlfriend gets vaccinated you are sure of protection from getting HIV from her and free to have sex without a condom*".

As regards perceptions in participating in HIV vaccine clinical trials some participants were in agreement with the fact that vaccines may be helpful to the community. Some of them even cited the past year vaccines that now prevent children and adults from dying (vaccines for polio and influenza). In this case participants are hopeful that one day vaccines that prevent the dreadful HIV will be found to the joy of the whole world. However some of the respondents think HIV vaccines may be harmful to participants hence they decline to participate.

5.6 Barriers and Fears

Some of the participants pointed out that HIV vaccine clinical trial contain a virus that makes people get HIV. This is a common talk in the township where this research was

conducted. However, some key informants such as research nurse and CAB members reiterated that this is a misconception spread in the community about vaccines and HIV vaccine clinical trials.

5.7 Lack of Adequate Knowledge about Vaccines

Based on the responses from participants, it is pertinent to note that the majority of participants are not knowledgeable enough about the clinical trials neither are they aware of their rights and benefits, save for some few who said they know their rights. On the contrary, some key informants especially those working in the HIV clinical research affirm that participants know their rights. To the researcher this gives an insight that participants and the wider community have not received enough information about HIV vaccines.

Due to inadequate knowledge in the community regarding HIV vaccine and clinical trials people have their own understanding of what vaccine clinical trials are. Some insinuate that this is a plan by the United States to wipe out the entire African continent where the majority of black people live. Another misconception is that the HIV vaccine contains a virus that causes HIV and the white people are testing in black people for experimental purposes. These controversies are being over-turned by community educators and CAB through creating awareness among the communities.

In terms of young women's attitudes towards participating in HIV vaccine clinical trials, the study found that few participants seemed to understand research concepts used in HIV prevention vaccine clinical trials. However some key informants think enough

education has been given to research participants and hence they expect them to understand these concepts since they have been translated in the local language used by the research community. But based on the demographic information of the participants it is very clear that most of them are not literate enough to read and understand clinical research terminologies.

5.8 Misconceptions about HIV Vaccines

The study found that there are increased incidences of high risky behaviour. Some participants testified that men whose spouses or partners are on HIV vaccine clinical trials tend to believe that their partners are protected so they get as many partners as they can and this renders them vulnerable to getting infected. Some participants also once they have gotten the trial vaccine go and *"try to see if it works*" because to them the vaccine is meant to prevention infection. This kind of practice increases incidences of HIV infections in the community.

5.9 Trust Issues due to Historical Trauma

Participants consistently mentioned that they do not trust researchers who have chosen to conduct research in the poor areas such as Nyanga Township. Accordingly, as explained by some participants, mistrust of clinicians has to do with the past history in South Africa where the apartheid policies tended to undermine the black people. For that matter people in black townships in South Africa still have that belief that whites take advantage of blacks. The researcher hence suggests that this is an identified critical need that calls for

dissemination of relevant information the community about vaccine clinical trials. The community needs to know the importance of HIV preventative vaccines.

Most participants indicated that for the most part they made their own decisions to participate in the HIV prevention vaccine clinical trials. This was attributed self-motivation and interest in the research aimed at discovering an effective HIV prevention vaccine. Key informants had similar views about participants being driven by enthusiasm and commitment to participate in the fight against HIV. However, in most African communities, women do not make decisions without consulting. This may also apply to men as well. So according to the participants they had to consult referent others in order to make decisions. Such consultative processes gives an insight of how some African culture rely on collective decision making mechanisms.

Lastly, individuals might declare a willingness to participate or reluctance to get involved due to general compliance with referent opinion. Most African people live and survive in a web of socialized family and friends networks that they do not wish to break. In this case they consult and get approval before decisions are made.

5.10 Risks to Participation in HIV Vaccine Clinical Trials

The study identified numerous factors in regards to risks in participating in HIV prevention vaccine clinical trials. These include ethnicity, socio-economic status, and sense of agency, and these influence how individuals assess risk and the actions they take as a result. Among the risks mentioned by the study participants are mistrust of the source of information based on individual or group historical events with research institutions, or

with government. Other classifications of risks include potential physiological risks and psycho-social risks which occur as a result of stress related to participation in complicated and lengthy clinical trial procedures.

5.11 Challenges Encountered by Vaccine Trial Participants

Participants expressed a variety of challenges as a result of their participation in HIV vaccine clinical trials. Noticeably, several stigma-related barriers which include the notion those volunteers are often labeled by family and community members to be HIV positive because of their participation in HIV prevention vaccine clinical trials. A major concern that featured in almost all the responses was vaccine-induced sero-positivity. As far as benefits related to their participation, the most commonly identified ones include financial incentives and access to medical care and treatment. On that basis, the medical ethical guidelines emphasize that efforts must be made to maximize the potential benefits of HIV vaccine research in order to avoid exploitation of vaccine clinical trial participants.

5.12 Rights to Participation in HIV Vaccine Clinical Trials

Although some participants seemed to understand what their rights are regarding their participation in HIV prevention vaccine clinical trials, it was feared that this may just be on paper but practically if they refuse to take directives from the researchers they may suffer negative repercussions.

5.13 Policies Guiding HIV Vaccine Clinical Trials

Regarding policies and legislative frameworks guiding HIV vaccine clinical trials, almost all participants including the key informants had little or no knowledge about policies that guide the HIV vaccine clinical trials. This is clear evidence that the government has not intervened enough in the area of HIV vaccine clinical trials.

The importance of decolonizing and indigenizing the research process has been stressed as a guide to guide the development of mutually beneficial research partnerships with indigenous communities (Karina, 2008). Principles for decolonizing and indigenizing research include reflection, respect, relevance, resilience, reciprocity, responsibility, re-traditionalization and revolution. It was also emphasized that for research to be relevant, researchers must educate the community in order to minimize misconceptions and guesses about clinical research (Karina, 2008).

The study therefore identified issues of promoting women empowerment processes so as to equip potential clinical trials participants with the knowledge and power to make informed decisions without having to rely on their male counter-parts. The researcher recommends that consideration be made to involve men in education and awareness programmes regarding HIV clinical trials to avoid misconceptions and suspicions about women participants as being promiscuous or having HIV, which usually culminates into domestic violence against women.

According to the Belmont Report (1972) persons who are economically or socially disadvantaged should not be used to benefit those who are better off than them and they if

they are to be used adequate justification is required for the involvement of subjects such as prisoners, students, subordinates, employees, and service personnel etc. who have reduced autonomy as research subjects. The report emphasized that the justification for including a vulnerable group in research is when a problem disproportionately affects that group (Belmont Report, 1972). It is therefore important that researchers follow internationally recognized guidelines by the Nuffield Council on Bioethics (1999) which stipulates that research organizations should not exploit the vulnerable populations in which clinical trials are conducted.

The international bioethics guidelines on health research disregard the idea of researchers selecting populations which are economically or politically weak, and therefore vulnerable to exploitation (Benatar, 2000). The echoes similar sentiments on bioethics guidelines and adds that before clinical trials are conducted, the communities in which clinical trials are to be conducted require on-going sensitization around the risks, benefits and rights expected of them as study participants in vaccine clinical trials.

The study participants did not give substantial responses around the issues of policies on HIV vaccine trials hence the government needs to put more emphasis these aspects.

As a social responsibility, researchers should also focus on helping the young women acquire life skills and income generating projects to alleviate the level of dependence of women on their male partners or husbands.

5.14 Summary and Conclusion

It is quite evident that humankind is relentlessly challenged by the HIV epidemic which has mystified humankind in various aspects. Based on this fact the HIV and AIDS epidemic needs to be confronted in a more collective and sophisticated manner. Recent research has shown that one of the key weapons in eradicating this scourge is to develop an effective HIV vaccine. But this has be done by engaging all the key stakeholders such as study participants and the community at large having to play as active role in vaccine design and development.

This study found that most study participants do not have sufficient knowledge regarding HIV prevention methods such as vaccine clinical trials. Although a few participants were able to tell what vaccine trials they have been enrolled in, most participants still do not understand the importance of HIV vaccines clinical trials done HIV negative people and yet much intervention is required to treat the already HIV positive people from dying. This shows that knowledge gaps exist and if not addressed it may in the long run affect the noble cause of trying to find the ever lasting solution towards eliminating the deadly killer HIV disease. It is fundamental therefore to ensure that relevant education and information is disseminated to communities in which these vaccine trials are conducted if any fruitful results are to be achieved. The researcher also recommends further research and investigation to explore more about the perceptions and experiences of young people in other provinces of South Africa in order to get an in-depth understanding of the concept of HIV prevention vaccine clinical trials.

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APPENDICES

Appendix 1: Consent Form for Participation in Research

Title of study: An Exploration of young women's perceptions and experiences of participating in HIV and AIDS prevention vaccine trials in Nyanga Township in the Western Cape, South Africa

Researcher name: Nandudu Norah

Department: Social Development – University of Cape Town

Course name: Masters Social Development

Invitation to Participate & Study Description

As one of the participants/community leader/service provider/spouse to participant/other, you are requested to participate in a research study about an exploration of young women's perceptions and experiences of participating in HIV and AIDS prevention vaccine trials in Nyanga Township in the Western Cape, South Africa.

This study will help us better understand how and why young women make decisions to participate in HIV vaccine clinical trials and their experiences about these trials. By agreeing to participate in this study, you are agreeing to be interviewed about issues surrounding HIV vaccine trials. Each interview will take about an hour to complete and will be recorded on a tape recorder.

Risks and Benefits

This study does not involve any type of physical risk; you will be asked to answer questions about your experiences and perceptions about HIV vaccine clinical trials and the information you contribute will help us better understand how young women make decisions to participate in clinical trials. The information from this study will only be used by researcher and supervisor of the University of Cape Town for academic purposes.

Confidentiality

The information you provide will be kept strictly confidential. To protect your privacy, your responses to the interview questions will only be identified with a pseudo names and will be kept by the researcher. All research outcomes will be kept for five years after the study has ended and will be accessible only to the researcher and the university supervisor. Your name will not be associated with the study materials or with the research findings. The information obtained in this study may be published in scientific journals and presented at professional meetings, but only group patterns will be described and your identity will not be revealed.

Right to refuse or withdraw

The decision to participate in this research project is entirely up to you. You may refuse to take part in the study without affecting your relationship with anyone. You may also choose not to answer any question posed.

Right to ask questions

You have the right to ask questions about this study and to have those questions answered by the researcher before, during or after the research.

Consent

Your signature below indicates that you have decided to participate voluntarily this study and that you have read and understood the information provided above. You will be given a copy of this form to keep.

You must be 18 years of age or older to take part in this research study.

I agree/do not agree* to the tape/transcript* being made available to me by the researcher (* delete as appropriate)

Name of Participant (Please print): ……

Participant's signature: …… Date: ……..

I certify that I have explained the study to the participant and consider that she/he understands what is involved and freely consents to participation.

Researcher's name …….....

Researcher's signature: ……..…….. Date…….…….

Appendix 2: Interview Schedule

I want to thank you for accepting to take time and meet with me today. My name is Norah Nandudu and I would like to talk to you about your experiences participating in the HIV vaccine clinical trials. Specifically, this study is about an exploration of young women's perceptions and experiences about HIV vaccine.

The interview should take less than an hour. I will be taping the session because I do not want to miss any of your comments. Although I will be taking some notes during the session, I cannot possibly write fast enough to get it all down. Because we are on tape, please be able to speak up so that I do not miss your comments.

All responses will be kept confidential and I will ensure that any information I include in my report does not identify you as the respondent. Remember, you do not have to talk about anything you do not want to and you may end the interview at any time.

Are there any questions about what I have just explained?

Are you willing to participate in this interview?

If yes, let us get started and I am going to switch on the tape recorder.

- Tell me about yourself
- How did you hear about HIV vaccine clinical trials?
- What motivated you to join the trials?

- Tell me about your own thinking and experiences of HIV vaccine clinical trials? (probe) How have your experiences as a study participant influenced or not influenced you in the decisions that you made to participate?

- What other factors influenced you to make a decision to participate or not to participate in HIV vaccine clinical trials? (Please give examples)

- What challenges/barriers related to participating in HIV vaccine clinical trials have you so far been faced with?

- Do you have any knowledge regarding the risks, benefits and rights related to your participation in HIV vaccine clinical trials?

- Of all the things you described to me about your experience in participating in the trials, what issues did strike you most? (Probe)

- Is there anything more you would like to add?

- What recommendations do you have for future efforts such as these?

- After analysing the information you and others interviewees gave me and submitting a report to the university I will be happy to send you a copy if you are interested.

Thank you for your time.