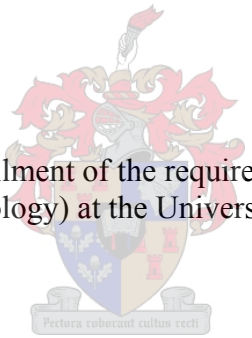
Willingness to participate (WTP) in a future HIV vaccine trial in a high risk sample:

Perceived barriers and facilitators to participation.

Fatima Bibi Parker



Thesis presented in partial fulfillment of the requirements for the degree of Masters of Science (Psychology) at the University of Stellenbosch

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December 2006

DECLARATION

I, the undersigned, hereby declare that the work contained in this thesis is my own original work, and that I have not previously in its entirety or in part submitted it at any university for a degree.

…….. … December 2006…

Signature Date

SUMMARY

HIV vaccines are currently being developed and tested worldwide. This thesis reports on a qualitative study that was conducted to determine the concerns and problems regarding participation in future HIV vaccine trials. The sample for the study was selected from a peri-urban township, Masiphumelele, in Cape Town, Western Cape province, South Africa. The HIV-prevalence rate in Masiphumelele is 25%. A total of 10 participants between the ages of 19 and 30 were recruited for the present study. All participants' first language was Xhosa and seven of them had English as a second language. Owing to a language barrier, an interpreter assisted the interviewer in conducting the interviews in the preferred language of the participants.

Participants were recruited by convenience sampling and were asked to participate in two semi-structured interviews, under confidential conditions. The first interview addressed knowledge regarding HIV/AIDS, HIV vaccines and HIV clinical trials. The second interview identified the concerns and problems participants had regarding participation in future HIV vaccine trials. The interviews were recorded, transcribed and entered into Atlas ti., a computer program that assists in the analysis of textual data. The analysis of the data focused on the content of participants' concerns about barriers to participation and their perspectives on facilitators to participation.

The data collected on concerns and problems which, may influence participants' willingness to participate in future HIV vaccine trials, was divided into two overarching themes, namely, barriers to participation and facilitators to participation. The barriers to participation included physical symptoms, stigma and discrimination, trypanophobia, distrust, psychological distress, sexual disinhibition and family responsibilities. The facilitators to participation included altruism, own protection from HIV infection, hopefulness, medical incentives, determining of HIV status, acquisition of knowledge, and equal treatment of participants in the experimental group and the placebo control group resulting from a double-blinded randomised trial.

The question of participants', recruited in the present study, willingness to participate in a future HIV vaccine trial are discussed in terms of Bronfenbrenner's (1979) theoretical

work on ecological systems, the social learning theory and the Health Belief Model (HBM). These theoretical frameworks deal with individuals, their behaviour and their environment, and how these influence one another.

The significance and future direction of this line of research helps to overcome the barriers to participation and enhance the facilitators to participation. Thus, the intended result of such efforts is to maximise individuals' participation in future HIV vaccine trials.

OPSOMMING

MIV-entstowwe word tans wêreldwyd ontwikkel en getoets. Hierdie tesis doen verslag oor ’n kwalitatiewe studie wat gedoen is om bekommernisse en probleme rakende deelname aan toekomstige MIV-entstofproefnemings vas te stel. Die steekproef vir die studie is uit ’n buitestedelike township, Masiphumelele, in Kaapstad, Wes-Kaap provinsie, Suid-Afrika, geselekteer. Die voorkoms van MIV in Masiphumelele is 25%. ’n Totaal van 10 deelnemers tussen die ouderdom van 19 en 30 het aan die studie deelgeneem. Alle deelnemers se eerste taal was Xhosa en sewe het Engels as tweede taal gehad. As gevolg van dié taalhindernis het ’n tolk die ondervraer en deelnemers gehelp om die onderhoude in die voorkeurtaal van die deelnemers te voer.

Deelnemers is volgens gerieflikheidsteekproefneming gewerf en gevra om in vertroulike omstandighede aan twee semi-gestruktureerde onderhoude deel te neem. Die eerste onderhoud het gehandel oor kennis met betrekking tot MIV/vigs, MIV-entstowwe en MIV-kliniese toetse. Die tweede onderhoud was daarop gemik om die bekommernisse en probleme rakende deelname aan toekomstige MIV-entstofproefnemings te identifiseer. Die onderhoude is opgeneem, getranskribeer en in Atlas ti., ’n rekenaarprogram wat die analise van tekstuele data vergemaklik, ingevoer. Die analise van die data was toegespits op die inhoud van deelnemers se bekommernisse oor struikelblokke tot deelname en hul perspektiewe oor fasiliteerders tot deelname.

Die data wat ingesamel is wat handel oor bekommernisse en probleme wat deelnemers se bereidwilligheid om aan toekomstige MIV-entstofproefnemings deel te neem moontlik kan beïnvloed, kan in twee oorkoepelende temas verdeel word, naamlik struikelblokke tot deelname en fasiliteerders tot deelname. Die struikelblokke tot deelname sluit in fisiese simptome, stigma en diskriminasie, tripanofobie, wantroue, sielkundige angs, seksuele ingeïnhibeerdheid en familieverantwoordelikhede. Die fasiliteerders tot deelname sluit in altruïsme, eie beskerming teen MIV-besmetting, hoopvolheid, mediese aansporings, bepaling van MIV-status, verkryging van kennis en gelyke behandeling van deelnemers in die eksperimentele groep en in die plasebo-kontrolegroep voortspruitend uit ’n dubbelblind ewekansige proefneming.

Die kwessie van deelnemers, in die huidige studie, se bereidwilligheid om aan ’n toekomstige MIV-entstofproefneming deel te neem word ingevolge Bronfenbrenner (1979) se teoretiese werk oor ekologiese stelsels, sosiale leer teorie en die *Health Belief Model* (HBM) bespreek. Dié teoretiese raamwerke handel oor individue, hulle gedrag en hulle omgewing en hoe dié faktore op mekaar inwerk.

Die belang en toekomstige rigting van dié soort navorsing help om die struikelblokke tot deelname te oorkom en die fasiliteerders tot deelname te versterk. Die beoogde uitkoms van sodanige pogings is dus om individue se deelname aan toekomstige MIV-entstofproefnemings te vermeerder.

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Chapter One

1. Introduction

1.1. Background to HIV prevention

Current efforts directed at HIV prevention have focused on achieving sustainable change in sexual behaviour such as abstinence, delay in sexual debut, reducing the number of sexual partners, and/or using condoms more regularly (Fishbein, 2002). The results of interventions aimed at sexual behaviour change appear to be mixed (Mills et al., 2004; Newman, Duan, Rudy & Johnston-Roberts, 2004; Strauss et al., 2001) while the HIV incidence rate has shown no indication of decreasing (Mills et al., 2004; Newman et al., 2004; Sahay et al., 2004). The lack of success in reducing the rate of HIV infection may be attributed to factors such as, the lack of awareness of the implications of risky sexual behaviour, the lack of access to free condoms and the lack of access to reproductive services such as sex education, or family planning clinics (Mills, et al., 2004; Newman et al., 2004; Sahay et al., 2004; Strauss et al., 2001). In light of the limited success of behavioural interventions in reducing infection rates, an HIV vaccine is likely to be an effective solution to this important public health problem (Mills, et al., 2004; Newman et al., 2004; Sahay et al., 2004; Strauss et al., 2001; Veljkovic, 2000). For a candidate vaccine to be tested, large numbers of HIV negative volunteers are required to enrol in a Phase III trial for at least two years and to accept randomisation to either a vaccine or placebo condition. A differential sero-conversion rate, between participants in the two conditions may suggest that a vaccine has some level of efficacy.

1.2. Defining the concepts

A vaccine is defined as: “An antigenic preparation used to stimulate the production of antibodies and procure immunity from one or several diseases” (Tulloch, 1993, p. 1736). This implies that a vaccine might defend or protect against a disease in people who are not infected with the disease. However, a vaccine does not act as a cure for people who are infected.

A textbook definition of a clinical trial is: "Any form of *planned experiment* which involves patients and is designed to elucidate the most appropriate treatment of future patients with a given medical condition" (Pocock, 1993, p. 1). Thus, a clinical trial is a scientific investigation that allows for a comparison of the effectiveness of a vaccine to be tested among several groups. A clinical trial tests that a vaccine is not harmful to humans and tests the efficacy of a vaccine (Croucamp, n.d.; Pocock 1993; Schwartz et al., 1980).

Vaccine trials take place when a new vaccine, which has been tested on animals, shows itself to be efficacious and harmless to animals. (Croucamp, n.d.; Pocock 1993; Schwartz et al., 1980). The next step is to test if a candidate vaccine would be as efficacious and harmless to human beings. In a future HIV vaccine trial, participants who are at a high risk of HIV infection, who are willing to participate and have an understanding about HIV vaccine trials are required to assist in testing a candidate HIV vaccine (Koblin, Holte, Lenderking & Heagerty, 2000; Suligoi, Wagner, Ciccozzi & Rezza, 2004). Thus, at least two groups are necessary, namely, an experimental group that would receive a candidate vaccine and a control group that would receive a placebo. The two groups would be necessary in order to test the efficacy of a candidate vaccine (Schwartz et al., 1980). More specifically, a HIV vaccine trial would entail administering a candidate vaccine to participants in order to test the safety and efficacy of it. This is aimed at reducing the number of HIV infections, to delay the further development of the HI virus and AIDS, or to reduce the transmission of the HI virus through, for example sexual intercourse (Crewe et al., 2003; Croucamp, n.d.; Kerns, 1997).

A HIV vaccine trial comprises of various phases (Crewe et al., 2003; Croucamp, n.d.; Kerns, 1997; Slack et al., 2004). Phase I HIV vaccine trials involve a small number of HIV negative participants (usually around 50-100 participants). The aim of Phase I vaccine trials is to assess the safety, tolerance and immunogenicity (whether it causes an immune response) of the vaccine in a human population. Phase II vaccine trials continues in assessing the safety of a candidate HIV vaccine, but also focuses on identifying the dosage and administration (for example, orally or intravenous) of a

candidate HIV vaccine (Crewe et al., 2003; Croucamp, n.d.; Kerns, 1997; Slack et al., 2004). The main objective of Phase III HIV vaccine trials is testing of the safety and the efficacy of a future HIV vaccine, in HIV negative participants, who are at a high risk for HIV infection. Phase III vaccine trials use a much larger sample of participants than Phase I and II vaccine trials, but the participants remain under the same controlled trial conditions in all three vaccine trial phases (Crewe et al., 2003; Croucamp, n.d.; Kerns, 1997; Slack et al., 2004).

There are behavioural, social and psychological issues associated with HIV vaccine trials that include willingness to participate (WTP), stigmatization, retention and attrition, and risk-taking behaviour. The fear of stigmatization identified in WTP research as a social and psychological issue, resulted from the likelihood of people associating potential trial participants as being at a high risk for HIV infection (Chesney, Lurie & Coates, 1995; Lurie et al., 1994; McGrath et al., 2001). A further concern is whether participants can be retained over the long time-periods required by efficacy trials (Mugusi et al., 2002). A future HIV vaccine trail entails that participants are likely too enrol for a period of 18 month to continuously test the efficacy of a candidate HIV vaccine.

1.3. Research aim

In the absence of any systematic research in South Africa in the area of enrolment of participants in an HIV vaccine trial, the aim of the present study was to identify the barriers and facilitators to enrolment among an HIV negative sample recruited in a community where the HIV prevalence is known to be high.

Chapter Two

2. Literature review

2.1. Anticipated barriers and facilitators to participation.

HIV/AIDS is the fastest growing disease, especially in Africa (Crewe et al., 2003; Koenane, 2000). Africa is a third-world continent, thus poverty has been a major factor in causing the spread of HIV (Crewe et al., 2003; Koenane, 2000). Studies conducted by Crewe et al. (2003) and Williams et al. (2000) found that the spread of HIV among poor communities is largely due to the lack of information as a result of having limited access to mass media, including radios and newspapers. Crewe et al. (2003) argued that poverty also leads to people engaging in behaviours that expose them to the risk of HIV infection. He stated that poor people might engage in sex work as a means of survival. Truck drivers and minors who leave their wife/girlfriend and family for long periods of time to earn a living, might fulfil their sexual desires by seeking sex elsewhere and might spread HIV to their wife/girlfriend when they return home (Crewe et al., 2003; Williams et al., 2000).

Vaccines are currently being researched and tested to combat the spread of HIV. As previously mentioned, a vaccine, when one is developed, may be used to defend against or prevent HIV/AIDS in people who are not infected with the HI virus (Tulloch, 1993.) However, a vaccine does not cure people who are infected (Crewe et al., 2003; Croucamp, n.d.; Kerns, 1997; Weidle, Mastro, Grant, Nkengasong & Macharia, 2002). A vaccine may prevent, or clear the further development of HIV in people who receive a candidate HIV vaccine prior to infection of HIV or it may reduce the likelihood of HIV infection through, for example, sexual intercourse (Crewe et al., 2003; Croucamp, n.d.; Kerns, 1997; Levy, 2001; Weidle, Mastro, Grant, Nkengasong & Macharia, 2002). The vaccine would teach the body's immune system to recognize a disease and enable the immune system to defend against a disease (Crewe et al., 2003; Croucamp, n.d.; Kerns, 1997).

A future HIV vaccine trial requires HIV negative participants, who are at a high risk of HIV infection, to participate in a clinical trial (Crewe et al., 2003; Croucamp, n.d.; Kerns, 1997). The purpose of the trial is to monitor the efficacy of a candidate HIV vaccine; that is, to determine whether the vaccine suppresses or reduces the number of HIV infections (Crewe et al., 2003; Croucamp, n.d.; Kerns, 1997).

However, there are risks attached to participating in future HIV vaccine trials (Kerns, 1997). A risk is defined as anything that causes adverse consequences to participants (Tulloch, 1993). Kerns (1997) hypothesised a risk factor and stated that participants who receive a candidate HIV vaccine may become immune to all future HIV vaccines. This implies that the immune system of the participants who receive a candidate HIV vaccine, that proves to be inefficient, would have already built up antibodies to that original antigen (Kerns, 1997). Thus, the immune system would be unresponsive to any future HIV vaccines. Kerns (1997) called attention to how the immune system reacts when introduced to a 'foreign substance', in the context of the present study, a HIV candidate vaccine. He stipulated that the immune system recognizes the vaccine and defends against it. Furthermore, the immune system takes time to prepare for the defence (Kerns, 1997). In the meantime the 'foreign substance' is beginning to multiply, intoxicating the body (Kerns, 1997). Subsequently, the body becomes ill and the individual has symptoms of a common cold, low resistance and fatigue (Kerns, 1997). However, after several days, the body builds up its defences and is able to bring the 'foreign substance' under control (Kerns, 1997). Croucramp (n.d.) also called attention to the potential risks that may be imposed on potential HIV vaccine trial participants. Participants who enrol in a future vaccine trial might experience side effects such as tiredness, swollen glands, and fevers, as a result of the immune system attempting to defend against the 'foreign substance'; that is, the vaccine (Croucramp, n.d.). If the vaccine were to be administered intravenously, which at this point researchers are uncertain about, some participants might experience side-effects from the injections (Croucramp, n.d.). Croucramp (n.d.) hypothesized that the possible side-effects could be redness and swelling of the skin resulting from the injection, as well as pain around the insertion point of the needle. Croucramp (n.d.) noted that there might be a possibility that a candidate vaccine would interact, in a harmful way, with the HIV virus if

participants seroconvert during the clinical trial. Thus, participants would be encouraged continuously throughout a clinical trial to avoid contracting the HI virus. Croucramp (n.d.) listed a number of other risks related to future HIV vaccine trials and stated that mental stress is the biggest risk participants may be faced with. Other risks to participation in future HIV vaccine trials mentioned by Croucramp (n.d., p22) include:

- Dealing with difficult scientific ideas.
- Being tested for HIV before joining the trial.
- Being injected and having blood taken regularly.
- Testing 'HIV-positive' because of the vaccine, although you may not have the virus.
- Convincing sexual partners that the vaccine does not protect you from HIV and that you still have to use condoms.
- The way people who fear HIV may treat you.
- The way people who disagree with the trial may treat you.
- Convincing a partner that you are HIV-positive because of the vaccine and not the virus.
- Being involved in the trial for a long period of time.

As a result of potential candidate participants being placed at these above-mentioned risks, an ethical imperative is to provide support, empathy and counselling. Tucker and Slack (2003) stated that if any participant were to seroconvert during a Phase III HIV vaccine trial, lifelong HIV treatment should be financed by the trial research committee for these participants. However, Kerns (1997) argued that researchers should ensure that medical care is minimal in order to prevent undue inducement.

With reference to the above-mentioned information, a literature review was conducted to identify the facilitators and barriers participants might have with regard to participation in future HIV vaccine trials. Several studies indicated that the facilitators to participating in a future HIV vaccine trial include: (i) the desire to help find an effective vaccine for altruistic reasons; (ii) wanting to receive protection from the experimental vaccine; (iii) wanting the financial incentive such as free medical treatment if or when the participant

becomes infected with HIV, that are given to trial participants; (iv) wanting to contribute meaningfully to scientific research; (v) and acquiring knowledge on HIV/AIDS, vaccines and clinical trials (Buchbinder et al., 2004; Crewe et al., 2003; Johnson, 2000; Kerns, 1997; Sengupta et al., 2000; Thapinta et al., 1999). These studies (Crewe et al., 2003; Johnson, 2000; Kerns, 1997; Mills et al., 2004; Sengupta et al., 2000) also called attention to the barriers associated with participation in a HIV vaccine trial. A barrier, within the context of the present study, is defined as an obstacle hindering the success of future HIV vaccine trials (Tulloch, 1993). Barriers perceived by potential participants in a future HIV vaccine trial include: (i) lack of access to health care; (ii) expected side-effects of the vaccine such as redness or swelling in the case of an injection; (iii) unforeseen side-effects as a result of the vaccine; (iv) stigmatization as a result of being enrolled in a vaccine trial; (v) discrimination as a result of testing HIV antibody-positive; (vi) and participants may have raised expectations of helping find a HIV vaccine soon (Buchbinder et al., 2004; Crewe et al., 2003; Kerns, 1997; Mills et al., 2004).

Hays and Kegeles (1999) conducted a study on gay men, identifying factors related to willingness to participate in HIV preventative trials. Their sample consisted of 390 gay or bisexual men who were HIV-negative or who had not been tested for HIV antibodies. The participants were between the ages of 18 and 29 years with a mean age of 24.6 years (standard deviation = 2.81 years). The sample consisted of 83% white, 7% Asian/Pacific Islander, 6% Latino, 2% Native American, and 1% African-American. Hays and Kegeles (1999) investigated reasons that would influence participants to participate in future vaccine trials including reasons that would influence participants to not participate in future HIV vaccine trials. Of the 390 participants, 226 participants provided reasons for participation in future HIV vaccine trials and 217 participants provided reasons for not wanting to participate in future HIV vaccine trials.

A thematic analysis of reasons for participating in vaccine trials included: the desire to contribute to ending the AIDS epidemic (39%), the desire to help research or the belief in the value of a vaccine (39%), altruism or the desire to help others (21), the possibility of reducing their own chance of HIV infection (18%), proof that the vaccine and study

procedures are safe (13%), characteristics of the study (for example, ensuring complete anonymity) (11%), moral responsibility; that is, participants feeling that it is their duty to help find a vaccine (10%), monetary compensation (5%), general positive; that is, providing researchers with encouragement to continue searching for a vaccine (3%) and educational value (2%).

Reasons for not wanting to participate in HIV vaccine trials yielded the following responses: fear of physical side-effects of the vaccine (28), the possibility of getting the placebo and not knowing about it (15%), the risk of becoming infected with HIV (15%), the temptation to have unsafe sex due to a false sense of protection from the vaccine (13%), qualms about study design or methods (12%), general cautiousness or participants worrying about the consequences of HIV vaccine trials (11%), personal cost or inconvenience (for example taking time off from work or having blood drawn) (9%), mistrust of government, scientists, or drug companies (9%), participants concerned about not being able to contribute to the research as they are not at a high risk of contracting HIV (8%), dislike of needles or medical procedures (7%), participants disapproved of being treated as a guinea pig (6%), and testing HIV false positive (1%).

A study conducted by Sengupta et al. (2000) identified anticipated facilitators and barriers in participants' decisions to participating in unspecified AIDS research. Their sample was based on a convenience sample of 301 adults (aged ≥ 18 years; mean = 33.1, standard deviation = 12.0). More than 80% of the participants had altruistic reasons for wanting to participate in AIDS research. Altruistic reasons for participation in AIDS research included helping to find a cure for AIDS, or helping people who are HIV positive or those who have AIDS. Access to transport and current health care benefits influenced over 50% of participants' decision in participating in future AIDS research (Sengupta et al., 2000).

Buchbinder et al. (2004) conducted a study on the determinants of enrolment in a preventative HIV vaccine trial. They conducted a study among 1795 high-risk HIV-uninfected participants over a period of 18-months. Of the 1795 participants, 952 refused enrolment in HIV vaccine trials. Of the 952 refusers, 593 participants gave

reasons for refusing to participate in HIV vaccine trials. Buchbinder at al. (2004) identified that the most common reasons for refusal to participate in future HIV vaccine trials included concerns about time commitment (21%), vaccine safety (14%), and potential harm associated with vaccine-induced antibody positivity (13%). Motivation for enrolment, once again, was for altruistic reasons. 94% of participants found altruistic reasons as their primary motivation for participation, with the most common response being: 'wanting to help find a cure for AIDS' (Buchbinder et al., 2004).

Mill et al. (2004) conducted a systematic review of barriers to participating in a HIV vaccine trial. Both quantitative and qualitative studies were reviewed. Mills et al. (2004) retrieved 211 searches on the related topic. 46 of these studies were relevant to their study, but 20 of these studies were found to be not original, not focusing on barriers to participation in vaccines trials, or relevant to HIV vaccination in particular. The remaining 26 literature reviews were found to be relevant to the specific topic of identifying barriers to participation in future HIV vaccine trials. Seven of these 26 studies were qualitative and the other 19 were quantitative studies. The studies reviewed were published across the United States, Thailand, Brazil, Uganda, Canada and Kenya. Mills et al. (2004) extracted common themes from each of the relevant literature searches. The present study is a qualitative study and thus focuses on the qualitative data of Mill et al.'s (2004) study. The qualitative studies yielded themes of safety concerns, fear or mistrust, concerns or misunderstanding about study design, discrimination/social risk, pragmatic obstacles and other concerns.

Five of seven qualitative studies discussed concerns about anticipated side-effects of the vaccine, five studies discussed concerns of safety and efficacy of HIV vaccine trials, five studies reported participants' concern about the risk of contracting HIV from the vaccine, and three studies identified the potential for increased high-risk behaviour.

Potential barriers to participation with regard to the theme of fear and mistrust found that three of the seven qualitative studies identified fear or mistrust of governments, fear or mistrust of researchers and the research process (3 studies of the 7) and fear or mistrust of pharmaceutical companies (1 study of the 7).

The most relevant themes regarding concerns or misunderstandings about study design found that participants were concerned with the issue of blinding and not being aware of treatment during future HIV vaccine trials (2 studies of the 7) and the possibility of receiving a placebo vaccine (2 studies of the 7).

Discrimination and social stigma risk was the most common theme identified among all seven qualitative studies. Concerns raised included sero-conversion (5 studies of the 7) and general discrimination against the participant and his/her family (4 studies of the 7).

Pragmatic obstacles identified in five of the seven qualitative studies included anticipated inconvenience encountered during the HIV vaccine trial, or personal limitations such as strained sexual relationships due to participation in future HIV vaccine trails (4 studies of the 7), travelling expenses and insurance (1 study of the 7) and employment concerns (1 study of 7).

Thus, Mill et al. (2004) identified and concluded in their study that safety concerns and fear of discrimination, were two important barriers that may inhibit or limit participation in future HIV vaccine trials.

The present study on WTP will thus provide information that may better assist with, and improve success of future HIV vaccine trials. It may identify, within a South African context, the issues that potential trial participants may face when considering WTP, including the identification of perceived barriers to WTP.

2.2 Theoretical framework

The theoretical perspective of the present study is based within the ecological model, with “person in context”. The “person-in-context” perspective of the ecological model acknowledges that all behaviour occurs in settings around the person (Scileppi, Teed & Torres, 1999). Within the context of this research the ecological model can be explained by how potential participants are influenced by his or her environment and how this model may influence his or her willingness to participate in a future a HIV vaccine trial.

Hence, it is necessary to investigate the person and his or her environment (Scileppi et al., 1999).

Furthermore, the theoretical perspective of this study also focuses on Bandura's social cognitive learning theory and the theory of self-efficacy. The theory of social cognitive learning and the theory of self-efficacy are reviewed in this research to depict how these may influence a potential participants decision in deciding whether to enrol in a future HIV vaccine trial or not.

Given the above, this research is placed within Bronfenbrenner's (1979) ecological systems as well as within Bandura's theory of social cognitive learning and self-efficacy., as explained below.

Bronfenbrenner (1979) argued that one has to consider four interacting dimensions in attempting to understand the person in context. These dimensions, as explained by Bronfenbrenner (1979) are:

1. The immediate settings, the home or the workplace containing the developing person, influences the development of person factors such as self-efficacy. The first level is termed the microsystem and as the name implies it makes up a small portion of the individual's context.

2. The next level goes beyond the single person settings to the relations between the person and the settings, that is, process factors such as the forms of interaction process occurring in family, or among friends or employers. Bronfenbrenner termed this level of interaction as the mesosystem.

3. A person's development is profoundly affected by events occurring in settings in which the person is not even present, that is, contexts such as local legislative bodies, for example, the church advisory board, or the community advisory board. The third level of Bronfenbrenner's ecological model is termed the ecosystem.

4. Finally, a persons settings at all three levels, outlined above, occurs within any culture or subculture, that is, the direct impact on the individual from the global system, for example, discrimination, cultural norms, and economic recession. The fourth and last level is termed the macrosystem, which makes up the largest portion of the individuals' context.

Thus potential participant's perceptions of barriers and facilitators to participation may be influenced by how they perceive themselves within the surrounding environment. For example, if a potential participant's self-efficacy is high, has support from the internal and external environment (i.e. support from the internal environment referring to the individuals' family and support from the external environment referring to the individuals' community) and is in line with the cultural norms, the potential participant would likely be more willing to participate in a future HIV vaccine trial. This may be due to support and encouragement from the environment rather than being excluded or discriminated against from the environment.

Bandura's social cognitive theory view of human nature (cited in Hergenhahn & Olson, 1999) argues that humans are rational but do not posses an autonomous free will. In other words Bandura (cited in Hergenhahn & Olson, 1999) rejects the notion that humans are "free to act independently of the environmental and personal influences impinging on them" (p. 367). According to Bandura (quoted in Hergenhahn & Olson, 1999, p.368), the factors that can limit personal freedom include:

1. deficiencies in knowledge and skills
2. perceptions of self-inefficacy
3. internal standards that are too stringent
4. social sanctions that limit a person's opportunities because of his or her skin color, sexual orientation, gender, religion ethnic background, or social class

Stretcher, DeVellis, Becker, and Rosenstock quoted in McKenzie and Smeltzer (1997) stated that self-efficacy, a construct of social learning theory, plays an important role in health promotion. Self-efficacy is defined as the competence individuals perceive themselves to have to be able to perform a desired task (McKenzie & Smeltzer, 1997).

They said that this state is situation specific. In other words, someone may be self-efficacious when it comes to participating in a future vaccine trial, but not when faced with reducing the risk of HIV infection. According to McKenzie and Smeltzer (1997), an individuals' perceived competence has been referred to as efficacy expectations. Thus, someone who thinks he or she can assist in testing a candidate vaccine, no matter the circumstances, has efficacy effects. Participants also have outcome expectations (McKenzie & Smeltzer, 1997). McKenzie and Smeltzer (1997) states that individuals might have efficacy expectations, however they might not want to engage in behaviour because they do not perceive it as beneficial to them. In other words, participants do not feel that the facilitators to participation would out-weigh the barriers to participation. Thus a number of potential participants would not be motivated and encouraged by the facilitators to participating in a future HIV vaccine trial in fear of also having to endure the barriers anticipated in enrolment in a future trial.

In keeping with the theory of social learning, reciprocal determinism is a construct of social learning theory identified by McKenzie and Smeltzer (1997). These authors found that the construct of reciprocal determinism refers to the interaction between the individual, the behaviour and the environment and individuals can shape his or her environment and vice versa. In other words, if potential participants perceive the facilitators to participation as encouraging, their behaviour is positive and they have favourable support and encouragement from the environment, there would be a strong likelihood that they would be determined to help test a vaccine. In contrast, if participants perceived the barriers from the environment as a threat, have a negative attitude toward the outcome of the trial and is not supported by the environment, it would minimize their willingness to participate.

In the context of the research, Bronfenbrenner's ecological model and the theory of social learning may play an influential role with regard to potential participant's willingness to participate. The way potential participants might perceive their level of self-efficacy and determination, as well as the support or lack thereof from the internal and external environment may influence their decision making of enrolling in a future vaccine trial.

Chapter Three

3.1 Research design and methodology

The research design chosen for this study was that of quantitative assessment. This is method of assessment uses qualifying words and descriptions to record and investigate aspects of social reality (Babbie & Mouton, 2002). Since the research topic is newly researched, it would be effective to gain further in-depth insight on anticipated barriers and facilitator that potential participants may perceive when deciding on participating in a future HIV vaccine trial. A central element in quantitative research is the administration of a semi- or unstructured interviews whereby rich data would be extracted (Babbie & Mouton, 2002). Thus in order to assess the range of methods, such as measuring instruments, required to conduct a quantitative study, a qualitative study was adopted.

3.2 Research setting

The study was conducted in a township community located south of Cape Town, in the Western Cape province of South Africa. The township has an HIV prevalence rate of 25% (The Desmond Tutu HIV Centre, 2005) and its community health clinic is one of the South African AIDS Vaccine Initiative's (SAAVI's) four vaccine trial-sites. SAAVI, which is a division of the Medical Research Council (MRC), was formed in 1999 to research, develop and test HIV/AIDS vaccines in South Africa (South African AIDS Vaccine Initiative, 2005b).

3.3 Participants

Participants were members of the township community who sought and received voluntary counselling and testing (VCT) at the community clinic and tested HIV negative. Following receipt of their negative result, they were invited to participate in the present study. A convenience sample size of 10 participants between the ages of 19 and 30 years were recruited with the assistance of HIV counsellors. We did not recruit participants over the age of 30 as most studies suggest that persons between the ages of 18 and 30 are more sexually active than those in other age groups (e.g. Williams et al.,

2000). The sample consisted of both males and females. Referrals of potential candidates to the present study were made by the HIV counsellors at Masiphumele clinic. The participants' age and HIV status were obtained from the HIV counsellors and the patients' folders were referred to, to confirm the participants' age and HIV status. Of the 10 participants, seven were demonstrated proficiency in English. An interpreter was retained to facilitate the interviews for those participants unable to converse in English Five participants had completed secondary school while three had not. The remaining two participants were currently in Matric. See Table 1 below for demographic details of participants.

Table 1

Participants Demographic Characteristics

Sample size	10
Gender	6 females; 4 males
Age	Range: 19 to 30; Mean 23
Racial background	Black
First language	Xhosa
Language	7 participants conversed in English;
	3 participants required a interpreter
Schooling	5 Completed Matric
	2 in Matric
	3 did not complete matric
Employment Status	3 Employed
	5 Unemployed
	2 Schooling

3.4 Data Collection

Data collection involved in-depth semi-structured interviews with participants during two sessions, one week apart. The first interview entailed discussing HIV/AIDS, vaccines and clinical trials. The second interview, participants expressed the concerns, problems, barriers and facilitators which they had regarding WTP in a future HIV vaccine trial. The time gap between the two interviews allowed participants to digest the information they obtained regarding HIV/AIDS, vaccines and clinical trials. This allowed participants to think about the concerns, problems, barriers and facilitators that they had regarding WTP in a future HIV vaccine trial. Allowing participants to digest the information regarding HIV/AIDS, vaccines and clinical trials at their own leisure, in a space of a week, was aimed at minimizing participants feeling intimidated and pressurized to express the concerns and problems to participation in a future HIV vaccine trial.. Open-ended questions formed the basis of both the interviews. The interviews involved face-to-face, interactive and dynamic conversations. Anticipated concerns, problems, barriers and facilitators of HIV negative participants', who are at a high risk of HIV infection, with regard to willingness to participate in a future HIV vaccine trial were identified. The first interview session lasted approximately 1hour 30minutes depending on the participants' indication of their level of understanding about HIV/AIDS, vaccines and clinical trials. The duration of the second interview depended on the feedback participants' had regarding the concerns, problems, barriers and facilitators to participation in a future HIV vaccine trial. The second interview lasted 30minutes to 1 hour, but varied greatly as some participants' contributions were lengthier than others. During both interviews it was emphasised that there is no vaccine available for HIV/AIDS. Interviewing consisted of paraphrasing, probing, sharing of information, iterating information where necessary, empathy and understanding.

3.5 Data analysis

The interviews were recorded and transcribed. The data was analyzed qualitatively in order to identify the behavioural, psychological, and social concerns experienced by individuals who are likely to be candidates for participation in a future HIV vaccine trial.

A computer programme, Atlas. ti, was used to analyse the textual data. Atlas.ti enables an investigator to manage large amounts of text with the use of linking and search functions. Atlas ti. thus facilitates textual analysis and interpretation, by means of selecting, coding, annotating, and comparing important segments of text. The analysis of the data focused on the content of the participants concerns and anticipated experiences surrounding enrolment in a future HIV vaccine trial.

Open coding, axial coding, and selective coding (Strauss & Corbin, 1998) formed the basis of the analytic outline. Open coding entailed identifying codes or themes in the original transcripts. Axial coding involved arranging the basic codes into inclusive categories. Selective coding is the process of identifying overarching core categories at greater levels of abstraction in order to form a conceptual model that is the grounded theory. Finally, Atlas ti. was used to call up all the linked data with each category for final examination to be certain that the grounded theory model indeed accurately represent the data. The above process resulted in the identification of a composite list of overarching themes that represent the concerns, issues and problems that participants associate with future enrolment in a potential HIV vaccine trial.

3.6 Ethics

The principle of beneficence and non-maleficence were adhered to; that is, every effort was made to maximize the participants' benefits from the present study (beneficence) and minimized inflicting harm on the participants (non-maleficence) (Bless & Higson-Smith, 2004, Moodley, 1999). Participation in the present study was voluntary and participants were not coerced to participate. They were allowed to withdraw from the study at any point without being questioned. The principle of confidentiality was upheld as participants sensitive and personal information was only made available to the interviewer. Participants were presented with the choice of giving their true name or a pseudonym since each participant was required to complete and sign an informed consent form. However, they were requested to provide the interviewer with their full names and telephone numbers so that each participants could be contacted and be reminded about the follow-up second interview. In upholding the ethical principal of

confidentiality and anonymity, each participant was given a pseudonym at the start of the first interview and this was followed through to the second interview. After briefing the participants on the aim and purpose of the present study, ethical principles were elaborated, and informed consent was obtained from each participant. Informed consent forms were available in English and Xhosa.

During the first interview, participants signalled signs of participation fatigue and highlighted the complex nature of the content of the interview. Thus, to reduce the incidence of participation fatigue, the interviewer encouraged the participants to actively engage in the interview and emphasised that it was an open-ended two way discussion. Interviews were scheduled on the working days of the week and consequently participants forfeited a day's work. Participants were compensated with the provision of an incentive which included a grocery hamper containing basic food commodities sponsored by a leading retail outlet in Cape Town. These hampers were distributed after the follow-up second interview was conducted. Grocery hampers were distributed after the follow-up second interview as only 10 hampers were donated towards the present study. Thus, if participants were given the hampers after the first interview and did not return for second interviews, there would not have been enough hampers for all participants.

Chapter Four

4 Results

4.1 Introduction

Potential candidates who were approached to participate in the present study responded positively to the request. However, one participant, who was approached, declined participation as she indicated her fear of being coerced into taking part in a future HIV vaccine trial. Most participants expressed eagerness to gain insight and knowledge on a future candidate HIV vaccine and future clinical trials. Participants articulated various levels of understanding regarding future HIV vaccine trials. The thematic analysis revealed two rich narratives. These included: 1) barriers to participation and 2) facilitators to participation that are summarized in Table 3. The results also identified the participants', who were recruited in the present study, willingness to participate (WTP) in a future HIV vaccine trial.

4.2 Knowledge and understanding about HIV vaccine trials

The participants' indicated their eagerness to acquire further knowledge on HIV/AIDS, vaccines and clinical trials. This encouraged their participation in the present study. All participants returned for their second interviews, which were interactive and dynamic. During the second interviews it was established that some participants had misconceptions and misperceptions regarding HIV vaccines and HIV vaccine trials. A HIV vaccine was indicated as a medication that would protect people from all diseases, as well as being able to protect people who are HIV infected. Participant P2 incorrectly stated that a vaccine is something that would protect people for all diseases:

P2: It protects diseases that I can get outside.

Participant P3 wrongly indicated that a HIV vaccine would protect people who are infected with the HI virus:

P3: Because it helps people when they are infected.

There was also a misconception that the vaccine would prevent HIV negative people 100% from contracting the HI virus. Participant P6 incorrectly stated that a vaccine is a medication that would be given to HIV positive people in order to fight against the HI virus and possibly reducing the rapid rate of HIV development.

> *P6: That medicine will try to, when you get it err… if you find someone who got HIV and that medicine is going to fight with that.*

Participant P10 incorrectly stated that once given the HIV vaccine she would be 100% protected from the HIV virus.

> *P10: While you using it you not going to get infected.*

It was apparent that participant P2 had trouble understanding the concept of a vaccine trial and referred to it as a means of testing HIV.

> *P2: A trial is a test of… a test of HIV... a test of HIV…*

On concluding the final set of interviews, all participants indicated that they had acquired better and high level of understanding regarding HIV/AIDS, a candidate HIV vaccine and a HIV clinical trial. See Table 2 for a summary of participants' knowledge and/or understanding regarding HIV/AIDS, a HIV vaccine and a HIV vaccine trial.

Table 2

Knowledge/Understanding regarding future HIV vaccine trials

Theme	Frequency
Misconception of HIV/AIDS.	0
Misconception of a vaccine.	4
Misconception of a vaccine trial	4
Knowledge about a vaccine.	14
Knowledge about HIV/AIDS.	21
Knowledge about method of infection.	13
Knowledge about vaccine trials.	18

The numbers in the frequency column refer to the number of times each theme was referred to by respondents in the sample.

Table 3

Summary of Barriers and Facilitators to WTP

Willingness to Participate (WTP)	
1. Barriers	**2. Facilitators**
1.1. Physical symptoms 1 Physical fatigue 2 Low resistance 3 Feeling sick 4 Having symptoms of HIV 5 Looking like a HIV positive person **1.2. Stigma/Discrimination.** 1 Fear of being judged 2 Fear of being rejected 3 Fear of being labelled **1.3. Trypanophobia** **1.4. Distrust** 1 Distrust of the researchers 2 Distrust of the vaccine **1.5. Psychological distress** 1 Testing HIV antibody positive 2 Fear of contracting HIV 3 Concern about effectiveness of vaccine 4 Double blinded placebo control **1.6. Sexual Disinhibition** **1.7. Family responsibilities**	**2.1. Altruism** 1 Protect HIV negative people from contracting the HI virus 2 Assist with research in finding a vaccine 3 Help reduce the rate of HIV infection, thereby reducing the rate of death **2.2. Own protection from HIV infection** **2.3. Hopefulness** 1 Believing that a HIV vaccine would be found 2 Believing that the HIV vaccine would be effective **2.4. Medical incentives** **2.5. Acquisition of knowledge** **2.6. Determining an individual's HIV status** **2.7. Equal treatment**

4.3 Barriers to participation

The results of the study yielded barriers expressed by the sample. Participants indicated concern about the physical symptoms, distrust, sexual disinhibition, trypanophobia, stigmatization and discrimination; psychological distress and family responsibilities associated with participation in a future HIV vaccine trial

The theme "physical symptoms" was divided into sub-themes. Physical fatigue, an anticipated side-effect of a candidate vaccine was stated by participants to be a barrier to participation. Several respondents expressed their concern of the possibility that a candidate vaccine could cause physical fatigue Participant P5 stated:

P5: Maybe I'll feel tired. When I get a job, I won't be able to work

Similarly, participant P4 and P8, who are currently employed, expressed their concern of the possibility of physical fatigue that may result from a candidate vaccine: they stated respectively:

P4: I'm scared of getting tired

P8: Like I know maybe it can make me tired.

Although participants expressed concerns about physical fatigue, they highlighted that their greatest fear was being unable to perform daily activities at work due to physical fatigue and tiredness. This concern is warranted as some participants of the sample population are the single bread-winners in the family. With the result, participants are reluctant to participate in a future HIV vaccine trial since they will fail to uphold and maintain their family responsibilities and commitments.

It has been hypothesized that a candidate vaccine may weaken the immune system, thus making it more susceptible to contracting the common cold for example (Kerns,

1997). Participant P3 expressed her concern of being able to contract a virus as a result of the immune system being weak. She stated:

> *P3: Because I don't know if I'm catching some virus…sometimes you have flu…And…or your body is weak.*

Participants were also concerned about the additional side-effects of the vaccine such as fevers and nausea, causing participants to feel ill. Participant P5 once again stated his concern of the side-effects of the vaccine. However, this time he expressed the concern of the vaccine causing him to feel sick, which could be linked to his concern of feeling tired, thus being unable to perform at work. Participant P5 stated:

> *P5: I'm worried about a vaccine that is going to make me sick*

The prevalence of the signs and symptoms of HIV, one of the hypothesized side-effects of a candidate vaccine, was deemed a barrier to participation. Participants expressed their fear that they might believe that they are HIV positive due to the hypothesized false positive induced by a candidate vaccine and the signs and symptoms associated with this anticipated side effect. Participants also expressed their concern or the possibility of being discriminated against if they were to show signs and symptoms of HIV while testing a candidate vaccine. Participant P10 expressed her fear of showing symptoms of HIV which could result in psychological distress associated with her perception of being HIV positive, although she indicated a high level of understanding that a candidate vaccine may have the ability to show a false positive.

> *P10: It bothers me because I look like an HIV positive person even though I will be negative… I'll be tested as a positive person, although I'm not and I will have the symptoms of a positive [person].*

Similarly, participant P9 expressed his concern of showing signs and symptoms of HIV, as a result he feared that members of the public might pass false judgement

against him. He indicated that he may lose hope of wanting to help find a HIV vaccine, which could result in attrition. Participant P9 stated:

> *P9*: Y*ou know like, with the symptoms of like a positive person. Like I will get worried because I will get some comments from the others. And maybe like that will frustrate me and end up like losing hope.*

Discrimination was deemed a barrier to some participants. Participants, who indicated discrimination to be a barrier to participation in a future HIV vaccine trial, expressed their fear of the lack of acceptance by their community, family, friends, and in some cases employers.

Several participants indicated concern about being falsely judged should they participate in a future HIV vaccine trial, as well as if they were to show signs and symptoms of HIV. Examples of the above sentiment is reflected in the following statements made by participants. As previously quoted participant P9 expressed his concern of being falsely judged by members of the public if he were to have symptoms of HIV. Moreover, he was concerned about becoming increasingly frustrated with people passing false judgment on him and, in the end losing hope and the motivation in helping find a candidate vaccine. Participant P9 stated:

> *P9: You know like, with the symptoms of like a positive person. Like I will get worried because I will get some comments from the others. And maybe like that will frustrate me and end up like losing hope.*

Similarly, participant P7 expressed his concern about the possibility that members of the public may falsely judge him for participating in a vaccine trial.

> *P7: If I tell them about this [referring to participation in a vaccine trial], they can think I'm HIV positive.*

"Fear of rejection" by significant others was also expressed as a barrier to participation in a future HIV vaccine trial. This hindered the participants' decision regarding willingness to participate in a future HIV vaccine trial. Participants indicated that they feared rejection in that they could be ill-treated signalled by the lack of respect and to the extent of being ostracized from their immediate family, friends, employers and the community at large... Participant P9 expressed his concern about being rejected by family as well the possibility of being dismissed from the workplace. He stated:

> *P9: You will [look] like [you have] HIV positive symptoms. So that's what I don't like, because maybe you might lose your job, then and your relatives.*

Similarly, participant P4 expressed her concern that, if she were to enrol in a future HIV vaccine trial, she could be treated differently by important others if they were to be under the false impression that she was HIV positive. She stated:

> *P4: They will…the people going to think I'm HIV positive. They're going to treat me different to others.*

On a related point, participants expressed their concern about being falsely labelled as an HIV positive person by members of the public. Not having the publics' support, but instead being stigmatized by the public was indicated as a barrier to participation. Participants P7 stated:

> *P7: Like I won't like, I won't like to take part in [the trial] because, because of the people, they going to think I am HIV positive, I have AIDS.*

Thus, participant P9 emphasized that awareness regarding future HIV vaccines and vaccine trials should be increased in order to reduce the likelihood of stigmatization and discrimination.

Not all participants indicated that discrimination was a barrier to participation in a future vaccine trial. Seven of the participants stated that discrimination would not be a barrier to participation in a future vaccine trial. Of the seven participants two were male of which one had completed schooling. However, both males were unemployed. Among the remaining five female participants three completed schooling, one participant was currently completing her matric and one participant did not complete her schooling. With regard to the employment rate of the female participants, two of them were unemployed, two were employed and one was currently schooling. None of these seven participants had tertiary education. During the course of the second interview of the present study, participants stated that they had a higher level of understanding regarding a future HIV vaccine trial, thus if they were to participate, they would have sufficient knowledge to inform members of the public of their role in a HIV vaccine trial. Participant P8 indicated why she would not fear being discriminated against by members of the public if she participated in a future HIV vaccine trial. She stated:

P8: I'm not afraid of the community to think that maybe that I am HIV infected. I'm not afraid about that.

I: Why aren't you afraid?

P8: It's because I know that I'm not HIV infected, I know that I'm negative.

The most prominent barrier in researching a candidate vaccine was distrust. Participants stated that they are duly concerned about the motives and intentions of the researchers as well as the proven effectiveness of the vaccine in that the vaccine would protect against HIV infection.

Distrust of the researchers was expressed by participants who hold the notion that researchers intentionally infect participants with the HI virus failing to mention their true intentions. Furthermore, a false notion was stated that researchers will encourage

them to engage in risky sexual behaviour so as to test a candidate vaccine. Participants P6 expressed his concern of the researchers infecting him with the HI virus as well as researchers asking him to place himself at risk of HIV infection. He stated:

P6: And for me I know to test that medicine [the candidate vaccine] if it is working you are going to get the blood, maybe someone that got HIV and to inject the someone who is HIV negative to know if it is working.

P6: I say like someone is going to get that medicine [the candidate vaccine] from you [the researchers] from trial…Because after get that medicine you must go to make action, you see. To know if that medicine is working, you see.

Similarly, participant P5 expressed his uneasiness of the researchers offering free medical treatment to participants who become infected during the trial.

P5: Because, it [the candidate vaccine] does not know is…it is working…it is working…I don't like the way they do they give you the free treatment. You are negative and they test a vaccine into you. You get infected. They give you the free treatment. I don't think that is right, that is good.

Participant P7 stated that he feared the true intentions of the researchers and would only consider participation should future HIV vaccine trials have been conducted on another set of participants, would he want to draw from their experiences. He also expressed his concern that participants would have to become HIV positive in order to test if the vaccine was effective. He stated:

P7: I'm afraid of maybe…it's another…it's another HIV disease. That they [the researchers] trying to …to lie to people, they talking about this vaccine…I'm afraid of…of…of taking part of…of on this….on this

thing [vaccine trial] because I don't want to be the first one who's…whose taking part in this. Unless I can…I can hear by some one else how it works and maybe I can be interested to take part.

P7: *I'm afraid about getting HIV positive, because in order to see this thing…this vaccine if it works or not, you must be HIV positive.*

Distrust was two-fold. Apart from distrusting the researchers, participants also expressed their distrust of a candidate vaccine. Participant P7 expressed his concern about the effectiveness of a candidate vaccine. He stated:

P7: *I'm worried about this…this vaccine, I'm not…I'm not…I don't trust this vaccine, because they are…what I heard a long time this HIV…you got this HIV by the chemicals. Have you ever heard about it, Boers, they…they mix the chemicals to…to in order to get the HIV.*

Similarly, participant P6 stated his distrust of the effectiveness of a candidate HIV vaccine.

P6: *If that medicine [candidate vaccine] is not going to work, that someone, you are going to kill the people.*

Trypanophobia (fear of needles) was expressed as another barrier to participation by fifty percent of the participants. Participants feared the pain they would experience from the injections at various intervals during the trial as well as having to draw blood on numerous occasions during the trial. Participant P1 expressed her fear of needles:

P1: *It get sores in an injection…*

Similarly, participant P3 expressed her concern of trypanophobia.

P3: *Maybe it's painful…The injector.*

Participant P5 also expressed his fear of needles.

P5: I'm afraid of that injection.

The fear of needles as well as the fear of having to draw blood throughout the trial was seen as a barrier to participant P10. She stated:

P10: It's to draw blood…Because it's going to be painful and they going to use injections.

The theme psychological distress was divided into sub-themes. The first sub-theme, testing HIV antibody positive proved to be a concern to participants. Participant P10 indicated that she feared the psychological distress attached to believing that she would be HIV infected during the trail, although she may only be HIV antibody positive. She stated:

P10: Because now I will think that I am HIV positive although I'm not. Then maybe that will do something to my mind.

Similarly, participant P5 expressed his concern with testing HIV antibody positive.

.P5: I thought that I am not going to test a HIV vaccine because I'm afraid that I will test like I am positive, but I know that I am not positive, but I test like I am positive and I will [be] afraid that I am going to sick.

Participants' indication of the fear of contracting HIV during the trial formed one of the sub-themes to psychological distress. Participant P7 feared sexual disinhibition and was concerned with the psychological stress attached to contracting HIV during the trial.

P7: I'm scared because I might get HIV positive and then that can frustrate me for the rest of my life.

I: *But the vaccine won't give you HIV infection. So why will you be scared of the injection?*

P7: *If I don't do…don't do protected sex, I can get HIV positive.*

Similarly, participant P8 expressed her concern of contracting the HIV virus during testing of a vaccine trial. She stated:

P8: *I'm scared [of contracting HIV].*

I: *Why?*

P8: *For the sake I know I'm negative now, so I don't want to become positive. But I'm interested to take the part in this vaccine.*

The theme "psychological distress" was also further divided into the sub-theme "concern about vaccine effectiveness". Participant P3 expressed her concern on the uncertainty of the effectiveness of the vaccine. She stated:

P3: *I don't know…is it [the candidate vaccine] working.*

The final sub-theme to psychological distress, was the distress attached to being assigned to a double blinded randomized placebo control trial. Several participants highlighted their insecurity regarding the protection by the candidate vaccine should they enrol in a future HIV vaccine trial. Participant P7 stated that he would be concerned about not knowing which group he would be assigned to in a future HIV vaccine trial. He indicated that he would fear receiving a placebo, as he would have no chance of protection against HIV.

P7: *The placebo is not working…* *I will be upset… because I have to know which one is working.*

Similarly, participant P8 expressed her dismay of a double-blinded randomized placebo control trial. She stated:

P8: If I will have the placebo…the placebo is not a vaccine, it is something like, but it's not. So, if I have the, the vaccine, I know that that is a protection.

I: But we only testing it.

P8: Yes, I know that we are only testing. But I believe that…I have the hope.

Participant P9 expressed why he thought the double-blinded placebo control to be a barrier. He stated:

P9: I think that in one point it will be a problem, because like, you don't know whether you will like maybe get the placebo or the vaccine… Maybe you get the vaccine and the vaccine on the other side is working and the placebo is maybe like in the same situation that you were before. So you might like ok, this thing is working, although you didn't get the real thing, the vaccine.

Participant P7 expressed his fear of sexual disinhibition and indicated it to be a barrier to participation. He stated that he may believe that the candidate vaccine would protect him. Thus, he indicated that he may be tempted to engage in unprotected sex. Participant P7 stated:

P7: So what I'm scared of is that…in this vaccine…vaccine trial….I'm going to think ok, now I'm protected I can go and sleep with…with… someone without a condom. The…the…the vaccine is there to help me.

From the statement above, it appears that the participant was concerned that enrolment in a vaccine trial would strip him of the volitionism associated with sexual decision-making.

One participant was concerned with responsibilities of assuming the responsibility of taking care of his sibling once his parents had passed on. Thus, additional family responsibilities were seen as barrier to participation by participant P9. He expressed:

> *P9: But I'm still in a like in between [regarding decision on WTP] because like at home, I live with my brother and I am 19 now, so like my parents were….are like dead like way back. So if maybe I will take decision to…to like take the vaccine and maybe afterwards I will have the symptoms of like a having like positive. Maybe there will like starting to get worried like about myself you know.*

In summary several participants feared the possibility of experiencing physical fatigue, weakness and illness, such as feeling feverish or nauseous, as hypothesized side-effects of the vaccine. The possibility of showing signs and symptoms, such as swollen glands, fevers or boils, of a HIV positive individual was also indicated to be a barrier to participation, due to the fear of discrimination and stigmatization. A participant expressed distrust of researchers claiming that they would infect him with HIV in order to kill him. Several participants indicated their fear that the researchers would be dishonest and not reveal their true intentions of testing a candidate vaccine. As a result, participants indicated their distrust of a candidate vaccine. Participants also indicated their fear of being prompted by the researchers to engage in risky sexual behaviour, placing themselves at a risk of HIV infection in order to help test a candidate vaccine. Several participants regarded the double-blinded randomized placebo control as a barrier, whereas other participants regarded it as a facilitator to participation in future HIV vaccine trial. Participants who found a double-blinded randomized placebo control to be a barrier to participation feared not getting the candidate vaccine, thus not having a chance of being protected by a candidate

vaccine. They sought the possibility of being protected by a candidate vaccine rather than being unprotected by the placebo. The participants' concerns were that they felt that they would be unprotected by the placebo, thus at a higher risk of contracting the HI virus. Although participants indicated a better and a higher level of understanding that there was a possibility that a candidate vaccine could not be effective, they stated that they were hopeful that there could be a small chance that a candidate vaccine could be more helpful than the placebo. Fear of needles (trypanophobia) was indicated as another barrier to participation, as a result of the anticipated fear of experiencing pain and bruising from the injections. Participants also indicated their fear of the psychological distress related to testing HIV antibody positive. They stated that they feared testing HIV false positive may cause them to believe that they were HIV positive, thus resulting in losing hope in assisting with finding a vaccine. This may however, be the result of attrition in participation in a future HIV vaccine trial.

4.4 Facilitators to participation

The major facilitators expressed by the sample were altruism, hopefulness, medical incentives, knowledge acquisition on vaccine trials, protection of oneself against HIV infection, determining an individual's HIV status and equal treatment to all participants.

All participants indicated altruism to be the main facilitator to participation. The theme altruism was divided into sub-themes. All participants expressed that one of the reasons they would be willing to test the vaccine, would be to protect HIV negative people from contracting the HI virus. Altruistic sentiments expressed by participants included: Participant P1 expressed her willingness not only protect her family, but the entire community. She stated:

> *P1: I want to help my family, not my family only, but the whole community… protected from HIV virus.*

Similarly, participant P4 stated that she wanted to help protect everyone who is HIV negative.

> *P4: I want to help all negative people in…they mustn't get AIDS.*

Altruism was also classified and subdivided into the theme of "assisting with research" to help find a candidate vaccine. Participant P8 said that she would be interested in taking part in a future vaccine trial to assist in finding out if a candidate vaccine would be effective or not. She stated:

> *P8: I want to take a part because I want to see does the vaccine working or not? Then I know if it is working I can help the people in... even in community, to tell them that if they test or if they draw the blood they know that they are still negative, then they can use the vaccine to protect us to infected.*

Similarly, participant P9 also expressed his interest in helping researchers find a candidate vaccine.

> *P9: Yes, like…like you did tell me about the vaccine and how it working and what's going to happen and so far. But also I want to help scientist who to know whether the vaccine works or not.*

Reducing the number of HIV infections, thereby reducing the rate of death was also a theme under altruism. Participant P9 once again expressed why he would like to participate in a future HIV vaccine trial some day. He sated:

> *P9: Like I would like to trial the vaccine, because like at the moment the rate of HIV is too high…So, I…I wish that one day maybe there will be a cure for HIV and AIDS…I'd like the standard of HIV to come low… I believe that like the youth is the future of tomorrow… So I believe that it is best now to try and help this society so that they can know*

whether the vaccine is working or not… And the scientist who will like know how to like whether the vaccine is working or not.

Similarly, participant P6 expressed his willingness to test a candidate vaccine in the future so that he can help reduce the rate of deaths caused by AIDS annually.

P6: *Us too, we want to help the people because the people always, every year the people is dead with AIDS. And their families left the children and there is no solution. If someone is going to get a solution to help the people is good idea.*

Several participants expressed that they were not only looking to help protect their family, friends and community, but they indicated that they would consider participation in a future vaccine trial so that they could also protect themselves against the HI virus. Participants P8 stated:

P8: *Its because, for the sake I'm negative, you know so, I know that it is going to prevent me or protect me against the HIV positive.*

Similarly, participant P5 stated that he would also like to have a chance of protecting himself again HIV infection. He stated:

P5: *I will take part because I like it, it's [the candidate vaccine] going to protect a negative person and me too.*

Participants stated that they were hopeful in finding a candidate vaccine that would be effective thereby strengthening their belief that a candidate vaccine will be found. Participant P7 expressed his hopefulness in finding a vaccine that would protect against HIV infection. He stated.

I: *What was good about it that you liked that you that will make you think about taking part?*

P7: What was good about it is that…I'm very glad because we gunna get at least we gunna get something now to protect if ever it's… its going to work. I'm not saying it's going to work, but at least now we have a…we are having something that we going to use to, to reduce the number of people who are who are staying with this with this disease.

Similarly, participant P10 expressed her hopefulness in finding a vaccine that will protect against HIV infection.

P10: I'm also hoping that we will find this vaccine, so that it can help.

Medical incentives that would be given to participants who become HIV infected during a vaccine trial were indicated as a facilitator to participation in future HIV vaccine trial. Participant P9 expressed why he indicated free medical treatment to be a facilitator to participation. He stated:

P9: The good thing about the trial, that will like maybe we are get infected, by mistake in this process you will be given free medication. And you will get free medication so that you can like, whether you are positive, maybe you can still live for longer.

Similarly, participant P8 stated that she would be dismayed should she contract HIV while testing a candidate vaccine. However, she indicated that being offered free medical treatment may compensate for the seroconversion. She stated:

P8: I'll be upset [if she becomes HIV infected during the trial], but for the sake I know I can get the…the free treatment, so I know that at least I can…

Acquisition of knowledge, a facilitator to participation, was identified by participants in the present study. They indicated their willingness to participate in a future vaccine trial so that

they could gain more knowledge about a vaccine trial. Participant P4 stated that she wanted to learn more about how the vaccine worked. She stated:

P4: *I want to learn.*

I: *What do you want to learn?*

P4: *If this vaccine is working.*

Similarly, participant P2 found that she would be able to learn more about vaccine trials if she were to participate in a future vaccine trial. She stated:

I: *Why will you want to take part?*

P2: *I want knowledge.*

I: *What you want to learn about?*

P2: *HIV…Vaccine and trials.*

One participant stated that another facilitator to participation would be testing and finding out ones HIV status. Participant P10 stated:

P10: *I will have to go and test.*

I: *m…So you will find out your HIV status?*

P10: *Yes, I will find out my HIV status*.

Double-blinded randomized placebo control trials were indicated as a facilitator to participation, as it would allow for equal treatment to all participants during a vaccine trial. Examples of the above sentiment are reflected in the following statements made by participants. Participant P5 explained that he liked the idea of the double-blinded

randomized placebo control trials as would allow for equal treatment to participants both in the experimental group and the placebo control group. He stated:

> *P5: I like the way they divide people in the two groups. The way they treat others and give others a placebo and other a vaccine and they don't tell others that some are given a placebo and some are given a vaccine. So I like that…It's because they are going to be treated the same, no one is going to undermine them.*

Similarly, participant P7 expressed why he thought a double-blinded randomized placebo control trial would be a facilitator to participation.

> *P7: It [double-blinded randomized control trials] is to differentiate which one is working and there…it is there to help to… to…. to…. to be sure that no one is being favoured in this in this testing.*

In summary, participants indicated their willingness to participate in a future HIV vaccine trial by assisting with research, by helping test a vaccine, in order to protect all HIV negative people from HIV infection and in doing so, reduce the death rate. Altruistic behaviour was prominent as participants were not only concerned with their own well-being, but also the well-being of all HIV negative people. Participants expressed their concern should they seroconvert during the trial. However, knowing that they would not be burdened with the cost of medical treatment would encourage them to participate in a future HIV vaccine trial. Hopefulness played a role in deciding whether participants were willing to test a candidate vaccine. Participants indicated that their hopefulness was a key facilitator to participation. Another facilitator to participation in a vaccine trial, expressed by the participants, was knowledge acquisition. Participants expressed their desire to learn more about vaccine trials through their participation in a future HIV vaccine trial. Participants stated that they would most likely be willing to take part in future vaccine trials so that they could gain more knowledge about candidate vaccines, hence create

awareness amongst people in their community as well as people in other communities. Establishing one's HIV status before and during the trial was also seen as a facilitator. Several participants stated that the double-blinded randomized placebo trial was a facilitator to participation, reassuring them that participants would be treated equally.

4.5 Willingness to participate

All participants stated that they had a higher level of understanding that they would have to practice safe sex during a future HIV vaccine trial as a candidate vaccine was being tested. In other words participants had a higher level of understanding that they were still at a risk of contacting HIV if they were to practice unsafe sex due to the uncertainty of the effectiveness of the candidate vaccine. Adherence to all appointments throughout the duration of the trial was not indicated to be a barrier to participation by the participants. Each participant indicated that they paid regular visits to the clinic without having to be reminded or coerced. The results yielded that all six female participants and one male participant were willing to participate in a future vaccine trial, two males were not willing at all to participate in a future vaccine trial, and one male was unsure about his willingness to partake in future vaccine trials.

Although participants expressed their concerns about the barriers to participation, most participants indicated that they would be willing to participate in a future HIV vaccine trial. All participants were driven by altruistic reasons as mentioned above, as well as wanting to protect themselves from HIV infection. One of the participant's who indicated his unwillingness to participate, stated that if he received further information regarding HIV vaccine trials and could talk to people in the future, those who would have participated in a future HIV vaccine trial, it would be likely that he would change his decision. Participant P7 stated:

P7: I'm afraid of…of…of taking part of….of on this….on this thing because I don't want to be the first one who's…whose taking part in this.

I: Why not?

P7: Unless I can…I can hear by some one else how it works and maybe I can be interested to take part.

Participant P9, who was the only participant who indecisive about his participation in a future HIV vaccine trial, indicated that he was likely to participate in a future vaccine trial if more awareness was made to the general public in order to help reduce discrimination and stigmatization. He stated:

P7: But I'm still in a like in between…maybe you guys can make some awareness of this vaccine or make a programme on TV so that parents can know and understand how the vaccine like the consequences and the outcomes of it.

4.6 Conclusion

Overall, participants expressed their concerns about anticipated barriers to participation in a future HIV vaccine trial. Barriers to participation included: fear of physical symptoms; fear of stigmatization and discrimination; trypanophobia; distrust; fear of psychological distress; fear of sexual disinhibition; and family responsibilities. Although participants identified barriers to participations, they also identified facilitators to participation in a future HIV vaccine trial. Facilitators to participation included: altruism; protecting oneself from HIV infection; hopefulness, medical incentives; acquisition of knowledge, determining one's HIV status; and equal treatment resulting from a double-blinded randomized placebo control trial. The majority of participants indicated that they would be willing to endure the barriers to participation so that they could assist in finding an effective HIV vaccine. It is evident that altruism can be deemed as a motivator influencing participants'

decisions regarding participation in a future HIV vaccine trial. The results of the present study yielded that of the 10 participants, 7 participants indicated their willingness to participate in a future vaccine trial, 2 participants indicated that they were unwilling to participate and one participant was concerned about family responsibilities, thus was unsure about his willingness to participate in a future HIV vaccine trial.

Chapter Five

5. Discussion

5.1 Introduction

Ten participants were questioned for the purpose of the present study. From the data elicited, concerns and problems were identified regarding perceived barriers to participation, as well as perceived facilitators to participation. Participants in the present study indicated their willingness to participate in a future HIV vaccine trial based on their present knowledge and understanding of vaccine trials. Their levels of knowledge and understanding of HIV/AIDS, a HIV vaccine and future clinical trials were identified in the present study and are summarized in Table 2. Results of the study are explained and hypothesized using Bronfrobrenner's (1979) ecological model and Bandura's theory of social learning . These two theoretical frameworks make reference to an individual's behaviour and his or her environment.

5.2 The relationship between self-efficacy, the environment and decision-making.

Individuals' decisions, as it appeared, were influenced by their level of self-efficacy.. Self-efficacy is defined as the competence individuals perceive themselves as possessing in a specific situation that enables them to perform a desired task (McKenzie & Smeltzer, 1997). In other words, an individual may have a high self-efficacy when it comes to participating in a future vaccine trial, but not when faced with the barriers associated with participation in a future vaccine trial. According to McKenzie and Smeltzer (1997), an individuals' perceived competence has been referred to as efficacy expectations. Thu, someone who thinks he or she can assist in testing a candidate vaccine, no matter the circumstances, has efficacy effects. In other words, participants do not feel that the facilitators to participation would exceed the barriers to participation. Thus a number of potential participants would not be motivated and encouraged by the facilitators to participating in a future HIV vaccine

trial in fear of also having to endure the barriers anticipated in enrolment in a future trial.

Brofenbrenner (1979) argued that there are four levels of interacting dimensions which influences an individual's behaviour. The first level, the microsystem, makes reference to the participant's immediate setting which could be his or her home or workplace, people with whom the individual interacts on a regular basis, and how the setting may influence his or her behaviour (Brofenbrenner, 1979). The second level, the mesosystem, explains the relationship between the individual and the support structure received from the immediate setting (Brofenbrenner, 1979). The third level, the ecosystem, makes reference to an individual's community and environment and how it may influence his or her self-efficacy (Brofenbrenner, 1979). The final level, the macrosystem, combines the above levels and places them within the culture or subculture (Brofenbrenner, 1979) of an individual. Cultural norms, discrimination or economic recession may play a role in an individual's self- efficacy, hence influencing his or her willingness to participate in a future HIV vaccine trial.

In the present study the microsystem may influence an individual's behaviour. People with whom an individual interacts on a regular basis may influence his or her person factors, such as self-efficacy, thus influencing his or her further development in society. The competence that individuals perceive themselves as having to assist in a future HIV vaccine trial may be influenced by the level of knowledge and understanding regarding future HIV vaccine trials that exists in the microsystem. If the level of knowledge regarding future HIV vaccine trails is high in the microsystem, participants may experience a higher sense of self-efficacy, which may be the result of reduced discrimination and stigmatization within the immediate setting. This could influence level of competence individuals perceive themselves as having to assist in a future HIV vaccine trial, hence influencing their decision-making.

The mesosystem may influence an individual's self-efficacy, which in turn may influence his or her decision-making. In other words, if participants' family members and colleagues provide support and reinforcement and are encouraging and in favour of finding an effective future HIV vaccine, potentially resulting in a reduction in discrimination and stigmatization from the immediate setting, participants may have a higher level of self-efficacy. Thus, he or she may be more willing to participate in a future HIV vaccine trial. Whereas, if family members and colleagues are discouraging and are against finding a candidate HIV vaccine, the level of stigmatization and discrimination may be high in the immediate setting and an individual may have lower levels of self-efficacy. Thus he or she may be less willing to participate in a future vaccine trial.

Similarly, the ecosystem may influence an individual's self-efficacy. In other words, the support structure and reinforcement obtained from the community may influence an individual's behaviour. If discrimination and stigmatization are perceived to be intense in the community, the competence that individuals perceive themselves as possessing to assist in a future HIV vaccine trial may be low. Thus he or she may be less willing to participate in a future HIV vaccine trial.

Finally, the marcosystem combines the above levels and contextualizes them within an individual's cultural norms. Cultural norms which occur within an individual's global setting may influence his or her behaviour. Thus if family members and the community discriminate against future HIV vaccine trials, individuals would be less likely to participate, as they are bound to cultural norms. See Figure 1 for a diagrammatic representation of the relationship between an individual and the four levels of interacting dimensions.

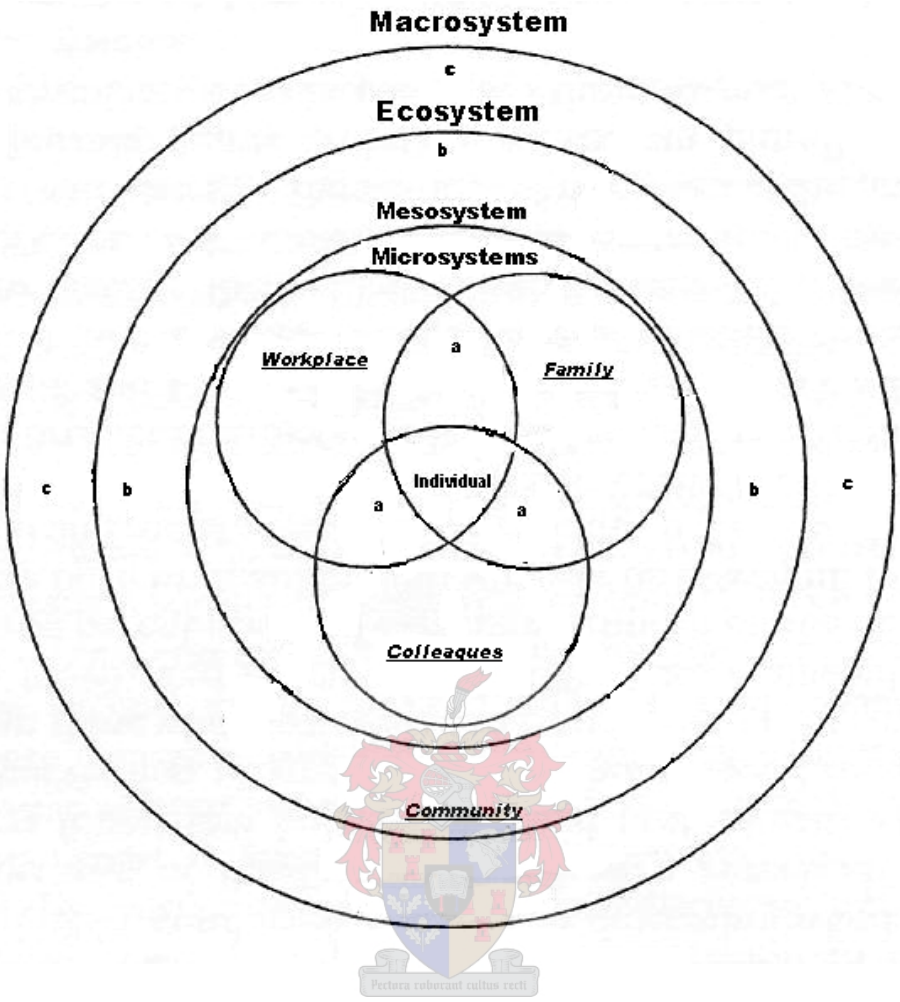

Figure 1: The Ecological Model: Person in context

Note:

a = relationship between individual and the mesosystem (i.e. immediate setting)

b = relationship between individual and the ecosystem (i.e. community)

c = relationship between individual and the macrosystem (i.e. combination of level within a culture)

With regard to participation in a future HIV vaccine trial, there are uncertainties regarding the efficacy of a future candidate HIV vaccine and the outcome of a future HIV vaccine trial (Kerns, 1997), for a candidate vaccine is still to be tested in South Africa. In other words, there is no guarantee that a candidate vaccine would protect against the HI virus. Furthermore, an individual might be faced with unforeseen risks such as, immunity against future candidate HIV vaccines, associated with a candidate

HIV vaccine. Thus, an individual might place his or herself at a greater risk of contracting HIV rather than obtaining protection against HIV from a future candidate HIV vaccine. As a result, these risks attached to participation in future HIV vaccine trials might hamper the self-efficacy of potential participants. This might be due potential participants fearing the anticipated barriers to participation, which might include seclusion and discrimination from the internal and external environment, resulting in fewer people wanting to assist with participation in vaccine trials.

Thus Bronfenbrenner's ecological model and the theory of social learning might play an influential role with regard to potential participants' willingness to participate. The way potential participants might perceive their level of self-efficacy and determination, as well as the support or lack thereof from the internal and external environment, might influence their decision making of enrolling in a future vaccine trial.

5.3 Appraisal of the barriers and the facilitators to participation

In an effort to understand the manner in which individuals construct meaning to participation in future HIV vaccines trial an in depth qualitative was conducted. The present study was aimed at identifying potential participant's concerns and problems to participation in a future HIV vaccine trial. Two overarching themes emerged, namely: (1) barriers to participation and (2) facilitators to participation, reflected in Table 3.

5.3.1 Barriers to participation

5.3.1.1 Physical symptoms

Physicals symptoms which included physical fatigue, low resistance, having symptoms of HIV, looking like a HIV positive person, and feeling sick at times due to the anticipated side-effects of a candidate vaccine were noted by participants as being potential barriers to participation in future HIV vaccine trials. Physical fatigue,

which was defined as feelings of fatigue and tiredness or exhaustion was anticipated as one of the intended side effects of the vaccine and was deemed a concern by participants in this study. Participants feared that they would be unable to conduct their daily tasks if they were to constantly feel fatigued or exhausted as a result of the candidate vaccine. In other words, participants stated that they feared that physical fatigue could impede their performance in their daily activities. Furthermore physical fatigue might result in lack of productivity and an added risk of losing their jobs. This could be detrimental to the livelihood of participants who enrolled in a future HIV vaccine trial, as they fall into the lower socio-economic group. Although many participants in the present study were unemployed at this point, concerns were raised regarding future employment and having to endure the consequences of anticipated symptoms of fatigue and tiredness due to a candidate vaccine. In keeping with these findings, a study conducted by Croucramp (n.d.) found that fatigue might be a possible side-effect of the vaccine, hence resulting in a barrier to participation in future vaccine trials. Although physical fatigue was indicated to be a barrier to participation, several participants in the present study, nevertheless indicated that they would be willing to consider participation in a future HIV vaccine trial.

Participants also expressed their concerns that a candidate vaccine might lower the immune system that could make them more susceptible to contracting viruses, such as influenza, tuberculosis, HIV, causing them to fall ill. According to a study conducted by Kerns (1997), he found that in some cases when a pathogen is artificially introduced to the immune system (that is, in the form of a vaccine) the body may exhibit physical symptoms resulting from the inoculation. In keeping with this finding, studies conducted by Buchbinder *et al.* (2004), Hays and Kegeles (1999) and Mills *et al.* (2004) found in their results that participants were also concerned about other side-effects of the vaccine such as, feeling ill.

Concern was also raised as participants expressed uneasy regarding having symptoms of HIV and even looking like a HIV positive person. From the data above,

discrimination was also identified as a barrier to participation, which will later be discussed. Thus participants expressed their concerns about showing signs and symptoms of HIV in fear of being discriminated against by friends, family and the community. Referring back to Bronfenbrenner's ecological model and the theory of social learning, these theories once again play a crucial deciding factor in enrolment in future HIV vaccine trials. If there is a lack in support from the internal and external environment, potential participants see this as a barrier to participation. Thus potential participants are less willing to enrol in future vaccine trials.

Related to the concern of the possibility of showing signs and symptoms of HIV, some participants reported further concern about psychological distress that might be associated with believing that they are HIV positive. A candidate vaccine has the property of causing participants to test false positive as explained previously. Thus participants expressed their concern about being under the false impression that they have seroconverted. They stated that their fear could result in their losing hope in a HIV vaccine being effective, as well become less motivated to continue with testing a candidate vaccine because they would be under the false impression that they have become HIV positive. As a result this could lead to attrition of participation in future HIV vaccine trials.

5.3.1.2 Stigma and discrimination

Data from the study yielded the themes of stigma and discrimination which was further categorized into sub-themes. Participants expressed their fears of being labelled HIV positive as previously discussed, hence resulting in the concern about stigmatization and discrimination from the internal and external environment. This may be due to the lack of self-efficacy and the lack of support from the internal and external environment.

As previously discussed, the anticipated physical symptoms associated with a candidate vaccine might result in the participants showing and having signs of HIV.

As a result, family members and members of the community and in some cases, employees might falsely perceive the falsely induced symptoms that a candidate vaccine might induce in an individual. Thus potential participants expressed stigmatization and discrimination to be a barrier to participation in future vaccine trials. A study conducted by Mills *et al.* (2004) found that discrimination and social stigma was the most common theme identified across all seven qualitative studies reviewed by them. They identified in their study that participants raised concern regarding sero-conversion and general discrimination against the participant and his/her family Similarly, participants in the present study expressed their concern about being judged, rejected and labelled by other people important to them in their homes, community and work places. Several participants indicated that they feared the possibility of being disowned by their families, friends and community. They also expressed their concern that they could be treated differently if other important persons in their lives were to assume that they were HIV positive. However, keeping this in mind, several participants on the other hand stated that they did not fear discrimination as they felt that if they were to participate in a future HIV vaccine trial they had sufficient knowledge to provide an explanation to those people who might tend to discriminate against them. This might be an indication of these participants having a higher level of self-efficacy as well support from the internal environment. The data yielded that the possible reason that some participants would not be perturbed by people who might discriminate against them due to a possibility of testing false positive and showing signs and symptoms of HIV, was that they indicated that they had sufficient knowledge of the anticipated barriers associated with a candidate vaccine. Thus they indicated that they would have a high level of knowledge to be able to explain to people who might discriminate against them and help them to understand the fundamental nature of a HIV vaccine trial.

5.3.1.3 Trypanophobia

In the present study, trypanophobia, the fear of needles was most commonly cited as a barrier to participation. Comments about needles from participants featured

prominently in their descriptions of their concerns. These comments took the form of participants expressing their fears of pain and bruising associated with injections. If the candidate vaccine were to be administered intravenously, which at this point there remains uncertainty regarding the administration of a candidate vaccine, participants stated that they feared the anticipated pain that could occur when having to draw blood on several occasions throughout the trial. Participants would be required to draw blood at various time intervals during the vaccine trial in order to monitor the efficacy of a candidate vaccine. Similarly a study conducted by Hays and Kegeles (1999) found that participants disliked needles or medical procedures owing to the pain that occurs when injected. The result of the present study is therefore in agreement with the findings of Hays and Kegeles (1999).

5.3.1.4 Distrust

A common barrier to participation was distrust, which was found both in the context of the present study, as well as in several of the literature reviews. The study conducted by Hays and Kegeles (1999) found that participants mistrusted government, scientists, and drug companies. Similarly, Mills *et al.* (2004) found that participants feared or mistrusted government, researchers and the research process, and pharmaceutical companies. Bearing in mind that the sample selected in this study consisted of Black Xhosa speaking participants, they expressed their distrust of researchers which they associated with as being White. This sentiment of distrust may be the result of the apartheid years. In the case of participant P7, such a sentiment was expressed in his dissatisfaction with his perception that researchers are White. He made reference to the "boerers [sic] mixing chemicals in order to get HIV", thus he expressed his concern about not being able to trust researchers. Therefore his reluctance to participate in future HIV vaccine trials might be driven by his fear of the ethnicity of the researchers. Several other participants also stated that they did not trust the researchers. Participant P5's reluctance in willingness to participate in future HIV vaccine trials was expressed in his dissatisfaction with his perception that as a result of the likelihood of free medical treatment offered by

researchers, to participants who might seroconvert during the course of a clinical trial, made him suspicious of the researchers' true intentions in testing a candidate HIV vaccine. He stated that he disliked the thought that researchers would be willing to provide participants who might seroconvert during the course of a HIV vaccine trial with free medical treatment, as he indicated that this appeared to be disturbing. The theme of distrust identified that participants feared that researchers would intentionally infect them with HIV. Distrust of researchers might have arisen as a result of the apartheid legacy. People of colour were discriminated against and undermined in their role in society during the apartheid legacy. Thus some participants expressed their concerns regarding the true intention of researchers.

Furthermore, participants also expressed distrust of a candidate vaccine in fear of it not being effective. This sentiment was expressed by participant P6, who stated that if a candidate vaccine would not be effective, participants would die. She expressed her concern about being at risk of contracting HIV if a candidate vaccine was not effective, as well as not being able to be protected from a future successful candidate vaccine. Kerns (1999) argues that participants who enrol in a vaccine trial, in which the candidate vaccine is unsuccessful, could become immune to future vaccines. Thus participants would be excluded from becoming immunized against the HI virus. Reference by participants was also made regarding the concern of a candidate vaccine being a new strain of the HI virus. They expressed their concern that through inoculation they would seroconvert. To quote participant P7, he expressed his concern regarding a candidate vaccine and said: "*I don't trust this vaccine, because they are…what I heard a long time this HIV…you got this HIV by the chemicals*".

Distrust of a candidate vaccine might have arisen as a result of myths about HIV/AIDS. A study conducted by Klonoff and Torres (1996) identified that a door-to-door survey yielded that 27% of their sample of African Americans believed that "HIV/AIDS is a man-made virus that the federal government made to kill and wipe out black people" (p. 455). A more recent study, Bogart and Thorburn (2005), conducted a random telephone survey and found that over 50% of males in the study

and over 36% of women in the study agreed to the statement that AIDS was produced in a government laboratory. Thus within the context of the present study, participants misconceptions about future candidate vaccine might stem from the myth that AIDS is a disease produced within a laboratory. Hence linking this myth back to participants P7's comments about contracting HIV as a result of chemicals being injected into the body.

5.3.1.5 Psychological distress

A sub-theme that emerged from the theme psychological distress was participants concerns about testing HIV antibody positive. As mentioned before a candidate vaccine has the property of making a HIV negative participant test HIV false positive. As a result, participants expressed their concern about not knowing for sure if they had contracted the virus or not. They stated that they would be concerned about their HIV status in fear of judgement that might be passed by the community and important others. Discrimination and the fear of lack of support from the internal and external environment of a potential participant might influence their self-efficacy, hence influencing decision making regarding enrolment in future vaccine trials. Participants also expressed their concern about the possibility of contracting the HI virus while testing the vaccine, which was categorized as another sub-theme of psychological distress. They indicated that they would fear not knowing whether they would receive the candidate vaccine or the placebo. This raised concern to participants as they stated that in the event that they would be given a placebo, they would not have the chance of being protected againt HIV infections during the clinical, if a candidate vaccine proved to be effective. Furthermore concern about not knowing who receives a placebo and a candidate vaccine led to the following sub-theme of participants' concern about effectiveness of vaccine. Concern was raised with regard to a placebo not being able to protect them at all against the HI virus; whereas if participants knew that they would receive a candidate HIV vaccine, it might be possible that they would experience less psychological distress as a result of having a chance of being protected by a candidate HIV vaccine. Overall the sub-

theme of double blinded placebo control emerged. Participants expressed their concern about being kept blinded throughout a vaccine trial in fear of being at a greater risk of HIV infection, compared to the experimental group. Participants indicated that although they understood that the candidate vaccine might or might not be effective, they would prefer to receive a candidate vaccine compared to a placebo in hope of a candidate vaccine being effective. Thus placing the potential participant at a lower risk of contracting HIV during a vaccine trial and leading to less psychological distress.

5.3.1.6 Sexual disinhibition

In terms of categorizing the cause of fear of sexual disinhibition, participant P7 stated that he feared that he might become reluctant to practise safe sex during the vaccine trial, suggesting that he would believe that a candidate vaccine would protect him against HIV infection. Aligned with these findings, the study conducted by Mills *et al.* (2004) identified the potential for increased high-risk behaviour among participants. What this implies is that potential participants might form misperceptions of the efficacy of a candidate vaccine and engage in high sexual risk behaviour. Thus participants might, through the course of the trial begin to believe that a candidate is working, placing themselves at a greater risk of contracting HIV.

5.3.1.7 Family responsibilities

An additional barrier that was identified within the present study was that of family responsibilities. Literature confirming or rejecting this theory has not been identified. Concern in the present study was raised regarding the anticipated physical side effects of a candidate vaccine and its influence on potential participants' family responsibilities. Participant P9 reported that he feared that the consequences of the hypothesised physical symptoms associated with a candidate vaccine could disrupt his family life, as well as undermine family responsibilities. He raised concern about the possibility of feeling ill and fatigued as a result of a candidate vaccine, thereby

not having the ability to uphold his responsibilities. He indicated that he was the breadwinner and caretaker of his family and experiencing fatigue and feeling ill could negatively influence his ability to uphold and meet his family responsibilities. Thus rendering the inability to uphold family responsibilities, due to anticipated physical side effects, was seen as barrier to participation in a future HIV vaccine trial.

5.3.1.8 Inconvenience

The literature revealed that concern was raised regarding the time period which potential participants would need to allocate for a vaccine trial. In other words, concern regarding the time that they would need to break away from their daily routine in order to attend follow-up visits during a vaccine trial would be of concern. The literature also found that personal or travel costs resulted in being an inconvenience to participants. In the present study however, participants indicated that they did not find the demands of coming for regular check-ups in a future vaccine trial to be an inconvenience to them. Several participants stated that presenting themselves for follow-up appointments would not be a problem as they were used to coming to the clinic out of their own accord for regular check-ups. Thus personal or travel costs were not identified by the participants in the present study as a barrier to participation. However, it could be possible that participants stated that presenting themselves for follow-up appointments would not be deemed as a barrier to participation in the present study as most of the participants are unemployed. Thus participants would not be concerned about follow-up appointments disrupting their daily activities.

5.3.2 Facilitators to participation

5.3.2.1 Altruism

Although participants indicated that they feared barriers to participation, in several cases altruism, a facilitator to participation, was expressed as rewarding and overshadowing the barriers. Thus participants indicated that altruism would be one of

the facilitators that would motivate them to participate in a future vaccine trial. Ubuntu a Xhosa concept that broadly refers to communality, oneness, cooperation, and sharing might be an explanation as to why participants in the present study felt strongly about altruism being a facilitator to participation in future HIV vaccine trials. Participants expressed their willingness to assist their community in overcoming the rate of HIV infections.

Altruistic reasons were the most commonly cited facilitators to participation, both in the literature review, as well as in the present study. Hays and Kegeles (1999) found that participants stated that moral responsibility (that is, participants feeling that it is their duty to help find a vaccine) and a general positive attitude (that is, providing researchers with encouragement to continue searching for a vaccine) were reasons that motivated them to participate in a future HIV vaccine trial. Buchbinder *et al.* (2004) also found that 94% of their sample stated that they would participate in a future vaccine trial for altruistic reasons. In accordance with these findings, the present study identified sub-themes to altruism. Participants' willingness was motivated by a desire to protect HIV negative people from contracting the HI virus. Participants stated that they would participate in a future vaccine trial so that they could find a candidate vaccine that would be able to protect friends and family and all people that are HIV negative. Ubuntu falls into place where participants are willing to stand together to combat the fight against HIV by assisting in testing a candidate vaccine. Participants also expressed their willingness to assist with research. Participants stated that they were curious of the effectiveness of a candidate vaccine and wanted to know if it would work or not. Thus participants were interested in taking part in the research to help identify the efficacy of a candidate vaccine and assist in finding a preventive measure against HIV. Participants also stated that they would like to enrol in a future vaccine trial so that they could help reduce the rate of HIV infection and the rate of resulting death. Concern was raised regarding the number of HIV/AIDS deaths in the country, thus participants expressed their eagerness to take part in a future vaccine trial in order to combat the death related to

HIV. Participants expressed their concern about the future of the country as well the youth, who would become the future leaders, thus most participants stated that they were willing to consider participating in a future vaccine trial in order to ensure the growth and future developments of South Africa.

Although participants indicated that they feared barriers to participation, in several cases altruism, a facilitator to participation, was expressed as rewarding and overshadowing the barriers. Thus participants indicated that altruism would be one of the facilitators that would motivate them to participate in a future vaccine trial. Ubuntu a Xhosa concept that broadly refers to communality, oneness, cooperation, and sharing might be an explanation as to why participants in the present study felt strongly about altruism being a facilitator to participation in future HIV vaccine trials. Participants expressed their willingness to assist their community in overcoming the rate of HIV infections.

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5.3.2.2 Own protection from HIV infection

In addition to protecting society, it was found in the present study that participants appeared to be motivated by the possibility of being able to protect themselves from the deadly HI virus. Participants were not only interested in enrolling in a future vaccine trial for altruistic reasons. Furthermore they were also concerned about their own health and future. Thus expressing their willingness to enrol in a future vaccine trial, they stated that they could assist in protecting themselves. Accordingly, Hays and Kegeles (1999) found that participants were motivated by the possibility of reducing their own chance of being infected by HIV.

5.3.2.3 Hopefulness

The theme of hopefulness was identified within the context of the present study. Literature confirming or rejecting this theory has not been identified. Participants of the present study indicated that their level of hopefulness of believing that a HIV vaccine would be found and believing that it would protect HIV negative people against HIV infection helped them to make a decision regarding their willingness to participate in a future HIV vaccine trial. Believing and having hope of a candidate

vaccine might increase a participants' self-esteem, motivating them to take part in a future vaccine trial regardless of the stigma and discrimination attached to enrolment.

5.3.2.4 Medical incentives

Although participants expressed their concern about contracting HIV during the trial, several participants indicated that it would be upsetting should they seroconvert. However, the medical incentives that they would receive from the trial, if they were to become infected with HIV, would probably, according to the participants, subdue their anger. It is possible that participants who are concerned about sero-converting during the trial might also consciously or sub-consciously fear sexual disinhibition, in view of the fact that participants in the present study have been identified as a high-risk sample. Thus medical incentives were indicated as a facilitator, since participants would not be burdened with the medical costs if they were to become infected during participation in a future HIV vaccine trial. Bearing in mind that the sample selected is of a lower socio-economic group and has been identified as being a high risk sample, the likelihood of participants perceiving medical incentives as a facilitator to participation might be linked to this. Participants might perceive themselves at a high risk, thus the opportunity for free medical treatment could resort to them enrolling in a future vaccine trial, knowing that they would receive medical treatment. In keeping with these findings, Kerns (1997) found that medical care might be an incentive for some participants. He added that researchers should ensure that medical care is minimal in order to prevent undue inducement.

5.3.2.5 Acquisition of knowledge

Curiosity to gain further insight into a future candidate vaccine and vaccine trials was driven by the desire for new knowledge by participants. Participant P2 indicated that her motivation to participate in a future vaccine trial was that she wanted to obtain further knowledge, and possibly share the knowledge with members of her community. It might be the case that participant P2 wishes to educate and empower

members of her community, thereby hoping to encourage more people to assist in testing and finding a candidate vaccine. This is in keeping with the finding of Hays and Kegeles (1999) that educational value was perceived as a facilitator to participation, thus motivating potential candidates to participate in a future HIV vaccine trial.

5.3.2.6 Determining HIV status

In addition, determining ones own HIV status before, during and after participation was indicated to be a facilitator to participation. No literature confirming or rejecting this theory has been identified. It might be the case that participants do not have the courage to undergo HIV testing on a regular basis. An inducement could be that testing during the trial would occur at set intervals and one could obtain ones HIV status. However, this could be problematic as Hennessy et al. (1996) argued that a candidate HIV vaccine might induce a false positive test result during the trial and possibly for a period thereafter. Thus participants could be under the false impression that they have seroconverted, although they have not. As a result this could lead to psychological distress attached to being HIV positive.

5.3.2.7 Equal treatment

Equal treatment that would result from a double-blinded randomised placebo control trial was also identified as a facilitator to participation within the present study. No literature has been identified to support or reject this theory. Participants in the present study stated that blinding with regard to a candidate vaccine would be a facilitator, as participants in the placebo control group would not be undermined and treated unequally compared to the participants in the experimental group. Participants expressed their satisfaction in knowing that equal treatment would apply to all participants regardless of whether placed in the experimental or control group.

5.4 Conclusion

Although all participants identified potential barriers to participation, the majority of participants indicated a likelihood of wanting to enrol in a future vaccine trial. All participants were driven by altruistic reasons. However, only seven participants of the sample indicated their outright willingness to participate in a future HIV vaccine trial. Of the remaining three participants, two participants indicated that they were not willing to participate in a future HIV vaccine trial. It appeared as if the participants' greatest fears were that of distrust of researchers and the vaccine, as well as the fear of physical fatigue, a possible side-effect of the vaccine.

5.5 Limitations

One of the limitations of the study was the language barrier. All the participants' first language was Xhosa, while the interviews were conducted in English. However, consent forms were provided in English and Xhosa and an interpreter was present. The language barrier proved to be a limiting factor as concepts such as HIV vaccines, HIV vaccine trials, HIV antibody positive and double-blinded placebo control groups were difficult to translate into the participants' home language. The participants who were able to converse in English had difficulty understanding and explaining the difficult concepts mentioned above. Time also played a factor in the study. The majority of patients, who came to the clinic for voluntary counselling and testing, came in the afternoon, after 14:00. The clinic closed at 16:30 in the afternoon. The interviews took place at the clinic and as a result the first interviews with the participants were rushed. Participants did not have sufficient time to digest the new information that they had obtained from the first interview. However, time was not a crucial limitation, as all participants returned for their second interview. In the second interview participants were able to reiterate information from the first interview and were also able to express what they found to be barriers and facilitators to participation.

5.6 Significance and future directions

The study yielded data on the behavioural, psychological, and social concerns anticipated by individuals who are likely to be candidates for participation in a HIV vaccine trial. These data offered an understanding of the perceived barriers and facilitators to participation in a future HIV vaccine trial. The implications for future research include the identification of the concerns and problems participants have regarding future participation in a future vaccine trial. Having identified the concerns and problems in respect of participation, future direction into preparation of a HIV vaccine trial may be aimed at reducing the potential barriers to participation. The intended result of such efforts is to maximise individuals' participation in future HIV vaccine trials. The ultimate result of this line of research is to maximise the effectiveness of socio-behavioural knowledge associated with future enrolment in a HIV vaccine trial.

5.7 Anticipated benefits

The data yielded by the study:

- Assisted in understanding the issues that potential trial participants identified when considering WTP.
- Identified perceived concerns to WTP.
- Identified perceived problems to WTP.
- Identified perceived barriers to WTP.
- Identified perceived facilitators to WTP.

5.8 Impact

The results of the qualitative analysis provided necessary data regarding the perceived problems, concerns, barriers and facilitators that participants deem important when considering enrolment in a future Phase III HIV vaccine trial. This

study addressed the behavioural, psychological, and social concerns anticipated by potential candidates for participation in a future HIV vaccine trial.

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APPENDIX I

Example of interview one.

Code: F=Researcher

P=Participant

No 4.1

I: How old are you?

P4: I'm 26 years.

I: Ok. Uhm…have you completed high school?

P4: Yes.

I: Grade 12 you finished?

P4: Grade 12.

I: Matric? You finished?

P4: Yes.

I: Are you working at the moment?

P4: Yes I'm working at Quarter Deck, Simonstown.

I: At?

P4: Simonstown. Quarter Deck.

I: Corner Deck?

P4: Quarter Deck.

I: Quarter Deck. And what do you do?

P4: I'm a cooking.

I: Oh that's nice. So have you uhm…after school did you go study? Or not?

P4: No.

I: No. Ok. Uhm….Do you anything about HIV/AIDS?

P4: No.

I: Nothing at all?

P4: No.

I: How you can get err HIV? Do you know?

P4: Yes, I don't have HIV.

I: No, I'm asking do you know somebody can become HIV…

P4: Ok, I know

I: Infected?

P4: I know.

I: Ok, if you can tell me.

P4: Sometimes about err relationships, sex relationships.

I: Ok.

P4: And then about the….when you touch somebody's blood…err

I: But…

P4: Err, that's all.

I: But if you touch somebody's blood and you got a cut, then you can get HIV…

P4: Yes…

I: Infection.

P4: Yes.

I: Ok. And what about….you said relationships? Sexual relationships? How? Can you get in sexual relationships…HIV infection?

P4: Err…yah.

I: How?

P4: When you have sex.

I: Unprotected sex.

P4: Yes.

I: If you use…

P4: Without a condom.

I: without the condom.

P4: Yes.

I: Yes. Do you know what HIV is?

P4: Ha'ah.

I: No. HIV is a virus that enters the body. Right.

P4: Yah.

I: Like you said if you have unprotected sex and if you got a cut on you finger or there is an opening…in…somewhere on your body you touch blood that's infected you can get HIV infection.

P4: Ok.

I: Ok. And do you know what AIDS is?

P4: Mmm, no.

I: See if you don't know anything, don't feel shy ok. That's why I'm here to explain to you. Ok. So if you don't understand something you ask me to repeat for you.

P4: Ok.

I: Ok. AIDS is the disease that you get. So AIDS stands for the Acquired Immune Disease Syndrome. So the acquired means you get a disease.

P4: Disease.

I: Right. You get cancer or you can get the flu or you can get tuberculosis and that makes you sick. So that turns into AIDS and you die.

P4: m

I: Ok. So you mentioned the two ways of getting HIV infection is, if you don't use condoms not only in a relationship but if you sleep with other people also.

P4: Ok.

I: And if you don't use condoms.

P4: Ok.

I: And you said if you touch infected blood and you get an opening also, you can get HIV infection.

P4: Yes.

I: Another way you can get HIV infection is if you do drugs and you share needles with people.

P4: Yes. Ok.

I: You can also get HIV infection. Ok. SO…so can you tell me what HIV is now?

P4: HIV?.....

I: HIV is a virus.

P4: It's a virus.

I: It… It's a virus.

P4: The HIV is is is a virus. A AIDS is the disease.

I: Is the disease. So what disease for example can you get?

P4: The diseases that you can get with AIDS?

I: No, the disease that causes the AIDS. The disease so you can get can…the disease can be cancer.

P4: Can be cancer and TB.

I: Or flu, or if you…if you get sick.

P4: Alright.

I: Then the body can't fight, so that can cause you to die.

P4: Ok.

I: OK, so that is AIDS. So what is HIV?

P4: HIV is a a di….No. HIV is a virus ne.

I: Yah. And is?

P4: A disease.

I: Ok. Which causes you to die eventually. Uhm…and how can you get HIV infection?

P4: HIV.

I: How can you get HIV infected?

P4: HIV you can get…HIV is like AIDS mos.

I: But how can you get infected? How can you become HIV positive? You said just now, if you have….

P4: if you get

I: unprotected sex.

P4: Oh, ok. If you touch somebody's blood, you have a cut in your body.

I: Yes.

P4: And then you can get.

I: And…?

P4: And then about the needles, you can use with drugs.

I: Ok. And through unprotected sex you said.

P4: Yah.

I: Ok. Do you know anything about what a vaccine is?

P4: No.

I: Ok. A vaccine is something that will try to protect you and defend a disease in people who become infected…uhm...I mean in people who are not infected with the disease. Do you understand what I'm saying? Or must she translate for you?

P4: I understand.

I: So what did I….

P4: But,….but how can you know if this is working?

I: Because we going to go through a trial. I'll explain that to you no….to you later. I just want to tell you what a vaccine is.

P4: Ok.

I: Ok, so what is a vaccine?

P4: (laughs)

I: A vaccine will try to protect you and it will defend against an infection like HIV.

P4: Is a trial this vaccine?

I: A vaccine. No. A vaccine is something that will try to protect you.

P4: Is a…is a medicine.

I: It's like a medicine yes. A vaccine will be like a medicine, it can be injection or tablet.

P4: Oh.

I: But they don't know because there is no HIV vaccine. Ok. They working on a HIV vaccine.

P4: Ok.

I: Ok so what they trying to do, they trying to protect people that are HIV negative from becoming HIV positive. Do you understand that?

P4: m

I: Ok, so do you know what a vaccine is now?

P4: You said the vaccine is something you can…it can defend a somebody with don't have an AIDS and then you can try it.

I: To stop getting HIV

P4: To stop getting HIV.

I: Ok. When you get….here you are HIV negative, you have unprotected sex, or you touch blood and you get a cut, you get HIV infected. Right?

P4: M

I: This is what happens in the body, you get HIV and it grows so quickly in the body. But then your body learns that the disease is not suppose to be……this virus is not suppose to be inside me; so the body learns to fight. So you don't look like you're sick, you don't look like you got HIV until you test

P4: Yah.

I: Because the body is fighting. Ok. So when the body is fighting, the virus is low in the body

P4: Okay

I: But now you realise the body becomes tired of fighting, because this dis…… the virus becomes very big. Do you understand that?

P4: Yah.

I: So the body is umh fighting, fighting the virus, but it becomes tired. Then you get ….. Say you….. you get tuberculosis or you get cancer. Now the body get no time to fight the cancer or tuberculosis. It….it just leaves the tuberculosis or the cancer in your body and then the cancer and the tuberculosis starts growing and it makes you sick and the HIV virus is getting stronger and stronger because the body can't fight two infections at the same time. So your body becomes sick and eventually you get AIDS and die. So do you understand this when you get HIV infection.

P4: You.

I: So you become HIV positive. And there you're dead.

P4: Okay.

I: Okay. So can you explain to me quickly what happens here (referring to the stages of HIV)?

P4: You said you got a HIV if …. Can you please explain again?

I: Okay, okay, here you're HIV negative.

P4: Negative, okay.

I: What happens? You have……. Sex... Unprotected sex.

P4: Okay.

I: Then you get HIV.

P4: Then you get HIV and then it grows.

I: The virus grows

P4: Yah.

I: But then the body learns to…..?

P4: To fight it.

I: But then the body becomes…....?

P4: Becomes tired to fight.

I: Then you get other disease like?

P4: Like 'TB'.

I: Then the body can't fight the HIV and the "TB".

P4: Yah.

I: So what happens, the HIV grows.

P4: Grow and you die.

I: And you get AIDS.

P4: AIDS and

I: You die

P4: Die.

I: Okay, now what the vaccine is trying to do. They are working on a vaccine that…..we said only HIV negative.

P4: Negative

I: People so when you only negative when you get the vaccine .Right?

P4: M.

I: Okay, that's your injection. So here, at this point remember you having unprotected sex.

P4: M.

I: Or you touch somebody's blood by mistake, right. So when you're HIV negative they give you the in…….. the vaccine, okay. And when you do have unprotected sex, this vaccine that you got when you were HIV negative, will fight off the HIV infection here, that you don't get HIV infection. So it will keep you negative through out.

P4: Okay.

I: It's only we not sure ……like you said, how do we know, we need to test it first. Okay, so this what the vaccine will try.

P4: You, you….. you can test first if…… before you give the people?

I: We need people to test it. You can't …….but I'm coming to the part.

P4: Oh alright.

I: So do you understand what the vaccine is trying doing here?

P4: Yah.

I: Can you just explain tome?

P4: You said that the vaccine….it can be a tablet or a needle.

I: An injection.

P4: Yah.

I: And it's given to…?

P4: To the negative people.

I: Ok. And the?

P4: You…you unprotected sex and if you got that vaccine, you cant get HIV.

I: We hoping that the vaccine will do that.

P4: Yah.

I: Ok

P4: Ok.

I: They not sure.

P4: O.

I: They need to test it still. Ok. Then you get….

P4: If this vaccine can't do that, if cant works and then you already put in somebody in the body.

I: m

P4: How can you do about that?

I: What do you mean now?

P4: If that err….err… is not working.

I: m

P4: You can't use it.

I: The vaccine is not working you can't use it.

P4: m.

I: Yah. If its not going to do anything, why must you take a vaccine. Ok. But they are trying to make one that will work. That's why they need to test one until they find one that will work.

P4: If you test someone ne… you can … you can… how can you know if it's working.

I: Because the doctors will know, they will take people who are HIV negative, Right. They will give people the vaccine, then they will see those people who do have unprotected sex, will this vaccine protect them.

P4: m.

I: Will they stay HIV negative or not. You se

P4: Okay.

I: But now they hoping that's what the vaccine will try to do. It ... it can't. do that, the trying to take people…. They take people who are HIV negative again. Okay. They give them the vaccine, right. Here you have unprotected sex, right. Now you become HIV infected, but

this vaccine that you got when you were HIV negative, will try to fight off the infection, that it will clear the infection that you don't have HIV again. So it will be there for a small period. The vaccine will fight it of and then you get HIV negative again. .Do you understand that one?

P4: Yah.

I: Okay, explain it to me.

P4: You said you take a negative person ad then they have unprotected sex.

I: But you… you give them the….the vaccine.

P4: The tablet or a needle

I: First okay and then.

P4: And then you get a HIV and then

I: You have?

P4: Unprotected sex.

I: Okay. And then you get

P4: Then after you get a HIV

I: Infection

P4: Infection

I: And the vaccine will try to …?

P4: To kill that

I: Kill the infection. That you become

P4: Become negative.

I: And this will only be for a

P4: hm.

I: The HIV infection will only be for a…short…..?

P4: For shorter.

I: Period.

P4: Period.

I: So you understand that's what they trying to do with a vaccine or that {referring to the first two graphs). Now if the vaccine can't do those two, they hoping that the vaccine…. You HIV negative, you given the vaccine, you have unprotected sex, so you become infected with HIV here, you get the virus, but this vaccine that you were given when you were HIV negative, it will slow down the virus in the body. So that you don't become sick so quickly. Okay. Can you explain this one to me Do you understand.

P4: You said you take a negative person, you give a vaccine.

I: Yah.

P4: Then they get unprotected sex and then they get HIV and then the vaccine can control that HIV.

I: Very good. So just quickly again, .the three things they are trying to do… for the vac…. Hoping the vaccine will do?

P4: You said they take a negative person.

I: Yes.

P4: And then that negative person give a vaccine and after that, they get an unprotected sex and then they must be negative.

I: The vaccine.

P4: Because of the vaccine.

I: The vaccine will keep them HIV

P4: Negative.

I: The second one is?

P4: The second one, you take again a that err negative person and then you give a vaccine and then they get unprotected sex and then they get a HIV.

I: HIV infected yah...

P4: Infection and then that vaccine can stop that HIV and then can stay negative.

I: And this one?

P4: This one, that negative person get that vaccine they get that unprotected sex and then they get err… HIV. That HIV can be protected by the vaccine.

I: The….?

P4: They can….

I: The vaccine will do what?

P4: That vaccine can control the HIV.

I: Make it slow. Yah.

P4: Make it slow.

I: So you don't get sick quickly. And, so you know there is no HIV vaccine yet.

P4: Yah.

I: Okay Now we come to the testing part that you were asking me. Do when they find this vaccine, they need to test the vaccine. They want to see if the vaccine is working

P4: Okay.

I: This is called a trial. Okay. Like when you go to court, they put you on trial to see if you a good person or a bad person.

P4: Yah.

I: So now we do the same thing with the vaccine. They give the vaccine to people and they try to test if the vaccine is working or not. Is the vaccine a good thing or is a bad thing. Okay. Will it protect you or won't it protect you...

P4: m.

I: So do you understand what a trial is?

P4: Yah.

I: Tell me what's a trial.

P4: You said a trial… a trial the.... you they take that vaccine.

I: Yes.

P4: They put in your body.

I: Yes.

P4: And then they can see if the vaccine is working or not.

I: So they testing the vaccine.

P4: Yah.

I: Okay. The important thing is they testing Okay. Uhm… so if… they only looking for HIV …?

P4: Negative.

I: Negative people, yes. So they look for people like you, other people in your community and other communities. So they trying to test it all over the world, when they find the vaccine right. They want to see if it's going to work, if it's going to protect. Okay.

Now do you know how they will try to test it? How will they know if it is working or not? …..If I give it to everybody, how will I know if it's the vaccine that protected you?

We won't know. So they take everybody that is HIV negative. Okay. They divide people up into two groups. Okay. But everybody is still negative. Right. Because we only taking negative people. So they give one group of people a vaccine, right. So they will give one group a HIV vaccine when they find it and the other group, they give something call a placebo. A placebo is a dummy okay. It's like ….it looks like the vaccine.

P4: m.

F But it doesn't do anything. It can't protect you, it can't harm you, it can't do anything. So if I give you alcohol…. White alcohol….I think Vodka, Vodka is white, right.

P4: m.

I: And I give you water, but I make it taste like Vodka, but I give you the Vodka and I give somebody else the water, but it's tasting like a Vodka

P4: m, that one.

I: The water, I make it taste like Vodka, but I don't put Vodka in the water. .The water looks like the Vodka, but it's not the Vodka, so it won't make the person drunk, but the Vodka can make the other person.

P4: Me, drunk.

I: Yes, you drunk. So do you understand what a placebo is...?

P4: Yah.

I: So it looks like a vaccine.

P4: But it's not a vaccine.

I: It won't do anything to you.

P4: Okay.

I: So they will give one group a vaccine and they'll give the other group a placebo, so that they can know, did the vaccine protect the people form HIV infection. Because the placebo people nothing… they won't be protected. So they know the placebo didn't do anything, so maybe it was the vaccine.

P4: Okay.

I: So that's how they will know. Do you understand?

P4: Okay, okay.

I: Do you understand? Okay tell me what they'll do when they find HIV negative people, how will they test the vaccine.

P4: You say they can take a negative people, a group.

I: Yes.

P4: And give a HIV vaccine and then another group you can give a placebo/dummy.

I: Or a dummy. Placebo or a dummy. A dummy is easier to remember than a placebo. So a dummy is like a doll, it looks like a human being, but it's not a human being.

P4: Ok.

I: That's why I call it a dummy. So it's easier to remember.

P4: Ok.

I: Ok. But now, so you understand why they take two groups.

P4: Yah.

I: Ok. Now, what they do with these two groups…

P4: m

I: None of them know who will get the vaccine and who gets the placebo. Do you know why?

P4: Ha'ah.

I: Ok. Some people will try to make the vaccine look good by trying to protect themselves, by abstaining from sex. And other people will think that the vaccine will protect them, but the trial is to….?

P4: Test.

I: Test the vaccine. So we don't know if the vaccine is going to help them or not. Some people will think, yes the vaccine is going to protect me, so I can have unprotected sex, I will be protected. And the placebo group they don't know also. So we don't want to tell them because we don't want people to think that the vaccine is protecting them, so they can have unprotected sex, because we only trying to test the vaccine. We can't tell you that the

vaccine is working. And to stop people from trying to make it look as if the vaccine is working when it is not, because they protected themselves from HIV infection.

P4: Ok.

I: So we don't want people to have unprotected sex and to let people make the vaccine look good.

P4: Ok.

I: So do you know now why we have one….. Why these people don't get told who gets the vaccine and who gets the placebo?

P4: Yah, I know.

I: Tell me.

P4: You said you don't want to tell the people because will make the vaccine look good and they get unprotected sex.

I: Ok. So we don't want them to change their behaviour or put themselves at risk of infection, because we only….?

P4: test.

I: The vaccine. So we don't know it will protect you.

P4: Ok.

I: Ok. Now, the people that will, uhmm….like see every time they need to test if people got HIV infection right. So those people who test the people every time, to see if they get infected, they also wont know because they don't want…these people are called researchers, the people that are doing the study. Ok. They're called researchers. They are not told so they don't treat the people who got the vaccine better that the people who got the placebo. Because why, resear…..researchers want answers, so they will tell the people don't have unprotected sex, don't. They want to make the vaccine work.

P4: Ok.

I: so they, in order fro them…them not to do that, they don't get told who gets the vaccine. So they just treat everybody the same way. So do you understand why researchers aren't told why they get….who gets the placebo and who gets the vaccine. The people who are doing the study, why won't they be told?

P4: Why they don't….they didn't told if they give someone?

I: Which group has got the vaccine, why the researchers not told which groups get the vaccine?

P4: Because they want to know if this vaccine is working or not.

I: Ok. And they have to treat everybody the same also. Ok. But somebody has to know, otherwise if I think you got, I wouldn't know if it was the vaccine. So the doctors that gave the

vaccine, they will know who get the vaccine and who didn't, because eventually you will have to know who did and who didn't, otherwise you won't know in order to test it. Ok.

P4: Ok.

I: So one person has to know. But the people who will take the blood and stuff, they won't know. Because they want everybody to be the same.

P4: They gunna take your blood?

I: Yes. I'm going to tell you all that now. So do you understand why the two groups won't know who gets the vaccine? Why? Why the groups….why the people in the groups, why don't they know if they got the vaccine or the placebo?

P4: If those groups….

I: The people in the groups, why don't they get told?

P4: Because…

I: For their safety.

P4: Ok.

I: Remember? Can you explain now to me?

P4: For their safety.

I: What about their safety?

P4: Because they don't want these people to….

I: Influence the study and to have unprotected sex.

P4: Influence the study and to have unprotected sex.

I: Why?

P4: Because they test the vaccine.

I: We don't know if it will protect them. So we don't want to…We don't want people in the groups to….?

P4: To have unprotected sex.

I: Ok. And do the people, the researchers, why aren't they told which groups get the vaccine and which group gets the placebo? Because they must treat….?

P4: Because they want to test it and they must treat everybody the same.

I: The same. Good. But somebody will know, why?

P4: Because they want to know if it's working or not.

I: Yes. So that we can eventually compare. But the people that didn't get the pla….that didn't get the vaccine, the people that got the placebo, if the vaccine worked, the people will get the….the people that got the placebo will get the vaccine.

P4: Ok.

I: Ok. So you understand that. So if, if only the vaccine worked, can you give it to somebody.

P4: Ok.

I: Ok, so these people get it all for free. Uhm, now, when you start the study, they will need to take blood. Ok. They need to test if you're HIV negative or HIV positive. Because they only looking for HIV……?

P4: Negative.

I: Yes. So they will test people. Ok. So they'll take, give you injection. Now when they give you the vaccine, they have to test every time, they'll call you back every three months, come test your blood, I want to see if the vaccine is working or not.

P4: Ok.

I: So every time they will call you back for injections.

P4: Injections.

I: Ok. Just to draw blood and test your blood. Now, this vaccine it can do a lot of things. Ok. To the person. So here's your vaccine. It can make you test HIV antibody positive. Ok. Do you know what this means?

P4: No.

I: It makes you test HIV antibody positive. Ok. You won't be HIV infected. Ok, so you won't be HIV positive. That's a NO.

P4: Ok.

I: It makes you test HIV antibody positive, so you….I said, they only taking a copy of the virus. A copy only looks like a virus, but it's not the virus. So it will make you test antibody positive, but you are not HIV infected. Do you understand that?

P4: Yah.

I: So explain to me. The vaccine…?

P4: Vaccine, they, they can test HIV antibody positive.

I: It makes you test. Ok.

P4: Ok.

I: Ok. So when they draw the blood it will test antibody positive.

P4: Positive.

I: But you…?

P4: You….you negative.

I: Yes. You not HIV infected.

P4: Yah.

I: Ok. You understand that part? Why will it only make you test antibody positive?

P4: why they can test?

I: why…why does it make you test antibody positive? Because we only tool a….?

P4: A little, a little…

I: A copy of the virus.

P4: Copy of the virus.

I: So the body thinks it's a virus, but it's not the virus. So it's acting like a virus, but its not doing the same thing as the virus. Its acting but it won't give you HIV infection. It makes you test antibody positive, but you not HIV infected. Do you understand that?

P4: Yes.

I: Yes. Good. Can you explain to me again?

P4: You said they can test HIV antibody positive.

I: what can test HIV antibody positive?

P4: The vaccine.

I: Yah.

P4: But you not HIV infected.

I: Why. Why do you only test antibody…….antibody positive?

P4: They want to test.

I: No, why does the vaccine make you test antibody positive?

P4: Because they take a smaller part of it, of HIV virus.

I: So it's only…?

P4: Small part of it.

I: So it looks like a virus, it's not a virus.

P4: Ok.

I: Ok. So we said you need to take blood. You have to come very three months to test your blood. Or I don't know, I'm just saying every three months, because they don't have a vaccine. I'm just assuming, right.

P4: Ok.

I: So you have to come often to take blood, right. You understand that? The vaccine can make you test antibody positive, ok, buy, you're not HIV infected. You won't be.

P4: That blood they can take after they…they put this vaccine?

I: the vaccine in you, because now they have to test every time, did this vaccine stop you from getting HIV infection.

P4: Ok.

I: They have to test it every time. They not sure if it will stop it.

P4: Ok.

I: Ok. Because some people are naughty, they will have unprotected sex and they might get infected. So, they want to see if the vaccine did protect them.

P4: Ok.

I: But we not sure. So you understand we have to…..the first thing we have to do take….?

P4: To take blood.

I: The vaccine will make you test….?

P4: They make you to test antibody positive.

I: But you won't?

P4: You won't get a HIV.

I: Ok. But now, the people don't understand this. Like you didn't know what a vaccine is. People that…if you decide to take part in a trial one day, they'll think you got HIV, because they think you testing, they know you testing antibody positive, but they don't know the difference between HIV infected and what that (referring to HIV antibody positive) is. They don't know it's a copy. So people think you got HIV infection.

P4: Ok.

I: You understand that? So people at your work, people in your family, people in your community, some people think HIV is a bad thing, so they'll treat you differently. You can get fired from your work. Your family can say I don't want you in the house anymore. Your community will say I don't want you. I'm not saying it will happen, but it could happen. Because people don't like HIV positive people. You know that.

P4: m

I: People discriminate against HIV positive people. Do you know that? So people can treat you differently. Right? So that not a good thing about this vaccine trial. But then you need to explain to people that you testing HIV antibody positive, because there is a copy of the virus in you.

P4: This…this copy of this.

I: Yes?

P4: It will grow in your body?

I: It won't grow, because it's a copy, like I told you, I give you…if I put a doll here that looks just like you, the doll can't do anything. It can't breathe, it can't talk, it cant, it looks like you, but it can't do anything that you can do. So this thing is a copy of the virus, so it can't do anything. It can make you sick.

P4: Ok.

I: But the body sees there's something different. The body can recogni…..I can see the doll, it looks like you, the body….so the body thinks….the doll next to me, I think its you, but if the doll cant talk, then only I'll know its not you.

P4: Ok.

I: Ok. The body can see there's something that looks like HIV, so I'm going to fight you, but the copy can't do anything, so it can't make the body sick.

P4: Ok.

I: Ok. So you understand that now? So people can treat you differently, because they think you got HIV infection.

P4: Ok.

I: Ok. Now, the vaccine, because it's teaching the body to fight, the body becomes tired and it becomes weak. So you can feel tired, so the vaccine will do that. Bit it doesn't mean you're sick. Because the body is fighting, it can make you feel sick. Do you understand that?

P4: Ok.

I: Ok. So what…what will they need to do first?

P4: They must take blood.

I: Ok. So you need to come often for blood. Then the vaccine can make you…….?

P4: Antibody positive.

I: And then people will think…? But you don't have……..?

P4: They think you HIV positive.

I: But you're not.

P4: Yes.

I: So people will……?

P4: Treat you different.

I: Treat you differently. And then the vaccine can also make you feel……..?

P4: Feel tired.

I: Feel tired because the body is……?

P4: Fighting.

I: Fighting, so the bo….So you can feel a bit sick. You feel like you hot, you feel sick and stuff. So that vaccine will do that.

P4: Ok.

I: Ok. But now the good thing about a vaccine trial, if you decide to take part one day, you'll be helping to test the vaccine. That will help protect people from HIV infection. Ok. So what is good about a vaccine?

P4: To test the…

I: If you take part in a trial?

P4: You can test if its can work.

I: Yes. Ok. And then….uhm…by testing if it works, what can you do? You'll be helping…..?

P4: You can find.

I: Find?

P4: Find that vaccine.

I: Find a vaccine that works.

P4: Is working.

I: Ok. And if you find a vaccine that works what will you do? What will that vaccine do then?

P4: The vaccine can cont….control that HIV infection.

I: It can protect.

P4: Yah.

I: So who all do you want to protect?

P4: Hmm?

I: Who all will you try to protect.

P4: Hmmm?

I: The…the vaccine who will it will try to protect.

P4: It protect everybody.

I: Everybody that is HIV….?

P4: HIV positive.

I: Ok. So if you take part in a trial one day, who will be helping?

P4: Hmmm?

I: If you take part in a trial one day, who will you be helping?

P4: I help everybody.

I: Now just name who is everybody. Who is everybody? To you…who is everybody to you?

P4: to me?

I: Yes. Who you want to help? Your family? Your community? Everybody that is HIV negative?

P4: The community.

I: Yourself?

P4: And myself.

I: From HIV infection. So who all do you want to help, if you help test the vaccine?

P4: to help community.

I: That…everybody that is HIV….?

P4: Positive.

I: Ha'ah! The vaccine can only be given to….?

P4: Oh to HIV negative.

I: so you trying to help everyone that is HIV negative.

P4: Oh, ok. They want, they this vaccine can help a HIV positive?

I: No.

P4: Oh, ok.

I: Because, why you said, we…if you positive you positive, we can't try to protect you.

P4: Oh, ok.

I: The vaccine tries to protect and defend.

P4: Defend you.

I: Yes. Remember you said it yourself. Ok. Now, remember I told you there is two groups. We don't know who gets the vaccine and who gets the placebo. Right? But now, if people do get HIV infection while they helping to test the vaccine and they get HIV infection, these people will get free medical treatment.

P4: Ok.

I: So, they will free…uhm…AZT. You know what AZT? They give when you got AIDS, to try to help you to make the disease better. Ok. But they give you free medical treatment to protect….to err, to hep them through the disease. So you get free medication for the HIV.

P4: Ok. If this is not working.

I: If you get HIV infection during this…if people who are helping to test the vaccine, if these people get HIV infection, they will get free medical treatment.

P4: Ok.

I: They will pay for….if you need to travel to their clinic and stuff, they will pay for your transport. So there is no money on your part. They will pay for anything, any expenses that occur to you.

P4: Ok.

I: Ok. So tell me what…what is good about a vaccine trial?

P4: It…it's to test if it's working.

I: Ok.

P4: And to find a vaccine that is right for the people.

I: For the people. So you helping to…?

P4: To protect err…negative people.

I: Very well done. Uhm…Do you have any other questions that you want to ask me?

P4: No.

I: Sure? Anything about the vaccine will do? What the vaccine won't do? What is good about the vaccine you want to ask me?

P4: No.

I: Ok. So tell me again, what is a vaccine?

P4: A vaccine is a….is a…. is a trial.

I: No, no, no. What is a vaccine?

P4: A vaccine…

I: It can be injection form.

P4: I must say it's a something?

I: What is a vaccine?

P4: A vaccine?

I: What does it try to do to people?

P4: The vaccine is trying to help the people and….

I: How will it help the people? Who will get the vaccine?

P4: The negative people.

I: Ok. Why will they get the vaccine?

P4: Because they want to test that vaccine is working.

I: No, that's a trial.

P4: Oh.

I: What is a vaccine itself? What will the vaccine do?

P4: It will defend the people in…in HIV.

I: Which people?

P4: The negative people.

I: Defend them from what?

P4: From HIV infection.

I: And what is a trial?

P4: A trial…is to find that a vaccine is working.

I: Ok, to test the vaccine.

P4: Yah.

I: Ok. What can the vaccine do to you?

P4: It's to protect your body.

I: No. Ok, uhm….the bad things about the vaccine. The vaccine will make you feel…?

P4: The bad thongs about the vaccine?

I: Vaccine, it can make you feel….?

P4: It can make you feel tired.

I: Why?

P4: Because the body is fighting and is tired to fight.

I: And will the vaccine give you HIV infection? Will it make you… give you HIV…. Will the vaccine itself give you HIV infection? Will you get HIV from the vaccine?

P4: No.

I: It will only make you test….?

P4: It will test HIV positive.

I: Because it's only a…?

P4: A…a small.

I: Small piece of the virus.

P4: Small piece of virus.

I: So, the body will think it's the real virus, but it's only a….its only..? Is a virus or does it look like a virus?

P4: Hm?

I: Will…will that…what in….the vaccine that is in the body, is a virus or does it look like a virus only?

P4: It looks like a virus.

I: So it won't harm…it won't give you HIV infection. Ok. Bur people will think that you got….?

P4: Got HIV.

I: So how will they treat you?

P4: They treat you differently.

I: They treat you differently. Ok. And…uhm…what is good about a vaccine trial? What will you be able…What will you…What will come from the trial?

P4: You can test if it is working.

I: Ok.

P4: And then you can find it.

I: And then?

P4: And then you can protect a negative people.

I: Good. And…uhm…if people do get HIV infected during the trial? Will they get….

P4: They get free medical

I: Treatment.

P4: Yah.

I: Ok. Good. So you understand everything I explained to you? Nothing is still…you not unsure about anything?

P4: (Sighs) But I can try.

I: Are you still unsure about something?

P4: I'm sure.

I: You sure. Ok. Now I want you, for the next interview to think about everything I told you about. Ok. What isn't nice about a vaccine, it will make you feel a bit sick, that it can make you test HIV antibody positive and people will think you're HIV infected, they need to take lots of inj….uhm blood, to test your blood that you are HIV negative. Ok. And the good things is that you will helping to test the vaccine, so that you can find a vaccine, so that you can protect HIV negative people. Uhm…I want you to think about why, if they find a vaccine one day, will you help to test the vaccine. Why will you want to take part in a vaccine trial. Ok. And then why, what will make you not want to take part in a vaccine trial. What will make you not want to test the vaccine if it works. Ok. What is good that you think and what is bad about the vaccine trial. What will you be afraid of? What would you like that you will take part. Ok.

So, would you be afraid of injections? Will you be afraid that people will think you are HIV positive? Will you…err…want to take part, because you think you can help with…help the community or HIV negative people, to protect them from HIV infection? To help find a vaccine? Uhm…Do you think its good that people…that you can learn more about what HIV is, about what a vaccine is. Ok. So do you think you will be able to think of these things for me and tell me what you didn't like and what you do like? Yes?

P4: Yes.

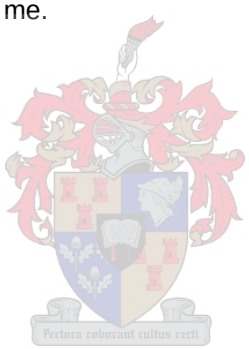
I: Uhm…what I ask people is, to write it down for me. Ok? So that if you go home and you think about something today, you write it down, so that you'll remember when you come back for your second interview. So if you think of another one tomorrow, you write it down.

P4: Ok.

I: So whatever you don't like and whatever other questions you still want to ask me, you write it down.

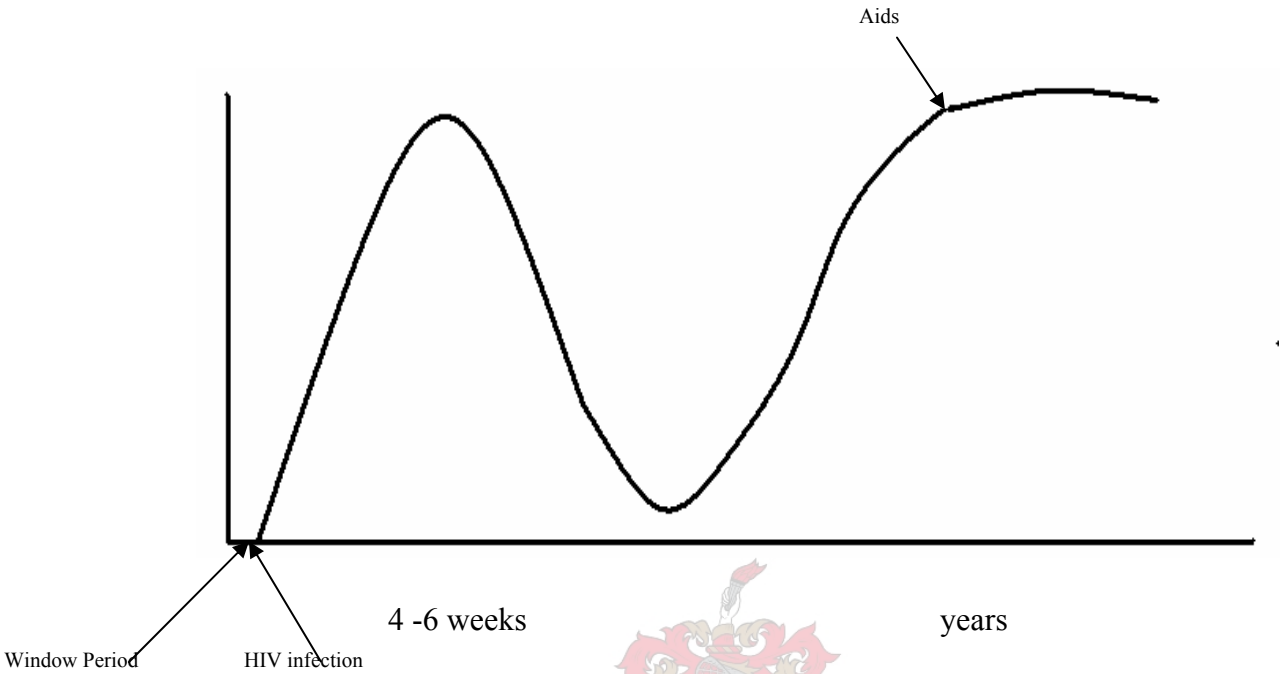
P4: Ok.

I: And at our next interview, you ask me.



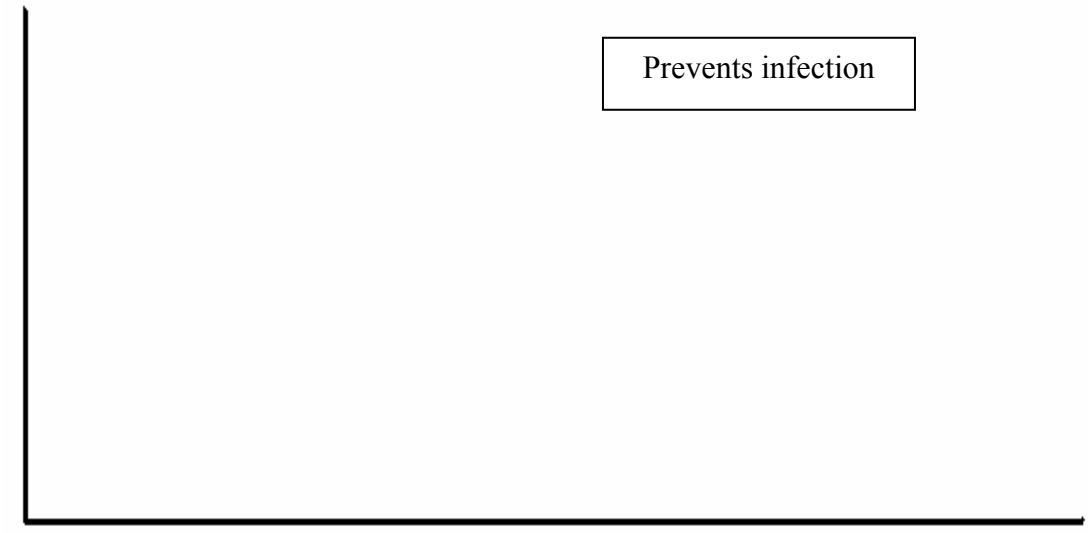
APPENDIX II

1. Progression of HIV/AIDS

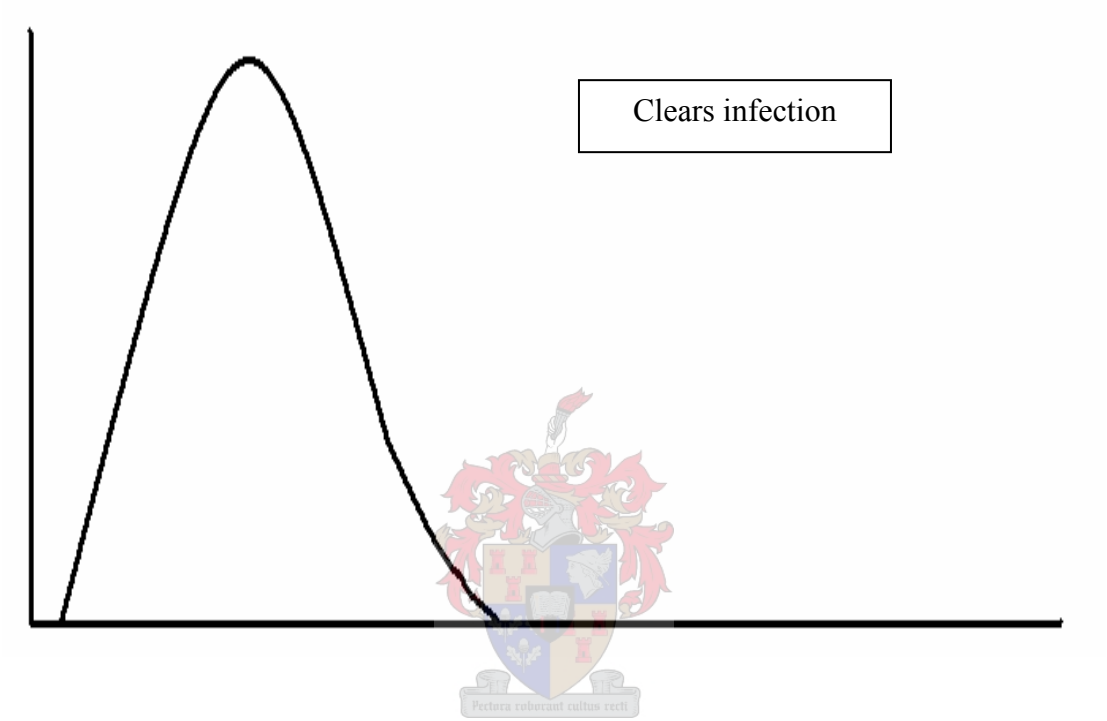


2. What will the HIV vaccine do?

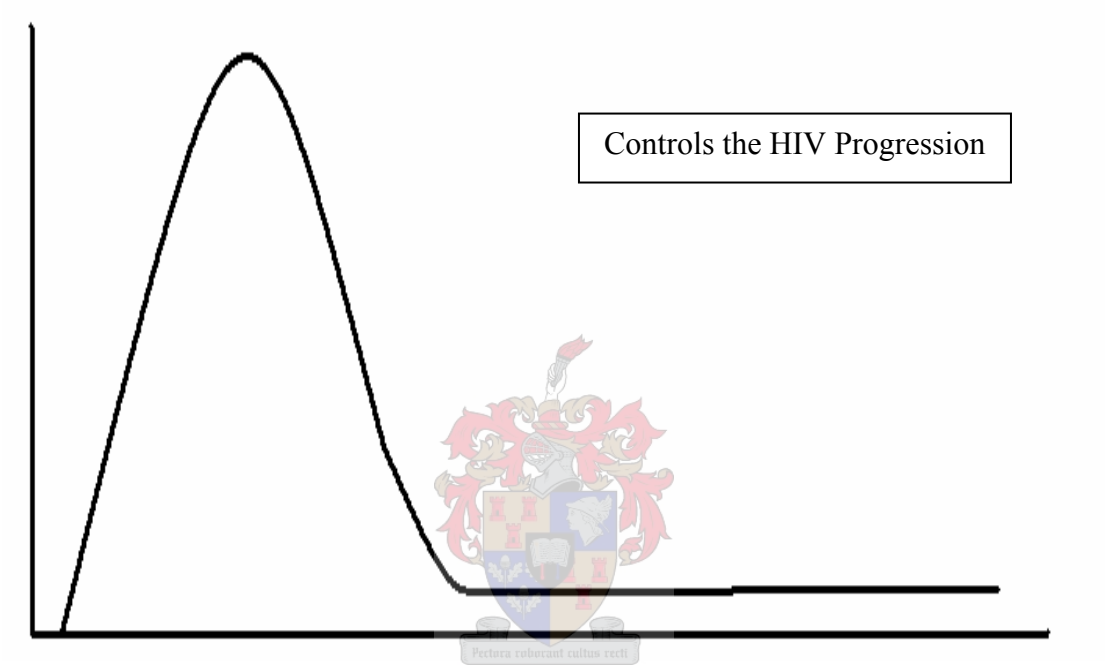
a) Researchers and doctors are developing a candidate HIV vaccine which they are hoping would protect against HIV infection.



b) If the above-mentioned criterion is not met, researchers and doctors are hoping that should an individual become infected with HIV, the candidate vaccine that was administered prior to the infection would clear the HIV infection.



c) If the above-mentioned criteria are not met, researchers and doctors are hoping that should an individual become infected with HIV, the candidate vaccine that was administered prior to the infection would control the progression of the HI virus.



APPENDIX III

Frequency Table of Barriers and Facilitators to WTP

Theme	Frequency
Barrier: Concern about side-effects of the vaccine.	17
Barrier: Discrimination.	10
Barrier: Distrust.	23
Barrier: Double-blinded randomized placebo control.	5
Barrier: Duration and extent of side-effects.	2
Barrier: Fear of sexual disinhibition.	10
Barrier: Fear of needles.	12
Barrier: Not being at a high risk of HIV infection.	3
Barrier: Stigma.	5
Barrier: Testing HIV antibody positive.	3
Facilitator: Hopeful in finding a vaccine that will protect against HIV infection.	2
Facilitator: Altruism.	28
Facilitator: Double-blinded randomized placebo control.	4
Facilitator: Knowing HIV status.	1
Facilitator: Medical incentives.	6
Facilitator: Knowledge.	15
Facilitator: Protect self from HIV infection.	9

The numbers in the frequency column refer to the number of times each theme was referred to by respondents in the sample.