Predicting adolescent willingness to participate in HIV vaccine trials: the role of sensation seeking

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DECLARATION

By submitting this thesis electronically, I declare that the entirety of the work contained therein is my own, original work, that I am the sole author thereof, that reproduction and publication thereof by Stellenbosch University will not infringe any third party rights and that I have not previously in its entirety or in part submitted it for obtaining any qualification.

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Abstract

Background: The prevalence rate of HIV for all age groups across South Africa is 12.6%, with approximately 6 422 179 South Africans living with the virus as of this writing. Approximately 469 000 new cases of HIV per year are reported. One of the promising technologies in development to reduce HIV incidence is an HIV vaccine. To be effective, vaccination must occur before exposure to the disease-producing agent, i.e., before sexual debut. An effective HIV vaccine must therefore be tested in adolescent populations.

Objectives: The first objective of the study was to determine the facilitators of and barriers to adolescent willingness to participate (WTP) in a hypothetical HIV vaccine clinical trial. The second objective was to determine which variables predicted adolescent WTP and what role sensation seeking would play in the relationship between the predictors of adolescent WTP and adolescent WTP.

Methodology: In the qualitative phase of the study I used purposive sampling to enrol the adolescent community advisory board (CAB) of the PHRU based at Chris Hani Baragwanath Hospital in Soweto which is a potential HIV vaccine clinical trial site. I conducted three focus group discussions (FGD) with the 25 CAB members, which were audio-recorded and transcribed. I analysed the transcriptions thematically and identified five barriers to and 11 facilitators of adolescent WTP in a hypothetical HIV vaccine clinical trial. In the quantitative phase of the study I developed a survey on the basis of the results from the qualitative phase. Based on prior research, I selected those facilitators of adolescent WTP that could be psychometrically measured to determine the variables that predicted adolescent

WTP and the role of sensation seeking in this relationship. I recruited 467 participants from five high schools in Soweto for the quantitative phase of the study.

Results: FGD participants identified five barriers: i) admitting sexual activity to an older individual; ii) difficulty in agreeing to participate; iii) potential side effects; iv) parents' concerns for their children; and; v) stigma, and eleven facilitators: i) perceived safety of the candidate vaccine; ii) potential rewards of participation; iii) salience of HIV; iv) positive peer pressure; v) social status; vi) personality characteristics; vii) congruent messages in communities; viii) increased information; ix) risk behaviour; x) altruism; and xi) leadership. I selected altruism, sexual risk behaviour, leadership, personality characteristics, and social status in addition to WTP and sensation seeking as the variables to include in the survey. I conducted regression analyses to determine which variables predicted adolescent WTP. Only altruism and leadership statistically predicted WTP ($p<.001$), accounting for 9.4% and 17.2% of the variance in adolescent WTP, respectively. Product-term regression analysis showed that altruism and leadership directly influenced adolescent WTP independently of each other.

Conclusion: Contrary to Swartz et al. (2005), sensation seeking did not predict adolescent willingness to participate in an HIV vaccine clinical trial. However, leadership and altruism confirmed the literature on adult WTP, in that they both predicted adolescent willingness to participate in an HIV vaccine clinical trial independently of each other.

Opsomming

Agtergrond: Die voorkomssyfer van MIV vir alle ouderdomsgroepe regoor Suid-Afrika is 12,6%, met ongeveer 6 422 179 Suid-Afrikaners besmet met MIV. Ongeveer 469 000 nuwe gevalle van MIV per jaar word aangemeld. Een van die belowende tegnologieë wat tans ontwikkel word om die voorkoms van MIV te verminder, is 'n MIV-entstof. Om effektief te wees, moet inenting voorkom voor die blootstelling aan die siekte vervaardigingsagent, d.w.s. voor seksuele debuut. 'n Effektiewe MIV-entstof moet dus getoets word in adolessente bevolkings.

Doelwitte: Die eerste doelwit van die studie was om die fasiliteerders van, en hindernisse tot adolessente bereidswilligheid om deel te neem (BDM) aan 'n hipotetiese MIV-entstof kliniese proef. Die tweede doelwit was om te bepaal watter veranderlikes adolessente BDM voorspel en watter rol sensasie soek sou speel in die verhouding tussen die voorspellers van adolessente BDM en adolessente BDM.

Metodiek: Ek het doelgerigte steekproeftrekking gebruik om die adolessente gemeenskapsadviesraad (GAR) van die PHRU gebaseer op Chris Hani Baragwanath-hospitaal in Soweto, wat 'n potensiële MIV-entstof kliniese proef site is, in te skryf. Ek het drie fokusgroepbesprekings (FGB) met die 25 GAR-lede gehou. Ek het ’n klankopname van die FGB’s gemaak en getranskribeer. Ek het die transkripsies tematies ontleed en vyf hindernisse tot en 11 fasiliteerders van adolessente BDM geïdentifiseer in 'n hipotetiese MIV-entstof kliniese proef. Ek het op grond van vorige navorsing die fasiliteerders van BDM wat psigometries gemeet kon word gekies, ten einde te bepaal watter veranderlikes adolessente BDM statisties voorspel en watter rol sensasie soek sou speel in die verhouding tussen

die voorspellers van adolessente BDM en adolessente BDM. Ek het 467 deelnemers gewerf uit vyf hoërskole in Soweto vir Fase 2 van die studie.

Resultate: FGB deelnemers het vyf hindernisse geïdentifiseer: i) om seksuele aktiwiteit te erken aan 'n ouer individu; ii) probleme om in te stem om deel te neem; iii) potensiële newe-effekte; iv) kommer wat ouers vir hulle kinders mag hê en; v) stigma, en elf fasiliteerders: i) veiligheid van die kandidaat entstof; ii) potensiële voordele van deelname; iii) opvallendheid van MIV; iv) positiewe groepsdruk; v) sosiale status; vi) persoonlikheidseienskappe; vii) kongruent boodskappe in gemeenskappe; viii) meer inligting; ix) risiko gedrag; x) altruïsme; en xi) leierskap. Ek het altruïsme, seksuele risiko gedrag, leierskap, persoonlikheidseienskappe en sosiale status gekies om as veranderlikes in die opname in te sluit asook BDM en sensasie soek. Ek het regressie-ontledings onderneem om te bepaal watter veranderlikes adolessente BDM voorspel. Slegs altruïsme en leierskap het BDM statisties voorspel ($p < 0,001$). Altruïsme was verantwoordelik vir 9,4% van die variansie in BDM, terwyl leierskap vir 17,2% van die variansie in adolessente BDM verantwoordelik was. Produk-term regressie analise het getoon dat altruïsme en leierskap adolessente BDM direk beïnvloed, onafhanklik van mekaar.

Gevolgtrekking: In teenstelling met Swartz et al. (2005), voorspel sensasie soek nie adolessente bereidwilligheid om deel te neem in 'n MIV-entstof kliniese proef nie. Leierskap en altruïsme bevestig die literatuur oor volwasse BDM, in dat hulle albei onafhanklik van mekaar adolessente bereidwilligheid om deel te neem in 'n MIV-entstof kliniese proef voorspel.

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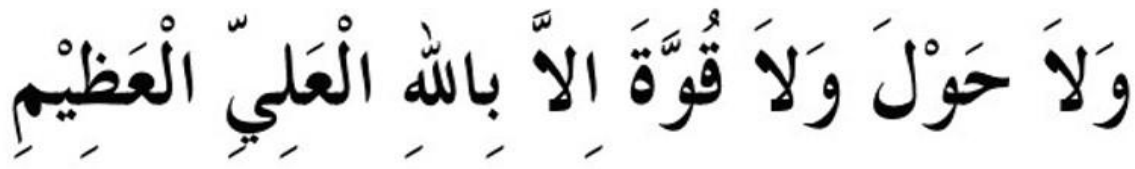
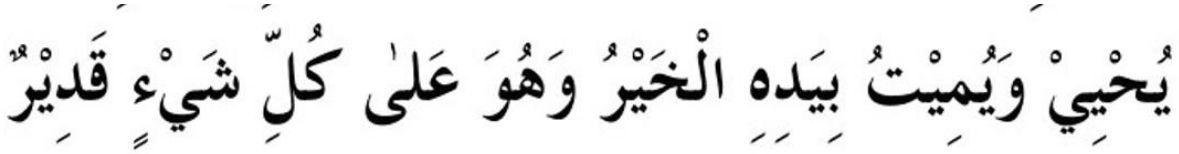
DEDICATION


وَلاَ حَوْلَ وَلاَ قُوَّةَ اِلاَّ بِاللهِ الْعَلِيِّ الْعَظِيْمِ

“There is no power nor might, except through Allah SWA, the most high, the great.”

To my creator, through whom I am but a tool. Nothing I do or achieve is without Allah’s consent.


يُحْيِيْ وَيُمِيْتُ بِيَدِهِ الْخَيْرُ وَهُوَ عَلٰى كُلِّ شَيْءٍ قَدِيْرٌ

“He gives life and causes death. In His hand is all good. And He has power over everything.”

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Chapter One

Introduction

1.1. History of HIV

The HIV pandemic has been with us for more than three decades. Since the first official report in 1981 of what would become known as the Human Immunodeficiency Virus (HIV) by the United States of America's (USA) Centers for Disease control and Prevention (CDC), we have seen the disease spread geographically and across age groups (UNAIDS, 2011). While the initial impact of the disease appeared to be confined to first world countries and particularly to gay men (and to a lesser degree intravenous drug users) and came to be known as the gay plague (Herek & Glunt, 1988), it was in fact spreading unnoticed in sub-Saharan Africa (UNAIDS, 2011), particularly through heterosexual intercourse.

1.2. Prevalence of HIV

Prevalence of HIV peaked in the late 1990's with South Africa reporting a national prevalence of 16.1% in 2000 in comparison to less than 1% in 1990, with similar increases in Lesotho (1% to 24.5%) and Botswana (3.5% to 26%) (UNAIDS, 2011). The South African Department of Health (DOH) reported similar increases in antenatal HIV prevalence from .8% in 1990 to 24.5% in 2000 and peaked in 2005 at 32% (Department of Health, 2011). The Department of Health (2011) reports that their data indicate a relatively stable prevalence from 2005 to 2011, ranging from a low of 29.1% in 2006 to a high of 30.2% in 2010.

This stabilisation of the epidemic in antenatal women in South Africa is confirmed in the national HIV prevalence report of the Human Sciences Research Council (HSRC) of South Africa (SA). The HSRC data shows that national prevalence for those older than two years in 2005 was 10.8% (CI 9.9 – 11.8) compared to 10.9% (CI 10.0 – 11.9) in 2008 (Shisana et al., 2009). However in 2012 HIV prevalence increased significantly to 12.6% (95% CI: 11.7 – 13.5, p< .001) (Shisana et al., 2014).

When considering age however, we can see a more than halving of the prevalence in 2-14 year olds from 5.6% in 2002 to 2.5% in 2008 (Shisana et al., 2009) and a further reduction to 2.4% in 2012 albeit that the 2012 data included children from birth to two years (Shisana et al., 2014). In contrast, prevalence in 15-49 year olds has increased from 15.6% in 2002 to 16.9% in 2008 (Shisana et al., 2009) and 19.6% in 2012 (Shisana et al., 2014). The reduction in prevalence in 2-14 year olds may be due to the increased coverage of the prevention of mother to child transmission (PMTCT) medication, nevirapine, in South Africa. The Department of Health reports that 91.3% of pregnant women received either antiretroviral (ARV – single drug treatment, usually nevirapine) or highly active antiretroviral therapy (HAART – multiple drug treatment) in 2010 (Goga, Dinh, & Jackson, 2012). The national Department of Health's 2013-2014 Annual Report (Department of Health, 2014) states that the implementation of fixed dose combinations of ARV's (multiple ARV's combined into one pill) to all pregnant women at public health care facilities, regardless of CD4 count, has further reduced the transmission of HIV from mother to child (Department of Health, 2014).

1.3. Exposure to Communication Programmes about HIV/AIDS

In a national representative survey of individuals residing in South Africa, Shisana et al. (2009) report that 80.9% of South Africans have been exposed to at least one of the communication programmes of the four national HIV/AIDS communication programmes (Khomanani, Soul City, Soul Buddyz and loveLife). Shisana et al. (2009) argue that the above-mentioned programmes have been instrumental in promoting the Abstain, Be faithful and Condomise (ABC) behavioural prevention approach as well as promoting testing for HIV and knowing your HIV status. As a result of the increase in the rate of condom use (27% in 2002 vs. 62% in 2008), Shisana et al. (2009) speculated that exposure to programmes such as loveLife, Soul Buddyz, Soul City and Khomanani may have translated into increased condom usage (Shisana et al., 2009). However, in their 2012 data Shisana et al. (2014) report a decrease in condom usage to 36.2% in respondents older than 15 years of age. Shisana et al. (2014) speculate that the decrease in condom usage may be attributed to a decrease in focus in South Africa between 2008 and 2012 on condom use as a means to prevent HIV infections. Shisana et al. (2014) further speculate that the increased acceptability of, and access to antiretroviral treatment may lead individuals to become behaviourally disinhibited. Behavioural disinhibition occurs when individuals increase their risk behaviour based on their perception of decreased risk of mortality.

In contrast to the increase and subsequent decline in condom usage, respondents who had voluntarily been tested for HIV increased from 21.4% in 2002 to 50.8% in 2008 (Shisana et al., 2009) and continued to increase to 66.2% in 2012 (Shisana et al., 2014), a statistically significant increase ($p<.001$). A similar increase is evident in the percentage of respondents who knew their HIV status. The percentage of

respondents who knew their HIV status increased from almost a quarter of all participants (24.7%) in 2008 (Shisana et al., 2009) to 40.9% in 2012 (Shisana et al., 2014).

1.4. Youth and HIV/AIDS

While the data above may seem promising, Shisana et al. (2014) caution against becoming optimistic too early and raise concerns in three main areas: age of sexual debut; intergenerational sex; and multiple sexual partners. The percentage of 15-24 year olds who report their age of sexual debut as younger than 15 has stayed relatively constant from 8.9% in 2002 to 8.5% in 2008 (Shisana et al., 2009) but has increased to 10.7% in 2012 (Shisana et al., 2014). When one considers the gender breakdown in 2012 however, a greater proportion of males (16.7%) than females (5.0%) report their age of sexual debut as younger than 15 (Shisana et al., 2014). These findings contradict prevalence data that shows the HIV prevalence in females 15-24 years old (11.4%) is more than triple that of males (2.9%). This discrepancy in prevalence may be accounted for by intergenerational sex. In 2012, less than 1% of 15-19-year-old males in comparison with 19.8% of 15-19-year-old females reported having a sexual partner that was more than five years older than them (Shisana et al., 2014). The percentage of 15-24 year olds who had more than one sexual partner in the 12 months preceding the survey is further reason for concern. Almost one quarter of 15-24 year olds (22.4%) report having more than one sexual partner in the 12 months preceding the survey (Shisana et al., 2014).

HIV prevalence is still unacceptably high among 15-49 year olds (18.8%) as well as among 15-24 year olds (7.1%) (Shisana et al., 2014). Shisana et al. (2009) mathematically estimate annual incidence rate for each age group in the 15-20 year

age range and report a decrease in incidence rate for each age group from 2002 to 2008. The annual incidence for 15 year olds decreased from 0.8 to 0.6, for 16 year olds from 1.1 to 0.5, for 17 year olds from 1.3 to 0.6, for 18 year olds from 1.6 to 0.8, for 19 year olds from 1.8 to 1.2 and for 20 year olds from 2.0 to 1.7. Shisana et al. (2014) report a similar downward trend in incidence from 2002 to 2012, with average annual incidence rates declining from 2.8% for 2002 – 2005, to 1.5% for 2008 – 2012.

A number of behavioural and medical interventions have been developed to prevent HIV infection. Coates, Richter, and Caceres (2008) argue that behavioural interventions on their own have had limited success, particularly when assessed over extended periods. Coates et al. (2008) argue that behavioural interventions on their own are not enough to reduce new HIV infections substantially and sustainably and call for the integration of behavioural interventions with other bio-medical interventions such as microbicides, male and female condom use, pre-exposure prophylaxis (PrEP) and male circumcision.

1.5. HIV Vaccine Trials

One of the promising strategies to prevent HIV infection and thus reduce incidence is vaccination. In order for HIV vaccination to be effective however, individuals would need to be vaccinated before they are exposed to the virus, which would mean that vaccination would need to occur in adolescence. Jaspan, Lawn, Safrit, and Bekker (2006) argue that the physiology and immunology of adolescents differ from those of adults and that HIV vaccine trials would therefore need to be conducted with adolescents. While the recruitment and retention of adults in HIV research has been

documented (Stanford et al., 2003), very little is known about the recruitment and retention of adolescents in HIV vaccine trials.

1.6. Adolescent Willingness to Participate in HIV Vaccine Trials

Adolescence is commonly understood as the period between childhood and adulthood. For the purposes of this study an adolescent is operationalised as an individual between the ages of 14 and 24 years. There has been limited research on adolescents' hypothetical willingness to participate (WTP). In the absence of existing HIV vaccine trials for adolescents, researchers have asked adolescents whether they would hypothetically be willing to participate in an HIV vaccine trial should one be ready for recruitment. In a study to determine HIV prevalence, sexual risk behaviours and hypothetical willingness to participate in a sample of 510 Xhosa-speaking adolescents living in an informal peri-urban area in Cape Town, South Africa, Jaspan, Berwick, et al. (2006) found that 79% of the 11- to 19-year-old adolescents were willing to participate in a hypothetical HIV vaccine trial. More recently, Middelkoop et al. (2008) report more conservative findings of 40%.

1.7. Adult Willingness to Participate

In the absence of data on adolescents, a number of factors have been identified as influencing willingness to participate in HIV vaccine trails among adults. These include trial related health risks (Buchbinder et al., 2004; Hayes & Kegeles, 1999; Mills et al., 2004; Strauss et al., 2001), stigma and trial-related discrimination (Allen et al., 2001), pragmatic and personal obstacles (e.g., the inability to take time off from work; the lack of a supportive network to assist with family commitments such as child-care) (Sahay et al., 2005), mistrust of researchers (McCluskey, Alexander, Larkin, Murgula, & Wakefield, 2005), lack of HIV and HIV vaccine knowledge

(Strauss et al., 2001), altruism (Sengupta et al., 2000), an individual need for self-protection (O'Connell et al., 2002), and financial incentives to participation (Sahay et al., 2005). Notwithstanding the above, Swartz et al. (2005) have suggested that adolescents willing to participate in HIV vaccine trials may also be motivated by the novelty of the experience and bravado in trying untested products. Related to this consideration is whether adolescents might participate in a trial due to a propensity towards sensation seeking.

1.8. Sensation Seeking among Adolescents

Epidemiological studies of young adults indicate that youths are more likely than older persons to engage in risky behaviour (Centre for Disease Control, 2004). Health risk behaviour has been shown to be associated with sensation seeking and a tendency to engage in physical and social risk taking behaviour (Llewellyn, 2003). Sensation seeking is ". . . a trait defined by the need for varied, novel, and complex sensations and experiences and the willingness to take physical and social risks for the sake of such experiences." (Zuckerman, 1983, p. 37). Assessing the role of sensation seeking among adolescents' willingness to participate in an HIV vaccine trial may thus have important social, psychological, ethical and logistical implications.

1.9. Aims

This dissertation therefore aims:

1. To identify the variables that affect hypothetical willingness to participate (WTP) in HIV vaccine trials among an adolescent sample.
2. To evaluate how sensation seeking as a third variable influences the relationship between the variables that predicts adolescent hypothetical WTP, and adolescent hypothetical WTP.

While Chapter One provided an introduction to the aims of the dissertation, Chapter Two will provide an overview of the literature related to aspects pertinent to this research. Chapter Three will detail the methods that were used, including all procedures and instruments used. Chapter Four will present both the qualitative and quantitative results of the study while Chapter Five will discuss the findings and relate it to the literature where such exists.

Chapter Two

Literature Review

I searched the American Psychological Association (APA) Psycnet database (http://psycnet.apa.org), Elsevier's Science Direct database (http://www.sciencedirect.com), and the Ebscohost database (https://www.ebscohost.com) for the following terms and keywords: "HIV vaccine trial"; "adolescent decision making"; "adolescent HIV vaccine"; "willingness to participate HIV vaccine"; "adolescent sensation seeking"; and "sensation seeking". Two factors may have influenced the results of these searches, particularly those related to adolescents and HIV vaccine trials. The first is that no adolescent HIV vaccine trials have been conducted and the second is that the field of research related to adolescents and HIV vaccines is quite novel. The literature related specifically to adolescents and HIV vaccine trials is thus very limited.

This chapter reviews the literature on clinical trials, particularly the process of HIV vaccine clinical trials and the different phases in which clinical trials are conducted. I then expand on the involvement of human subjects in HIV vaccine clinical trials and related social and behavioural factors. I argue for the inclusion of adolescents in HIV vaccine clinical trials, elucidating the bio-medical and psychological developmental arguments. I then examine the challenges to conducting HIV vaccine trials with adolescents, including the trial site factors that may occur.

I review the literature on willingness to participate (WTP) in HIV vaccine clinical trials and what the barriers and facilitators to willingness to participate are as well as the reported levels of hypothetical WTP in adolescents. I then examine the literature on

sensation seeking, its components and how sensation seeking relates to risk behaviour, particularly in adolescents. I end with the theoretical framework I have chosen for this study and link it to my research aims.

2.1. Clinical Trials to Test the Effectiveness of Candidate Vaccines

In order for medication to be considered safe and effective for use in human populations, they need to be tested in clinical trials. Clinical trials typically proceed through three phases (U.S. Food and Drug Administration, 2014). In the case of HIV vaccine trials, Phase 1 trials generally involve a small (20-100) number of low risk HIV negative individuals in order to test the safety, tolerance, immunogenicity of the vaccine and vaccine-related side effects (U.S. National Library of Medicine, 2008). Phase 2a trials can last for longer than two years and focus on the dosage and administration of the vaccine (e.g., orally or intravenously) while still assessing safety and immunogenicity with between 100 and 300 volunteers. Phase 2b trials are smaller and less expensive to conduct than Phase 3 trials and are known as “proof of concept” trials. Phase 2b trials typically enrol between 2000 to 5000 volunteers and could potentially indicate whether there are any immune responses to the candidate vaccine (Fauci et al., 2008). In this way, Phase 2b vaccine trials may provide preliminary evidence of efficacy, or lack thereof, thereby expediting vaccine research by identifying promising candidate vaccines as well as eliminating those not worth pursuing further. Phase 3 trials require large numbers (more than 10 000) of high-risk HIV negative individuals in order to assess safety and efficacy (SAAVI, 2007a). These participants are expected to commit to attending trial site clinics regularly (approximately every three months) over a period ranging from eighteen months to three years (Crewe et al., 2003; Kerns, 1997; Slack et al., 2004).

Since the first HIV vaccine clinical trial was conducted in 1987 (Clinical Trials of HIV Vaccines, 2008), there have been more than 250 HIV vaccine clinical trials of all phases conducted globally, 12 of which have been conducted in South Africa (Clinical Trials Database, 2015). At the time of this writing (June 2015) there are 29 phase 1 trials (of which 2 are in South Africa), four phase 1b trials, eight phase 2 trials (of which 1 is in South Africa), one phase 2b trial and four phase one/two trials of which one is on South Africa (Clinical Trials Database, 2015).

2.2. Social and Behavioural Factors in HIV Vaccine Trials

Due in part to the length of the commitment required from volunteers, which may be as long as two years, social and behavioural factors related to participation in a vaccine trial are pertinent. Factors such as participants' levels of willingness to participate (WTP), their retention in the trial, discrimination they might encounter and how participation might influence their risk taking behaviour, have all been identified as salient to vaccine trials (South African AIDS Vaccine Initiative (SAAVI) Socio-behavioural Working Group, 2006). In a gap analysis of the literature Lau, Stansbury, Gust, and Kafaar (2009) argue that careful selection of samples based on psychological attributes (such as altruism) during the development of an HIV vaccine may enhance the smooth conduct of such trials. For example, potential participants who score high on sensation seeking and are susceptible to boredom may withdraw from a two-year-long HIV vaccine trial and be lost to follow-up, decreasing retention in the vaccine trial.

As a consequence of the importance of psychological and behavioural factors, socio-behavioural research is necessary as such knowledge may enhance the conduct of HIV vaccine clinical research. Examples of SB areas in need of further research are

trial preparedness, feasibility, contextual factors, social impacts and behavioural disinhibition (Lau et al., 2009). Lau et al. (2009) further argue that research is also needed in the form of outcomes evaluations, research on how policies at government level impacts on trial participation and research on the ethical conduct of vaccine trials.

2.2.1. Adolescent Sexual Behaviour

For a vaccine to be effective, vaccination needs to occur before exposure to the disease-producing agent, in the present case, the HI virus. In the case of HIV, vaccination therefore should occur before sexual debut. Shisana et al. (2014) report that 10.7% of 15-24 year olds in their national study in South Africa reported sexual debut before the age of 15. Additionally 22.4% of 15-49 year olds report having more than one sexual partner in the 12 months preceding the survey and 10.1% of young people between 15 and 19 years of age reported having sexual partners more than five years older than them (Shisana et al., 2014). Thus, given the high likelihood of exposure to HIV it is reasonable to conclude that vaccination of adolescents before sexual debut is necessary.

As early as 2001 Litt argued that if an effective HIV vaccine were to be developed, vaccination should occur just prior to or immediately after the onset of puberty. Litt (2001) further argues that we need clinical trials in adolescent populations, in addition to those conducted with adults. Jaspan, Lawn, et al. (2006) agree with this view and argue that to license a vaccine for HIV, data are needed on the immunogenicity, safety, and efficacy of such a vaccine in all the age groups in which it is to be used. Jaspan, Lawn, et al. (2006) further contend that there are immunological and physiological differences between children and adults that may

have an impact on the safety and immunogenicity of the developed vaccine. Citing the examples of hepatitis A and hepatitis B, Jaspan, Lawn, et al. (2006) explain that the dosage for the hepatitis A vaccine for 2-18 year olds is half that of the adult dose while adolescents require the same dosage of the hepatitis B vaccine as adults but spread over two administrations. Jaspan, Lawn, et al. (2006) thus recommend two considerations for HIV vaccine trials regarding adolescents: 1) determining the effect of changes related to puberty, specifically sex steroids such as testosterone and oestrogen, on the vaccine by evaluating immunogenicity at various menstrual cycle stages; and 2) determining whether the vaccine works better in adolescents than in adults by conducting small safety and immunogenicity trials in adolescents with candidate vaccines that did not stimulate an immune response (were not immunogenic) in adults but which may be immunogenic in adolescents due to the type of vaccine (adjuvant, vector, etc.). Notwithstanding the biological necessity for clinical trials with adolescents as presented above, Jaspan, Lawn, et al. (2006) contend that there is a moral imperative to develop an HIV vaccine that considers the age-specific immune responses.

Given the above, adolescents are an important group to target with an HIV vaccine, thus necessitating clinical trials of HIV vaccines in adolescents. Both McClure, Gray, Rybczyk, and Wright (2004) and Stevens and Walker (2004) have argued that exposing/ innoculating adolescents with a safe and effective HIV vaccine prior to sexual debut is potentially one of the most effective means to reducing the number of new HIV infections among this population. This thesis therefore assumes that an HIV vaccine is needed and that an effective vaccine administered to adolescents has the the potential to reduce HIV incidence dramatically. HIV vaccine trials in adolescents thus becomes a necessity

2.2.2. Adolescent Decision Making

Given that HIV vaccine clinical trials are needed in adolescent populations, adolescents will need to decide whether to participate in clinical trials or not. Our understanding of how adolescents make decisions is thus important.

2.2.2.1. Cognitive-developmental factors in adolescent decision making

In addition to the biological changes that occur during adolescence, as children mature their decision making capabilities increase. Children's decision making capabilities have been studied in the broad discipline of developmental psychology. However, the field of developmental psychology is too broad for the scope of this thesis. I will therefore focus on the cognitive developmental changes that occur in adolescence that may influence adolescent decision making. I will focus in particular on the constructivist school of thought in developmental psychology.

One of the key theories in developmental psychology has been the constructivist school of thought that argues that humans actively contruct their understanding and knowledge. Two of the most well-known developmental constructivist theorists are Vygotsky (1978) and Piaget (1972). While Piaget emphasised a cognitive constructivist approach in which individuals cognitively constructed knowledge and understanding, Vygotsky emphasised a social constructivist method where individuals cooperated with others to produce knowledge and understanding (Santrock, 2001).

Vygotsky (1978) was a Soviet theorist who differed from most Western theorists in that he did not propose developmental stages through adolescence but rather explained development through three complementary constructs: the Zone of

Proximal Development (ZPD); the more knowledgeable other (MKO); and mediation, where mediation refers to the influence that external factors have on each individuals' development. Vygotsky argues that any task that an individual struggles to complete, but that may be possible to complete, occurs in the Zone of Proximal Development. With the help of the MKO, the child or adolescent may be able to synthesise the information received from the MKO into their existing mental structures and thus be able to perform the skill or complete the task. The More Knowledgeable Other could either be a peer who had already mastered the task or skill, or could be an adult or older adolescent. In the context of an HIV vaccine clinical trial, adolescent CAB members may play the role of the More Knowledgeable Other to the adolescent members of the communities targeted for trial enrolment. Through mediation, the adolescent CAB member may take the adolescent community member from a mental structure that does not have the ability to make an informed decision to the Zone of Proximal Development where the adolescent community member is able to make an informed decision regarding trial participation.

Piaget (1972), on the other hand, argues that it is best to view adolescent development in stages. Piaget contends that the onset of adolescence is marked by a change from what he calls the concrete operational stage, which lasts from approximately 7 years to 11 years, to the formal operations stage, which starts at 12 years. The distinctive feature of the concrete operational stage is that children remember an abstract concept or principle while simultaneously completing a related problem or task. Children in this stage physically have to test ideas, as they are not yet able to manipulate outcomes mentally. Children in the concrete operational stage demonstrate an understanding of conservation. For example, they are able to

recognize that six apples have the same quantity as six cats and that a short fat jug can hold the same quantity of water as a tall thin jug (Smith, Cowie, & Blades, 1998). They are also able to understand the related concepts of seriation and transitivity. Seriation refers to children's ability to organise objects in ascending or descending orders of length, weight, height, etc. Transitivity refers to the logical ability to determine that if X is taller than Y and Y is taller than Z, then X is taller than Z (Sutherland, 1992).

The transition from the concrete operational stage to the formal operational stage is marked by the individual's ability to think in a logically consistent way without using concrete items. The classic example is the experiment of Piaget and Inhelder (1958) in which they explained the concept of infinity to an almost 12-year-old child and then asked the child to guess how many points it was possible to make on a line. Regardless of the extent of probing and cajoling, the child could not be made to guess, indicating an understanding of infinity and therefore a generalized approach to problem solving, which is indicative of the formal operational stage of development. The formal operational stage of development is thus associated with an increased ability to: think abstractly; evaluate both hypothetical and real situations; consider various dimensions of a problem; and reflect on his or her capability in relation to complicated problems (Eccles, 1999). When considering the inclusion of adolescents into HIV vaccine clinical trials, it is important to take these developmental changes into account as these changes influence the decision making capabilities of adolescents at both an interpersonal as well as an intrapersonal level.

2.2.2.2. Interpersonal factors in adolescent decision making

At an interpersonal level, competent decision making in adolescents requires nine elements (Mann, Harmoni, & Power, 1989): a) choice; b) comprehension; c) creativity; d) compromise; e) consequentiality; f) correctness; g) credibility; h) consistency; and i) commitment. While this is not an exhaustive list, Mann et al. (1989) argue that it offers a helpful framework to consider when conducting research regarding competent decision-making among adolescents. Mann et al.'s (1989) framework has been used to inform research in disability with adolescents (Schloss, Alper, & Jayne, 1994), risk behaviours of children who had survived cancer (Hollen & Hobbie, 1996), adolescents' ability to consent to medico-legal procedures (Fundudis, 2003) and children's ability to participate in healthcare decisions (Beidler & Dickey, 2001). I will consider each of these nine elements in relation to HIV vaccine trial participation next.

Choice

One of the most pertinent indicators of competent, mature decision making is the ability and willingness to choose (Mann et al., 1989). Coleman (1980) argues that one of the features of early adolescence is the tendency to conform to peer group norms. Conformity of American adolescents has been shown to decrease from its highest levels in early adolescence (10-14) through middle (15-17) and late adolescence (>18) (Steinberg & Silverberg, 1986). Steinberg and Silverberg's (1986) work builds on the seminal work of Berndt (1979) who conducted research on conformity with children aged 9 to 18 years. Berndt (1979) reported that conformity to peers peaked between 12 and 15 years of age, after which it steadily declined. More recently, Santor, Messervey, and Kussumakar (2000) reported that the 16 to

18 year old adolescents in their study who scored high on conformity were also more likely to engage in risk behaviour.

Brown, Clasen, and Eicher (1986) concur with the findings of Steinberg and Silverberg (1986) in that conformity starts to decline between 14 and 15 years of age. Brown et al. (1986) report that adolescents' disposition to conform peaks at 14 years and then steadily declines. Mann et al. (1989) argue that during middle adolescence, there is a transitional stage during which adolescents start to resist peer pressure to conform and start to make independent choices. Kaser-Boyd, Adelman, & Taylor (1985) similarly argue that there is an increased competence in: a) using innovative combinations to create alternative options; b) identifying the potential range of risks and benefits of an action; c) recognising the potential consequences of all alternatives; and d) assessing the credibility of information from sources. As shown above, early adolescents are more conforming and display less competence than their late adolescent counterparts. Thus, it has been argued that HIV vaccine trial site staff should exclude early adolescents in vaccine trials (Kafaar, Swartz, Kagee, Lesch, & Jaspan, 2007).

Comprehension

Comprehension refers to the cognitive process that needs to occur for a decision to be taken (Mann et al., 1989). Metacognitive understanding is adolescents' knowledge of their own cognitive processes and is a requirement for decision making (Flavell, 1983). Flavell (1979) argues that metacognitive understanding comprises person knowledge (one's own knowledge of decision making characteristics and limitations), task knowledge (understanding that each cognitive task's demands may influence one's performance on the task) and strategy knowledge (knowing that

there are different methods and actions for different cognitive tasks). Ormond, Luszcz, Mann, and Beswick (1991) report that Australian middle adolescents had significantly greater task, person and strategy knowledge than early adolescents did. Kafaar, Swartz, et al. (2007) thus argue that true informed consent and/or assent with adolescents in HIV vaccine trials may require more than one information session to enhance the likelihood of comprehension of scientific concepts such as randomization, placebos and double blinding.

Creativity

Ormond et al. (1991) also report that middle adolescents use the decision-making strategy of generating options significantly more frequently than do early adolescents. Kafaar, Swartz, et al. (2007) thus argue in favour of multiple sessions that inform adolescents of all the available options, including the option to decline to participate.

Compromise

Mann et al. (1989) argue that competent adolescent decision making should include the ability to recognize that if the optimal choice in a decision is not available, then compromising to choose a less advantageous option may be the more realistic option. Yet, no data exist to show whether decision making competence increases as individuals progress through adolescence.

Consequentiality

Kaser-Boyd et al. (1985) report that older adolescents (14-20 year olds) were consistently able to identify the consequences of an action to a greater extent than younger adolescents (10-13 year olds) were. It has been suggested therefore that

HIV vaccine trial site staff should use age-appropriate language and place equal emphasis on both the risks and benefits of trial participation (Kafaar, Swartz, et al., 2007).

Correctness

The idea that a correct choice can be made assumes that a logically correct choice exists, independent of the deciding agent. In the context of decision making regarding health outcomes, Weithorn and Campbell (1982) evaluated whether there were any differences between 9-year-old children, 14-year-old adolescents and adults (≥18) in choosing the most reasonable outcome in hypothetical treatment dilemmas for the treatment of diabetes, epilepsy, depression and enuresis. Weithorn and Campbell (1982) determined what a reasonable outcome was for each treatment dilemma by asking a panel of experts in each field to determine how reasonable each of the options in their treatment dilemma was. Weithorn and Campbell (1982) report that 14-year-old adolescents did not differ from adults in their ability to choose reasonable outcomes. Individuals younger than 14, however, differed significantly from 14 year olds and adults in that they were less likely to select a reasonable outcome in all four treatment dilemmas. As a result, Kafaar, Swartz, et al. (2007) urged trial sites to carefully implement parental informed consent in addition to adolescent assent as the decisions young adolescents might be asked to make in the recruitment for an HIV vaccine trial raises important ethical considerations. Adolescents may not have the decision making ability that is required of them when considering the implications of medical research on their short and long-term health.

Credibility

Lewis (1981) reports that adolescents younger than 15 were significantly less likely than adults to identify the vested interests of advice-givers. In a similar vein, Ormond et al. (1991) report that a larger percentage of middle adolescents than early adolescents indicated that they had to check the facts they were given during an information session before making a decision. Kafaar, Swartz, et al. (2007) therefore argue that recruiting adolescents into HIV vaccine trials should be a process rather than an event and should allow these adolescents the opportunity to verify information with other sources. Trial site recruiters should also determine whether adolescents had in fact consulted others outside of the trial site staff and make this a requirement for enrolment (Kafaar, Swartz, et al., 2007).

Consistency

Mann et al. (1989) argue that until proven otherwise we should assume that older adolescents have more consistency in their decision making than younger adolescents. There is, however, no empirical evidence to support this assumption.

Commitment

Taylor, Adelman, and Kaser-Boyd (1983, 1985) have shown that older adolescents were more likely to follow through with choices, indicating a greater commitment to their decisions than younger adolescents. As a result Kafaar, Swartz, et al. (2007) have cautioned HIV vaccine trial site staff not to recruit younger adolescents into HIV vaccine trials as they may not commit to their initial decisions to participate, which may in turn negatively affect the retention/attrition rates in trials.

At an interpersonal level, it is evident that adolescent decisions are made with several contextual factors taken into account, and the relationships adolescents have with family members, peers and other adults all may influence the decision that he or she is making. Bednar and Fisher (2003) argue that such relationships all influence the adolescent's decision making competence.

2.2.2.3. Reference groups in adolescent decision making

As early as 1942, Hyman (1942) defined reference groups as others whom an individual would rank him or herself against instead of against an objective external criterion. Seltzer (1989) argues that reference groups can be either membership or non-membership, positive or negative, normative or comparative or even both normative and comparative.

In their seminal study, Young and Ferguson (1979) investigated the reference groups adolescents referred to when making informational, moral and social decisions. These authors reported that adolescents chose their reference group based on which groups' individuals seemed to offer better information, the authority of the individuals in the group, closeness with individuals in the group, and the familiarity with the decision-making environment individuals in the group possessed (Young & Ferguson, 1979). When making informational decisions, adolescents referred to adults outside the family, whereas decisions regarding morality were referred to parents. Adolescents selected their peers most frequently as reference groups when they had to make decisions regarding what was socially acceptable and which friends to select.

More recently, Bednar and Fisher (2003) investigated whether Baumrind's (1991) parenting styles, viz. authoritative, authoritarian, permissive and neglecting-rejecting

parenting had any influence on whom adolescents chose as their reference group for decision making. Bednar and Fisher (2003) report that adolescents always used peers as their reference group when the decision was in the social domain, regardless of parenting style. Authoritarian, permissive and neglecting-rejecting parents' adolescents all were more likely to reference peers for decisions in the informational domain, while authoritarian and neglecting-rejecting parents' adolescents chose to reference peers for moral decisions. Conversely, authoritative parents' adolescents were most likely to reference their parents for moral and informational decisions (Bednar & Fisher, 2003).

Kafaar, Swartz, et al. (2007) argue that given the interpersonal aspects influencing adolescent decision making, HIV vaccine trial site staff should be careful not to engage with adolescents in an authoritarian style or convey the idea that the decision occurs in the social domain. These authors suggest that such an emphasis could lead adolescents to refer to peers when deciding whether to enrol in an HIV vaccine trial. Peers may exert either positive or negative peer pressure to enrol. Negative peer pressure may take the form of the spread of misinformation resulting in an aversion to volunteer. On the other hand, positive peer pressure may be seen where adolescents who had already enrolled may influence their peers to enrol without being completely informed about the potential risks and benefits of trial participation. Kafaar, Swartz, et al. (2007) further argue that HIV vaccine trial site staff should instead frame their message as an informational decision as this would most likely lead adolescents to reference other adults who may have domain-specific knowledge. Examples of other adults are doctors, schoolteachers and religious leaders (Kafaar, Swartz, et al., 2007).

2.2.3. Operational and Trial Site Challenges to Including Adolescents in HIV Vaccine Clinical Trials

In addition to the biological and psychological considerations of including adolescents in HIV vaccine trials, there are operational and trial site concerns that pose challenges to conducting HIV vaccine trials with adolescents. These include legal, ethical and operational concerns such as the legal requirement that both adolescent assent and parental informed consent are necessary for research with adolescents, adolescent recruitment and retention, community involvement, existing adolescent health services and willingness to participate (Bekker, Jasper, McIntyre, Wood, & Gray, 2005; McClure et al., 2004).

The legal and ethical concerns in South Africa primarily concern the requirement that if research poses a greater than minimal risk to an adolescent, he or she needs to provide assent while both parents need to provide consent. Acquiring both adolescent assent and parental consent from both parents may prove problematic in a number of scenarios such as child-headed households, single-parent families, and grandparent- as-parent households, all of which may be common in communities in which there is a high prevalence of HIV. HIV vaccine clinical trial site staff often target these communities with high HIV prevalence rates for participants. Singh et al. has called attention to the fact that those adolescents who do not reside with, or who do not have access to both parents, will not be able to participate in HIV vaccine trials (Singh et al., 2006).

In order to maximise the demonstrable effectiveness of a candidate HIV vaccine in a trial, adolescents targeted for enrolment need to be at high risk for HIV infection. Thus, trial investigators would need to enrol sexually active adolescents. Proper

informed consent of parents thus necessitates explaining to them that the reason their child is being asked to participate is partly due to the child's sexual activity. Proper informed consent may have repercussions for enrolment into HIV vaccine clinical trials in a number of ways. Parents who deny their child's sexual activity may refuse enrolment, while parents who are concerned about their child's sexual health may think that participation confers some form of protection from HIV infection on the child. At the same time, Susman, Dorn, and Fletcher (1992) demonstrate that both parental and adolescent understanding of the science of vaccine trials is limited. While adolescents are able to understand the concrete aspects of trial participation such as potential benefits to themselves and the duration of the trial, they struggle to understand the more abstract concepts such as the specific purpose of the trial, the potential benefit to others and alternative treatments (Susman et al., 1992).

2.2.4. Contextual Factors Affecting the Inclusion of Adolescents in HIV Vaccine Clinical Trials

Current health care services, particularly for adolescents, can often be inadequate, particularly in the communities with the highest prevalence of HIV. The South African Department of Health acknowledges this deficit and has a national programme for adolescent-friendly clinics (Department of Health, 2001). Boswell and Baggaley (2002) contend that research is more likely to succeed in instances where the basic services that are required are provided to the communities in which participants reside and when immediate needs are met. Bekker et al. (2005) take this point further and argue that health service providers need to show respect for adolescents' right to privacy and their opinion as well as have easily accessible primary health care services available for adolescents such as voluntary counselling and testing (VCT), contraceptive services and sexually transmitted infection (STI) management.

Bekker et al. (2005) argue that a lack of such services may increase distrust from individuals and reduce cooperation from the community, while the provision of such services may increase retention through ensuring the adolescent returns for the necessary follow-up appointments.

Recruitment and retention of adolescents into HIV vaccine clinical trials pose significant barriers to the inclusion of adolescents into such trials. Bekker et al. (2005) argue that using the same recruitment strategies for adolescents as for adults may prove expedient in the short term but could prove to be counterproductive to recruitment and retention. Bekker et al. (2005) contend that youth-friendly, comfortable surroundings, easy access via public transport routes and flexible clinic hours that accommodate school opening and closing times are essential to the recruitment and retention of adolescents. Some of the aforementioned would need the input of peer consultants such as adolescent community advisory boards (CABS) as well as organisations that serve adolescents such as adolescent health care specialists, schools and community HIV/AIDS prevention and support groups (McClure et al., 2004). McClure et al. (2004) also caution that parental attitudes to HIV vaccine clinical trials as well as attitudes to their child's risk, particularly sexual risk, need to be assessed and their concerns allayed if HIV vaccine clinical trials are to succeed in recruiting the large numbers of adolescents required for Phase 3 trials.

One manner in which to attain the large numbers needed is to work through community organisations. Bekker et al. (2005) argue that community members may be distrustful of research and researchers and may be protective of their youth, and therefore propose that trials should engage with communities through representative parental groups as well as youth groups. Such engagement would keep the communities informed about relevant aspects of the clinical trial such as progress,

safety concerns, reported side effects and other outcomes of the study. Engagement may provide sought-after “buy-in” from community members for adolescent participation in HIV vaccine clinical trials. This in turn may increase the willingness to participate in trials in communities that include individuals targeted for enrolment in HIV vaccine clinical trials (Bekker et al., 2005).

2.3. Willingness to Participate in HIV Vaccine Trials

One may consider willingness to participate as comprised of two complementary components, namely barriers to participation and facilitators of participation in HIV vaccine clinical trials (Lesch, Kafaar, Kagee, & Swartz, 2006). Participation is negatively influenced by the barriers to trial participation and positively influenced by facilitators to participation.

2.3.1. Barriers to Participation in HIV Vaccine Clinical Trials

Mills et al. (2004) conducted a systematic review of the barriers to participating in HIV vaccine trials and reported on both quantitative and qualitative studies conducted in Brazil, Canada, Kenya, Thailand, the United States and Uganda. Mills et al. (2004) reported that mistrust of researchers, safety concerns, as well as scientific illiteracy regarding concepts such as placebos, double-blinding and randomization posed potential barriers to participation in HIV vaccine trials for community members. Other authors have identified fears regarding discrimination as a result of vaccine induced seropositivity, being infected with HIV from the candidate vaccine, safety and potential side effects of the candidate vaccine (Buchbinder et al., 2004; Celentano et al., 1995; Jenkins et al., 2000; Koblin, Holte, Lenderking, & Heagerty, 2000; Moodley, Barnes, Van Rensburg, & Myer, 2002; Thapinta et al., 1999). These fears may be grouped into trial-related health concerns, discrimination

and stigma related to trial participation, pragmatic and personal obstacles, lack of trust in researchers, and limited knowledge about HIV, particularly HIV vaccines (Lesch et al., 2006). More recently, Dhalla and Poole (2011) reviewed the barriers to enrolment in HIV vaccine trials and proposed that barriers may be categorised into either personal risks, social risks, personal costs, social costs and misconceptions. Dhalla and Poole (2011) define risks as events or effects that have the potential to occur, costs as events or actions that will definitely occur and misconceptions as a highly unlikely or impossible consequence of trial.

2.3.1.1. Trial-related health concerns

The most oft-mentioned concerns related to HIV vaccine trial participation are the safety of the candidate vaccine, the risk of negative side effects, and the fear of infection with the HI virus by the candidate vaccine (Mills et al., 2004). Other concerns that participants have raised include: a) that they may engage in increased risk taking behaviour as a consequence of trial participation due to a false sense of protection afforded by the candidate vaccine; b) misconceptions regarding study design and related aspects such as randomization, double-blinding, placebos and what treatments were available to study participants (Buchbinder et al.,2004; Hays & Kegeles, 1999); c) suspicions about the lack of use of disposable syringes and the concomitant fear of being infected with HIV from a used syringe (Sahay et al., 2005); and d) the effect of the candidate vaccine on reproductive health, particularly on long-term fertility, the unborn foetus, and the effect that the candidate vaccine may have on breast milk (Rudy et al., 2005). While none of these concerns necessarily have their basis in fact, the fact that potential trial participants raise these as concerns may potentially negatively influence their willingness to participate in an HIV vaccine clinical trial.

2.3.1.2. Trial-related stigma and discrimination

While stigma relates to prejudice and negative attitudes, discrimination relates to behaviours such as avoidance and abuse. Participants in the study conducted by Rudy et al. (2005) reported concerns related to potential stigmatization and discrimination they may experience as a result of trial participation, particularly "being rejected by society" (p. 260) due to vaccine-induced seropositivity. Allen et al. (2001) sampled 1 516 HIV vaccine trial participants who reported discrimination due to their participation in an HIV vaccine trial and found that more than half of the reported incidents were negative reactions from family, friends and co-workers after the participants had disclosed their participation in the HIV vaccine trial. These negative reactions were related to concerns that family members had that participants might be exposed to harmful side effects from the vaccine, as well as an assumption by community members that participants were at high-risk of contracting HIV due to either sexual risk behaviour or drug use and the courtesy stigma that participation may attract. Goffman (1963) defines courtesy stigma as stigma received by an individual because of their association with someone or something that is stigmatized.

2.3.1.3. Pragmatic and personal obstacles

Some of the most significant barriers to participation in HIV vaccine clinical trials are also the most pragmatic. Hays and Kegeles' (1999) participants were most concerned about the demands on the time that trial participation would have, particularly if they would have to take time off from work. Sahay et al. (2005) report that time demands may have a particular effect on female participation in HIV vaccine trials. Female participants in their study were concerned that their family

commitments and the lack of a support network to assist them would make them less likely to participate in a vaccine trial. Other studies have reported that participants were also concerned that their sexual partners may refuse to engage in sexual relationships with them (Mills et al., 2004). Participants were also concerned that trial participation and vaccine-induced seropositivity may limit their ability to travel and emigrate, as the common test for HIV would indicate that they were HIV positive (Allen et al., 2001; Koblin et al., 1998; O' Connell et al., 2002; Sheon et al., 1998).

2.3.1.4. Lack of trust in researchers

Hays and Kegeles (1999), Rudy et al. (2005) and Mills et al. (2004) all argue that fear and mistrust of the government and researchers are significant barriers to participation in HIV vaccine clinical trials. McCluskey et al. (2005) conducted a cross-sectional survey of the general population of the United States of America (USA) and report that African-Americans and Latin- Americans reported strong mistrust of researchers. Similarly, Sengupta et al. (2000) report that mistrust of researchers was the strongest inverse predictor of willingness to participate in HIV vaccine clinical trials among African-American participants.

2.3.1.5. Limited knowledge about HIV and particularly HIV vaccines

Lack of information on HIV, vaccines and clinical trials, as well as the consequences of participation in an HIV vaccine trial such as potential side effects have been raised as a concern in a number of studies (Koblin et al., 2000; Sahay et al., 2005; Strauss et al., 2001). In Strauss et al.'s (2001) study, for example, participants wanted to know more about vaccine trial methodology, how confidentiality would be ensured, how participants would be supported if they were to experience complications due to their participation, what potential health complications participants may have to face,

how the clinical trial site would deal with these health complications, and what incentives participants could expect to receive.

2.3.1.6. Risks, costs and misconceptions

Dhalla and Poole (2011) define risks as potential events or effects that have the potential to occur. Personal risks are therefore risks in the participants' personal life. Personal risks that influence willingness to participate negatively could thus be side effects of either the candidate vaccine or the placebo, vaccine-induced seropositivity, and potential increased sexual risk behaviour due to a false sense of protection. Social risks that influence willingness to participate negatively occur in the community and/or society in which the participant resides, and include being labelled HIV positive and suffering the resultant stigma and discrimination, and the effect that trial participation may have on participants' sex lives (Dhalla & Poole, 2011).

Costs, on the other hand, are events or actions that will definitely occur. Personal costs that influence willingness to participate negatively include time and transport costs, the inconvenience of having to take time off work, the length of the clinical trial, the requirement to delay pregnancy and having to regularly have blood drawn for both the study and HIV testing (Dhalla & Poole, 2011). Social costs that negatively influence willingness to participate include the impact that trial participation may have on the familial commitments and responsibilities (e.g., child-caring) that female participants may have (Sahay et al., 2005).

Dhalla and Poole (2011) define misconceptions as a highly unlikely or impossible consequence of trial participation. Misconceptions that influence willingness to participate negatively include receiving a vaccine that has not been tested for safety,

having participants' right to confidentiality and privacy disregarded, and being injected with live HIV (Dhalla & Poole, 2011).

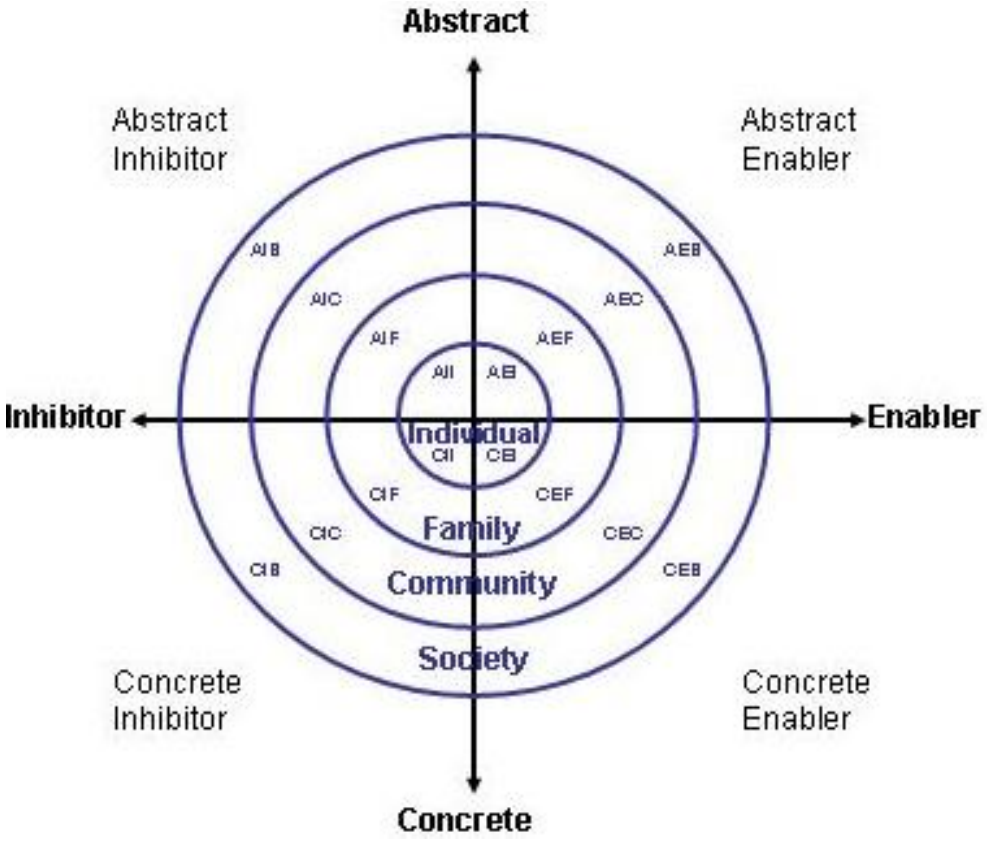
While the barriers presented above seem daunting and potentially insurmountable, many potential participants remain willing to participate. In the REACH study (Wilson, Houser, & Partlow, 2001) 496 adolescents, both HIV positive and negative, were observed in order to provide a better understanding of HIV disease progression. These 12-18-year-old adolescents had blood samples drawn, received physical examinations every three months, had gynaecological and urogenital examinations every six months and had anal examinations every year. Regardless of all these physical requirements, Wilson et al. (2001) report a retention rate of 90%. While the REACH study was not an HIV vaccine clinical trial, the biomedical requirements and social factors were quite similar. The REACH study thus provides good insight into the potential for retaining adolescents in an HIV vaccine clinical trial.

2.3.2. Facilitators to Participation in HIV Vaccine Clinical Trials

Some of the factors identified as enabling to vaccine trial participation include altruism and wanting to contribute to scientific research (Koblin, Avrett, Taylor, & Stevens, 1997; MacQueen et al., 1999; Sahay et al., 2005; Strauss et al., 2001), free medical care (McGrath et al., 2001), being aware of current HIV vaccine efforts (Sahay et al., 2005), self-protection (Buchbinder et al., 2004; Hays & Kegeles, 1999; Koblin et al., 1998; Rudy et al., 2005) and monetary compensation for participation (Jenkins et al., 2000) or the equivalent provision of health insurance (Sahay et al. 2005). Assisting participants to overcome pragmatic obstacles such as free transport to the clinic or reimbursement for their travel costs, providing free health care to

participants and enforcing the participants' rights to privacy and confidentiality may all increase the likelihood of potential participants being willing to participate (Hays & Kegeles, 1999; Sengupta et al., 2000). Participants in Hayes and Kegeles' (1999) study indicated that they would participate in an HIV vaccine trial on condition that the candidate vaccine was completely safe and that the safety of all other trial procedures was guaranteed. Rudy et al. (2005) go as far as to argue that it is essential to include HIV immunization as part of routine care. Including HIV immunization as part of routine care may potentially reduce stigma and discrimination and increase willingness to participate.

Lesch et al. (2006) conducted a national qualitative study into the barriers and facilitators to willingness to participate and argued that we can best understand both barriers and facilitators as occurring on two axes. In their model, the X-axis indicates barriers and facilitators, while the Y-axis indicates where on a continuum from abstract to concrete the barrier or facilitator occurs. This model creates four quadrants in which one can locate abstract barriers, abstract facilitators, concrete barriers or concrete facilitators. Lesch et al. (2006) further contend that each barrier or facilitator can occur at an individual, family, community or society level. A barrier or facilitator to willingness to participate could therefore be classified into one of eight categories each as per Figure 2.1 below.



Note:

AII	=Abstract Inhibitor at the Individual Level	AEI	=Abstract Enabler at the Individual Level
AIF	=Abstract Inhibitor at the Family Level	AEF	=Abstract Enabler at the Family Level
AIC	=Abstract Inhibitor at the Community Level	AEC	=Abstract Enabler at the Community Level
AIS	=Abstract Inhibitor at the Societal Level	AES	=Abstract Enabler at the Societal Level
CII	=Concrete Inhibitor at the Individual Level	CEI	=Concrete Enabler at the Individual Level
CIF	=Concrete Inhibitor at the Family Level	CEF	=Concrete Enabler at the Family Level
CIC	=Concrete Inhibitor at the Community Level	CEC	=Concrete Enabler at the Community Level
CIS	=Concrete Inhibitor at the Societal Level	CES	=Concrete Enabler at the Societal Level

Figure 2.1. Enablers and Inhibitors quadrant model.

Lesch et al. (2006) identified abstract barriers at the individual (fear of illness and/or death), community (lack of information), and societal levels (associations with HIV) and abstract facilitators at the individual level (altruism, quality of life and optimism). Concrete barriers were identified at the individual (fear of being tested and the financial costs of participation), family (negative reactions to participation from family members), and community levels (mistrust of researchers and negative reactions to

participation from community members). Concrete facilitators were identified at the individual level (convenience and practicality of participation, confidentiality of HIV testing and financial incentives), family and community levels (positive reactions from family and community members, and knowing someone with HIV), and societal level (positive role models who support HIV vaccine clinical trials).

2.3.3. Barriers of, and Facilitators to, Adolescent Participation in HIV Vaccine Clinical Trials

While there has been extensive research on the barriers and facilitators to willingness to participate among adults, limited published data exist on adolescent barriers and facilitators. In an earlier study Jaspan, Berwick, et al. (2006) reported that 79% of their adolescents were willing to participate in an HIV vaccine clinical trial and that older adolescents, and those who had resided in their communities for longer, were more willing to participate. Otwombe et al. (2011) report that having a higher number of sexual partners predicted being unwilling to participate while having less stressors and not being sexually active predicted being willing to participate. Stressors in this context included having a close family member who was HIV positive or who had died of AIDS (Otwombe et al., 2011). Otwombe et al.'s (2011) findings should give vaccine trial site staff reason for concern given that HIV vaccine trials require large numbers of HIV negative participants who are at risk of contracting HIV, and that a higher number of sexual partners increases the risk of contracting HIV.

Giocos, Kagee, and Swartz (2008) assessed the utility of the Theory of Planned Behaviour (TPB) (Ajzen & Fishbein, 1980) in understanding adolescent willingness to participate in a hypothetical HIV vaccine trial. In their sample of 224 grade 10 and

11 learners, they report that an earlier version of the TPB, the Theory of Reasoned Action (TRA) (Fishbein & Ajzen, 1975), better predicted willingness to participate than the TPB. These authors hypothesize that the lack of predictive power of the TPB may be due to the difficulty in measuring one of the components of the TPB, namely, perceived behavioural control. Two factors may explain why the TRA was better at helping to understand adolescent willingness to participate than the TPB: 1) there is no behaviour to control in a hypothetical clinical trial; and 2) it is difficult to measure perceived behavioural control.

Giocos et al. (2008) present the only data that I could find that tested any theory of health behaviour. Kafaar, Kagee, Lesch, and Swartz (2007) ponder on the applicability of health behaviour theories to participation in HIV vaccine clinical trials given that there may not be any direct benefits to participants in HIV vaccine clinical trials. The field of adolescent willingness to participate in HIV vaccine clinical trials is still in its infancy and very limited theoretical testing has occurred, prompting Kafaar, Kagee, et al. (2007) to argue for the concurrent processes of theory testing and theory building in relation to adolescent willingness to participate in HIV vaccine clinical trials.

While adolescent willingness to participate is undoubtedly important when considering adolescent involvement in HIV vaccine clinical trials, one needs to take cognisance of the increased levels of sensation seeking during adolescence and how sensation seeking may influence willingness to participate. As mentioned above, sensation seeking peaks during adolescence (Centre for Disease Control, 2004).

2.4. Sensation Seeking

Notwithstanding the barriers and facilitators to willingness to participate in adolescents, Swartz, et al. (2005) argue that adolescent willingness to participate may be influenced by the novelty of the experience of participating in an HIV vaccine trial, as well as the bravado of trying untested products which seems to indicate a propensity to sensation seeking. Zuckerman (1983) defines sensation seeking as "the need for varied, novel, and complex sensations and experiences and the willingness to take physical and social risks for the sake of such experiences" (p.37). Zuckerman (1971) reports four factors/subscales of his sensation seeking scale, namely thrill and adventure seeking, experience seeking, disinhibition and boredom susceptibility. Thrill and adventure seeking relates to seeking arousal through behaviour that may lead to autonomic arousal, e.g., through speed and danger. Experience seeking relates more broadly to seeking out new experiences and indicates a need for novel experiences that do not conform to societal norms, e.g., experimenting with illegal drugs. Disinhibition relates to feeling less inhibited by societal norms regarding, e.g., sex and sexuality. Finally, boredom susceptibility relates to the need for change and variety and is most closely linked to a tendency to be satiated earlier than others are (Zuckerman, 1971).

Zuckerman (1994) argues that even though most people believe that the increase in restraint as one ages is a result of lessons learned as one ages, data exists that indicate that changes in sensation seeking mirror age-related biological changes. As testosterone levels increase during male adolescence, sensation seeking increases too. Testosterone is linked to increased arousal levels and the concomitant increase in sensation seeking (Daitzman, Zuckerman, Sammelwitz, & Ganjam, 1978; Zuckerman, Buchsbaum, & Murphy, 1980). Sensation seeking appears at

approximately 11 years of age, increases noticeably from grades 7 to 9 (Donohew, Palmgreen, & Lorch, 1994) and then declines from approximately 16 years of age (Zuckerman, Eysenck, & Eysenck, 1978). Other authors have found similar biological correlates of sensation seeking. Graham (1979) reports that high sensation seekers demonstrate a larger orienting response to novel stimuli than low sensation seekers. An orienting response occurs when the individual orients towards the source of the stimulation. It is the opposite of the defensive response in which the individual orients away from the source of stimulation (Zuckerman et al., 1980). High sensation seekers also display greater electrodermal reactivity (in which the conductivity of participants' skins is measured) to novel stimuli than low sensation seekers, (Robinson & Zahn, 1983). Increased conductivity signifies an increase in sweat gland activity, a proxy for an orienting response (Zuckerman et al., 1980). In a study that examined sleep patterns, high sensation seeker insomniacs exhibited greater cortical arousal (increased wakefulness, vigilance, heart rate, etc.) than low sensation seeker insomniacs did (Hauri & Olmstead, 1989).

While some evidence suggests that high sensation seekers have a stronger physiological response to novel stimuli, other data show no physiological differences between high and low sensation seekers (Golding & Richards, 1985; Robinson & Zahn, 1983; Zuckerman, 1990). Electroencephalogram readings, cardiac arousal and skin conductance are commonly referenced measures of arousability. Yet there seem to be no differences between high sensation seekers and low sensation seekers on electroencephalogram readings (Golding & Richards, 1985), cardiac arousal (Robinson & Zahn, 1983) and skin conductance (Zuckerman, 1990). The evidence connecting sensation seeking to biology is thus inconclusive.

The behavioural correlates of sensation seeking are more conclusive than the physiological correlates. Hansen and Breivik (2001) report that in their 12-16 year adolescent sample, scores on a measure of sensation seeking are positively associated with both positive risk behaviours that have a low probability for negative consequences (e.g., bungee jumping) and negative risk behaviours that have a high probability for negative consequences (e.g., shoplifting, drug use, etc.). Sensation seeking is also associated with adolescent alcohol use (Newcomb & McGee, 1989), with Donohew et al. (1994) reporting that adolescents who score high on a measure of sensation seeking are 2-7 times more likely to admit to consuming alcohol than those who score low on the same measure. Donohew et al. (2000) report that in their adolescent sample, high sensation seekers were more likely to have had sex, used alcohol, used marijuana, or engaged in non-penetrative sex than low sensation seekers. Sensation seeking is also associated with cocaine use (Ball, 1995), lack of concern about contracting HIV (Lasorsa & Shoemaker, 1988), reckless driving (Zuckerman & Neeb, 1980), and sexual risk behaviour among university students (Arnett, 1991). Gillis, Meyer-Baulberg, and Exner (1992) report that sensation seeking accounts for 7% of the variance in sexual risk behaviour among university students.

One needs to interpret the data above with caution though as there is a gendered relationship between sensation seeking and risk behaviours. Males report higher scores on sensation seeking than females, especially on the thrill and adventure seeking and disinhibition subscales (Zuckerman, 1994). Males also participate in more risky behaviour than females as evidenced by Donohew (1988) who reports that high sensation seeking male adolescents were more likely than their female counterparts to use alcohol as well as illegal drugs such as cocaine. While

Zuckerman (1994) suggests that these gender differences in sensation seeking are due to differences in testosterone levels, Eysenck and Haapasalo (1989) report that these differences may be attributed to gender differences on personality dimensions as measured by the Eysenck Personality Questionnaire. The Eysenck Personality Questionnaire claims to measure four dimensions of personality, psychotism, extraversion and neuroticism (PEN), in contrast to Cattell, Eber, and Tatsuoka's (1970) 16 personality factors (16PF) and Costa and McCrae's (1992) Neuroticism-Extraversion-Openness Five-Factor Inventory (NEO-FFI). While Eysenck (1991) has stated that there is no agreement on what the major dimensions of personality are, it is interesting to note that gender differences were reported for neuroticism, extraversion, psychoticism and social desirability (Eysenck & Haapasalo, 1989).

2.5. Conclusion

In the context of current HIV prevalence and incidence rates, HIV vaccines promise to make a substantial contribution to the reduction and possibly even eradication of HIV. In order to do so, an effective HIV vaccine will need to be administered prior to sexual debut. As I have shown in this chapter, sexual debut commonly occurs in early adolescence in South Africa. Thus, for a vaccine to be developed that is effective in reducing HIV incidence among adolescents, vaccine trials with adolescents are a necessity. However, conducting HIV vaccine clinical trials with adolescents poses a number of challenges. One of these challenges is that adolescence is also the period in which sensation seeking peaks.

Given that sensation seeking is consistently associated with risk behaviour, it follows that high sensation seekers may be targeted for enrolment into HIV vaccine trials due to the likelihood that they will engage in sexual risk behaviour. While this may be

theoretically sound for recruitment, clinical trial sites need to be cognisant of the potentially high dropout rates of high sensation seekers who may be satiated earlier than others may (Zuckerman, 1971). The role that sensation seeking plays in adolescent willingness to participate has both ethical and logistical implications for conducting clinical trials with adolescent participants. Ethically, adolescent participants who enrol in the search of novel experiences may not adequately assess the potential risks to participating, or may even participate due to the risky nature of the trial. High sensation seeking adolescents may lose interest in a trial early on and may be lost to follow-up. By considering the role that sensation seeking may play in willingness to participate, clinical trial sites may improve the retention of adolescents in their HIV vaccine clinical trials.

2.6. Theoretical Framework

This current study therefore elucidates the role sensation seeking plays in the factors that influence adolescent willingness to participate, and describes how the different levels of context interact with each other whilst at the same time affecting the individual. The study is located within the ecological systems paradigm of Bronfenbrenner (1989) as it proposes to identify factors that influence adolescent willingness to participate at the individual, familial, community and societal levels, corresponding in some measure to Bronfenbrenner's (1989) micro-, meso-, exo- and macrosystems. These levels of context interact with each other whilst at the same time affecting the individual (Lloyd, 2002).

Swartz et al. (2006) propose a model, similar to Bronfenbrenner's (1989) ecological systems theory, that organizes the different factors influencing willingness to participate on a continuum from enablers to inhibitors, from abstract to concrete and

occurring at the individual, familial, community and societal levels as indicated in Figure 2.1 above.

The aims of this thesis are thus:

1. To identify the variables that affect willingness to participate (WTP) in HIV vaccine trials among an adolescent sample.
2. To evaluate the impact of sensation seeking on the relationship between the variables that affect adolescent WTP, and adolescent WTP.

I report on the first aim in Chapter Three below and the second aim in Chapter Four below.

Chapter Three

Qualitative Examination of the Variables that Affect Willingness to Participate in HIV Vaccine Trials among an Adolescent Sample

This chapter reports on the qualitative phase of my research on what adolescents, who were potential HIV vaccine trial volunteers, perceived as the facilitators to trial participation. I was interested in what they thought would facilitate their, as well as their peers' participation in an HIV vaccine clinical trial. I report on the methods used to elicit this data, the results of my data collection and conclude with a discussion of my results.

3.1. Methods

In prior work I had been involved with in the South African AIDS Vaccine Initiative (SAAVI), from approximately 2005, I established a working relationship with the Perinatal HIV Research Unit (PHRU) based at Chris Hani Baragwanath Hospital in Soweto. Soweto is a syllabic abbreviation of SOuth WEstern Townships, denoting the areas southwest of Johannesburg designated as living areas for African Black South Africans from as early as 1904. After the implementation of apartheid in 1948, African Black South Africans were forcefully removed from areas such as Martindale, and more famously Sophiatown, and relocated to townships such as Tladi, Chiawelo and Dhlamini that had basic site and service plots. Middle class residents built their own homes in Dube. In 1963, these and other townships were officially included under the moniker Soweto. Soweto is currently home to approximately 1 300 000 mostly working class inhabitants (Soweto, 2015).

Baragwanath Hospital was originally designated as a hospital for the Black population of Johannesburg, South Africa and opened in 1948 with 480 beds. Today Baragwanath Hospital is known as Chris Hani Baragwanath Hospital after having been renamed in 1997 after the assassinated chief-of-staff of Mkhonto we Sizwe, the military arm of the African National Congress. Chris Hani Baragwanath Hospital has approximately 3 200 beds and 6 760 staff members and is a teaching hospital for the University of the Witwatersrand Medical School (Chris Hani Baragwanath Hospital, 2015).

The Perinatal HIV Research Unit (PHRU) is a research unit of the University of the Witwatersrand and the Wits Health Consortium based at Chris Hani Baragwanath Hospital. The PHRU is an HIV vaccine clinical trial site whose staff have conducted HIV vaccine clinical trials with adults. As of this writing, they are currently preparing for the possibility of HIV vaccine clinical trials with adolescents and further to this point had established an adolescent Community Advisory Board (CAB). Due to the good relationship that I had established with the social scientists working with the adolescent CAB at the PHRU, I was able to secure access to their adolescent CAB for my focus group discussions. While there were new adolescent CAB members who were not familiar with HIV, vaccines and clinical trials, adolescent CAB members were mostly well informed about HIV, vaccines and clinical trials and were thus the ideal information-rich participants for my study.

3.1.1. Ethics

Although the PHRU is located at Chris Hani Baragwanath Hospital in Soweto, they are a research unit of the University of the Witwatersrand (Wits) and a division of the Wits Health Consortium. I therefore applied for ethical clearance from the University

of the Witwatersrand's Human Research Ethics Committee (Medical) and granted ethical approval (Clearance Certificate M110222)

3.1.2. Participant Selection

I recruited adolescents from communities targeted for HIV trials in SOWETO by means of purposive sampling. The social scientists at the PHRU arranged for me to meet with their adolescent CAB in March 2012 and in this meeting I was able to inform the adolescent CAB members of my study, what it entailed and what would be expected of them should they agree to participate. I verbally stressed that their participation in this project was voluntary and that they were free to withdraw from the study at any stage. I emphasised that I was not recruiting for an HIV vaccine trial and that they would not be expected to be part of such an HIV vaccine trial for this study. Once I had an indication of who among the CAB members was willing, I handed them informed consent forms (see Appendix A) and obtained their written informed consent.

3.1.3. Data Collection

Focus Group Discussions (FGD's) followed an interview schedule (see Appendix B) and lasted between an hour and a quarter and an hour and three quarters. All the focus group discussions were tape recorded and transcribed. Three FGDs were conducted between March and October 2012. All FGDs were conducted in a private meeting room at Chris Hani Baragwanath Hospital away from the PHRU. The FGDs were lively discussions with opposing opinions expressed freely. The participants all seemed comfortable to engage with each other. I purposefully selected the adolescent CAB because they had worked together previously and knew each other before participating in my FGD. As a means to mitigate the fact that I was

substantially older than my participants were (I was 39 when the focus group discussions were held), I chose to dress very informally in jeans and a T-shirt with flip-flops. I also infused my engagement with humour and I rarely directly asked the focus group participants about their sexual activity, choosing rather to ask about their peer group's sexual behaviour.

The first FGD consisted of six adolescent CAB members (three female and three male), the second FGD nine (five female and four male) and the third FGD 10 (eight female and two male) adolescent CAB members. These numbers are within the ideal 6-12 FGD participants as suggested by Krueger (1994). The participants' ages ranged from 15 to 24 and the median age was 17.

I facilitated all three FGDs and ensured that there were at least two audio recorders in each FGD. Each FGD commenced with an introduction clarifying who I was and that I was not recruiting for an HIV vaccine trial and then proceeded to the interview schedule.

I had arranged for refreshments and non-alcoholic drinks for the FGD participants after the FGD ended and each participant received between R12 and R15 network-specific airtime for their cellphones and R150.00 cash as participant remuneration.

3.1.4. Data Analysis

The recordings from the focus group discussions were transcribed and imported into Atlas Ti. Atlas Ti is a computer programme that assists in the management of large text databases. Data were thematically analysed according to the method proposed by Braun and Clarke (2006).

Braun and Clarke (2006) propose six phases of thematic analysis: 1) familiarization with the data; 2) generating codes; 3) searching for themes; 4) reviewing themes; 5) refining and naming themes; and 6) producing the report. In Phase 1 I familiarized myself with the data, transcribed the recorded interviews and then read and re-read the transcriptions in order to make note of any initial ideas. In Phase 2 I generated initial codes where I coded aspects of the data I found interesting to this study. Coding was done systematically across all the transcriptions. Data in the form of quotations that were relevant to each code were then collated. Phase 3 entailed searching for themes and grouping codes into themes, while collating all data relevant to each theme. In Phase 4 I reviewed all the themes in order to determine whether the themes related well enough to the codes as well as the entire data set and in this way I generated a thematic “map” of the analysis. In Phase 5 the ongoing analysis to refine the specifics of each theme continued, in order to generate names and clear definitions for each theme. Finally, in Phase 6 I selected the most compelling examples of each theme to report.

3.2. Results

The data collected is based on my research participants’ perceptions of what they believed the factors were that might influence their decision to participate in an HIV vaccine trial for themselves as well as for adolescent members of their communities. The research participants were informed at the outset of each FGD that I was not enrolling them into an HIV vaccine trial but that I wanted to know what the factors were that might influence their decision regarding whether or not to participate in an HIV vaccine trial. The results presented here are thus based on hypothetical willingness to participate in an HIV vaccine clinical trial.

I divided the results of the analysis into barriers to, and facilitators of participation in HIV vaccine clinical trials as shown in Table 3.1 below. A note of interest is that even though I steered the discussions towards factors that would facilitate participation in HIV vaccine clinical trials, at least one third of all factors that I identified were barriers to participation.

Table 3.1.

Barriers and Facilitators of Adolescent WTP in HIV Vaccine Clinical Trials

Barriers		Facilitators	
Concrete	Abstract	Concrete	Abstract
Admitting sexual activity	Side effects	Safety	Personality characteristics
It's hard for you to say yes	Parents are going to get scared	Rewards	Community
	We run away from stigma	Salience	Information
		Positive peer pressure	Risk behaviour
		Social status	Altruism
			Leaders

Barriers to adolescent participation in HIV vaccine clinical trials are admitting sexual activity to an adult, difficulty in deciding to agree to participate, parents' concern for the well-being of their children, the potential repercussions of side effects of the candidate vaccine and potential stigma and discrimination.

Participants expressed the following factors that may facilitate HIV vaccine trial participation: safety of the candidate vaccine; the rewards and/or benefits that participation in an HIV vaccine clinical trial may hold; the salience of HIV in a potential trial candidate's life; positive peer pressure; and the socio-economic level of the potential participant. The focus group discussants also identified the desire to be part of the group of people who would contribute to finding a vaccine that could stop the HIV epidemic, risk behaviour, the inclusion of leaders and role models,

personality characteristics, enabling communities, and the empowering effect of information as factors that may facilitate participation. I discuss each of these barriers and facilitators in more detail below and organise each according to the model proposed by Swartz et al. (2006) which is based on the ecological systems paradigm of Bronfenbrenner (1989).

3.2.1. Adolescent Barriers to Participation in HIV Vaccine Clinical Trials

Even though the focus of this study was on facilitators of HIV vaccine trial participation for adolescents, a third of the themes that were identified were barriers to participation. These barriers were evident at both the abstract and concrete levels. Lesch et al. (2006) define abstract barriers or facilitators as existing in theory rather than in reality, while concrete barriers or facilitators exist tangibly in participants' every day lived experience. Admitting sexual activity and difficulty in agreeing to participate both occur at the concrete level while parents' concern for the well-being of their children, the potential repercussions of the side effects of the candidate vaccine and potential stigma and discrimination occur at the abstract level.

3.2.1.1. Concrete barriers to participation in HIV vaccine clinical trials

Both of the concrete barriers occur at the individual level of the Swartz et al. (2006) model as seen in Figure 2.1 above. No other concrete barriers were evident. Participants reported that admitting that they were sexually active, a prerequisite for enrolment into an HIV vaccine clinical trial, could be a substantial barrier to participation. Participants also reported that prior knowledge of the mechanisms and details of HIV vaccine clinical trials could make it difficult for them to agree to participate in an HIV vaccine clinical trial.

Admitting sexual activity

One of the barriers that participants deemed most pertinent to participating in an HIV vaccine clinical trial for adolescents was admitting to being sexually active to an older person, whether it was to clinical trial site staff or to their parents. Participants admitted to being sexually active without their parents' knowledge whilst knowing that their parents disapproved of premarital and underage sex. Some participants felt that the part of the informed consent form that indicated that sexual activity is a prerequisite for enrolment into an HIV vaccine clinical trial should be removed. Others were concerned about what the effect would be should their parents find out at a later stage that the HIV vaccine clinical trial only recruited sexually active adolescents. A related concern was that parents may misunderstand the requirement that participants be sexually active as an encouragement from trial site staff that adolescent participants commence with sexual activity. Admitting to being sexually active to parents was a significant barrier to participation in an HIV vaccine clinical trial in the context of parents' lack of communication about sex.

The following exchange regarding the hypothetical situation of disclosing sexual activity to an adult between Gift[1], a 19-year-old man and I reflects the difficulty participants felt they might experience in admitting they were sexually active. Gift argued that even if it meant that he would not be able to enrol in a trial, he would lie about being sexually active.

> *GIFT: the person who's asking you, you get a bit shy to say ja I'm sexually active. If you look at the persons' age and you look at your age.*
>
> *ZUHAYR: So let's say Pindi comes in, to you Gift, and she'll ask you that,*

[1] All participants' names are their own since the CAB members' identities are in the public domain.

> *"We're enrolling for a trail but we need people who are sexually active", that's one of the questions. If you say no then you can't be part of the trial. Are you sexually active?*
>
> *GIFT: I'll say no, I'll say no I'm not.*
>
> *ZUHAYR: You'd say no, you're not and then she says, "Well you can't be part of the trial".*
>
> *GIFT: Then that would be so – that would be . . .* FGD 1[2]

A number of the adolescent participants in the FGDs admitted that they were sexually active without their parents' knowledge. Admitting to being sexually active posed a significant barrier to participation as participants indicated that they did not want their parents to know that they were sexually active. For adolescents to admit that they are sexually active to their parents may prove to be an even bigger barrier to participation than admitting sexual activity to any other adult.

> *KHANYE: Already I am sexually active and to actually come out to my parents and say but I am sexually active and I want to get into the study it's going to be, you know, another problem on its own.* FGD 1

Participants agreed that for most adolescents, admitting that they were sexually active could pose a significant barrier to enrolment in an HIV vaccine clinical trial. Participants agreed that premarital sex and underage sex were activities their parents disapproved of.

[2] Each quotation is labelled with FGD (Focus Group Discussion) and which one of the three FGDs the quotation is from.

> *LOPEZ: They will say, "How! Sex before marriage?!"*
>
> *KHANYE: They don't even go to 21, they go 18 you not even yet 18 and you already sexually active, you know, so it's . . .* FGD 1

Some participants indicated that the sentence referring to sexual activity should be removed from the informed consent form that parents would be asked to sign. Gift argued that you could not admit that you were sexually active to your parents, knowing that it is an activity they disapprove of. Gift argued that speaking about sex to your parents, particularly your own sexual activity, was disrespectful.

> *GIFT: That sentence should be removed from the parent's informed consent like on the informed consent because sometimes – it's respect, you cannot tell your parents that, yes I'm sleeping around. Sometimes they know we are – they know it but* . . . FGD 1

Khanye, an 18-year-old female, raised concerns about the implications of removing the sentence referring to sexual activity from the parents' informed consent forms. Khanye argued that parents who believed that their sexually active adolescents were not sexually active would not want their children to socialise with adolescents who were sexually active.

> *KHANYE: If ever your parents catch onto that those kids that are in that study are sexually active they going to take it up with the research staff and the Principal Investigator . . . because they don't know that you sexually active they going to say, "My child is not sexually active, how do you mingle my child with those kids!"* FGD 1

Simpiwe, an 18-year-old male raised the tension that trial site staff may have to deal with between the adolescent's right to confidentiality and the need to disclose the adolescents' sexual activity to their parents. Simpiwe argued that he was willing to go as far as begging the trial site staff (Pindi) not to speak with his parents. Simpiwe would even go as far as nominating someone other than his parent to sign the informed consent form in order that his parents not learn of his sexual activity.

> *SIMPIWE: Whoa! Whoa! I would beg her not to go.*
>
> *ZUHAYR: You would beg who not to go?*
>
> *SIMPIWE: Pindi to go to my parents. On the form I'd make aunty or friend's mother, sister sign. Not my parents!* FGD 1

Khanye refers to the problem of discussing sex, sexuality and her own sexual activity and admits that speaking about her sexual activity to her parent or parents is another problem on its own. Talking about sex to parents is a challenge for these adolescents.

> *KHANYE: . . . very few parents would accept the fact that their adolescents are now sexually active* FGD 1

Khanye started by stating her opinion that parents generally would not accept the fact that their adolescents are sexually active. She continued to argue that parents' lack of acceptance that their adolescents are sexually active stems from a lack of communication about sex even though, in her opinion, parents know that they are supposed to talk about sex to their children.

> *KHANYE: . . . they supposed to talk to us about this things but because of like – it is still such a stumbling block for them to actually come out and talk those things with us.* FGD 1

Given the lack of communication about sex, the requirement that participants be sexually active in order to participate in HIV vaccine clinical trials may be misunderstood by parents. Khanye argues that parents may be under the mistaken impression that the trial site staff are encouraging adolescent participants to become sexually active.

> *KHANYE: And if ever my family like my parents they like "you sexually" – they don't know that I'm sexually active and they see that part on the informed consent that we want sexually active people, they going to be like "Sexually active? You want my child to be sexually active now? Hell no!"* FGD 1

Participants were of the opinion that if they had to admit to being sexually active it would probably pose a significant barrier to participating in an HIV vaccine trial. Nomti, a 16-year-old adolescent girl, contended that her mother feels strongly about her not being sexually active and used exaggeration and repetition to express how seriously her mother would view her being sexually active. Nomti believes that there would be serious consequences for her should her mother ever find out that she was sexually active and equates the consequence of her mother discovering that she is sexually active to being killed by her mother.

> *SIMPIWE: It would be a big problem to all families I think.*
>
> *NOMTI: MY mom would bury me alive! She'd bury me alive!* FGD 1

Khanye concludes by saying that even though she has a sibling who is HIV positive, her father would have a problem allowing her to enrol in an HIV vaccine trial if being sexually active was a prerequisite. For Khanye, admitting to being sexually active is a greater barrier than the salience of having a sibling who is HIV positive is as facilitator.

> *KHANYE: Well in my family I do have a sibling who is HIV positive and so the only part that I think that would make especially my father not to support me is the part where they want sexually active people.* FGD 1

Quite a significant portion of time was spent discussing the very real requirement that HIV vaccine clinical trials would require sexually active participants, and the effect that this would have on potential adolescent participants. This is reflected in the passages above.

It's hard for you to say yes

Participants in the focus group discussions stated that knowing more about HIV vaccine clinical trials may prove to be a barrier. For example, knowing that the potential for side effects exist makes it more difficult to agree to participate. Lopez, a 20-year-old man, explains that having prior knowledge of vaccine trials and other HIV preventative biomedical trials may inhibit willingness to participate.

> *LOPEZ: You know it's a difficult decision to make you know because if you know much with these vaccines and everything it's hard for you to say yes.*
> *KHANYE: You want to join but knowing everything . . . about people who were diagnosed with other things what they -- they were in the study so it becomes*

difficult for you to say, "Yes I'll do it!" and then at the same time want to say yes. FGD 1

3.2.1.2. Abstract barriers to participation in HIV vaccine clinical trials

Participants identified abstract barriers at the individual, family and societal levels. At the individual level, participants were concerned about the effect that potential side effects may have had on their well-being. At the family level, there was concern that parents would be afraid for their children's well-being. At a societal level, participants argued that stigma attached to anything related to HIV would be a barrier to participation. Participants did not identify any barriers at the community level.

Side effects (Individual level)

Participants were particularly concerned about the potential side effects that trial participation might have on their well-being. Having knowledge of previous trials and the side effects that participants in those trials experienced would negatively affect willingness to participate. Lopez, who had argued that having prior knowledge of other biomedical trials would inhibit willingness to participate in an HIV vaccine clinical trial, also raised the concern that knowing about the potential side effects of the candidate vaccine would negatively affect willingness to participate in an HIV vaccine trial.

LOPEZ: So knowing that knowledge of people maybe side effects affected them during the study, ja those things, the side effects and everything are those things that can make you not to join the study FGD 1

Participants' concerns included both short and long term side effects and included the potential to gain weight, develop rashes, headaches and fever. While RT, a 16-

year-old male indicated that he would be willing to participate as long as there were no long-term effects, Nomti, a 16-year-old female said she would not be willing to participate if there were any side effects.

> *NOMTI: I'm not comfortable with maybe you know per sé, where you know you get the side effects while on the trial you get a rash and you gain weight and you know all of that.* FGD 1
>
> *RT: If there's only side effects then I would but then if there are long term effects I wouldn't.* FGD 3

The degree of severity of the side effects would also influence participants' decision to participate. The more severe the side effect, the less likely Portia, a 17-year-old female, said she would be to participate in an HIV vaccine clinical trial.

> *PORTIA: If it's just . . . manageable side effects then ja I would be part of it but if it's like severe side effects then no I wouldn't.* FGD 2

Parents are going to get scared (Family level)

Participants stated that their parents would not allow them to participate in an HIV vaccine clinical trial due to concerns for their health and safety. Leonard, a 17-year-old male argued that given the bad publicity that trials such as the Phamibili study received, parents may consider participation too risky for their children.

> *LEONARD: I think the parents are going to get scared because maybe they going to think about the Phambili what, what, they going to think about that . . . and they going to tell you that they know it's dangerous, don't do it so also it's going to influence you to make that decision.* FGD 2

Participants also mentioned that negative conceptions regarding trial participation, such as the concept that trial participants were guinea pigs, would negatively influence parental decisions to allow their children to participate. Guinea pigs are generally considered expendable animals that are used to test products such as candidate vaccines. Morris, a 24-year-old male and past chairperson of the adolescent CAB, argued that parents would want to protect their children from being taken advantage of.

> *MORRIS: a parent would not let their child go and be used as a guinea pig as we use to think that you know people in trial participation used to be called.* FGD 2

Participants nodded their agreement with Nomti when she said that if her mother withheld permission then she would not participate. Nomti was clear that her mom would be concerned for her safety and would discuss her participation with her neighbour.

> *NOMTI: You know how – maybe part of my family don't have a clear understanding of the study and my mom would tell her neighbour, eish my child is in this study and you know I think this study would make her vulnerable to HIV you know* FGD 1

Nomti also mentioned that her mother would enlist the support of her extended family to discourage her from participating in an HIV vaccine trial. This would bring added pressure on her to decline to participate.

> *NOMTI: . . . and maybe if we have a family reunion they would discourage me to be part of the study because they wouldn't know and if I tried to tell them*

> *they would think I'm persuading them to agree with me being part of the study.* FGD 1

The final say would, however, lie with Nomti's mother. Nomti acknowledged that she is significantly influenced by her mother's opinion and that she would find it difficult to agree to participate in an HIV vaccine trial if her mother did not agree with her decision to participate.

> *NOMTI: You know I take my mom's opinion very seriously. If she say something, if she says no then it's a no going, it's no and if my mom says no then it would be a problem for me you know.* FGD 1

Parents have the final say regarding adolescent involvement in HIV vaccine trials and false media reports may thus be influencing parents negatively regarding the participation of their children in HIV vaccine clinical trials.

We run away from stigma (Societal level)

Participants mentioned that participating in an HIV vaccine trial might attract courtesy stigma (Goffman, 1963) due to the association between HIV vaccine trials and HIV infection. Goffman (1963) defines courtesy stigma as stigma received by an individual because of their association with someone or something that is stigmatized. Gift and Nomti agreed that there was still confusion in their community about the distinction between treatment for HIV and being part of an HIV vaccine clinical trial.

> *GIFT: Generally I think we are living in a community which it's still not well informed about this HIV thing and everything, so by seeing you carrying your bag coming to here they think maybe you are . . .*

NOMTI: HIV.

GIFT: You are HIV, you are coming here for treatment and everything instead they don't know what maybe you are coming here to do. FGD 1

Gift mentioned the lack of knowledge regarding HIV vaccine trial participation in his community and how lack of knowledge may lead to erroneously associating vaccine trial participation with being HIV positive. Thulani concurred and stated that once community members had labelled you as HIV positive you were likely to experience stigma.

THULANI: It would be due to the stereotypical thinking of the community. Maybe they going to tell no, go, you going to die alone so you also going to get scared, you see now.

ZUHAYR: Tell me more about you going to die alone, what does that mean?

THULANI: Like maybe I'm telling Thando, hey Thando man I want to go to the trial. Then you see maybe he's going to say, "I'm scared man, you can go, what if you get infected?" then I'm going to get scared you see so when Thando is going to say, "Go man you going to die alone of HIV" then I'm going to get scared. FGD 2

Nomti concluded by stating that fear of being stigmatized would deter most individuals in her community from participating in an HIV vaccine trial. Fear of being stigmatized would also deter her personally from participating in an HIV vaccine trial.

NOMTI: Family, friends, the community that I live in, you know how we run away from stigma. So I wouldn't want to be the topic of the town you know. Ja . . . so some of the things that would make me personally not be part of the study. FGD 1

Participants were explicit in stating their propensity to avoid stigma including stigma from family, friends, and the communities they were part of.

While I asked specifically about what would facilitate participation, more than a third of responses were classified as barriers to participation in HIV vaccine trials. While I was not necessarily trying to identify barriers to participation, the fact that so many responses first considered barriers is indicative that barriers and facilitators are two inseparable facets of HIV vaccine trial participation.

3.2.2. Facilitators of Participation in HIV Vaccine Clinical Trials

The thematic analysis of the focus group discussions highlighted 11 facilitators of willingness to participate in HIV vaccine trials for adolescents. Both abstract and concrete facilitators were evident. Abstract facilitators were evident at the individual and community levels while concrete facilitators were evident at all four levels (individual, family, community and society).

Abstract facilitators that were identified at the individual level were altruism, risk behaviour, leadership, and personality characteristics. The facilitating role of communities as well as the empowering effect of having information was evident at the community level.

Concrete facilitators identified at the individual level were the safety of participation and the rewards of participation. Concrete facilitators evident at the family and community levels were positive peer pressure and the salience of HIV for the participants. The lone concrete facilitator at the societal level was the socio-economic status of the families from which adolescent participants may be recruited.

3.2.2.1 Abstract facilitators of participation in HIV vaccine clinical trials

I'll be part of the people who make the change (Individual level)

Participants mentioned that contributing to the greater good was a facilitator of willingness to participate. This contribution to the greater good is evident at the individual level. Palesa, a 16-year-old female, contends that participation for her was a way of helping her community and country.

> *PALESA: I don't know sometimes it's just nice to help wherever you can you know. So me participating in a way it's me helping and then ja, and helping my community and my country.* FGD 3

Thami, a 19-year-old female, was willing to participate for the altruistic reason of wanting to be part of the group of people who were responsible for contributing to finding an effective HIV vaccine.

> *THAMI: I'll take it because I'll be part of the people who make the change if ever it works.* FGD 3

Risk behaviour (Individual level)

Participants identified adolescents who exhibit risk taking behaviours as likely to participate in HIV vaccine clinical trials. Lindiwe, a 16-year-old female, argued that adolescents who preferred to engage in activities where the outcome was uncertain would participate in HIV vaccine clinical trials. Her statement was supported by Thami and Nomti.

LINDIWE: I think there would be those people that really like to experiment you know.

THAMI: . . . people who like extreme sports and they put their bodies on the line. Because it's risky, you know risking – the vaccine. Yes and that's the way they similar. FGD 3

Leaders will participate (Individual level)

Participants felt that leaders in various spheres of society would be more willing to participate than the average community member. Portia, a 17-year-old female, and Mpho, a 17-year-old male, argued that leaders, by virtue of being leaders, would be willing to participate in an HIV vaccine trial. Portia states that it is the title that someone may have that would be facilitate their participation.

PORTIA: I think someone who is a leader as well you know? . . . I think that person . . . given that I'm given that title they would be, you know, more willing to be involved. FGD 2

MPHO: If I'm a community leader or an adolescent in my community and then I'll go into the clinical trials FGD 3

Palesa also argues that leadership comes with power and that power is something she as a leader would use to change her community by enrolling in an HIV vaccine trial. Mpho explains that once a leader showed willingness to participate in an HIV vaccine trial, others would follow.

PALESA: I feel that I've got a power you know I've got a power to change my community and so far I think I've played my part.

MPHO: I'll go into the clinical trials then – and people see . . . that okay, Mpho is like going to all those clinical trials and she's not HIV positive and stuff then other adolescent in my community . . . they'll do it. FGD 3

Participants also declared that in addition to leaders, positive role models in their communities would encourage other adolescents to enrol. These include peers as well as celebrities.

KHANYE: Maybe one of the peers within their age group that they look up to . . . when I look at her I just think, damn she is going very far and whatever she does, if ever it motivates me I'll also want to follow suit. If ever she would enter a trial study, I would say, if ever she is entering a trial study that means it must be good for our future then I'll also follow suit.
NOMTI: If I see Lira being part of a clinical trial I'd also want to go there because I would think it's a cool thing to do you know? FGD 1

Personality characteristics (Individual level)

When I asked the participants of the focus groups to describe the type of adolescent who would be willing to enrol in an HIV vaccine clinical trial they listed a number of personality characteristics that included courage, extroversion, boredom susceptibility (a component of sensation seeking), curiosity and motivation.

PALESA: . . . you know there are those people who will come here, they have nothing to do at home not because they want the money or something, (if) they (are) bored they will come and participate here. FGD 3
LINDIWE: I think people who are determined and dedicated especially with

the community that they can make a change. FGD 3

RT: Curious people, courageous also. FGD 3

PORTIA: I just think it's encouragement and motivation. FGD 2

PORTIA: Okay if you're an extrovert then ja you like – ja most of the times you like going . . . FGD 2

MORRIS: . . . like to be involved. FGD 2

PORTIA: Ja, involved in things, you want to experience it so you go there and get the vaccine you know whereas with an introvert no you don't want to be much there, you just want to be kept to yourself ja. So you wouldn't go. FGD 2

PARTICIPANT: Like maybe if you want to go and then for instance you going to go, if you committed to go, you going to go. FGD 1

Community plays a vital role (Community level)

Participants mentioned that supportive communities would facilitate willingness to participate. Portia stated that greater exposure to vaccine information would increase willingness to participate in an HIV vaccine trial.

PORTIA: I think from my community, because there's like a lot of this things and most of the time people get more information about this and it's like, you know, like vaccine thing research projects . . . and some of the people know more of the things I think it could have a good influence because people would think okay we've seen this thing happen before so you can go in and do it. FGD 2

Leonard on the other hand argues that congruent messages across communities would increase willingness to participate in an HIV vaccine trial. Leonard argues that if the message received from the different components of his community is not the same or similar, i.e., congruent, members of the community would be less willing to participate.

> *LEONARD: Okay, ja, a community plays a vital role in one making a decision . . . Thulani did say earlier on that if ever I talk to a friend and then your friend says something negative obviously I'm going to take a step back and then if I get to Portia and then there's that supportive community whereby the community is actually comprised of different . . . components maybe put it that way. Where there's a church community and then there's sports community . . . so say I go to the church, the church will give me positive information . . . whatever that's going to come from them it's going to influence me in me joining the study, but say I go back to the kasi corners and then we talking to each other, that's going to give me a negative response to the whole trial thing.* FGD 2

Information empowers (Community level)

One of the most salient and oft-repeated facilitators of willingness to participate is access to, and dissemination of information. Participants were quite vocal about the need for more information. In contrast to Lopez, who had argued that knowing too much about prior studies and side effects would inhibit willingness to participate in an HIV vaccine trials, Morris, a 24-year-old male, argued that more information would facilitate enrolment in HIV vaccine clinical trials. Khanye argued that prior to

receiving the information she had received through her involvement in the adolescent Community Advisory Board (CAB) she was unwilling to participate. Subsequent to receiving information regarding the details of trial participation, Khanye felt that she would be more willing to participate.

> *MORRIS: I think the most important thing is to give out as much information as possible. . . . I think information as a tool is very much important through, maybe even you know, press releases, workshops, conferences to skill young people you know. I think information is the most important thing.* FGD 2
>
> *KHANYE: If ever I know that entering a study you will, like increase the chances of me living a very better future, I would want to be part of that study . . . without the information that I have I think it would be maybe a boundary that would keep me from participating . . . because I have information that would be the empowerment of my decision to participate.* FGD 1

Participants in this study identified both individual and community factors at an abstract level that may facilitate willingness to participate in an HIV vaccine trial.

3.2.2.2. Concrete facilitators of participation in HIV vaccine clinical trials

I want to be 100% sure that I'm safe (Individual level)

Participants were quite emphatic in their need for reassurance that their health would not be negatively affected by trial participation. Portia alludes to the need to know more about all aspects of trial participation that may impact on her health.

> *PORTIA: Ja I need to be 100% sure about them.*
>
> *ZUHAYR: Okay, 100% sure about what?*

PORTIA: The whole vaccine, the effects and everything like that ja, so I want to be 100% sure that I'm safe. FGD 2

Maybe there'd be rewards (Individual level)

While Thandi indicated that she would be willing to participate in an HIV vaccine clinical trial if there were benefits to her, Portia argued that if the reward was monetary, more poor people would volunteer, alluding to the potential for perverse incentives to exist in HIV vaccine clinical trials.

THANDI: I'll participate. . . . maybe there'd be what, what, rewards after that, like maybe. FGD 3

PORTIA: If there's money the – more of the poor side is going to be on the study. FGD 2

While Thandi and Portia mentioned that monetary compensation would increase willingness to participate in an HIV vaccine clinical trial, Morris and Buhle stated that intangible benefits would also increase willingness to participate. While Buhle, a 20-year-old female mentioned trial sites helping people, Morris was more direct and explained that it was the continued engagement with health professionals that was the direct benefit.

BUHLE: I think if maybe they going to help people they will come.

MORRIS: You know trial participants are probably the healthiest people that you will ever meet anywhere in research because how many times in a year do you go for your blood pressure test, how many times do you go for your HIV test, how many times do you get a free medication you know all full holistically

> *body check, how many times do you do that in a year except for when you are sick?* FGD 2

Salience of HIV as a facilitator (Family and Community levels)

Participants stated that knowing someone infected with HIV would encourage adolescents to participate in HIV vaccine clinical trials. Khanye stated that the more salient the HIV epidemic was for adolescents, the more willing to participate adolescents would be, particularly if they knew someone close to them that was infected with HIV.

> *KHANYE: I think especially for those who are not infected by it but know someone . . . who is infected they want to, like protect themselves. And also, like think about other people who maybe are in, maybe vulnerable of catching the virus, just, like to help them not to be infected.* FGD 1

Nomti countered by stating that everyone is affected by HIV. Nomti argued that she would be willing to participate in an HIV vaccine clinical trial even if she did not know someone close to her had HIV, as everyone is affected by HIV.

> *NOMTI: Ja, it does add a lot because if you really, like take a very good look everyone is affected whether we like it or not, everyone is affected by HIV. So if we – if personally I'm affected I'd really want to see something happen and something being done about this HIV thing, you know, ja so.* FGD 1

Positive peer pressure as a facilitator (Family and Community levels)

Participants spoke about the effect that peer pressure would have on adolescent willingness to participate. Khanye argued that peer pressure could be harnessed to influence adolescents to be more willing to participate in an HIV vaccine clinical trial.

> *KHANYE: Ja, peer pressure, so like if ever they are able to influence each other with bad things they obviously are able to influence themselves with positive and good things.* FGD 1

Gift stated that if more individuals in his age group were willing to participate he would be willing to participate, suggesting that perceived group norms would positively influence adolescent willingness to participate.

> *GIFT: My age, especially my age are not into trials . . . but if I have more people my age joining this things you'd get encouraged because you'd want to go do it because they doing it.* FGD 1

Palesa commented on the responsibility that she felt CAB members had to practice what they preach. Palesa stated that in her opinion CAB members should participate in HIV vaccine trials as a means of showing others that it is safe to do so. Palesa indicated that she felt a sense of responsibility as a CAB member that goes beyond her duties as a representative of her community. Palesa argued that CAB members also need to represent the trial site to their communities.

> *PALESA: As a CAB member some people you know, some people from outside that areas they also want to see people from inside, if they do take it, if we practise what we preach. So on my side I will take it.* FGD 3

Social status as a consideration for trial participation (Societal level)

Focus group participants raised the issue of socio-economic status (SES). Morris argued that parents from a lower SES would be more likely to allow their child to participate.

> *MORRIS: I think given the fact that, maybe you know, they do not have anything else that they do when they get back home or they do not have any kind of support structure, nobody is monitoring their books, nobody is giving them any kind of money perhaps when they go to school.* FGD 2

Morris identified a lack of after-school supervision as one of the markers of social status. He stated that an adolescent who lacks after school supervision would most probably not be receiving money to spend at school.

> *MORRIS: . . . and then they are thinking to themselves I heard of a trial maybe in a newspaper or maybe at a school presentation that you know I can go to Bara and get R150.00 of reimbursement and food if I come at such and such a time. Just to give out blood and maybe share some information. I think that kind of a person, number one, would actually, you know, be much more susceptible.* FGD 2

Morris continued by alluding to the possibility that receiving R150.00 as participant reimbursement may prove to be a perverse incentive for the adolescent described above.

> *MORRIS: . . . as opposed to someone who will be coming from a comfortable family you know is well supported, is being well monitored by the parents. Maybe, probably you know, gets taken to school every day in the morning.*

> *That person would not be in a trial, that person would never join a trial . . . the gap between the rich and the poor is very, very, very wide you know in our communities.* FGD 2

Morris then juxtaposed the previous example of an adolescent from a lower SES to one who was being well monitored by his or her parents and whose parents are probably executives in a company. He argued that such a parent would not allow their child to be used as a means to test an unproven product. It is interesting to note that Morris uses the word “susceptible” when speaking about the adolescent from the lower SES.

> *MORRIS: If we were to make a study right now to, say between Motsoaledi, the shacks, and Dobsonville or Diepkloof, where can we get more participants? We’ll only get in Motsoaledi.* FGD 2

Morris concluded by using examples of suburbs in Soweto with differing levels of SES. He argued that HIV vaccine trial site clinics would be able to recruit adolescents from the lower SES suburbs more easily than from the higher SES suburbs. Leonard voiced his agreement with Morris.

> *MORRIS: Ja, we were saying here amongst the group that the issue of social standard play*(s) *a very, very . . .*
> *LEONARD: . . . a vital role.* FGD 2

Even though a larger quantity of themes were facilitators, participants struggled to conceptualise facilitators without lapsing into mentioning barriers. It is evident that participants found it easier to identify barriers than to identify facilitators.

3.3. Discussion

The following section discusses the themes reported in the results section above. I start the discussion with concrete barriers, followed by abstract barriers, then concrete facilitators, and conclude with abstract facilitators.

3.3.1. Barriers to Participation in HIV Vaccine Clinical Trials

3.3.1.1. Concrete barriers to participation in HIV vaccine clinical trials

Two concrete barriers identified by participants are evident at the individual level. They are difficulties that participants felt that they would experience in saying yes to participating in an HIV vaccine clinical trial given their prior knowledge and admitting sexual activity to an older person. Neither of these have been identified as barriers in other HIV vaccine studies and may prove influential in the recruitment and retainment of adolescents in HIV vaccine clinical trials. While authors such as Tanner, Short, Zimet, and Rosenthal (2009) have identified that parental consent and adolescent participants' right to privacy and confidentiality may prove to be a barrier to participation in microbicide trials, the data above is the first data from potential adolescent participants to verify that parental consent for sexually active adolescents may be a barrier to participation in HIV vaccine clinical trials.

I purposively selected the participants in the focus group discussions due to their prior involvement with the adolescent CAB of the HIV vaccine clinical trial site at the PHRU located at Chris Hani Baragwanath Hospital in Soweto. As a result, they had knowledge of the workings of clinical trials that the average layperson would not have had. I wanted to access this insight given that Lesch et al. (2006) report that participants in their national qualitative study indicated that greater amounts of

information would translate to greater eagerness and willingness to participate in HIV vaccine clinical trials. However, participants in this study indicated that greater knowledge and insight created an inconsistency between what would be better for them as individuals (*". . . it becomes difficult for you to say yes."*) and what they felt would be helpful for their communities (*". . . at the same time you want to be there and help people, help the community"*). This concurs with Swartz and Kagee (2006) who hypothesized that information does not necessarily lead to enrolment, and that greater knowledge may well lead to a lower likelihood of enrolling in HIV vaccine trials. Swartz and Kagee (2006) argue that if one considers willingness to participate as being either willing or not willing, and empowered to make a decision as empowered and not empowered, and then create a 2X2 table to categorise participants, one would see that an empowered individual would be empowered to choose to participate or refuse to participate. Thus, while information may lead to the ability to make an informed decision, the decision may be not to participate in an HIV vaccine clinical trial.

One of the most pertinent barriers to participation in HIV vaccine clinical trials for adolescents is the requirement that they be sexually active. While 18% of adolescents nationally admit to being sexually active in anonymous surveys (Shisana et al., 2009), participants in the present study were reticent to admit this to an older individual. As can be seen in the results section, one participant said, "*You get a bit shy to say ja I'm sexually active. If you look at the person's age and you look at your age."* A number of participants in this study admitted that they were sexually active without their parents' knowledge (*". . . you cannot tell your parents that, "Yes I'm sleeping around", ". . . sometimes they know we are – they know it but . . .*) and would prefer that the trial site staff not inform their parents that they needed

to be sexually active in order to participate in an HIV vaccine clinical trial ("*That sentence should be removed from the parent's informed consent"*).

From the results section in Chapter Three above one can see that other participants expressed concern that their parents may misunderstand the requirement that participants be sexually active as a request from the HIV vaccine clinical trial site that adolescents who were not currently sexually active need to commence with sexual activity (*". . . they don't know that I'm sexually active and they see that part on the informed consent that we want sexually active people, they going to be like 'Sexually active? You want my child to be sexually active now? Hell no!'"*). This misunderstanding may impede parents' willingness to allow their adolescents to participate in an HIV vaccine clinical trial. McClure et al. (2004) similarly argues that parental concerns about the requirement that adolescents need to be sexually active to participate in an HIV vaccine clinical trial may impede their willingness to allow their children to participate. McClure et al. (2004) suggests that parental concerns regarding the sexual activity of their children as well as the related adolescent concern regarding privacy are important issues to attend to.

In the results section above, one participant expressed the opinion that even if she convinced her parent to agree to her participation in an HIV vaccine clinical trial, she would have to explain to her mother why she was sexually active when she was still under 18 years of age (*"I do have to explain the fact that when you sexually active and you not yet even 18"*). She followed this by saying that even though she has a sibling who is HIV positive, her father would not support her in participating in an HIV vaccine clinical trial if he knew of the requirement that she needs to be sexually active (*". . . in my family I do have a sibling whose HIV positive and so the only part*

that I think that would make especially my father not to support me is the part where they want sexually active people").

3.3.1.2. Abstract barriers to participation in HIV vaccine clinical trials

Participants identified abstract barriers at three of the four levels identified by Lesch et al. (2006). Side effects were evident at the individual level, parents' fear at the familial level, and concerns regarding stigma at the societal level.

At the individual level participants were particularly concerned about the potential short and long term side effects of the candidate vaccine (*"If there's only side effects then I would but then if there are long term effects I wouldn't"*). They raised concerns about the potential for skin rashes and weight gain (*"I'm not comfortable with maybe . . . you get the side effects while on the trial you get a rash and you gain weight"*) as well as the potential of disease developing over the longer term and affecting their health when they are older (*"Maybe disease can develop without knowing. Eventually when I'm older or I'm a grandfather I see blood sugar so I don't want that"*). These concerns about side effects concurs with previous research in adult populations that identified concerns regarding the safety and efficacy, as well as the physical side-effects of the candidate vaccine (Buchbinder et al., 2004; Hays & Kegeles, 1999). Buchbinder et al. (2004) report that participants in their sample of men who have sex with men (MSM), intravenous drug users (IDU's) and women who were at high risk (WAHR) of contracting HIV across eight major US cities identified vaccine safety concerns as one of the most commonly cited reasons for refusing to participate in an HIV vaccine clinical trial. Hays and Kegeles (1999) state that the potential for physical harm, be it from side effects from the candidate vaccine or from acquiring HIV, were reported by participants across all three of their samples in the

US: men who have sex with men (MSM) in San Francisco; intravenous drug users (IDU's) from Philadelphia; and African American men and women in Durham.

At the familial level participants stated that the media coverage of previous trials such as the Phamibili study (Gray et al., 2011) will most probably negatively influence parents' decisions to allow their children to participate (*"Parents are going to get scared because maybe they going to think about the Phambili what, what . . . and they going to tell you that they know it's dangerous, don't do it. So also it's going to influence you to make that decision"*). The Phambili study was closed early due to the potential for participants in the vaccine arm to have an increased susceptibility to HIV acquisition (South African AIDS Vaccine Initiative, 2007b). Reports in certain media outlets however, gave the impression that it was the candidate HIV vaccine that caused the HIV infection (Mbao, 2010; Moran, 2010). While Mbao (2010) insinuates that the HIV vaccine may have been responsible for the HIV infections, Moran (2010) explicitly states that the candidate vaccine caused the HIV infection.

> Controversy has risen in the African continent after Microbicides Development Programme trial (MDP), which was testing if the gel PRO2000 would prevent HIV infections, took place between 2005 and 2009 with 9,385 participants and actually infected at least 46 Zambian women with the virus. (p. 1)

Participants argued that media such as Mbao (2010) (Trial HIV vaccine leaves 46 infected) and Moran (2010) (HIV vaccines in Zambia leaves 46 women infected with the virus) would scare parents away from allowing their children to participate.

At the societal level participants were concerned about what Goffman (1963) calls courtesy stigma. Goffman (1963) defines courtesy stigma as stigma that is received due to an association with someone or something that is stigmatized. In this

instance, participants were concerned about the connection between HIV infection and HIV vaccine clinical trials. Participants were concerned that other community members may see them visiting the HIV vaccine clinical trial site and mistakenly assume that they were HIV positive (*"so by seeing you carrying your bag coming to here they think maybe you are – HIV"*). This finding concurs with previous studies of adult participants in HIV vaccine clinical trials where trial participants reported that they were treated negatively by less well-informed others who assumed that since they were participating in an HIV vaccine clinical trial they were at risk of being infected with HIV through high risk sexual behaviour or through drug use practices such as needle sharing (Allen et al., 2001; Rudy et al., 2005; Sheon et al., 1998).

3.3.2. Facilitators of Participation in HIV Vaccine Clinical Trials

3.3.2.1. Concrete facilitators of participation in HIV vaccine clinical trials

Five concrete facilitators were identified by participants and occurred at all four levels identified by Lesch et al. (2006). Safety of participation and the rewards of participating occurred at the individual level. Positive peer pressure and the salience of the HIV epidemic straddled the family and community levels, while the socio-economic status of the families from which trial participants will be recruited occurred at the societal level.

Safety of participation is the other side of the coin of side effects. While potential side effects would limit participation, participants stated that if they were assured of the safety of the candidate vaccine in an HIV vaccine clinical trial they would be willing to participate (*"I want to be 100% sure that I'm safe"*). The data from my participants

concurs with prior research where participants indicated that they would have a greater willingness to participate in an HIV vaccine clinical trial if there was a guarantee that the candidate vaccine was safe (Celentano et al., 1995; MacQueen et al., 1999; Moodley et al., 2002; Sahay et al., 2005). It would be unethical of trial site staff to guarantee that a candidate vaccine was safe given that participants would probably differ in terms of how their bodies might react to the candidate vaccine. However, trial site staff could refer concerned participants to the results of Phase 1 HIV vaccine clinical trials in which the safety of the candidate vaccine would have needed to be shown before further phases could progress.

Celentano et al. (1995) report that in their study of female commercial sex workers, male STD patients, and current or recently discharged Thai Royal Army members, 32% of civilians and 61% of their military participants were concerned that candidate vaccines would be unsafe. Concerns regarding the safety of the candidate vaccine would thus impede their willingness to participate in an HIV vaccine clinical trial. Macqueen et al. (1999) surveyed 193 intravenous drug users and report that their participants were less likely to participate in an HIV vaccine trial due to concerns that the candidate vaccine might accelerate HIV's progression to AIDS. Moodley et al. (2002) report that willingness to participate in an HIV vaccine trial was negatively associated with fears of vaccine induced infection in their sample of medical professionals. Sahay et al. (2005) report that assuring potential participants of the safety of the candidate vaccine increased their study participants' willingness to participate in an HIV vaccine clinical trial.

The other concrete facilitator at the individual level is the possibility of rewards that may be received as a result of participating in an HIV vaccine clinical trial. Participants in the current study identified both financial rewards (*". . . if you say they*

will give them money they will go") as well as improved health and health care as rewards of participating in an HIV vaccine clinical trial (*". . . trial participants are probably the healthiest people you will ever meet"*).

Previous studies have highlighted the role that financial incentives play in ensuring enrolment in HIV vaccine clinical trials. While some studies have indicated that financial incentives and/or discounted medication would increase willingness to participate in an HIV vaccine clinical trial (Jenkins et al., 2000; Strauss et al., 2001) Moodley et al. (2002) have warned against creating perverse incentives. Perverse incentives may occur when impoverished individuals disregard the potential risks to themselves due to the financial incentives offered by HIV vaccine trial sites (Moodley et al., 2002).

Participants in this study identified improved health and health care as rewards of participating in an HIV vaccine clinical trial which concurs with Kafaar, Kagee, et al. (2007) who have argued that participating in an HIV vaccine clinical trial may in itself be a health promoting behaviour. Kafaar, Kagee, et al. (2007) argue that the regular trial site clinic visits required of HIV vaccine clinical trial participants serves as a constant reminder of their actuarial risk (the statistical estimation of the probability of HIV infection within a particular population) of HIV infection. Merely participating may therefore increase awareness and thus decrease infection rates. Participants in the Swartz et al. (2006) study indicated that they would be protecting themselves from HIV infection by participating in an HIV vaccine trial and then staying protected.

Two facilitators that participants identified straddled the family and community levels of Lesch et al. (2006). Positive peer pressure referred to the positive effect that peers may have on adolescents' participation in HIV vaccine clinical trials, while salience of

the HIV epidemic referred to how noticeable the HIV epidemic was in participants' lives.

Participants stated that knowing someone who was HIV positive and/or dying from AIDS would motivate them to participate in an HIV vaccine clinical trial (*". . . personally I'm affected, I'd really want to see something happen and something being done about this HIV thing you know, ja so"*). This concurs with Lesch et al. (2006) who reported that participants in their study stated that knowing someone who had died of AIDS or who had been affected by HIV would make them more willing to participate in an HIV vaccine clinical trial. Lesch et al. (2006) further argue that there was a high likelihood of trial participation in most trial site communities due to the high salience of HIV in these communities. Knowing a family member, friend or community member who was infected or affected by HIV may thus increase willingness to participate in an HIV vaccine clinical trial.

Participants stated that since peer pressure could lead to adolescents adopting behaviour that was detrimental to them, peer pressure may also be able to motivate them to participate in an HIV vaccine clinical trial (*". . . if ever they are able to influence each other with bad things they obviously are able to influence themselves with good things"*). Lesch et al. (2006) report similar findings where their participants indicated that they would be more willing to participate in an HIV vaccine clinical trial if their families and communities reacted favourably to their participation. Efforts to educate communities about HIV vaccine clinical trials may encourage larger amounts of adolescents and their parents to allow adolescents to participate. This finding concurs with Kalichman, Somlai, and Sikkema (2001) who argue that involvement in, and interventions with communities should form an integral part of any effort to curb the spread of HIV.

The final concrete facilitator is the issue of social standard. Participants in this study argued that potential participants of an HIV vaccine clinical trial were more likely to be sourced from areas of lower socio-economic status (*"I don't see a parent from Diepkloof extension, you know, being able to let their child go to a trial at a [unintelligible][50.49], as opposed to one that will let them go from Motsoaledi"*). They argued that poorer, less educated parents would be more willing to allow their adolescent children to participate in an HIV vaccine clinical trial. Similar findings, showing how socio-economic status influences willingness to participate in HIV vaccine trials, have been reported by O' Connell et al. (2002) in their study of gay and bisexual men in Vancouver, Canada, Koblin et al. (1998) in their study of MSM, IDU's and WAHR of HIV infection across the US, and Bartholow et al.'s (1997) sample of gay men across the US.

3.3.2.2. Abstract facilitators of participation in HIV vaccine clinical trials

Six abstract facilitators were identified by my participants. Altruism, risk behaviour, leadership, and personality characteristics were evident at the individual level while the role of communities and information were evident at the community level.

Participants in my study reported that they would be willing to participate in an HIV vaccine clinical trial so that they could state that they had contributed to the development of an effective vaccine for HIV and AIDS (*"I'll take it because I'll be part of the people who make the change if ever it works"*). Altruism is one of the most widely cited facilitators of HIV vaccine clinical trial participation. Samples as diverse as gay and bisexual men across the USA (Hays & Kegeles, 1999), men who have sex with men (MSM), intravenous drug users (IDU's) and women who were at high risk (WAHR) of contracting HIV across eight major US cities (Buchbinder et al.,

2004; Koblin et al., 2000), male and female attendees of an STI clinic in western India (Sahay et al, 2005) and men in the Ugandan military (McGrath et al., 2001) have reported altruism as a facilitator of HIV vaccine clinical trial participation. It may be worthwhile noting here that altruism may also be strongly influenced by social desirability, or what is known as the Hawthorne Effect (McCarney, et al., 2007).

The sample in the study conducted by Jaspan, Berwick, et al. (2006) most closely resembles the participants in this study. Jaspan, Berwick, et al. (2006) report that their adolescent sample from a peri-urban Xhosa-speaking community near Cape Town, South Africa were motivated to participate in an HIV vaccine clinical trial by altruistic motives. Jaspan, Berwick, et al. (2006) report that their participants saw vaccine trial participation as a means of helping to "find a vaccine against HIV to protect their loved ones and the rest of the world" (p. 645).

Risk behaviour was identified as a facilitator of HIV vaccine trial participation. Participants in this study reported that individuals who were willing to take risks in other areas of their lives would probably be willing to risk participating in an HIV vaccine clinical trial (*". . . people who like extreme sports and they put their bodies on the line. Because it's risky, you know risking – the vaccine. Yes and that's the way they similar"*). Koblin et al. (1998) report that the MSM, male and female intravenous drug users (IDU's) and women at high risk (WAHR) of HIV infection in their study across the USA indicated willingness to participate in an HIV vaccine clinical trial because they engaged in risky sexual behaviour. Buchbinder et al. (2004) report similar results. Rates of enrolment in Buchbinder et al.'s (2004) sample of MSM, IDU's and WAHR of HIV infection in the USA were significantly higher for participants who engaged in high risk sexual behaviour. However, in Jaspan, Berwick, et al.'s (2006) study with adolescents in South Africa, sexually active

adolescents were 2.2 times more likely to be willing to participate than adolescents who were not sexually active (OR 2.2, 95% CI 1.04-4.71). No other risk factors were associated with increased willingness to participate.

Being a leader (*"If I'm a community leader . . . in my community and then I'll go into the clinical trials"*) and having other leaders and influential others like celebrities participate in HIV vaccine clinical trials would facilitate willingness to participate for adolescents (*"If I see Lira being part of a clinical trial I'd also want to go there"*). Swartz et al. (2006) report that the adult participants in their South African study maintained that real community leaders should lead by example and participate in HIV vaccine clinical trials. Swartz et al. (2006) also recommend that, in keeping with social diffusion theory, key community members be enrolled in HIV vaccine clinical trials as a means of encouraging potential trial participants to enrol. Swartz et al. (2006) argue that as key community leaders accept and enrol in HIV vaccine trials, other community members will see this acceptance and enrolment and they in turn will accept and enrol into an HIV vaccine trial through a trickle-down effect from key community members to other members of the community.

A number of personality characteristics were identified as facilitators of willingness to participate, including the following personality characteristics: boredom susceptibility (*"*(if) *they* (are) *bored they will come and participate here"*); curiosity (*"Curious people"*); determination and dedication to a cause (*". . . people who are determined and dedicated"*); and extraversion (*". . . if you're an extrovert then ja you like – ja most of the times you like going"*). Johnson (2000) specifically examined personality correlates of HIV vaccine clinical trial participation in a sample of adult participants in the US and reported that of the five personality factors measured (neuroticism, extraversion, openness, agreeableness and conscientiousness) only neuroticism

was associated with willingness to participate. I could find no other data that considered personality characteristics related to trial participation.

Participants in my study were of the opinion that the reaction of members of their community plays a vital role in their decision to participate in an HIV vaccine clinical trial or not (*". . . it was more community . . . I think it could have a good influence"*). Allen et al. (2001) report similar findings in their sample of HIV vaccine trial site volunteers across the US. Allen et al. report that negative reactions to trial participation from family, friends and co-workers were the most commonly reported. In South Africa, Lesch et al. (2006) report that the adult community members in their study who resided in potential trial site communities were similarly concerned about potential negative reactions from members of their respective communities. Lesch et al. (2006) further report that their participants argued that it was due to apathy on the part of religious and community groups that would potentially lead to negative attitudes to HIV vaccine trial participants. Participants in this study therefore argued that congruent messages between different components of their communities would most probably increase willingness to participate (*"there's that supportive community whereby the community is actually comprised of different – components"*). While I could find no other research where participants reported that congruent messages across components of a community would increase willingness to participate, Kalichman, et al. (2001) argue that community involvement and intervening at community levels should form an integral part of efforts to curb the spread of HIV.

Participants in this study reported that being given information on HIV vaccine clinical trials would increase willingness to participate (*"I think information as a tool is very much important through, maybe even you know, press releases, workshops, conferences to skill young people, you know"*). Lesch et al. (2006) report similar

findings in their study of South African adults. Lesch et al. (2006) report that their participants indicated that a lack of information would inhibit willingness to participate. Conversely, in adult MSM populations in the US, increased knowledge about HIV and HIV vaccine has been associated with decreased levels of willingness to participate (Bartholow et al., 1997). Murphy et al. (2007) report that in their adolescent sample from three major cities in the US, increased knowledge about HIV and HIV vaccines in adolescents was similarly related to decreased levels of willingness to participate. However, Sahay et al. (2005) report that in their sample of male and female attendees at an STI clinic in western India increased levels of knowledge of HIV and HIV vaccines was associated with increased levels of willingness to participate. Similarly, in South Africa, Middelkoop et al. (2008) report that in their sample of adolescents residing in a peri-urban area in Cape Town, increased knowledge of HIV vaccines was strongly associated with increased willingness to participate ($p < .001$) and that adolescents were 28 times more likely to be willing to participate after attending two one-and-a-half hour educational group workshops on HIV, HIV vaccines and vaccine trials (OR 28, 95% CI 4.63-1111).

3.4. Conclusion

This study is the first that I know of that has conducted an in-depth qualitative study into the barriers and facilitators to adolescent willingness to participate in HIV vaccine clinical trials. Whilst Jaspan, Berwick et al. (2006) and Middelkoop et al. (2008) do report on their participants' responses to open-ended questions on their surveys, I have thematically analysed what adolescent potential HIV vaccine trial participants consider to be the barriers and facilitators to their and their peers' willingness to participate in HIV vaccine clinical trials.

Many of the adolescent barriers to participation in HIV vaccine clinical trials mirror those of adult barriers, including concerns regarding side effects and potential stigma related to HIV vaccine trial participation. In addition to the barriers mentioned above, the participants in this study also identified two barriers to participation in HIV vaccine clinical trials that are unique to adolescents. The first of these is the concern that parents may have in allowing their children to participate in an HIV vaccine clinical trial, mostly due to media reports that have attributed HIV infections in biomedical trials to the candidate substance. The second barrier, admitting sexual activity to an adult, is even more vexing. For an adolescent to admit to an adult at the HIV vaccine clinical trial site that they are sexually active seems to be the most pertinent barrier second only to admitting sexual activity to their parents. Trial site staff will need to carefully consider how to deal with the paradoxical requirements of ensuring confidentiality regarding adolescent participants' sexual activity and the ethical and legal requirement that parents need to give informed consent for their adolescent children to participate in an HIV vaccine clinical trial. One solution to this barrier to participation may be that trial site staff employ young adults as the contact person for adolescents. Minimising the difference in age between the potential adolescent participant and the trial site staff member may prove to be crucial in the enrolment process. Potential adolescent HIV vaccine trial participants may also benefit from training in engaging with their parents when speaking about sex and sexuality.

Many of the facilitators reported by my participants concur with facilitators of adult willingness to participate in HIV vaccine clinical trials. Examples of these include altruism, socio-economic status and access to information. My participants also identified unique facilitators that was not evident in the literature. The two most

striking examples of unique facilitators are congruent messages across the various components of communities and the indirect benefits of trial participation. While Kafaar, Kagee, et al. (2007) hypothesised that trial participation may have indirect health benefits to trial participants, this is the first set of data that indicates that potential trial participants recognize the possibility of the indirect health benefits of HIV vaccine trial participation. Finally, my participants agreed with Kalichman et al.'s (2001) argument to involve communities and intervene at a community level as an integral part of preventing further IHV infections.

Chapter Four

Multivariate Analysis to Determine the Role of Sensation Seeking Between the Predictor Variables and Willingness to Participate In HIV Vaccine Trials

This study triangulated qualitative and quantitative data. Deacon, Bryman, and Fenton (1998) contend that triangulation is a process of verifying findings from qualitative and quantitative research. The first phase qualitatively identified the variables that influence willingness to participate in HIV vaccine trials among an adolescent sample. Table 4.1 below contains the themes identified in Chapter Three above as facilitators of HIV vaccine trial participation. I selected themes to include in the survey after careful consideration of prior research as well as based on their ability to be measured quantitatively. Those themes which concurred with prior research on adult WTP and for which psychometric scales were available were included in the survey. I then selected appropriate psychometric measures for each of the selected themes.

Table 4.1

Themes and related measurements

Theme	Psychometric measure	Reference
I'll be part of the people who make the change	Generative Altruism Scale	Büssing, Kerksieck, Günther, & Baumann (2013)
Risk behaviour	Sexual Risk Behaviour	
Leaders will participate	Roets Scale for Leadership	Roets (1986)
Personality characteristics	Big Five Inventory	John, Donahue, & Kentle (1991)
Social status as a consideration for trial participation	Living Standards Measure	Haupt (2012)

I could not contact seven of the focus group discussion participants and thus piloted these scales with the 18 of the original 25 participants who had participated in my focus group discussions who were available. Given that I had not yet received permission from the Gauteng Department of Education to access learners at schools, I wanted to determine at least internal consistency before commencing with my survey.

Yurdugül (2008) argues that a minimum of n=30 is required to determine reliabilities. However, within the limitations of this study, attaining 30 participants for the pilot study with ethical approval was not possible. I report on the reliabilities in section 4.1.3. below.

The second phase of this study quantitatively determined whether sensation seeking moderated or mediated the relationship between each of altruism, sexual risk behaviour, leadership potential, personality attributes and socio-economic status and willingness to participate, or whether it acted indirectly to affect willingness to participate in HIV vaccine trials.

4.1. Methods

4.1.1. Ethics

The second phase of this study used a quantitative cross-sectional survey methodology. I applied for, and received, ethical clearance from the University of the Witwatersrand's Human Research Ethics Committee (Medical). I then requested permission to conduct research in High Schools in Soweto from the Gauteng Education Department and the relevant schools' governing bodies and principals. For participants younger than 18, participants' parents were asked to complete an

informed consent form and these participants completed an adolescent consent form. Participants older than 18 completed and signed their own informed consent forms. To ensure anonymity of survey participants, I recorded no identifying details such as name and school attended. To ensure confidentiality during the completion of the survey, no teachers were allowed in the venue where participants were completing the survey.

4.1.2. Sampling

The sampling frame was adolescents who attended high schools in the communities targeted for HIV vaccine trials in Soweto. There are 62 high schools in Soweto. I used purposive sampling to identify high schools in Soweto that had previously been included in research conducted by the Perinatal HIV Research Unit (PHRU). I chose to work only with schools that had had some contact with the PHRU since students at these schools might have had more information about HIV vaccine clinical trials than those students at schools who had not had any contact with the PHRU. After I had contacted the principals of the seven schools identified by staff members at the PHRU, five schools' principals agreed to allow me to collect data from their students and two declined. The principals who declined gave no reasons for declining.

The principals of each of the five schools arranged a designated teacher with whom I could liaise regarding my research. I requested access to either Grade 10 or grade 11 learners. I asked for access to approximately 100 learners at each school and based on each school's class size I was allowed to address either three or four classes. I also asked that I have an information session with learners in the week prior to administering the survey.

At each school, I spoke to learners about my research in their classes for between 45 and 60 minutes and explained what my research entailed, what I expected of them should they agree to participate, and what their rights as research participants were. I emphasised that I was not recruiting for an HIV vaccine trial and that they would not be expected to be part of such an HIV vaccine trial for this study. I handed all learners informed consent forms (see Appendix A). I asked learners under 18 to request their parents' informed consent if they wanted to participate. Learners who were older than 18 years old completed the informed consent forms themselves. I asked learners to take the informed consent forms home and return the forms the following week.

In the second week, I administered a questionnaire containing demographic questions as well as a battery of psychometric instruments in a group setting (see Appendix C), at a time convenient to each school, at each of the identified schools. The week in which I administered my survey was also the last week of the third term of school and since there was no teaching during this week, I was allowed to administer the survey during school hours. I requested that the teachers not be present in both the information sessions and the administration of the survey. At some schools, I was able to administer the survey to all the learners at the school in one venue, while at others the survey was administered in each class.

INCLUSION CRITERIA

Inclusion criteria for the study were:

1. Adolescents aged between 14 and 24 years.
2. Residing inside communities targeted for HIV vaccine trials in Soweto.
3. Attending school.

EXCLUSION CRITERIA

Exclusion criteria for the proposed study was:

1. Older than 25 or younger than 14 years of age

4.1.3. Research Instruments

The survey included instruments based on the results from the qualitative data. The survey consisted of a demographics section that asked the participants' age, gender, first language, race, whether they knew anyone who has or had HIV and whether they had been involved with anything related to HIV vaccines. The psychometric instruments included in the survey were the Clinical Research Involvement Scale (CRIS), Brief Sensation Seeking Scale (BSSS), a Sexual Risk Behaviour (SRB) scale, the Big Five Inventory (BFI), the Generative Altruism Scale (GAS), the Roets Rating Scale for Leadership (RRSL) and the Universal Living Standards Measure (SU-LSM). Huysamen (1996) argues that reliability coefficients of .85 and higher are necessary to make decisions about individuals and reliability coefficients of 0.60 and higher are necessary to make decisions about groups.

4.1.3.1. Clinical Research Involvement Scale (CRIS)

The Clinical Research Involvement Scale (CRIS) of Frew et al. (2010) was used to assess willingness to participate (WTP) in a hypothetical HIV vaccine clinical trial. Frew et al. (2010) argue that the CRIS can be used in any biomedical research trial, but used a version of their scale for use in HIV vaccine clinical trials. I was thus able to use their scale in the same context of HIV vaccine clinical trials as the context in which it was developed. The scale used Likert-type scale items that asked participants to select one of five options ranging from 1=strongly agree to 5=strongly

disagree for each of the 41 items. The total score ranged from a minimum of 41 to a maximum of 205. Higher scores indicated greater willingness to participate. The scale could be used both summatively where all 41 items are summed or by using any of the eight subscales: Behavioural Beliefs (7 items); Outcome Evaluation (5 items); Normative Beliefs (6 items); Motivation to Comply (5 items); Attitude (5 items); Subjective Norms (3 items); Organizational Involvement (3 items); and Personal Relevance (7 items). Reliabilities are reported in Table 4.2 below. Frew et al. (2010) reported Cronbach's α reliability in their representative sample of inhabitants of Atlanta, Georgia of: Behavioural Beliefs (.85); Outcome Evaluation (.81); Normative Beliefs (.78); Motivation to Comply (.82); Attitude (.73); Subjective Norms (.85); Organizational Involvement (.80); and Personal Relevance (.92). Frew et al. (2010) did not report on reliability for the overall scale.

The pilot data indicated good reliability for the overall scale (Cronbach's α .86) as well as the behavioural beliefs (Cronbach's α .87), subjective norms (Cronbach's α .869), and personal relevance (Cronbach's α .82) subscales. The organizational involvement subscale indicated acceptable reliability (Cronbach's α .67). The other subscales showed questionable reliability (Cronbach's α < .60).

In the final dataset the reliability for the overall scale remained good (Cronbach's α .84) while the reliability for the behavioural beliefs (Cronbach's α .69), subjective norms (Cronbach's α .72), and personal relevance (Cronbach's α .76) subscales ranged from acceptable to reasonably good. The remaining subscales showed questionable reliability (Cronbach's α < .60) and were excluded form all further analyses.

4.1.3.2. Sensation Seeking Scale (SSS)

In the development of the Sensation Seeking Scale (SSS) Zuckerman (1994) identified four constructs that contribute to the concept of sensation seeking, namely: i) Thrill and adventure seeking; ii) Experience seeking; iii) Disinhibition; and iv) Boredom susceptibility. Hoyle, Stephenson, Palmgreen, Lorch, and Donohew (2002) built on the work of Zuckerman (1994) to construct an eight-item Brief Sensation Seeking Scale (BSSS) that accesses the same four constructs. The scale used Likert-type scale items that asked participants to select from five options from 1=strongly disagree to 5=strongly agree for each of the eight items. Total scores ranged from a minimum total scale score of 8 and a maximum scale score of 40. Higher scores indicate greater propensity to seek out novel and stimulating sensations. The BSSS exhibited an overall reliability score in American youth of .76 (Hoyle et al., 2002). This 8-item scale showed good reliability (Cronbach's α .80) in the pilot data and acceptable reliability in the final dataset (Cronbach's α .62).

4.1.3.3. Sexual Risk Behaviour Scale

Sexual Risk Behaviour was assessed with a scale that had been used in prior research conducted with adolescent girls (Kafaar, Van Wyk, & Mohammed, 2012). The scale used 25 Likert-type scale items that asked participants to select from six options from 1=Always to 6=Never for each of the 25 items that resulted in a minimum total scale score of 25 and a maximum scale score of 150. Higher scores indicated lower levels of sexual risk behaviour. Kafaar et al. (2012) report Cronbach's α of .75 in their sample of University students. In the present study the scale displayed excellent reliability in both the pilot (Cronbach's α .95) and final datasets (Cronbach's α .94).

4.1.3.4. The Big Five Inventory (BFI)

Personality attributes were measured according to the five-factor model that is commonly used in personality research (John, Naumann, & Soto, 2008; John & Srivastava, 1999). The Big Five Inventory (BFI) of John, Donahue, and Kentle (1991) was used to measure the following five factors: extraversion; agreeableness; conscientiousness; neuroticism; and openness. The BFI consisted of 44 statements and asked participants to indicate the extent to which they agreed with each statement on a 5-point Likert-type scale, ranging from 1=strongly disagree to 5=strongly agree. The BFI scores range from a minimum of 44 to a maximum of 176.

Hassan (2014) reported Cronbach's alpha reliabilities from a South African cross-sectional non-clinical sample as follows: extraversion (.84); agreeableness (.70); conscientiousness (.84); neuroticism (.83); and openness (.67). In this study, the pilot data indicated acceptable reliability for extraversion (Cronbach's α .63), agreeableness (Cronbach's α .76) and conscientiousness (Cronbach's α .66) with questionable reliability for neuroticism and openness (Cronbach's α < .50). However, in the main study, none of the subscales had adequate reliability in the final dataset (Cronbach's α < .50). They were therefore excluded from all analyses.

4.1.3.5. Generative Altruism Scale (GAS)

Altruism was measured with the Generative Altruism Scale (GAS) of Büssing, Kerksieck, Günther, & Baumann (2013) that measured the affective and behavioural elements of altruism. Büssing et al. (2013) defined generative altruism as the pleasure derived from promoting the well-being and success of another. The 7-item scale used 4-point Likert-type scale items that range from 0=Never to 3=Very Often for each of the seven items that resulted in a minimum total scale score of 0 and a

maximum scale score of 21. Higher scores indicated greater altruism. The scale is scored summatively. Büssing et al. (2013) reported Cronbach's α of .81 in their sample of late adolescents in Germany. In this study the scale indicated good reliability in the pilot data (Cronbach's α .82) and reasonably good reliability in the final dataset (Cronbach's α .75).

4.1.3.6. Roets Rating Scale for Leadership (RRSL)

Leadership capacity was measured by the Roets Rating Scale for Leadership (RRSL) as developed by Roets (1986). While the scale has no sub-scales, Roets (1986) argued that the scale is based on the themes (and included items that measured) project planning, achievement, debate-discussion and leadership language. The RRSL comprised of 26 5-point Likert-type scale items that ranged from 1=almost always to 5=never for each of the 26 items that resulted in a minimum total scale score of 26 and a maximum scale score of 130. Higher scores indicated less leadership. Roets (1986) reported a reliability coefficient of .85 in their sample of teenagers in the continental USA. Chan (2000) reported a similar reliability of .88 in his sample of teenage students in Hong Kong. In this study the scale indicated good reliability in the pilot data (Cronbach's α .83) and excellent reliability (Cronbach's α .89) in the final dataset.

4.1.3.7. SAARF Universal Living Standards Measure (SU-LSM)

The final instrument in the survey was the South African Audience Research Foundation's (SAARF) Universal Living Standards Measure (SU-LSM) that measured socio-economic status according to the presence or absence of products or services in the household (http://saarf.co.za/LSM/lsms.asp). The LSM is scored by adding a weight to each true answer and then summing each of these weights. The

total score is then used to determine which of the 10 categories each case qualifies for. Higher scores indicate a higher standard of living. The LSM was developed by SAARF in 1989 as a segmentation tool and has been continuously developed since then, with items being added or removed from the original 13-item scale as the instrument was developed to the current 29-item true/false scale that is currently in use (Haupt, 2012). While Haupt (2012) claims that the SU-LSM is reliable, I could find no published data to confirm this. In this study however, the SU-LSM indicated good reliability in the pilot data (Cronbach's α .81) and the final dataset (Cronbach's α .86).

Table 4.2

Pilot and Final Reliability Data for all Instruments

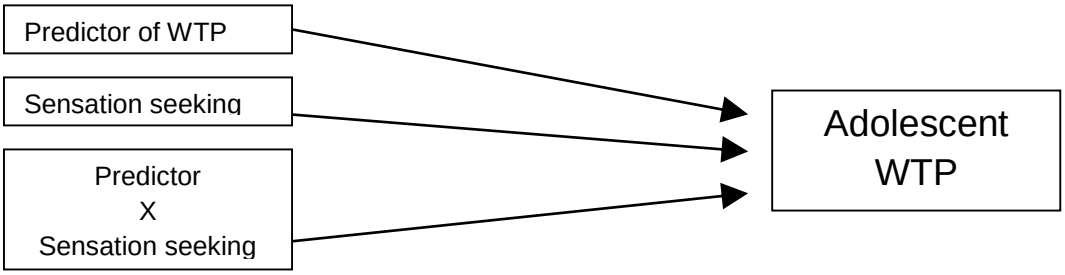
Survey Section	No. of Items	Scales	Pilot reliability	Reliability
Demographics	8	Demographics		
A	8	Brief Sensation Seeking Scale	0.796	0.620
		Clinical Research Involvement Scale	0.857	0.841
B	7	Behavioural Beliefs	0.873	0.686
C	5	Outcome Evaluation	0.589	0.522
D	6	Normative Beliefs	0.408	0.552
E	5	Motivation to Comply	0.506	0.406
F	5	Attitude	0.593	0.573
G	3	Subjective Norms	0.869	0.719
H	3	Organizational Involvement	0.671	0.552
I	7	Personal Relevance	0.815	0.763
J	28	Sexual Risk Behaviour	0.948	0.941
K	44	Big Five Inventory		
		Extraversion	0.630	0.442
		Agreeableness	0.755	0.451
		Conscientiousness	0.657	0.468
		Neuroticism	0.366	0.384
		Openness	0.446	0.530
L	7	Generative Altruism Scale	0.819	0.752
M	26	Roets Scale for Leadership	0.826	0.892
N	29	Living Standards Measure	0.807	0.863

4.1.4. Data analysis

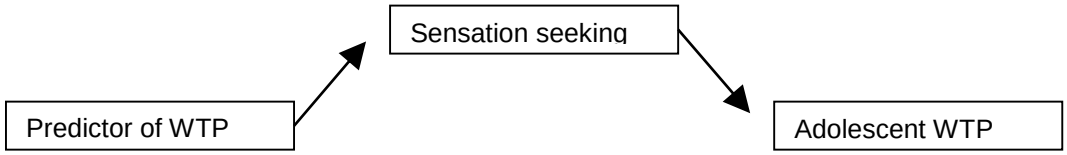
I entered the quantitative data into SPSS (Statistical Package for Social Sciences) and conducted initial descriptive analyses as well as co-efficient Alpha's for each of the relevant scales. I determined correlation coefficients between all the variables and conducted five univariate linear regression analyses with WTP as dependent variable and sensation seeking, SRB, altruism, leadership and socioeconomic status as individual independent variables.

As mentioned in Chapter Two above, sensation seeking peaks in adolescence (Llewellyn, 2003). One of the components of sensation seeking is boredom susceptibility. Given the long duration (up to 18 months) of HIV vaccine clinical trials, individuals who score high on sensation seeking measures may be lost to follow-up. Product-term multiple regression analysis was utilised to determine whether sensation seeking as a third variable moderates, mediates or indirectly affects adolescent WTP.

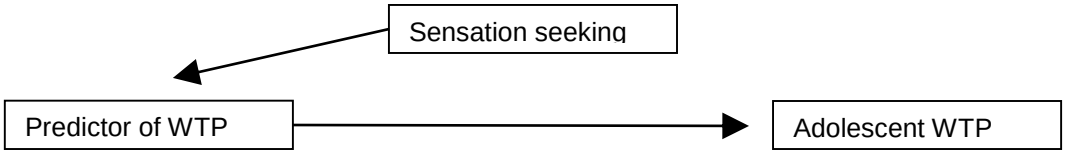
The moderating function of third variables occurs when the predictor and third variable interact to influence the dependent variable. Mediation occurs when the predictor operates through the third variable. Indirect function of the third variable occurs when the third variable affects the predictor without directly influencing the dependent variable (Pretorius, 2007). I illustrate the roles of third variables in Figure 4.1 below.



a) Moderator effect – sensation seeking interacts with the predictor of adolescent WTP to influence WTP



b) Mediator effect – sensation seeking acts as the mechanism through which the predictor of adolescent WTP affects WTP.



c) Indirect effect – sensation seeking leads to the interpretation of the predictor of adolescent WTP in a certain way, which in turn affects WTP.

Figure 4.1. Illustration of moderator, mediator and indirect effects of third variables

4.2. Results

Given the reliability data in Chapter Three, the following section will only speak to the following scales: the Clinical Research Involvement Scale (CRIS) including the behavioural beliefs (CRIS-BB), subjective norms (CRIS-SN) and personal relevance (CRIS-PR) subscales, the Brief Sensation Seeking Scale (BSSS), the Sexual Risk Behaviour scale (SRB), the Generative Altruism Scale (GAS), the Roets Rating Scale for Leadership (RRSL) and the SAARF Universal Living Standards Measure (SU-LSM).

4.2.1. Sample

I collected data from 467 students in Grade 10 and 11 at five high schools in Soweto. Table 4.3 below shows the demographic data for the sample. The average age for the sample was 16.75 years with a standard deviation of 1.24 years. Of those who indicated their gender, 143 (31.15%) self-identified as male while 316 (68.85%) self-identified as female. The large percentage of females in this sample is accounted for by the fact that one of the schools is a girl's only school. The home language most often reported in this sample was isiXhosa (n=114, 23.80%) followed by Sesotho (n=101, 21%) and isiZulu (n=87, 18.10%).

Table 4.3

Language

Language	Frequency	Percent	Valid %	Cumulative %
Afrikaans	6	1.3	1.3	1.3
English	26	5.4	5.5	6.8
IsiNdebele	9	1.9	1.9	8.7
IsiXhosa	114	23.8	24.1	32.8
IsiZulu	87	18.1	18.4	51.2
Sepedi	11	2.3	2.3	53.5
Sesotho	101	21.0	21.4	74.8
Setswana	17	3.5	3.6	78.4
SiSwati	1	.2	.2	78.6
Tshivenda	33	6.9	7.0	85.6
Xitsonga	68	14.2	14.4	100.0
System Missing	7	1.5		
Total	480	100.0		

4.2.2. Regression analyses

4.2.2.1. Assumptions of regression analyses

Osborne and Waters (2002) argue that there are four assumptions that a researcher needs to test before conducting multiple regression analyses. These assumptions are: that the variables are measured reliably; that the variables are normally distributed: that there is a linear relationship between the independent and dependent variable; and that the independent variable is homoscedastic. Homoscedasticity refers to the uniformity of the variance of errors in the DV across all levels of the IV (Osborne & Waters, 2002). Table 4.2 above indicates that the CRIS, BSSS, SRB, GAS, RRSL and SU-LSM display adequate reliability.

Bulmer (1979) argues that a good rule of thumb for skewness is as follows: skewness values < -1 and > 1 indicate highly skewed data; skewness values

between -1 and -.5 or between 1 and .5 indicate moderately skewed data and; skewness values between -.5 and .5 indicates approximately symmetric data. As is evident in Table 4.4 below, CRIS-BB, CRIS-SN, SRB and RRSL were moderately skewed while CRIS, CRIS-PR, BSSS, GAS and SU-LSM were approximately symmetric. All the scales were thus normally distributed.

Table 4.4

Skewness

	CRIS	CRIS-BB	CRIS-SN	CRIS-PR	BSSS	SRB	GAS	RRSL	SU-LSM
Skewness	-.261	-.673	-.785	-.461	.216	-.841	.447	.884	-.470
SE of skewness	.137	.118	.115	.118	.122	.255	.117	.124	.111

The test to determine whether a linear relationship exists between the IV and DV and the test for homoscedasticity both require an examination of the plot of the standardized residuals by the regression standardized predicated values (Osborne & Waters, 2002). In order to verify linearity, a visual examination of the plots should show no obvious deviation from a linear relationship as one might find in a curvilinear relationship. Applying a fit line to the scatterplot assists in this regard while at the same time allowing me to see whether the plots were evenly distributed around the line, randomly scattered about the line, and thus homoscedastic. From Figure 4.2 below one can see that the scatterplot is both linear and homoscedastic.

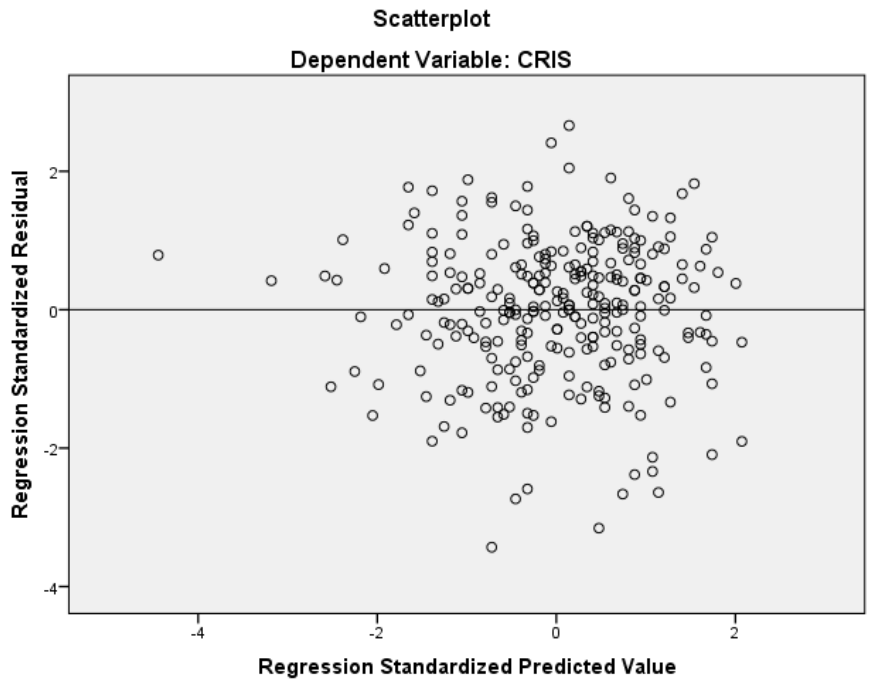


Figure 4.2. Scatterplot of standardized residuals by the regression standardized predicted values

The scales in the analyses thus satisfied all four requirements of Osborne and Walters (2002) and I thus used these scales in regression analyses.

4.2.2.2. Regression analyses

In order to determine the third variable effects of sensation seeking on WTP, the BSSS needed to predict the CRIS in a linear regression. Similarly, each of the independent variables needed to individually predict WTP. Table 4.5 below reports the regression coefficients and the p-values for the BSSS, SRB, GAS, RRSL and SU-LSM when regressed onto CRIS.

Table 4.5

Regression Coefficients and p-values of Scales Regressed onto CRIS

	Sensation seeking (BSSS)	Sexual risk behaviour (SRB)	Altruism (GAS)	Leadership (RRSL)	SES (SU-LSM)
R^2	.001	.038	.094	.172	.000
R	.036	.194	.306	-.415	.005
p-value	.547	.114	.000**	.000**	.931

** p<.001

As is evident from Table 4.5 above, only altruism and leadership significantly predicted WTP. While altruism showed a significant positive relationship with WTP that accounted for 9.4% of the variance in WTP, leadership showed a significant negative relationship with WTP that accounted for 17.2% of the variance in WTP. Since higher GAS scores indicated greater altruism and higher RRSL scores indicated less leadership, higher levels of both altruism and leadership were associated with higher levels of being willing to participate in HIV vaccine trials.

I then examined whether any of the scales predicted any of the three reliable subscales of the CRIS, namely the CRIS-BB, CRIS-SN, and CRIS-PR.

Table 4.6

Regression Coefficients and p-values of Scales Regressed onto CRIS Sub-scales

CRIS subscale	BSSS	SRB	GAS	RRSL	SU-LSM
Behavioural Beliefs					
R^2	.010	.019	.048	.135	.006
R	.100	.137	.220	-.368	.080
p-value	.053	.234	.000**	.000**	.098
Subjective Norms					
R^2	.001	.013	.050	.060	.002
R	-.030	.114	.224	-.245	-.042
p-value	.559	.305	.000**	.000**	.377
Personal Relevance					
R^2	.000	.014	.034	.059	.004
R	-.002	.120	.184	-.242	-.060
p-value	.976	.284	.000**	.000**	.217

** p<.001

As is evident in Table 4.6 above, altruism and leadership consistently predicted overall willingness to participate, as well as the behavioural beliefs, subjective norms and personal relevance components of WTP. Altruism accounted for approximately 5% of the variance in behavioural beliefs and subjective norms and 3.5% of the variance in personal relevance. While leadership accounted for 13.5% of the variance in behavioural beliefs, leadership only accounted for 6% of the variance in subjective norms and personal relevance. Those individuals with high levels of leadership were thus likely to have a greater belief in their abilities.

4.2.3. Product-term regression analyses

As sensation seeking did not significantly predict willingness to participate, I could not examine the third variable effect of sensation seeking on the predictors of WTP. However, the data indicated that altruism and leadership predicted WTP. I therefore examined the relationship between altruism, leadership and WTP using product term regression.

Pretorius (2007) argues that one may test third variable effects using product-term regression analyses. To examine the role that altruism plays in the relationship between leadership and willingness to participate, two separate product-term regression analyses were conducted. The first regression analysis used WTP as the dependent variable. Leadership was entered as step one, leadership and altruism were entered together in step two, and the product of the deviation scores for altruism and leadership was entered in step three of the regression analysis. The second regression analysis differed only in that altruism was entered in the first step in place of leadership. The results of these analyses are presented in Table 4.7 below. The product term of altruism and leadership was non-significant indicating no

interaction and thus no moderating effect. In both regression analyses, both leadership and altruism remained significant predictors of WTP indicating that there was no mediating or indirect effect. Altruism and leadership thus both had a direct effect on WTP. Increasing leadership skills will thus increase WTP regardless of the levels of altruism and vice versa.

Table 4.7

Product Term Regression Analyses using Willingness to Participate as Outcome, and Leadership and Altruism as Predictors

	df	Cum. R^2	t-value	Beta	p-value
First regression					
Step 1					
Leadership	273	.18	-7.7	-.42	.000**
Step 2					
Leadership	272	.19	-5.56	-.35	.000**
Altruism	272	.19	2.162	.14	.032*
Step 3					
Leadership X Altruism	271	.19	-.47	-.03	.642
Second regression					
Step 1					
Altruism	273	.1	5.53	.32	.000**
Step 2					
Altruism	272	.19	2.16	.14	.032*
Leadership	272	.19	-5.56	-.352	.000**
Step 3					
Leadership X Altruism	271	.19	-.47	-.03	.642

* p<.05; ** p<.001

In conclusion, I have shown that the only reliable predictors of willingness to participate in this sample were leadership and altruism. Altruism and leadership directly affected WTP without influencing each other. Greater levels of altruism increased willingness to participate and similarly greater levels of leadership increased WTP.

4.3. Discussion

My aims with this study were twofold: 1) to qualitatively determine the variables that affect willingness to participate in HIV vaccine trials among adolescents; and 2) to evaluate how sensation seeking as a third variable influenced the relationship between the predictors of adolescent willingness to participate, and adolescent WTP. In Chapter Three, I presented the themes that affects adolescent WTP and in the present chapter, I explained how I used those themes to select psychometric instruments able to measure the selected themes from Chapter Three.

One of the first problems I encountered was the lack of reliability of all of the subscales of the BFI that measured personality attributes, as well as certain subscales of the CRIS that measured willingness to participate. Given the lack of reliability, I could not use the BFI or the outcome evaluation, normative beliefs, motivation to comply, attitude, and organisational involvement subscales of the CRIS.

The second problem I encountered was that with the exception of leadership and altruism, no other scales statistically predicted willingness to participate. As my chosen third variable, sensation seeking, did not predict WTP at all, I chose to determine whether leadership and altruism mediated, moderated or worked indirectly with each other in their relationship with WTP.

The fact that altruism predicts willingness to participate in adolescents concurs with similar findings internationally (Koblin et al., 1998; MacQueen et al., 1999; Sahay et al., 2005; Sengupta et al., 2000; Strauss et al., 2001) as well as in South Africa (Jaspan, Berwick, et al., 2006; Lesch et al., 2006). The national qualitative study conducted by Lesch et al. (2006) most closely approximates the context that

participants in this study will have experienced, with the exception that this study's participants were adolescents and Lesch et al. (2006) had adult participants. While Jaspan, Berwick, et al. (2006) conducted their research with an adolescent sample from a peri-urban Xhosa-speaking community near Cape Town, the sample in the present study was mixed in terms of language and residence in Gauteng. Both Jaspan, Berwick, et al. (2006) and Lesch et al. (2006) report on qualitative findings that link altruism with being willing to participate in HIV vaccine clinical trials. The present study is the first that I know of that statistically determined that altruism predicts willingness to participate in an HIV vaccine clinical trial using psychometric scales.

As mentioned in the discussion of Chapter Three above, Swartz et al. (2006) report that participants in their study felt that real community leaders should lead by example and participate in HIV vaccine clinical trials. The adolescent participants in this study concurred and argued that leaders, or those who showed leadership potential, would be more likely to participate in HIV vaccine clinical trials. The statistical analysis supported the qualitative data, and showed that leadership potential significantly predicted willingness to participate in hypothetical HIV vaccine clinical trials. I could not find any other study that reported leadership or leadership potential as a predictor of willingness to participate in HIV vaccine clinical trials for either adults or adolescents.

4.4. Conclusion

In contrast to concerns raised by Swartz et al. (2005) that adolescents may be influenced by the novelty of the experience of participating in an HIV vaccine trial, as well as the bravado of trying untested products, this study has shown that there is a

non-significant relationship between sensation seeking and adolescent willingness to participate in adolescents living in communities that are targetted for HIV vaccine trial enrolment in Soweto, Gauteng. In keeping with international and South African literature, altruism and leadership potential predicted adolescent willingness to participate independently of each other.

Chapter Five

Reflections

5.1. Context

The genesis of this study can be traced back to work that I was involved with for the South African AIDS Vaccine Initiative (SAAVI). In 2005 Professors Leslie Swartz and Ashraf Kagee employed Ms. Anthea Lesch and I to work as researchers for the Socio-behavioural Working Group of SAAVI. This group was tasked with promoting social and behavioural research linked to HIV vaccine clinical trials and to help improve social and behavioural scientific research at HIV clinical trial sites run by SAAVI. In addition to the above-mentioned tasks, we also conducted our own research (e.g., Lesch et al., 2006) and wrote conceptual papers (e.g., Kafaar, Kagee, et al., 2007). One of the earlier conceptual papers we wrote raised the concern that sensation seeking may affect adolescent willingness to participate (Swartz et al., 2005). At that stage, no adolescents had been included in any HIV vaccine clinical trials. With the advent of the Phambili study in 2005 (South African AIDS Vaccine Initiative, 2007b) researchers started to turn their attention to the inclusion of adolescents in HIV vaccine clinical trials (e.g. Jaspan, Berwick, et al.,2006; Jaspan, Lawn, et al., 2006; Kafaar, Swartz, et al., 2007; Middelkoop, et al., 2008). This study thus evolved from all of the above publications, with special emphasis from Swartz et al. (2005), Kafaar, Kagee, et al. (2007) and Kafaar, Swartz, et al. (2007).

In reviewing the literature, I have shown that although there was a period in which the prevalence of HIV stabilised (Shisana et al., 2009), more recent data raises concerns about the progress of the HIV epidemic. Shisana et al. (2014) report an

increase in the percentage of 15-24 year olds who report their age of sexual debut as younger than 15, a decrease in condom usage with a concomitant significant increase in prevalence overall. One of the strategies that seem promising in the efforts to reduce new HIV infections is the development of an effective HIV vaccine (Jaspan, Lawn, et al., 2006). Since a vaccine will need to be administered before exposure to the virus, vaccination of adolescents will become a necessity. Jaspan, Lawn, et al. (2006) argue that this in turn will necessitate HIV vaccine clinical trials with adolescent participants. However, we know very little about adolescent willingness to participate in HIV vaccine clinical trials. This study therefore aimed to determine qualitatively, what adolescents thought the barriers to and facilitators of willingness to participate in HIV vaccine clinical trials were, and then statistically determine the role that sensation seeking played in the relationship between the facilitators of adolescent willingness to participate, and adolescent WTP.

5.2. Studies

The data I gathered through the three focus group discussions I conducted with the members of the adolescent community advisory board of the PHRU were analysed thematically and resulted in five barriers to, and 11 facilitators of adolescent willingness to participate in a hypothetical HIV vaccine trial as is evident in Table 3.1 above. Barriers to participation in an HIV vaccine clinical trial were admitting sexual activity to an older individual, difficulty in agreeing to participate, potential side effects of the candidate vaccine, parents concerns for their children and stigma. The qualitative analysis both confirms that some of the adult barriers to participation in HIV vaccine clinical trials are true for adolescents (e.g., side effects) but also introduces unique barriers to participation for adolescents. Barriers to participation that are unique to adolescents are the concerns that parents may have in allowing

their children to participate in an HIV vaccine clinical trial and that adolescents will have to admit to being sexually active to an adult in order to participate in an HIV vaccine clinical trial.

Facilitators of participation in an HIV vaccine clinical trial were the perceived safety of the candidate vaccine, the potential rewards participation would provide, how salient the HIV epidemic was to potential participants, positive peer pressure, the social status of participants' families of origin, personality characteristics, congruent messages across different components of communities, increased information, individuals who engaged in risk behaviour, individuals who were altruistic and those who showed leadership or leadership potential. The thematic analysis confirmed that many of the adult facilitators were true for adolescents (e.g., safety of the candidate vaccine) but also introduced two unique facilitators. The adolescents in this study identified congruent messages across various components of communities as a facilitator of participation in HIV vaccine clinical trials and identified that the indirect health benefits of trial participation such as regular medical check-ups could possibly increase willingness to participate in HIV vaccine clinical trials for adolescents.

After careful consideration of prior research as well as whether psychometric scales existed to measure the themes, I selected five themes to include in the survey in addition to willingness to participate in an HIV vaccine clinical trial and sensation seeking. I measured these themes as follows: 1) Altruism with the Generative Altruism Scale of Büssing et al. (2013); 2) Sexual risk behaviour with the Sexual Risk Behaviour Scale as used by Kafaar et al. (2012); 3) Leadership with the Roets Scale for Leadership of Roets (1986); 4) Personality characteristics with the Big Five Inventory of John et al. (1991); and 5) social status with the Living Standards Measure of the South African Audience Research Foundation (Haupt, 2012).

Adolescent willingness to participate in HIV vaccine clinical trials was measured by the Clinical Research Involvement Scale (CRIS) of Frew et al.(2010), while sensation seeking was measured by Hoyle et al.'s (2002) Brief Sensation Seeking Scale (BSSS). I conducted all my statistical analyses with SPSS.

After removing those scales with inadequate internal consistency, I proceeded to determine whether the data from the psychometric scales measuring altruism, sexual risk behaviour, leadership, social status, willingness to participate and sensation seeking violated any of the assumptions of regression analysis. When none of the scales violated the assumptions of regression analysis I proceeded to run regression analyses to determine whether any of the psychometric scales predicted adolescent willingness to participate. The only variables that statistically predicted adolescent WTP was altruism and leadership. Contrary to the concern that Swartz et al. (2005) raised, sensation seeking did not predict adolescent willingness to participate in an HIV vaccine clinical trial. In the absence of sensation seeking as a third variable I then proceeded to determine whether altruism and leadership influenced each other's relationship with adolescent willingness to participate. However, leadership and altruism conformed to the international and South African literature on adult willingness to participate in an HIV vaccine trial, in that they both predicted adolescent willingness to participate in an HIV vaccine clinical trial independently of each other.

5.3. Limitations

There are a number of limitations that I would like to mention that may have adversely affected the results of this study. These limitations were evident in both the qualitative study as well as the quantitative study. One of the limitations in the qualitative study was the lack of member checks after the conclusion of the qualitative data analysis. Member checks, also known as respondent validation, may have increased the credibility and transferability of these results. The selection of the adolescent CAB members for my focus group discussions was both useful and detrimental. The focus group discussion participants were useful in the sense that adolescent CAB members were mostly well informed about HIV, vaccines and clinical trials and were thus the ideal information-rich participants to determine what the barriers to, and facilitators of adolescent willingness to participate in HIV vaccine trials were. However, the adolescent CAB members did not accurately reflect the average adolescent in Soweto who may not have had access to the same quantity and quality of information regarding HIV vaccine clinical trials as the adolescent CAB members had. I attempted to mitigate this difference through only selecting schools for the survey that the PHRU had had some contact with but this may not have been sufficient.

In the quantitative study, I purposively selected schools based on their exposure to the PHRU and consequently lost generalizability to the population of Soweto high schools in attempting to match the schools to the adolescent CAB. I could have conducted longer information and educational sessions regarding HIV, vaccines and clinical trials with randomly selected schools in Soweto but after such sessions those schools would also not have been representative of the majority of high schools in

Soweto. This limitation seems insurmountable at present, unless all schools in Soweto receive the same information and education sessions.

Finally, the survey that I administered was available only in English, which probably influenced the internal consistency as can be seen by the low Cronbach's alphas in Table 4.2 above. The linguistic diversity evident in Soweto, as well as the preference for English as a second language subject at high schools in Soweto, led me to believe that administering an English survey to grade 10 and grade 11 learners would be manageable if I was available to explain concepts or terms that learners might struggle with. While I did not receive many such requests, it may well be that learners were too intimidated to ask.

5.4. Recommendations

The field of social and behavioural factors influencing adolescent willingness to participate in HIV vaccine clinical trials is a novel and relatively under-researched field. It is also hampered by the lack of actual adolescent HIV vaccine clinical trials. All the studies currently published, including this one, have determined hypothetical willingness to participate in adolescents. While hypothetical willingness to participate provides useful insights into what may occur in potential HIV vaccine clinical trials, what may be more useful is to conduct more studies such as the REACH study (Wilson et al., 2001). Such a mock trial could require adolescents to commit to all the requirements of participation in an HIV vaccine clinical trial (blood draws, regular HIV testing and counselling, injections of a placebo, etc.) over an extended period of time and will most likely give the best indication of the factors influencing adolescent involvement in HIV vaccine clinical trials.

5.5. Conclusion

This study qualitatively determined the barriers and facilitators to adolescent WTP and triangulated quantitatively by means of a survey which variables predicted adolescent WTP and what role sensation seeking plays. Of the factors qualitatively identified as affecting WTP, altruism, sexual risk behaviour, leadership, personality characteristics, social status, WTP and sensation seeking were included in a survey. Regression analyses identified that altruism and leadership predicted adolescent WTP independently of each other. Sensation seeking therefore did not predict adolescent WTP.

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Appendix A

Informed consent form

PARENT INFORMATION LEAFLET AND CONSENT FORM

TITLE OF THE RESEARCH PROJECT:

Predicting adolescent willingness to participate in HIV vaccine trials: the role of sensation seeking.

REFERENCE NUMBER: N08/08/217

PRINCIPAL INVESTIGATOR: Zuhayr Kafaar

ADDRESS:

Room 212, Wilcocks Building,

c/o Ryneveld and Victoria Streets,

Stellenbosch

CONTACT NUMBER: 083 411 5228

You are being invited to take part in a research project. Please take some time to read the information presented here, which will explain the details of this project. Please ask the study staff or doctor any questions about any part of this project that you do not fully understand. It is very important that you are fully satisfied that you clearly understand what this research entails and how you could be involved. Also, your participation is **entirely voluntary** and you are free to decline to participate. If you say no, this will not affect you negatively in any way whatsoever. You are also free to withdraw from the study at any point, even if you do agree to take part.

This study has been approved by the Committee for Human Research at Stellenbosch University **and will be conducted according to the ethical guidelines and principles of the international Declaration of Helsinki, South African Guidelines for Good Clinical Practice and the Medical Research Council (MRC) Ethical Guidelines for Research.**

What is this research study all about?

This study will be conducted in the greater SOWETO area, and will include at completion, between 200 and 400 participants.

The research aims to determine what would influence adolescents' willingness to be part of an HIV vaccine trial. I will attempt to answer this research question both by talking to adolescents in groups as well as by asking them to answer a set of questions in a survey.

You will be asked to be part of a group discussion with 6-11 other young people. I will be asking you what you think will encourage you and other young people like yourself to participate in an HIV vaccine trial and what will discourage them and yourself from participating in an HIV vaccine trial. The discussion should last between 45 minutes and an hour and a half.

Alternatively, you will be asked to complete a set of pen-and-paper questions related to HIV vaccine trial participation which should take no longer than 45 minutes to complete.

Why have you been invited to participate?

I have asked you to participate in this study since you live in an area which has been identified as a potential site for the testing of an HIV vaccine.

What will your responsibilities be?

The only requirement I would like to ask is that you be honest in your responses.

Will you benefit from taking part in this research?

While there will be no immediate benefit to you personally, your responses will assist in the smooth implementation and conduct of HIV vaccine trials in your neighbourhood.

Are there in risks involved in your taking part in this research?

There are no risks involved in this study.

If you do not agree to take part, what alternatives do you have?

Not applicable.

Who will have access to your medical records?

No medical records will be used.

What will happen in the unlikely event of some form of injury occurring as a direct result of your taking part in this research study?

There is no risk of injury to you in this study.

Will you be paid to take part in this study and are there any costs involved?

No, you will not be paid to take part in the study but your transport and meal costs will be covered for each study visit. There will be no costs involved for you, if you do take part.

Is there anything else that you should know or do?

While the results of the study will be made public, as well as be published, please be assured that this will be accomplished without compromising your confidentiality

You can contact the Committee for Human Research at 021-938 9207 if you have any concerns or complaints that have not been adequately addressed by the researcher.

You will receive a copy of this information and consent form for your own records.

Declaration by participant or parent in the case of minors

By signing below, I ……..……. on behalf of myself/my son/my daughter, agree to take part in a research study entitled *Predicting adolescent willingness to participate in HIV vaccine trials: the role of sensation seeking*.

I declare that:

I have read or had read to me this information and consent form and it is written in a language with which I am fluent and comfortable.

I have had a chance to ask questions and all my questions have been adequately answered.

I understand that taking part in this study is **voluntary** and I have not been pressurised to take part.

I may choose to leave the study at any time and will not be penalised or prejudiced in any way.

I may be asked to leave the study before it has finished, if the study doctor or researcher feels it is in my best interests, or if I do not follow the study plan, as agreed to.

Signed at (*place*) .SOWETO.....…….. on (*date*) ……3rd October 2012.

Signature of participant Signature of witness

……. …….

Declaration by minor

By signing below, I ……..……. agree to take part in a research study entitled *Predicting adolescent willingness to participate in HIV vaccine trials: the role of sensation seeking*.

I declare that:

I have read or had read to me this information and consent form and it is written in a language with which I am fluent and comfortable.

I have had a chance to ask questions and all my questions have been adequately answered.

I understand that taking part in this study is **voluntary** and I have not been pressurised to take part.

I may choose to leave the study at any time and will not be penalised or prejudiced in any way.

I may be asked to leave the study before it has finished, if the study doctor or researcher feels it is in my best interests, or if I do not follow the study plan, as agreed to.

Signed at (*place*) ……..…….. on (*date*) ……...

Signature of participant	Signature of witness
……..	…….

Declaration by investigator

I *(name)* …Zuhayr Kafaar…….…… declare that:

I explained the information in this document to ……..

I encouraged him/her to ask questions and took adequate time to answer them.

I am satisfied that he/she adequately understands all aspects of the research, as discussed above.

I did/did not use an interpreter. (*If an interpreter is used then the interpreter must sign the declaration below.*

Signed at (*place*) .....…… on (*date*) …….

Signature of investigator Signature of witness

…….. …….

Declaration by interpreter

I *(name)* ……..…… declare that:

I assisted the investigator (*name*) ……. to explain the information in this document to (*name of participant*)
……..…….. using the language medium of
……...

We encouraged him/her to ask questions and took adequate time to answer them.

I conveyed a factually correct version of what was related to me.

I am satisfied that the participant fully understands the content of this informed consent document and has had all his/her question satisfactorily answered.

Signed at (*place*) .....…..…….. on (*date*) ……...…….. 2012.

Signature of interpreter	Signature of witness
…….	…….

Appendix B

Focus group interview schedule

Introduction:

- Self
- SAAVI
- Project/Study
  - Aim
  - What are we trying to access. ***<u>This exercise is not a recruitment for a vaccine trial.</u>***

1. What is your understanding of what a vaccine does?

   Probe: *a)* *Difference between ART and vaccine?*
   b) *Other diseases that can be vaccinated*
   c) *Similarity between child inoculations and HIV vaccines*

2. Could you please explain what you understand by the term “clinical trial” i.t.o. HIV vaccines.

   Probe: *a)* *Control and experimental group*
   b) *Placebo*
   c) *Double blind*
   d) *Phases of vaccine trials*
   e) *False positive test*

3. ***<u>Repeat that this exercise is not a recruitment for a vaccine trial.</u>***

   However, if I were recruiting for a vaccine trial, what would your immediate response be?

   Probe: *a)* *Can you explain how you made that decision?*
   b) *What was your decision based on?*
   i. *Could you elaborate/expand on your personal beliefs that may have influenced your response?*

ii. *Was your decision influenced in any way by how you thought your family might react to your participation in an HIV vaccine trial? Please explain.*
Include both safety of family issues and stigma from family issues.

iii. *Was your decision influenced in any way by how you thought the community you live in might react to your participation in an HIV vaccine trial? Please explain.*
Social stigma, alienation from community, popularity in community, being shunned or ignored in community.

iv. *Could you identify issues in the way we live today (as opposed to when you were growing up) that may have influenced your decision? What about these issues influenced your decision in this way?*

v. *Would you agree that people's culture and/or their religion influences their behaviour? If Yes, how has your culture/religion influenced your response? If No, please explain.*

vi. *Is there anything else that influenced your decision that we have not mentioned yet?*

Repeat all of the above i.t.o. what your participant thinks people in his/her community will say.

REMEMBER TO PROBE FOR BOTH ISSUES THAT PROMOTE AND HINDER WTP FOR ALL OF THE ABOVE.

Appendix C

Survey

DEPARTMENT OF PSYCHOLOGY

UNIVERSITY * STELLENBOSCH * UNIVERSITEIT

Thank you for agreeing to complete this questionnaire. Please read this page carefully.

Participating in this study entails answering the questions in this questionnaire. Please answer all the questions. You are not forced to complete the questionnaire and, if you feel uncomfortable or wish to stop at any point in time, you may do so. All of the information we collect will be kept confidential and no one will see it except for the University of Stellenbosch research staff. **No one else** will see your responses to the questions. More importantly, **no one will be able to link you to the responses** to the questions in this survey.

PLEASE DO NOT SPEAK TO ANYONE WHILST COMPLETING THIS QUESTIONNAIRE.

DO NOT WRITE YOUR NAME ANYWHERE ON THIS QUESTIONNAIRE.

Demographics and background information

1. Age (in years)

2. Gender:

Male	1
Female	2

3. First Language

Afrikaans 1	English 2	IsiNdebele 3	IsiXhosa 4	IsiZulu 5	Sepedi 6
Sesotho 7	Setswana 8	SiSwati 9	Tshivenda 10	Xitsonga 11	Other 12

4. Race

(Please note that the use of racial categories is only used in the interests of research and does not imply any inherent differences or similarities)

African 1	Asian 2	Black 3	Coloured 4
Indian 5	White 6	Uncertain 7	Other 8

5. Do you know anyone that currently has, or has had HIV?

Yes	1
No	2

6. If yes, were they:

A celebrity	Yes 1	No 2
Someone in your community	Yes 1	No 2
An acquaintance	Yes 1	No 2
A friend	Yes 1	No 2
A family member who does not live with you	Yes 1	No 2
Someone who lives, or lived, in your home	Yes 1	No 2

7. Have you heard of, or been involved with anything related to HIV vaccines?

Yes	1
No	2

8. If Yes, please explain

INTEREST AND PREFERENCE SURVEY

This questionnaire has a number of questions about your interests and preferences.

There is no right or wrong answers.

It is accordingly important that you answer each question as honestly as you can.

Please mark the appropriate box with an X on the 'Survey/Answer Sheet'.

Please choose the *one* most appropriate response to each question. Mark the box on the Answer Sheet that best fits your immediate reaction. Do not spend a long time on each item: your first reaction is probably the best one. Please answer each item.

Do not worry about projecting a good image. Your answers are CONFIDENTIAL and ANONYMOUS.

Thank you for your cooperation.

SURVEY/ANSWER SHEET

Part A

1. I would like to explore strange places.

Strongly Disagree 1	Disagree 2	Neither agree nor disagree 3	Agree 4	Strongly Agree 5

2. I get restless when I spend too much time at home.

Strongly Disagree 1	Disagree 2	Neither agree nor disagree 3	Agree 4	Strongly Agree 5

3. I like to do frightening things.

Strongly Disagree 1	Disagree 2	Neither agree nor disagree 3	Agree 4	Strongly Agree 5

4. I like wild parties.

Strongly Disagree 1	Disagree 2	Neither agree nor disagree 3	Agree 4	Strongly Agree 5

5. I would like to take off on a trip with no pre-planned routes or timetables.

Strongly Disagree 1	Disagree 2	Neither agree nor disagree 3	Agree 4	Strongly Agree 5

6. I prefer friends who are excitingly unpredictable.

Strongly Disagree 1	Disagree 2	Neither agree nor disagree 3	Agree 4	Strongly Agree 5

7. I would like to try bungee jumping.

Strongly Disagree	Disagree	Neither agree nor disagree	Agree	Strongly Agree
1	2	3	4	5

8. I would love to have new and exciting experiences, even if they are illegal.

Strongly Disagree	Disagree	Neither agree nor disagree	Agree	Strongly Agree
1	2	3	4	5

Part B

1. My community would really benefit from an HIV vaccine

Strongly Disagree	Disagree	Neither agree nor disagree	Agree	Strongly Agree
1	2	3	4	5

2. My actions can inspire others to act

Strongly Disagree	Disagree	Neither agree nor disagree	Agree	Strongly Agree
1	2	3	4	5

3. My participation in an HIV vaccine study would be very good

Strongly Disagree	Disagree	Neither agree nor disagree	Agree	Strongly Agree
1	2	3	4	5

4. I benefit from health science research

Strongly Disagree 1	Disagree 2	Neither agree nor disagree 3	Agree 4	Strongly Agree 5

5. My involvement in this cause will result in more ethical research

Strongly Disagree 1	Disagree 2	Neither agree nor disagree 3	Agree 4	Strongly Agree 5

6. My involvement in this cause will improve my community's trust in medical research

Strongly Disagree 1	Disagree 2	Neither agree nor disagree 3	Agree 4	Strongly Agree 5

7. I would participate in an HIV vaccine research study because it would help to prevent AIDS

Strongly Disagree 1	Disagree 2	Neither agree nor disagree 3	Agree 4	Strongly Agree 5

Part C

1. My participation in an HIV vaccine research study would be more trouble than it's worth

Strongly Disagree 1	Disagree 2	Neither agree nor disagree 3	Agree 4	Strongly Agree 5

2. Even if I wanted to participate in an HIV vaccine research study, I just don't have the time.

Strongly Disagree 1	Disagree 2	Neither agree nor disagree 3	Agree 4	Strongly Agree 5

3. Participating in an HIV vaccine research study seems risky.

Strongly Disagree 1	Disagree 2	Neither agree nor disagree 3	Agree 4	Strongly Agree 5

4. I would participate in an HIV vaccine research study, but I don't like needles.

Strongly Disagree 1	Disagree 2	Neither agree nor disagree 3	Agree 4	Strongly Agree 5

5. I am concerned that an HIV vaccine would cause me to test positive for HIV.

Strongly Disagree 1	Disagree 2	Neither agree nor disagree 3	Agree 4	Strongly Agree 5

Part D

1. I think my doctor would approve of my involvement in HIV vaccine research.

Strongly Disagree 1	Disagree 2	Neither agree nor disagree 3	Agree 4	Strongly Agree 5

2. I think my work colleagues would approve of my involvement in this cause.

Strongly Disagree	Disagree	Neither agree nor disagree	Agree	Strongly Agree
1	2	3	4	5

3. My immediate family is supportive of my involvement in HIV vaccine research.

Strongly Disagree	Disagree	Neither agree nor disagree	Agree	Strongly Agree
1	2	3	4	5

4. Most people important to me think my involvement in HIV vaccine research is good.

Strongly Disagree	Disagree	Neither agree nor disagree	Agree	Strongly Agree
1	2	3	4	5

5. Most people important to me usually support my interests.

Strongly Disagree	Disagree	Neither agree nor disagree	Agree	Strongly Agree
1	2	3	4	5

6. If my pastor supported HIV vaccine research, I would be inclined to get involved.

Strongly Disagree	Disagree	Neither agree nor disagree	Agree	Strongly Agree
1	2	3	4	5

Part E

1. I tend to be concerned about what people think of me, even if I don't know them.

Strongly Disagree 1	Disagree 2	Neither agree nor disagree 3	Agree 4	Strongly Agree 5

2. I generally do what my family expects of me.

Strongly Disagree 1	Disagree 2	Neither agree nor disagree 3	Agree 4	Strongly Agree 5

3. I would not want to do something my friends disapproved of.

Strongly Disagree 1	Disagree 2	Neither agree nor disagree 3	Agree 4	Strongly Agree 5

4. If my superiors told me to do something I disagreed with, I would obey their wishes.

Strongly Disagree 1	Disagree 2	Neither agree nor disagree 3	Agree 4	Strongly Agree 5

5. Sometimes I do what my friends say to do, even though I know they are wrong.

Strongly Disagree 1	Disagree 2	Neither agree nor disagree 3	Agree 4	Strongly Agree 5

Part F

1. I like to do good for others.

Strongly Disagree 1	Disagree 2	Neither agree nor disagree 3	Agree 4	Strongly Agree 5

2. I like getting involved with HIV vaccine research.

Strongly Disagree 1	Disagree 2	Neither agree nor disagree 3	Agree 4	Strongly Agree 5

3. HIV is a serious concern in my immediate community.

Strongly Disagree 1	Disagree 2	Neither agree nor disagree 3	Agree 4	Strongly Agree 5

4. HIV testing is a benefit of an HIV vaccine study.

Strongly Disagree 1	Disagree 2	Neither agree nor disagree 3	Agree 4	Strongly Agree 5

5. I would benefit from the medical care associated with an HIV vaccine study.

Strongly Disagree 1	Disagree 2	Neither agree nor disagree 3	Agree 4	Strongly Agree 5

Part G

1. Most people who are important to me think I should participate in the HIV vaccine effort.

Strongly Disagree 1	Disagree 2	Neither agree nor disagree 3	Agree 4	Strongly Agree 5

2. Most people who are important to me would approve of my involvement in this cause.

Strongly Disagree 1	Disagree 2	Neither agree nor disagree 3	Agree 4	Strongly Agree 5

3. Most people who are important to me would support my interest in this cause.

Strongly Disagree 1	Disagree 2	Neither agree nor disagree 3	Agree 4	Strongly Agree 5

Part H

1. Being active with the (clinical research site) would help me to express who I am.

Strongly Disagree 1	Disagree 2	Neither agree nor disagree 3	Agree 4	Strongly Agree 5

2. Hearing that somebody else is involved with the HIV vaccine clinical research site tells me a lot about that person.

Strongly Disagree 1	Disagree 2	Neither agree nor disagree 3	Agree 4	Strongly Agree 5

3. Others would view me favourably if I volunteered for a study at the HIV vaccine clinical research site.

Strongly Disagree 1	Disagree 2	Neither agree nor disagree 3	Agree 4	Strongly Agree 5

Part I

1. Being involved with the HIV vaccine clinical research site helps me to feel empowered.

Strongly Disagree 1	Disagree 2	Neither agree nor disagree 3	Agree 4	Strongly Agree 5

2. I experience a sense of community in this cause.

Strongly Disagree 1	Disagree 2	Neither agree nor disagree 3	Agree 4	Strongly Agree 5

3. I feel a sense of belonging through my participation in this effort.

Strongly Disagree 1	Disagree 2	Neither agree nor disagree 3	Agree 4	Strongly Agree 5

4. My involvement is helping to protect the rights of others.

Strongly Disagree 1	Disagree 2	Neither agree nor disagree 3	Agree 4	Strongly Agree 5

5. I am advancing the public's health and well-being through my support of this cause.

Strongly Disagree 1	Disagree 2	Neither agree nor disagree 3	Agree 4	Strongly Agree 5

6. Getting involved in the HIV vaccine effort is liberating.

Strongly Disagree 1	Disagree 2	Neither agree nor disagree 3	Agree 4	Strongly Agree 5

7. I feel a sense of purpose in this cause.

Strongly Disagree 1	Disagree 2	Neither agree nor disagree 3	Agree 4	Strongly Agree 5

PART J

1. In the past three months have you ever had sex or engaged in sexual behaviour? (Sex is defined as penetrative sexual intercourse. Sexual behaviour includes oral sex, and hand to genital masturbation)

Yes	1
No	2

2. How many sexual partners have you had in the past three months?

0	1	2	3	4	5	More than 5

3. How old were you when you first had sex?

4. I have had more than one sexual partner at the same time.

Always	Almost Always	A lot of the time	Some of the time	Almost never	Never
1	2	3	4	5	6

5. I use condoms during sex.

Always	Almost Always	A lot of the time	Some of the time	Almost never	Never
1	2	3	4	5	6

6. I have known the person before having sex with them.

Always	Almost Always	A lot of the time	Some of the time	Almost never	Never
1	2	3	4	5	6

7. I have engaged in unplanned sexual activity.

Always	Almost Always	A lot of the time	Some of the time	Almost never	Never
1	2	3	4	5	6

8. I have had sex with someone whom I'd known for less than 48 hours.

Always	Almost Always	A lot of the time	Some of the time	Almost never	Never
1	2	3	4	5	6

9. I have had sex with someone whom I'd known for less than 1 week.

Always	Almost Always	A lot of the time	Some of the time	Almost never	Never

1	2	3	4	5	6

10. I have had a sexual partner whom I was not in a relationship with.

Always	Almost Always	A lot of the time	Some of the time	Almost never	Never
1	2	3	4	5	6

11. I have had sex with someone who has had multiple sexual partners.

Always	Almost Always	A lot of the time	Some of the time	Almost never	Never
1	2	3	4	5	6

12. I have had sex with someone that I do not trust.

Always	Almost Always	A lot of the time	Some of the time	Almost never	Never
1	2	3	4	5	6

13. I have had sex with someone who was also engaging in sex with others during the same period.

Always	Almost Always	A lot of the time	Some of the time	Almost never	Never
1	2	3	4	5	6

14. I have gotten so drunk that I couldn’t control my sexual behaviour.

Always	Almost Always	A lot of the time	Some of the time	Almost never	Never
1	2	3	4	5	6

15. I have gotten so turned on that I couldn’t control my sexual behaviour.

Always	Almost Always	A lot of the time	Some of the time	Almost never	Never
1	2	3	4	5	6

16. I have engaged in anal sex without using a condom.

Always	Almost Always	A lot of the time	Some of the time	Almost never	Never
1	2	3	4	5	6

17. I have used protection against pregnancy when I have had vaginal intercourse.

Always	Almost Always	A lot of the time	Some of the time	Almost never	Never
1	2	3	4	5	6

18. I have given fellatio (oral sex on a man) without using a condom.

Always	Almost Always	A lot of the time	Some of the time	Almost never	Never
1	2	3	4	5	6

19. I have received cunnilingus (oral sex on a woman) without using a dental dam (a thin sheet of latex used as a prophylactic device during cunnilingus and anilingus).

Always	Almost Always	A lot of the time	Some of the time	Almost never	Never
1	2	3	4	5	6

20. I have had vaginal intercourse without using a condom.

Always	Almost Always	A lot of the time	Some of the time	Almost never	Never
1	2	3	4	5	6

21. My partner and I have engaged in anal sex without using a condom.

Always	Almost Always	A lot of the time	Some of the time	Almost never	Never
1	2	3	4	5	6

22. I have given or received analingus (oral stimulation of the anal region) without using a dental dam (a thin sheet of latex used as a prophylactic device during cunnilingus and anilingus).

Always	Almost Always	A lot of the time	Some of the time	Almost never	Never
1	2	3	4	5	6

23. I have had sex while being drunk.

Always	Almost Always	A lot of the time	Some of the time	Almost never	Never
1	2	3	4	5	6

24. I have had sex while under the influence of drugs.

Always	Almost Always	A lot of the time	Some of the time	Almost never	Never
1	2	3	4	5	6

25. I have had sex with a new partner before discussing their sexual history with them.

Always	Almost Always	A lot of the time	Some of the time	Almost never	Never
1	2	3	4	5	6

26. I have had sex with a new partner before discussing intravenous drug use with them.

Always	Almost Always	A lot of the time	Some of the time	Almost never	Never
1	2	3	4	5	6

27. I have had sex with a new partner before discussing their sexually transmitted disease status with them.

Always	Almost Always	A lot of the time	Some of the time	Almost never	Never
1	2	3	4	5	6

28. I have had sex with a new partner before discussing possible current sexual partners with them.

Always	Almost Always	A lot of the time	Some of the time	Almost never	Never
1	2	3	4	5	6

PART K

1. I am someone who is talkative.

Strongly Disagree	Disagree	Neither agree nor disagree	Agree	Strongly Agree
1	2	3	4	5

2. I am someone who tends to find fault with others.

Strongly Disagree	Disagree	Neither agree nor disagree	Agree	Strongly Agree
1	2	3	4	5

3. I am someone who does a thorough job.

Strongly Disagree 1	Disagree 2	Neither agree nor disagree 3	Agree 4	Strongly Agree 5

4. I am someone who is depressed, blue.

Strongly Disagree 1	Disagree 2	Neither agree nor disagree 3	Agree 4	Strongly Agree 5

5. I am someone who is original, comes up with new ideas.

Strongly Disagree 1	Disagree 2	Neither agree nor disagree 3	Agree 4	Strongly Agree 5

6. I am someone who is reserved.

Strongly Disagree 1	Disagree 2	Neither agree nor disagree 3	Agree 4	Strongly Agree 5

7. I am someone who is helpful and unselfish with others.

Strongly Disagree 1	Disagree 2	Neither agree nor disagree 3	Agree 4	Strongly Agree 5

8. I am someone who can be somewhat careless.

Strongly Disagree 1	Disagree 2	Neither agree nor disagree 3	Agree 4	Strongly Agree 5

9. I am someone who is relaxed, handles stress well.

Strongly Disagree	Disagree	Neither agree nor disagree	Agree	Strongly Agree
1	2	3	4	5

10. I am someone who is curious about many different things.

Strongly Disagree	Disagree	Neither agree nor disagree	Agree	Strongly Agree
1	2	3	4	5

11. I am someone who is full of energy.

Strongly Disagree	Disagree	Neither agree nor disagree	Agree	Strongly Agree
1	2	3	4	5

12. I am someone who starts quarrels with others.

Strongly Disagree	Disagree	Neither agree nor disagree	Agree	Strongly Agree
1	2	3	4	5

13. I am someone who is a reliable worker.

Strongly Disagree	Disagree	Neither agree nor disagree	Agree	Strongly Agree
1	2	3	4	5

14. I am someone who can be tense.

Strongly Disagree	Disagree	Neither agree nor disagree	Agree	Strongly Agree

1	2	3	4	5

15. I am someone who is ingenious, a deep thinker.

Strongly Disagree 1	Disagree 2	Neither agree nor disagree 3	Agree 4	Strongly Agree 5

16. I am someone who generates a lot of enthusiasm.

Strongly Disagree 1	Disagree 2	Neither agree nor disagree 3	Agree 4	Strongly Agree 5

17. I am someone who has a forgiving nature.

Strongly Disagree 1	Disagree 2	Neither agree nor disagree 3	Agree 4	Strongly Agree 5

18. I am someone who tends to be disorganized.

Strongly Disagree 1	Disagree 2	Neither agree nor disagree 3	Agree 4	Strongly Agree 5

19. I am someone who worries a lot.

Strongly Disagree 1	Disagree 2	Neither agree nor disagree 3	Agree 4	Strongly Agree 5

20. I am someone who has an active imagination.

Strongly Disagree 1	Disagree 2	Neither agree nor disagree 3	Agree 4	Strongly Agree 5

21. I am someone who tends to be quiet.

Strongly Disagree 1	Disagree 2	Neither agree nor disagree 3	Agree 4	Strongly Agree 5

22. I am someone who is generally trusting.

Strongly Disagree 1	Disagree 2	Neither agree nor disagree 3	Agree 4	Strongly Agree 5

23. I am someone who tends to be lazy.

Strongly Disagree 1	Disagree 2	Neither agree nor disagree 3	Agree 4	Strongly Agree 5

24. I am someone who is emotionally stable, not easily upset.

Strongly Disagree 1	Disagree 2	Neither agree nor disagree 3	Agree 4	Strongly Agree 5

25. I am someone who is inventive.

Strongly Disagree 1	Disagree 2	Neither agree nor disagree 3	Agree 4	Strongly Agree 5

26. I am someone who has an assertive personality.

Strongly Disagree 1	Disagree 2	Neither agree nor disagree 3	Agree 4	Strongly Agree 5

27. I am someone who can be cold and aloof.

Strongly Disagree 1	Disagree 2	Neither agree nor disagree 3	Agree 4	Strongly Agree 5

28. I am someone who perseveres until the task is finished.

Strongly Disagree 1	Disagree 2	Neither agree nor disagree 3	Agree 4	Strongly Agree 5

29. I am someone who can be moody.

Strongly Disagree 1	Disagree 2	Neither agree nor disagree 3	Agree 4	Strongly Agree 5

30. I am someone who values artistic, aesthetic experiences.

Strongly Disagree 1	Disagree 2	Neither agree nor disagree 3	Agree 4	Strongly Agree 5

31. I am someone who is sometimes shy, inhibited.

Strongly Disagree 1	Disagree 2	Neither agree nor disagree 3	Agree 4	Strongly Agree 5

32. I am someone who is considerate and kind to almost everyone.

Strongly Disagree	Disagree	Neither agree nor disagree	Agree	Strongly Agree
1	2	3	4	5

33. I am someone who does things efficiently.

Strongly Disagree	Disagree	Neither agree nor disagree	Agree	Strongly Agree
1	2	3	4	5

34. I am someone who remains calm in tense situations.

Strongly Disagree	Disagree	Neither agree nor disagree	Agree	Strongly Agree
1	2	3	4	5

35. I am someone who prefers work that is routine.

Strongly Disagree	Disagree	Neither agree nor disagree	Agree	Strongly Agree
1	2	3	4	5

36. I am someone who is outgoing, sociable.

Strongly Disagree	Disagree	Neither agree nor disagree	Agree	Strongly Agree
1	2	3	4	5

37. I am someone who is sometimes rude to others.

Strongly Disagree	Disagree	Neither agree nor disagree	Agree	Strongly Agree

1	2	3	4	5

38. I am someone who makes plans and follows through with them.

Strongly Disagree	Disagree	Neither agree nor disagree	Agree	Strongly Agree
1	2	3	4	5

39. I am someone who gets nervous easily.

Strongly Disagree	Disagree	Neither agree nor disagree	Agree	Strongly Agree
1	2	3	4	5

40. I am someone who likes to reflect, play with ideas.

Strongly Disagree	Disagree	Neither agree nor disagree	Agree	Strongly Agree
1	2	3	4	5

41. I am someone who has few artistic interests.

Strongly Disagree	Disagree	Neither agree nor disagree	Agree	Strongly Agree
1	2	3	4	5

42. I am someone who likes to cooperate with others.

Strongly Disagree	Disagree	Neither agree nor disagree	Agree	Strongly Agree
1	2	3	4	5

43. I am someone who is easily distracted.

Strongly Disagree 1	Disagree 2	Neither agree nor disagree 3	Agree 4	Strongly Agree 5

44. I am someone who is sophisticated in art, music, or literature.

Strongly Disagree 1	Disagree 2	Neither agree nor disagree 3	Agree 4	Strongly Agree 5

PART L

1. When I see individuals in need, I ask them how I can help.

Never 0	Sometimes 1	Often 2	Very Often 3

2. When I see individuals in need, I think about how to relieve their distress or meet their needs.

Never 0	Sometimes 1	Often 2	Very Often 3

3. If someone I do not know asks me for help, I will immediately help them.

Never 0	Sometimes 1	Often 2	Very Often 3

4. If someone I do not know intends to borrow something which is really important to me, I will lend it to them nonetheless.

Never 0	Sometimes 1	Often 2	Very Often 3

5. I help others even when there is no direct benefit to me.

Never 0	Sometimes 1	Often 2	Very Often 3

6. I can relinquish my material goods in favour of the common good.

Never	Sometimes	Often	Very Often
0	1	2	3

7. When I see suffering, I try to find ways to alleviate it.

Never	Sometimes	Often	Very Often
0	1	2	3

PART M

1. I have strong convictions about things.

Almost Always	Quite Often	Sometimes	Not Very Often	Never
1	2	3	4	5

2. When I believe in something, I work to promote it.

Almost Always	Quite Often	Sometimes	Not Very Often	Never
1	2	3	4	5

3. I listen to both sides of the issue before I make up my mind.

Almost Always	Quite Often	Sometimes	Not Very Often	Never
1	2	3	4	5

4. I have self-confidence.

Almost Always	Quite Often	Sometimes	Not Very Often	Never
1	2	3	4	5

5. I am able to say my opinions in public.

Almost Always	Quite Often	Sometimes	Not Very Often	Never
1	2	3		5

			4	

6. I usually am satisfied with the decisions I make.

Almost Always	Quite Often	Sometimes	Not Very Often	Never
1	2	3	4	5

7. When I am criticized for some action I have taken, I can usually go about my work.

Almost Always	Quite Often	Sometimes	Not Very Often	Never
1	2	3	4	5

8. I like to be in charge of events.

Almost Always	Quite Often	Sometimes	Not Very Often	Never
1	2	3	4	5

9. I am able to see what materials are needed to complete a project.

Almost Always	Quite Often	Sometimes	Not Very Often	Never
1	2	3	4	5

10. I am able to see the sequence of steps necessary to complete a project.

Almost Always	Quite Often	Sometimes	Not Very Often	Never
1	2	3	4	5

11. When I am convinced of something, I have courage to act for it.

Almost Always	Quite Often	Sometimes	Not Very Often	Never
1	2	3	4	5

12. I often lead in projects.

Almost Always	Quite Often	Sometimes	Not Very Often	Never
1	2	3		5

			4	

13. When I see somebody who is a leader, I think that I could do as well as that leader.

Almost Always	Quite Often	Sometimes	Not Very Often	Never
1	2	3	4	5

14. I can speak to persons in authority.

Almost Always	Quite Often	Sometimes	Not Very Often	Never
1	2	3	4	5

15. I have energy to complete projects that I am interested in completing.

Almost Always	Quite Often	Sometimes	Not Very Often	Never
1	2	3	4	5

16. I can understand the viewpoints of others.

Almost Always	Quite Often	Sometimes	Not Very Often	Never
1	2	3	4	5

17. I am willing to change my mind if new facts suggest that I should change my mind.

Almost Always	Quite Often	Sometimes	Not Very Often	Never
1	2	3	4	5

18. I get anxious and excited and am able to use this energy to complete a task.

Almost Always	Quite Often	Sometimes	Not Very Often	Never
1	2	3	4	5

19. I am able to work with many types of persons and personalities.

Almost Always	Quite Often	Sometimes	Not Very Often	Never
1	2	3		5

			4	

20. I usually understand the plot of a story or play or the main point in a conversation.

Almost Always	Quite Often	Sometimes	Not Very Often	Never
1	2	3	4	5

21. I am willing to try new experiences when these seem wise.

Almost Always	Quite Often	Sometimes	Not Very Often	Never
1	2	3	4	5

22. I know when to lead, to follow, and to get out of the way.

Almost Always	Quite Often	Sometimes	Not Very Often	Never
1	2	3	4	5

23. I admire people who have achieved great things.

Almost Always	Quite Often	Sometimes	Not Very Often	Never
1	2	3	4	5

24. I dream of the day and time when I am able to lead myself or others to great accomplishment.

Almost Always	Quite Often	Sometimes	Not Very Often	Never
1	2	3	4	5

25. I feel at ease asking people for help or information.

Almost Always	Quite Often	Sometimes	Not Very Often	Never
1	2	3	4	5

26. I can be a “peacemaker” if I want to be.

Almost Always	Quite Often	Sometimes	Not Very Often	Never
1	2	3		5

			4	

PART N

I have the following in my home:

1	A TV set	Yes 1	No 2
2	Swimming pool	Yes 1	No 2
3	DVD player/ Blu Ray Player	Yes 1	No 2
4	Pay TV (M-Net/DStv/Top TV) subscription	Yes 1	No 2
5	Air conditioner (excl. fans)	Yes 1	No 2
6	Computer /Desktop/ Laptop	Yes 1	No 2
7	Vacuum cleaner/floor polisher	Yes 1	No 2
8	Dishwashing machine	Yes 1	No 2
9	Washing machine	Yes 1	No 2
10	Tumble dryer	Yes 1	No 2

11	Home telephone (excluding a cell)	Yes 1	No 2
12	Deep freezer –free standing	Yes 1	No 2
13	Refrigerator or combined fridge/freezer	Yes 1	No 2
14	Electric stove	Yes 1	No 2
15	Microwave oven	Yes 1	No 2
16	Built-in kitchen sink	Yes 1	No 2
17	Home security service	Yes 1	No 2
18	3 or more cell phones in household	Yes 1	No 2
19	2 cell phones in household	Yes 1	No 2
20	Home theatre system	Yes 1	No 2

I have the following amenities in my home or on the plot

21	Tap water in house/on plot	Yes 1	No 2
22	Hot running water from a geyser	Yes 1	No 2
23	Flush toilet in/outside house	Yes 1	No 2
24	There is a motor vehicle in our household	Yes 1	No 2
25	I am a metropolitan dweller	Yes 1	No 2
26	I live in a house, cluster or town house	Yes 1	No 2
27	I live in a rural area outside Gauteng and the Western Cape	Yes 1	No 2
28	There are no radios, or only one radio (excluding car radios) in my household	Yes 1	No 2
29	There is no domestic workers or household helpers in our household (incl. both live-in & part time domestics and gardeners)	Yes 1	No 2

Thank you for taking the time to complete this survey.