Predicting hypothetical Willingness to Participate (WTP) in a future Phase III HIV vaccine trial among high risk adolescents

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Thesis presented for the degree of Master of Arts (Psychology) at the University of Stellenbosch

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March 2007

DECLARATION

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

09.03.2007

Date

ABSTRACT

The first objective of the present study was to determine whether the Theory of Planned Behaviour (TPB) could predict Willingness to Participate (WTP) in a future Phase III HIV vaccine trial among high risk adolescents in the Western Cape. The second objective was to determine whether the additional predictor variables of Self-perceived risk of HIV infection, Knowledge of HIV vaccines and HIV vaccine trials, Attitudes toward HIV/AIDS and Health-promoting behaviours could further explain WTP in a future Phase III HIV vaccine trial among adolescents. A convenience sample of 224 adolescents attending secondary schools located in an African township on the Cape Flats was recruited for the present study. Hierarchical logistic regression analyses indicated that the TPB significantly improved the prediction of WTP in an HIV vaccine trial. Prediction success was 79.9%. Of all the predictor variables, only Subjective norms significantly predicted WTP in an HIV vaccine trial (OR = 1.19, 95% C.I. = 1.06-1.34). A second stepwise logistic regression analysis showed that Subjective norms (OR = 1.19, 95% C.I. = 1.07-1.34) and Attitude towards participation in an HIV vaccine trial (OR = 1.32, 95% C.I. = 1.00-1.74) were significant predictors of WTP in an HIV vaccine trial. Prediction success was 80.4%. These findings provide support for the Theory of Reasoned Action (TRA) and suggest that psychosocial factors may play a role in WTP in a future Phase III HIV vaccine trial among adolescents. HIV vaccine trial preparedness programs targeting adolescents should aim to influence group norms positively and promote positive attitudes toward participation in a future Phase III HIV vaccine trial.

OPSOMMING

Die eerste oogmerk van die huidige studie was om te bepaal of die teorie van beplande gedrag (TBG) die bereidwilligheid tot deelname (BTD) aan 'n toekomstige fase III-MIV-entstofproefneming onder hoë risiko adolessente in die Wes-Kaap kan voorspel. Die tweede oogmerk was om te bepaal of die bykomende voorspellingveranderlikes, naamlik selfwaargenome risiko vir MIV-besmetting, kennis van MIV-entstowwe en MIV-entstofproefnemings, houdings jeens MIV/vigs en gesondheidsbevorderende gedrag BTD in 'n toekomstige fase III-MIV-entstofproefneming kan verduidelik. 'n Geriefsmonster van 224 adolessente wat sekondêre skole geleë in 'n dorpsgebied in Kaapstad, bywoon, is vir die huidige studie gewerf. Hiërargiese logistiese regressie-analises toon dat die TBG die voorspelling van BTD aan 'n MIV-entstofproefneming aanmerklik verbeter het. Voorspellingsukses was 79.9%. Van al die voorspellingveranderlikes het slegs subjektiewe norme BTD aan 'n MIV-entstofproefneming beduidend voorspel (RK = 1.19, 95% VI = 1.06-1.34). 'n Tweede stapsgewyse logistiese regressie-analise toon dat subjektiewe norme (RK = 1.19, 95% VI = 1.07-1.34) en houding jeens deelname aan 'n MIV-entstofproefneming (RK = 1.32, 95% VI = 1.00-1.74) beduidende voorspellers van BTD aan 'n MIV-entstofproefneming was. Voorspellingsukses was 80.4%. Hierdie bevindinge verleen steun aan die teorie van beredeneerde aksie (TBA) en doen aan die hand dat psigososiale faktore moontlik in die toekoms 'n rol in BTD aan 'n fase III-MIV-entstofproefneming onder adolessente kan speel. Programme wat op adolessente se gereedheid vir entstofproefnemings afgestem is, behoort te poog om

groepnorme positief te beïnvloed en positiewe houdings jeens deelname aan 'n toekomstige fase III-MIV-entstofproefneming te bevorder.

ACKNOWLEDGEMENTS

I would like to thank the outstanding Professor Ashraf Kagee for his enduring supervision and support this year. I would like to thank him for always having my best interests at mind, for guiding me and for making research funds available to me. Above all else, I would like to thank him for making this year the most beneficial year of my life yet. Special thanks to my wonderful parents for all they have done to get me this far. For their love, support, encouragement and undying faith in my ability to complete this degree. Not to mention, their financial support. Without them, I couldn't have accomplished this. Thanks are due to the rest of my wonderful family and friends for standing by me through this very lengthy and solitary process. Thanks to Dylan, your continuing encouragement this year kept me going at the worst of times! I would like to thank the members of the SAAVI Socio-behavioural working group at Stellenbosch University for all their assistance. I am extremely grateful to them for all their guidance and input. I am also grateful to the school principals and HIV counselor for accommodating me and for all the assistance in organising the data collection. Thank-you to Renier for his assistance in the data collection. I couldn't have done it without him there! Thank-you to Professor Nel and Dr Kidd for their statistical advice. Thank-you to Marieanna le Roux for her help and advice in the support groups! Last but not least, the biggest thanks and acknowledgement goes to Jaco for being the stability in my life. For making me want to pursue my dreams and for picking me up when I fall. No amount of words could ever express my gratitude to you!

G Giocos (November 2006)

DEDICATION

I dedicate this thesis to the participants in my study, for so willingly and tolerantly filling in the questionnaires. May this thesis contribute to the eventual development of a safe and effective preventative HIV vaccine.

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CHAPTER 1

INTRODUCTION

1.1 The global AIDS epidemic

Regardless of the ongoing efforts to reduce high risk sexual behaviour and encourage the use of preventative contraceptives, HIV/AIDS is currently the most infectious disease as well as the most common cause of death in Africa (Esparza & Bhamarapravati, 2000). More than 25 million people have died from HIV/AIDS related causes since 1981 (UNAIDS/WHO, 2006). By the end of 2005, 40.3 million people were living with HIV/AIDS worldwide. Moreover, 4.9 million people became newly infected with HIV in 2005 and a total of 3.1 million people died of HIV/AIDS related causes in 2005 alone. Young people aged 15-24 account for half of all new HIV infections worldwide, with approximately 6000 young people becoming infected with HIV every day (UNAIDS/WHO, 2006).

The majority of people (96%) infected with HIV live in the developing world, with the greater part in sub-Saharan Africa (Global Health Council, 2006). UNAIDS/WHO (2006) report a total of 24.5 million people living with HIV/AIDS, 2.7 million newly infected individuals and 2 million deaths in sub-Saharan Africa for 2005. In South Africa, an estimated 5.5 million people were living with HIV/AIDS at the end of 2005 (UNAIDS/WHO, 2006). The national antenatal survey showed that the HIV prevalence rate was 29.5% in 2004 (South African Department of Health, 2005). Moreover, the HIV prevalence rate for individuals under the age of 20 was estimated at 16.1% and 30.8% for individuals aged 20-24. The HIV prevalence rate for the Western Cape was estimated at 15.4% (South African Department of Health, 2005).

1.2 Sexual behaviour among adolescents in South Africa

It appears that South African adolescents commence sexual activity at an early age: a study conducted in a rural area of South Africa found that 76% of girls (with a mean age of 15) and 91% of boys (with a mean age of 16) reported being sexually active (Buga, Amoko, & Ncayiyana, 1996). Other studies have confirmed early sexual debut (Kuhn, Steinberg, & Matthews, 1994; Visser, 1995) as well as multiple sexual partners among South African adolescents (Richter, 1996, cited in Hartell, 2005). Despite relatively good knowledge

levels and awareness of HIV/AIDS among these samples, low self-perceived susceptibility to HIV infection partly accounts for the high-risk sexual behaviour among South African adolescents (Galloway, 1999; Kuhn et al., 1994).

Given the position of sexual behaviour among adolescents in South Africa and the alarming HIV prevalence rate among this population, HIV/AIDS prevention is a priority for young people, especially as adolescence represents a period of discovering and experiencing sexuality and, for some, the use of drugs (Redjimi & Lert, 1993).

1.3 The HIV preventative vaccine

An effective, safe and affordable HIV preventative vaccine offers the most promising long-term hope to control the global epidemic (Esparza & Bhamarapravati, 2000). Moreover, it has been identified as a highly desirable goal and is becoming increasingly important (Smit et al., 2005). However, aside from the fact that trial participants risk exposure to an experimental vaccine that has not been widely tested on human subjects (in the case of Phase II and III trials), by participating in an HIV vaccine trial, these individuals are required to endure many inconveniences (McCluskey, Alexander, Larkin, Murguia, & Wakefield, 2005). Moreover, in order to test vaccine efficacy, a minimum of two thousand HIV-negative participants who are at high risk of HIV infection are required to participate in a Phase III HIV vaccine trial. Enrolment in a Phase III HIV vaccine trial entails regular assessment over a number of years (Grinstead, 1995). Subsequently, these requirements raise the question of whether individuals at high risk of HIV infection will be interested in volunteering for such trials. Moreover, as stated by Mugusi et al. (2002) there is an additional concern of whether volunteers in Phase III HIV vaccine trials can be retained over the long-periods of time required to test vaccine efficacy. The recruitment and retention of Phase III HIV vaccine trial participants is therefore very important to provide evidence for efficacy of the candidate vaccine (O'Connell et al., 2002).

In addition to these considerations, there are also ethical considerations. Volunteers in a Phase III HIV vaccine trial are required to provide informed consent before enrolment in such a trial (Lindegger & Richter, 2000). In the event of high levels of illiteracy, individuals may not fully understand vaccine trial processes and concepts and subsequently be drawn into participating by incentives (Lindegger, Slack, &

Vardas, 2000). It is therefore imperative that research examines knowledge of research procedures and HIV vaccines among potential participants before the onset of Phase III HIV vaccine trials. As stated by Esparza and Bhamarapravati (2000), to ensure the future availability of HIV vaccines, preclinical research efforts need to be improved.

1.4 Predicting Willingness to Participate (WTP) in an HIV vaccine trial

There has been extensive international research conducted on WTP in HIV vaccine trials (e.g.: Celentano et al., 1995; Golub et al., 2005; Koblin, Holte, Lenderking, & Heagerty, 2000; MacQueen et al., 1999; O'Connell et al., 2002; Strauss et al., 2001). Additionally, the completion of the first Phase III HIV vaccine trials in the United States and Thailand has motivated similar studies in developing countries. Nonetheless, there is a lack of valid data focusing on the issues that affect WTP in HIV vaccine trials in the South African context as well as other developing countries where the epidemic is paramount (Smit et al., 2006). Moreover, a review of the literature revealed that there is an absence of valid data on the appraisal of this construct among South African adolescents. Consequently, this indicates an urgent need to gain an understanding of WTP in future HIV vaccine trials and to identify the issues that potentially affect WTP in future Phase III HIV vaccine trials among individuals who are at high risk of HIV infection.

1.4.1 Perceived risk of HIV infection

There is evidence that perceived risk of HIV infection is significantly related to WTP in an HIV vaccine trial (e.g.: Jenkins et al., 2000; Johnson, 2000; Kiwanuka et al., 2004; McGrath et al., 2001; Newman et al., 2006; O'Connell et al., 2002; Périssé et al., 2000; Sahay et al., 2005; Sherr, Bolding, & Elford, 2004; Smit et al., 2006; Starace et al., 2006). There is however a paucity of research focusing on this relationship among South African adolescents. The relationship between self-perceived risk of HIV infection and WTP in future Phase III HIV vaccine trials among South African adolescents requires investigation.

1.4.2 Knowledge of HIV vaccines and HIV vaccine trial processes

There is a vast amount of research that has assessed knowledge of HIV vaccines and HIV vaccine trial methodology among specific samples (e.g.: MacQueen et al., 1999; McGrath et al., 2001; Strauss et al., 2001). Results of these studies have consistently shown a lack of knowledge regarding HIV vaccines and

HIV vaccine trial methodology. Additionally, numerous studies have investigated the association between knowledge of HIV vaccines, HIV vaccine trial methodology and WTP in HIV vaccine trials among various samples (e.g.: Halpern, Metzger, Berlin, & Ubel, 2001; Kiwanuka et al., 2004; Koblin et al., 2000; O'Connell et al., 2002; Priddy, Cheng, Salazar, & Frew, 2006; Sahay et al., 2005; Smit et al., 2006; Starace et al., 2006). The findings of these studies are mixed. While some studies have found that WTP in an HIV vaccine trial was significantly higher in participants with a greater knowledge about HIV vaccines and HIV vaccine trials (e.g.: Sahay et al., 2005; Starace et al., 2006), other studies have found that knowledge was not significantly associated with WTP in an HIV vaccine trial (e.g.: Priddy et al., 2006). In addition, some studies have found that the acquisition of new knowledge regarding HIV preventative vaccine trials may lead to a paradoxical decrease in WTP in these trials (Koblin et al., 2000).

In South Africa, previous research focusing on WTP in an HIV vaccine trial has been of little utility as South African participants have frequently shown low levels of knowledge of HIV vaccine trials and what enrolment in these trials entails (Smit et al., 2006). This lack of understanding and knowledge of HIV vaccines and HIV vaccine trials indicates a need to assess knowledge levels among South African adolescents and to determine the relationship (if any) between this construct and WTP in a future Phase III HIV vaccine trial.

1.4.3 Attitudes toward HIV/AIDS

There is extensive international research conducted on attitudes toward HIV/AIDS. There is however a lack of research focusing on adolescent attitudes toward HIV/AIDS in South Africa. Moreover, there is a paucity of research specifically focusing on the relationship between attitudes toward HIV/AIDS and WTP in an HIV vaccine trial among adolescents. There is however evidence that negative attitudes toward HIV/AIDS persist in South Africa and these attitudes have been cited as an inhibitor to HIV vaccine trial participation (Lesch, Kafaar, Kagee, & Swartz, 2006). The relationship between attitudes toward HIV/AIDS and WTP in an HIV vaccine trial among South African adolescents requires assessment.

1.4.4 Health-promoting behaviours

There is no research which explicitly describes and predicts the relationship between health-promoting behaviours and WTP in an HIV vaccine trial among adolescents. Prior research has focused on the relationship between health behaviours and the acceptance of a hypothetical HIV preventative vaccine (Liau & Zimet, 2000; Zimet, Fortenberry, & Blythe, 1999) and the relationship between health behaviours and WTP in HIV preventative intervention programs (Yang et al., 2004). Given that these studies are vastly unrelated to WTP in a future HIV vaccine trial, the relationship between health-promoting behaviours and WTP in an HIV vaccine trial among adolescents awaits investigation.

1.4.5 Theoretical framework

There is a paucity of theoretical work conducted around WTP in an HIV vaccine trial. Moreover, there is skepticism around the extent to which conventional theories can be used to explain a complex construct such as WTP in an HIV vaccine trial. Nevertheless, a social cognitive model that has been shown to predict behavioral intentions and overt behaviours is the Theory of Planned Behaviour (TPB) developed by Ajzen (1988). The TPB has been used to assess a variety of behaviours including health-related behaviours such as testicular self-examination (e.g.: Brubaker & Wickersham, 1990), clinical glove use (e.g.: Watson & Myers, 2001), treatment adherence in various populations (e.g.: Conner, Black, & Stratton, 1998; Povey, Conner, Sparks, James, & Shepherd, 2000), HIV preventative behaviours (e.g.: Albarracín, Johnson, Fishbein, & Muellerleile, 2001; Boer & Mashamba, 2005; Giles, Lidell, & Bydawell, 2005; McCabe & Killackey, 2004) as well as intentions to receive various vaccinations (e.g.: de Wit, Vet, Schutten, & van Steenbergen, 2004; Gagnon & Godin, 2000). However, a review of the literature revealed that no studies both internationally and within South Africa have used the TPB to predict WTP in an HIV vaccine trial.

Although participation in an HIV vaccine trial is not conventionally regarded as a health behaviour, from the perspective of a participant, receiving a vaccine in the context of a trial may increase the likelihood of protection from HIV infection above that of an individual who does not participate in an HIV vaccine trial. Therefore, trial participation is framed as a health behaviour with the expectation that protection from infection may follow (Kafaar, Kagee, Lesch, & Swartz, 2006). In light of the above prospect, it may be useful to apply existing theories of health behaviour to gain an understanding of WTP in future Phase III HIV

vaccine trials. The application of existing theoretical models can aid social scientists to engage in a process of theory-testing and theory-building (Kafaar et al., 2006). The ability of the TPB to predict WTP in future phase III HIV vaccine trials among South African adolescents therefore requires assessment.

1.5 Definition of adolescence

The criteria for the beginning of adolescence are clear and defined. However, the question of when this period typically ends is challenging and less concrete. Newman and Newman (1999) subdivided adolescence into two periods, namely, early adolescence and late adolescence. Early adolescence begins with the onset of puberty and ends at the completion of secondary school education (or roughly at 18 years of age). Late adolescence begins at approximately 18 years of age and continues for approximately six years (roughly at 24 years of age). Meyer (2004a) defines late adolescence as typically stretching between 18 and 22 years of age. The longer adolescent period in Western culture is the result of an earlier onset of puberty, prolonged financial dependency on parents and relatively lengthy education and training (Meyer, 2004b). Therefore, following the guidelines offered by Newman and Newman (1999) and Meyer (2004a, 2004b), adolescence, in the present study, is regarded as a period typically ending at approximately 22 years of age. Consequently, all participants younger than 22 years of age were included in the present study.

1.6 Objectives of the present study

The first objective of the present study was to determine whether the TPB could significantly predict WTP in future Phase III HIV vaccine trials among high risk adolescents in the Western Cape. The second objective of the present study was to determine whether the inclusion of additional predictor variables (Self-perceived risk of HIV infection, Knowledge of HIV vaccines and HIV vaccine trials, Attitude towards HIV/AIDS and Health-promoting behaviours) could further explain WTP in future Phase III HIV vaccine trials among high risk adolescents in the Western Cape.

CHAPTER 2

LITERATURE REVIEW AND THEORETICAL FRAMEWORK

The objective of the present study was to determine whether the TPB could significantly predict WTP in future Phase III HIV vaccine trials among high risk adolescents in the Western Cape. The second objective of the present study was to determine whether the additional predictor variables of Perceived risk of HIV infection, Knowledge of HIV vaccines and HIV vaccine trials, Attitudes toward HIV/AIDS and Health-promoting behaviours could further explain WTP in future Phase III HIV vaccine trials among high risk adolescents in the Western Cape. In this chapter, the existing literature around each predictor variable included in the present study will be reviewed. Subsequently, the theoretical model used in the present study will be explained and discussed.

2.1 Perceived risk of HIV infection

Perceived risk of HIV infection is consistently shown to be a significant predictor of WTP in HIV vaccine trials among various samples. For example, among young Thai men (e.g.: Jenkins et al., 2000), American samples (e.g.: Johnson, 2000), Ugandan samples (e.g.: Kiwanuka et al., 2004; McGrath et al., 2001), low-socioeconomic communities in America (e.g.: Newman et al., 2006), young gay and bisexual men in Canada (e.g.: O'Connell et al., 2002), men who have sex with men (MSM) in Brazil (e.g.: Périssé et al., 2000), Indian samples (e.g.: Sahay et al., 2005), London gay men (e.g.: Sherr et al., 2004) and finally, Italian samples (e.g.: Starace et al., 2006).

In the South African context, Smit et al. (2006) reported that in a sample of 16-40 year old participants, self-perceived HIV risk was significantly associated with WTP in an HIV vaccine trial. Although numerous studies have reported a significant relationship between perceived HIV risk and WTP in an HIV vaccine trial in specific samples, there is a paucity of research focusing on this relationship among South African adolescents. Therefore, the relationship between self-perceived risk of HIV infection and WTP in future Phase III HIV vaccine trials among South African adolescents requires further investigation.

2.2 Knowledge of HIV vaccines, HIV vaccine trials and related concepts

Numerous studies conducted on WTP in HIV vaccine trials have assessed knowledge of HIV vaccines and knowledge of HIV vaccine trial methodology (e.g.: MacQueen et al., 1999; McGrath et al., 2001; Strauss et al., 2001). Results of these studies have shown a lack of knowledge regarding HIV vaccines and HIV vaccine trial methodology among participants.

In a study conducted on WTP in an HIV vaccine trial among injection drug users (IDUs) in Thailand, MacQueen et al. (1999) assessed changes in participants' knowledge of an HIV vaccine trial over a week. Results showed that knowledge was high at baseline and improved at follow-up for the majority of participants. However, there were participants who had low knowledge levels. The results showed that participants did not understand that an HIV vaccine is preventative rather than curative. Moreover, participants did not understand concepts relating to HIV vaccine trial methodology such as double blinding procedures (MacQueen et al., 1999). Continuing educational efforts should be made to ensure that low knowledge levels and little scientific literacy to understand HIV vaccine trial methodology do not prevent participation in future HIV vaccine trials.

McGrath et al. (2001) found that the majority of participants in a Ugandan sample were familiar with the HIV vaccine but did not clearly understand whether the HIV vaccine that they were informed about was preventative or curing in function. Moreover, the participants were not knowledgeable about vaccine trial methodology such as a placebo control group, randomisation, and blinding procedures.

Strauss et al. (2001) assessed WTP in an HIV vaccine trial among three US communities. The majority of participants emphasised the need for information regarding the HIV vaccine, HIV vaccine trial methodology and processes that would be followed in an HIV vaccine trial. Participants required knowledge and understanding of issues relating to confidentiality, possible health complications, assistance/support in dealing with these complications, incentives that would be offered to compensate for participation, the effectiveness of the vaccine and future availability of the vaccine. Moreover, participants emphasised the need for information and education regarding vaccine trial methodology such as experimental versus placebo control groups (Strauss et al., 2001). The desired information reported by participants highlights the need to

educate communities and potential trial participants about the HIV vaccine trial process. Educational initiatives may improve understanding of HIV vaccine trials in communities at risk for HIV/AIDS.

The lack of knowledge regarding the HIV vaccine and HIV vaccine trial methodology raises the concern that potential trial participants who do not understand how the vaccine trial works and the related uncertainty of the trial process may decrease efforts to reduce high risk behaviours or increase engagement in high risk behaviours (Koblin, Avrett, Taylor, & Stevens, 1997). Strauss et al. (2001) argue that educating communities about the implementation of Phase III HIV vaccine trials is not only crucial for the conduct of ethically sound research, but is critical to the process of developing a safe and effective vaccine to help control the HIV pandemic worldwide.

2.2.1 Informed consent

Linked to knowledge of HIV vaccines and HIV vaccine trial methodology are ethical considerations such as the process of informed consent. Volunteers in a Phase III HIV vaccine trial are required to provide informed consent before enrolment in such a trial (Lindegger & Richter, 2000). Individuals require a complete understanding of the utility of HIV vaccines as well as the risks and benefits involved in participating in an HIV vaccine trial. There are many potential risks associated with HIV vaccine trials and participants may not entirely appreciate their implications (Koblin et al., 2000). Moreover, an important aspect of obtaining true informed consent from trial participants requires an ability to fully understand the various technical aspects and procedures of the HIV vaccine trial (Lindegger et al., 2000). In the event of high levels of illiteracy, individuals may not fully understand vaccine trial processes and concepts and subsequently be drawn into participating by free medical benefits or monetary compensation (Lindegger et al., 2000). It is therefore an imperative that potential participants' knowledge of HIV vaccines and HIV vaccine trial procedures undergo assessment before the onset of Phase III HIV vaccine trials in order to ensure ethically, legally and scientifically valid research, as well as the eventual development of a safe and effective vaccine to control the HIV epidemic.

2.2.2 Knowledge of HIV vaccines and WTP in an HIV vaccine trial

There are numerous studies that have assessed the association between knowledge of HIV vaccines, HIV vaccine trials and WTP in an HIV vaccine trial (e.g.: Halpern et al., 2001; Kiwanuka et al., 2004; Koblin et al., 2000; O'Connell et al., 2002; Priddy et al., 2006; Sahay et al., 2005; Smit et al., 2006; Starace et al., 2006; Lesch et al., 2006). While some studies have found that knowledge of HIV vaccines was not associated with WTP in an HIV vaccine trial (Halpern et al., 2001; Priddy et al., 2006), other studies have found a significant relationship between knowledge of HIV vaccines and WTP in an HIV vaccine trial (Kiwanuka et al., 2004; Koblin et al., 2000; Sahay et al., 2005; Smit et al., 2006; Starace et al., 2006).The results of these studies are discussed in turn.

Halpern et al. (2001) assessed changes in the stated WTP in, and knowledge of a hypothetical HIV vaccine trial among a sample in Philadelphia over an 18-month period. Following educational initiatives aimed at promoting increased knowledge of HIV vaccines and vaccine trials, results showed an increase in HIV vaccine knowledge at follow up. However, this increase in knowledge was not significantly associated with WTP in an HIV vaccine trial. However, a limitation of this study was that several items appearing on the knowledge questionnaire used to identify participants' understanding of trial concepts were used repeatedly at testing sessions. Therefore, this assessment may have represented participants' familiarity with the measuring instrument rather than a true assessment of HIV vaccine knowledge.

In a study assessing racial and ethnic differences in WTP in an HIV vaccine trial among college students in the US, Priddy et al. (2006) found that knowledge of HIV vaccines was not significantly associated with WTP in an HIV vaccine trial.

Kiwanuka et al. (2004) investigated knowledge of HIV vaccines and WTP in HIV vaccine trials among adolescents and adults in Uganda. Following a community education program, awareness of HIV vaccines increased to 81% compared to 68% at baseline (Kiwanuka et al., 2004). Knowledge that the HIV vaccine is preventative in function was relatively high in the sample (71%) and higher in men than in women (Kiwanuka et al., 2004). However, the majority of participants, including more than half of the men believed that only women and children are eligible to receive an HIV vaccine once it becomes available. Moreover,

93.7% of the sample believed that adolescents are most eligible to participate in an HIV vaccine trial (Kiwanuka et al., 2004). The belief that adolescents are most eligible for HIV vaccine trial enrolment is problematic as it may influence adult participation in future HIV vaccine trials (Kiwanuka et al., 2004). More than half the participants (60.2%) believed that HIV-positive individuals are eligible for participation in HIV vaccine trials and only 20% believed that the HIV vaccine can control HIV (Kiwanuka et al., 2004). Willingness to participate in an HIV vaccine trial was assessed at follow up and was 77% (Kiwanuka et al., 2004). However, a limitation of this study is that WTP was only measured at the follow up survey. The data do not contain pre-test measures of WTP in an HIV vaccine trial. As a result of this flaw, it is not feasible to conclude that an increase in HIV vaccine knowledge led to an increase in WTP in HIV vaccine trials. In fact, the acquisition of new knowledge regarding HIV preventative vaccine trials may have led to decreased WTP in an HIV vaccine trial.

This possibility is supported by the findings of Koblin et al. (2000). Changes in HIV vaccine knowledge and WTP in an HIV vaccine trial were assessed in a high risk sample of gay men (MSM), male and female injection drug users (IDU) and non-injecting women at heterosexual risk (WAHR) for a period of 18 months. Knowledge levels increased for all study populations by the 18-month visit. However, results showed a lack of knowledge concerning the possible effects of the vaccine on the immune system and the effectiveness of the vaccine at the start of a trial (Koblin et al., 2000). An increase in HIV vaccine knowledge was significantly associated with WTP in an HIV vaccine trial among certain subpopulations. However, among MSM men with low knowledge levels, an increase in knowledge about HIV vaccines was significantly associated with becoming unwilling to participate in HIV vaccine trials. This finding implies that WTP among individuals with higher knowledge levels is likely to remain unchanged with the acquisition of further knowledge regarding HIV vaccine trials. On the contrary, a paradoxical decrease in WTP among those with low knowledge levels is likely to occur with acquiring new knowledge regarding HIV vaccine trials (Koblin et al., 2000).

Similarly, O'Connell et al. (2002) assessed the changes in WTP between a hypothetical HIV vaccine trial and an HIV vaccine trial offered in the period of the ongoing AIDSVAX B/B phase III trial in Vancouver,

Canada. The results showed that WTP decreased between 1997 and 2001. Although stated willingness to participate in a hypothetical trial does not guarantee enrolment into an actual trial, O'Connell et al. (2002) argue that this decline in WTP may have been driven by an increase in awareness or understanding of HIV vaccine trial concepts and potential implications of participation in an actual HIV vaccine trial.

Conversely, Sahay et al. (2005) assessed the correlates of HIV vaccine trial participation in an Indian sample. The results of this study showed that the majority of the participants were aware of the seriousness of the HIV pandemic and were familiar with the term "vaccine". However, less than half of the participants were aware of the ongoing struggle for developing an effective HIV vaccine. Although only a small number of participants were aware that the HIV vaccine is preventive in function, no participants felt that the HIV vaccine would be completely ineffective. Consistent with the findings of Kiwanuka et al. (2004), many participants were unaware of adult participation in HIV vaccine trials. Participants who were familiar with the HIV vaccine and who had a greater understanding of the function of an HIV vaccine were significantly more willing to participate in an HIV vaccine trial (Sahay et al., 2005). Moreover, participants with a better awareness of the current efforts to develop an effective HIV vaccine and belief in the success of the HIV vaccine were significantly more willing to participate in an HIV vaccine trial (Sahay et al., 2005).

Starace et al. (2006) assessed knowledge of HIV vaccine trials among an Italian sample. Results showed that over 50% of the sample had an adequate knowledge about HIV vaccines and HIV vaccine trial processes. Moreover, WTP in an HIV vaccine trial was significantly higher in participants with a greater knowledge about HIV vaccines and HIV vaccine trials.

In the South African context, Smit et al. (2006) assessed WTP in an HIV vaccine trial among 16-40 year old participants. Similar to the findings of Sahay et al. (2005) and those of Starace et al. (2006), increasing knowledge of HIV vaccines was significantly associated with WTP in an HIV vaccine trial. Results showed that an increase of one unit in HIV vaccine knowledge scores was associated with a 10 fold increase in WTP in HIV vaccine trials respectively (Smit et al., 2006). Nonetheless, despite this significant finding, more than 70% of the participants in this study emphasised the need for more information regarding the HIV vaccine and HIV vaccine trials in order for them to answer questions related to WTP in an HIV vaccine trial.

Therefore, prospective trial participants lack knowledge about HIV vaccine trials and have limited scientific literacy to understand HIV vaccine trial methodology. This lack of knowledge may be a crucial factor affecting potential participants' decision to participate in an HIV vaccine trial. Therefore, while WTP in an HIV vaccine trial is relatively low in this sample, educational initiatives may be crucial in impacting on individuals' WTP in HIV vaccine trials (Smit et al., 2006). A possible limitation of this study is that the questionnaires used were derived from international sources and were therefore not validated in South African samples. It is therefore a possibility that that the high rate of non-responses from participants was not due to a lack of HIV vaccine knowledge but because questions did not tap into salient concerns of the South African population.

Similarly, Lesch et al. (2006) qualitatively assessed WTP in an HIV vaccine trial in a South African sample. Research participants emphasised the need for information and education regarding HIV vaccines and HIV vaccine trials for themselves and community members. Moreover, the participants reported that a lack of information and education regarding HIV vaccines and HIV vaccine trials may act as a potential inhibitor to participation in an HIV vaccine trial (Lesch et al., 2006). Therefore, further assessment among South African samples is required in order to identify the information that potential trial participants require in order to make a decision about trial participation.

2.3 Attitudes toward HIV/AIDS

As stated by Parker and Aggleton (2003) negative social responses to the HIV epidemic remain pervasive in communities, even in those seriously affected by HIV/AIDS. These negative social responses to HIV/AIDS impede efforts aimed at promoting voluntary counseling and testing and other HIV/AIDS prevention efforts (Kalichman & Simbayi, 2004). Consequently, there has been a great deal of focus on HIV and AIDS-related stigma and discrimination. Moreover, much of the empirical research that has been conducted on HIV and AIDS-related stigma has focused on the beliefs and attitudes of those who are perceived to stigmatise individuals affected by HIV/AIDS. There has been a specific focus on negative attitudes toward groups who are believed to be excessively affected by the epidemic, for example: gay and bisexual men, injecting drug users and sex workers (Herek, Capitanio, & Widaman, 2002). Moreover,

attitudes toward HIV/AIDS have been extensively investigated in numerous other international populations such as nurses and health care professionals (e.g.: Tierney, 1995), medical students (e.g.: Li & Cole, 1993) and various adult samples (e.g.: Barr, Waring, & Warshaw, 1992; Roberts & Blakey, 1994).

Fears, misconceptions and negative attitudes toward individuals with HIV/AIDS are common (Valimaki, Suominen, & Peate, 1998). There is a great deal of confusion about the nature of HIV and cynicism towards those perceived as exhibiting high-risk behaviours (Roberts & Blakey, 1994). HIV infection is frequently regarded as a punitive consequence of a sexually promiscuous lifestyle (Redjimi & Lert, 1993). Among a sample of medical students, Li and Cole (1993) found that many of the participants believed that prostitutes, drug addicts and homosexuals are to blame for AIDS and people living with AIDS got what they deserve (Li & Cole, 1993). Attitudes toward HIV/AIDS have been highly resistant to change (Valimaki et al., 1998) and education has been identified as a key determinant to improving knowledge of and attitudes toward HIV/AIDS.

Brook (1999) assessed attitudes toward HIV/AIDS among a sample of 1724 adolescents attending three different urban high schools (academic, vocational and religious) in Israel. The three samples were diverse and varied in their socio-economic status, education and family status (Brook, 1999). Attitudes toward HIV/AIDS and people living with HIV/AIDS were diverse. Results showed that pupils attending the academic high school were most tolerant toward HIV/AIDS and people living with HIV/AIDS than the pupils attending the vocational high school. Pupils attending the religious school were most conservative and intolerant toward HIV/AIDS. Only one third of the adolescents surveyed stated a willingness to volunteer in medical and rehabilitation centers devoted to helping HIV/AIDS patients (Brook, 1999). The learners stated that all pupils should be made aware of HIV positive pupils attending the school. Several of the pupils stated that an HIV positive student should be banned from school completely (Brook, 1999). The adolescents acknowledged that they preferred not to sit next to a fellow student who was HIV positive. Additionally, numerous students stated that they would discontinue any relationship with a friend who was diagnosed HIV positive. They stated that keeping a diagnosis of HIV/AIDS in confidence should be avoided. The majority of pupils received information regarding HIV/AIDS from television and the media. The adolescents reported

that physicians and nurses in clinics and schools were in last place for teaching students about HIV/AIDS (Brook, 1999). This finding provides motivation for more comprehensive and systematic HIV/AIDS instruction in schools and clinics and may contribute to more tolerant attitudes toward HIV/AIDS and individuals living with HIV/AIDS.

Similarly, Dias, Matos, and Gonçalves (2006) assessed adolescent attitudes toward HIV/AIDS in Portugal. Results showed that the majority of adolescents were tolerant toward HIV/AIDS and people living with HIV/AIDS. The majority of adolescents acknowledged the stigma, discrimination and social exclusion experienced by HIV-infected individuals. The adolescents stated that HIV-infected individuals are frequently avoided due to a lack of adequate knowledge about HIV transmission and a fear of contracting HIV. Moreover, half of the adolescent sample reported feeling compassionate toward HIV/AIDS patients (Dias et al., 2006). On the contrary, several adolescents were intolerant toward HIV/AIDS. Some adolescents reported fears of HIV-infected people, acknowledged that they would avoid an infected individual and feel oppressed if they were in the same room as an HIV-infected individual (Dias et al., 2006). Similar to the findings of Brook (1999), information regarding HIV/AIDS was mostly obtained from the mass media. Adolescents stated that information regarding the social and mental problems associated with HIV/AIDS had never been discussed at school (Dias et al., 2006). This finding poses a problem as inaccurate and negative attitudes toward HIV/AIDS may encourage fear and discrimination. In turn, this may perpetuate the stigma associated with HIV/AIDS and therefore create a barrier to HIV testing and prevention (Klein, Karchner, & O'Connell, 2002).

Numerous other studies have assessed attitudes toward HIV/AIDS among various adolescent samples internationally (e.g.: Agrawal, Rao, Chandrashekar, & Coulter, 1999; Katz, Mills, Singh, & Best, 1995; Levy et al., 1995; Savaser, 2003; Yong & Miller, 1993; Zimet et al., 1993). Ambivalent attitudes toward HIV/AIDS are common among adolescents and results consistently indicate a need for education in order to promote accurate knowledge about HIV/AIDS and tolerant attitudes toward HIV/AIDS.

According to Kalichman and Simbayi (2004) HIV and AIDS-related stigma is pervasive in South African communities. There is however a lack of research focusing on adolescent attitudes toward HIV/AIDS

in South Africa. Moreover, a review of the literature revealed no research directly focusing on the association between attitudes toward HIV/AIDS and WTP in an HIV vaccine trial among adolescents. Nonetheless, in a recent study conducted among South African community members, participants reported that the HIV vaccine's association with HIV/AIDS may be a potential limitation to HIV vaccine trial participation (Lesch et al., 2006). Moreover, participants reported that there is a pervasive negative perception of HIV/AIDS within South African communities (Lesch et al., 2006). Individuals are therefore ambivalent and cautious toward anything which may be HIV-related (Lesch et al., 2006).

Similarly, Allen et al. (2001) found that volunteers in an HIV vaccine trial reported experiencing negative reactions from friends, family and co-workers following self-disclosure of trial participation. For some of the volunteers, these negative reactions were related to the vaccine's association with HIV/AIDS. As stated by Rudy et al. (2005) there are many misconceptions about HIV/AIDS and preventative vaccines. There is a great tendency for HIV to be thought of as a gay disease and individuals consequently fear being labeled gay, promiscuous and engaging in risky behaviours (Rudy et al., 2005). Therefore, the risk of being stigmatised and discriminated against may influence potential participants' final decision to participate in an HIV vaccine trial. Allen et al. (2005) suggest that attitudes toward HIV/AIDS vary by population and that these attitudes need to be addressed in order to ensure an adequate number of volunteers for future HIV vaccine trials.

2.4 Health-promoting behaviours

As reported by Kulbok and Cox (2002) the Centers for Disease Control and Prevention have reported that health-risk behaviours such as unprotected sexual relations, substance abuse, poor diet, reduced physical activity, reckless driving, failure to use seatbelts and violence significantly contribute to adolescent morbidity and mortality. Moreover, as suggested by Zhuravleva (2001) health behaviours have become increasingly important with the dramatic increase in individuals' susceptibility to diseases such as HIV/AIDS, particularly among adolescents and young adults.

Prior research has focused on the relationship between certain health beliefs (such as self-perceived risk of HIV infection) and the acceptance of a hypothetical HIV preventative vaccine (Liau & Zimet, 2000;

Liau, Zimet, & Fortenberry, 1998; Zimet, Liau, & Fortenberry, 1997). Additionally, past research has assessed the relationship between health behaviours and the acceptance of a hypothetical HIV preventative vaccine (Liau & Zimet, 2000; Zimet et al., 1999). Research has also investigated the association between health behaviours and WTP in HIV preventative intervention programs (Yang et al., 2004).

In the study conducted by Yang et al. (2004), results showed that participants who were not willing to participate in HIV preventative programs were more likely to engage in health-compromising behaviours. Health-promoting behaviours were significantly related to WTP in HIV prevention programs. Those participants who were more willing to participate tended to engage in more health-promoting behaviours (Yang et al., 2004).

Zimet et al. (1999) found that increased engagement in health-risk behaviours was associated with greater HIV vaccine acceptance among adolescents. Moreover, health-promoting behaviours were not associated with greater HIV vaccine acceptance among the adolescent sample. Therefore, contrary to the expectation that a hypothetical HIV vaccine would be less accepted among individuals engaging in high risk behaviours, the adolescents engaging in health-risk behaviours were accepting of the hypothetical HIV vaccine and showed a heightened interest in the potential protection associated with being vaccinated (Zimet et al., 1999).

Conversely, Liau and Zimet (2000) assessed hypothetical HIV vaccine acceptability among university undergraduates aged 18 years and older. The results showed that less engagement in health-risk behaviours was associated with increased HIV vaccine acceptance for the entire sample. This finding supports the hypothesis that engagement in certain health-compromising behaviours may lead to decreased hypothetical HIV vaccine acceptance (Liau & Zimet, 2000).

The results of these studies suggest that certain health behaviours are likely to influence an individual's decision regarding HIV vaccination or participation in HIV prevention programs. The acceptance of a hypothetical HIV preventative vaccine and WTP in HIV preventative intervention programs is vastly unrelated to participation in an HIV vaccine trial and is therefore beyond the scope of interest in the present study. However, a review of the literature revealed that there are no studies which explicitly describe

and predict the relationship between health-promoting behaviours and WTP in an HIV vaccine trial among adolescents. This relationship (if any) therefore awaits investigation among South African adolescents.

2.5 Demographic characteristics

A review of the literature revealed that although the majority of studies assessing WTP in HIV vaccine trials have incorporated a variety of demographic characteristics, not all of these studies have found a significant relationship between these variables and WTP in an HIV vaccine trial. The findings of these studies are mixed and are discussed in turn.

2.5.1 Age

While some evidence suggests that age is not related to WTP in an HIV vaccine trial (e.g.: Jenkins et al., 2000; Kiwanuka et al., 2004; McGrath et al., 2001; Viera De Souza, Lowndes, Szwarcwald, Sutmöller, & Bastos, 2003), it has been reported that age is significantly related to WTP in an HIV vaccine trial (e.g.: Bartholow et al., 1997; Buchbinder et al., 2004; Jenkins et al., 1998; Koblin et al., 1997; O'Connell et al., 2002; Smit et al., 2006). Some studies have reported that younger age is significantly associated with WTP in an HIV vaccine trial (Buchbinder et al., 2004; Jenkins et al., 1998; O'Connell et al., 2002), and others have reported that increasing age is significantly associated with WTP in an HIV vaccine trial (Bartholow et al., 1997; Koblin et al., 1997; Smit et al., 2006).

2.5.2 Gender

While some studies have reported that gender is not related to WTP in an HIV vaccine trial (Kiwanuka et al., 2004; Sahay et al., 2005), it has been reported that a significant relationship between gender and WTP in an HIV vaccine trial does exist (e.g.: Jenkins et al., 1998; Smit et al., 2006). The studies conducted by Jenkins et al. (1998) and Smit et al. (2006) found males to be more willing to participate in an HIV vaccine trial.

2.5.3 Education

Some researchers have not found a significant relationship between education level and WTP in an HIV vaccine trial (e.g.: Kiwanuka et al., 2004), however some have reported a relationship between education and WTP in an HIV vaccine trial (e.g.: Jenkins et al., 2000). Jenkins et al. (2000) reported that

participants who were relatively well educated were more WTP in an HIV vaccine trial. Conversely, Périssé et al. (2000) reported that a low level of education was positively associated with WTP in an HIV vaccine trial. Consistent with this finding is those of Bartholow et al. (1997) and Viera De Souza et al. (2003).

2.5.4 Race

Although some studies have not reported a significant association between race and WTP in an HIV vaccine trial (e.g.: Viera De Souza et al., 2003), there is evidence that race is significantly associated with WTP in an HIV vaccine trial (e.g.: Bartholow et al., 1997; Buchbinder et al., 2004; Halpern et al., 2001).

2.6 Theoretical Framework

The Theory of Reasoned Action (TRA) (Fishbein & Ajzen, 1975) and the Theory of Planned Behaviour (TPB) (Ajzen, 1988) are theories commonly used to understand numerous behaviours including health-related behaviours. The TRA was first introduced to the literature at the crucial period when the relationship between attitudes and behaviour was under increasing scrutiny (Ajzen & Fishbein, 1980). The TRA deals with the relationship between beliefs, attitudes, intentions and behaviour and is based on the assumption that human beings are rational in their decision making and make logical use of information available to them (Ajzen & Fishbein, 1980). The TRA postulates that human social behaviour is not controlled by unconscious motives, nor is it a thoughtless process. Instead, individuals consider the implications of their actions before engaging in a specific behaviour (Ajzen & Fishbein, 1980).

According to the TRA, the key determinant of behaviour is an individual's intention to perform or not perform the specific behaviour (Ajzen & Fishbein, 1980). Moreover, an individual's intention to perform a specific behaviour is a function of two variables, namely: the individual's attitude toward the behaviour and the individual's perception of existing subjective norms concerning the behaviour (see Figure 1). Attitudes toward the behaviour and Subjective norms concerning the behaviour are comprised of information or beliefs relevant to the particular behaviour (Ajzen, 1988). Therefore, attitudes toward the behaviour include the individual's positive or negative evaluation of performing the behaviour. These attitudes are a function of behavioural beliefs concerning the particular behaviour (Ajzen & Fishbein, 1980). An individual who

believes that performing the behaviour will lead to positive outcomes will hold a favourable attitude toward performing the behaviour. Conversely, an individual who believes that performing the behaviour will lead to negative outcomes will hold an unfavourable attitude toward performing the target behaviour (Ajzen & Fishbein, 1980). Subjective norms concerning the behaviour include an individual's perception of existing social pressure to perform or not perform the target behaviour (Ajzen & Fishbein, 1980). Subjective norms concerning the behaviour are a function of normative beliefs (Ajzen & Fishbein, 1980). An individual who believes that significant others think he/she should perform the behaviour will perceive social pressure to do so. Conversely, an individual who believes that significant others think he/she should not perform the target behaviour will perceive social pressure to avoid the behaviour (Ajzen & Fishbein, 1980).

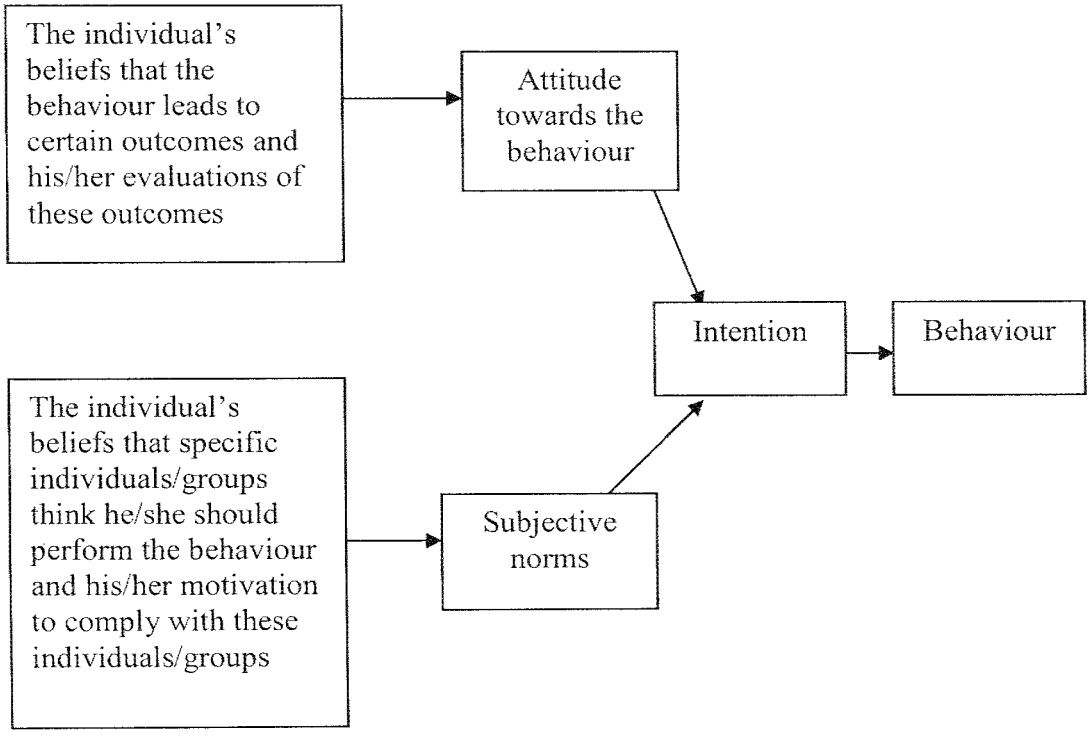

Figure 1. Components of the Theory of Reasoned Action (Ajzen & Fishbein, 1980).

2.6.1 The Theory of Planned Behaviour (TPB)

The TPB (Ajzen, 1988) is an extension of the TRA and is directed at behaviours which may not be under the complete control of the individual (Ajzen, 1988). External obstacles and a lack of adequate resources can interfere with the performance of any behaviour (Ajzen, 1988). Therefore, a behavioural intention can best be understood as an individual's willingness to attempt performing a given behaviour. The performance of the intended behaviour relies on the individual's control over various factors that may impede it (Ajzen, 1988).

The difference between the TRA and the TPB is the inclusion of a third variable, alongside Attitudes and Subjective norms[1] which acts as an additional determinant of an individual's intention to perform a specific behaviour. This variable is Perceived Behavioural Control (PBC) and refers to an individual's evaluation of the realistic constraints that may exist (such as the ease or difficulty of performing the behaviour) and the external factors that may play a role (such as available resources and anticipated obstacles) (Ajzen, 1988). An individual's PBC is a function of control beliefs concerning the particular behaviour (Ajzen, 1988). If an individual believes that he/she has requisite resources and opportunities to perform the behaviour and anticipates few impediments, the greater their perceived behavioural control over the target behaviour (Ajzen, 1988). The TPB postulates that the key determinant of an individual's behaviour is his/her intention to perform the target behaviour. Behavioural intention is a product of three determining factors: an individual's attitude towards performing the behaviour, an individual's perception of social pressure to perform the behaviour and lastly, an individual's perceived capacity to perform the behaviour (see Figure 2). Overall, the theory postulates that the more positive the attitude toward the behaviour, the more positive the subjective norms concerning the behaviour and the greater the perceived behavioural control over the behaviour, the stronger the individual's intention to perform the behaviour (Ajzen, 1988). In addition, Ajzen (1988) suggests that PBC holds a motivational function for intentions. Therefore, behaviour can be directly influenced by PBC, without the mediating effects of Attitudes toward the behaviour and Subjective norms concerning the behaviour. Consequently, if an individual believes that he/she has neither

[1] Subjective norms may be used interchangeably with perceived group norms

the resources nor the opportunity to perform the behaviour, he/she is unlikely to hold strong behavioural intentions, regardless of his/her attitudes toward the behaviour or his/her perception of existing social pressure to perform the given behaviour.

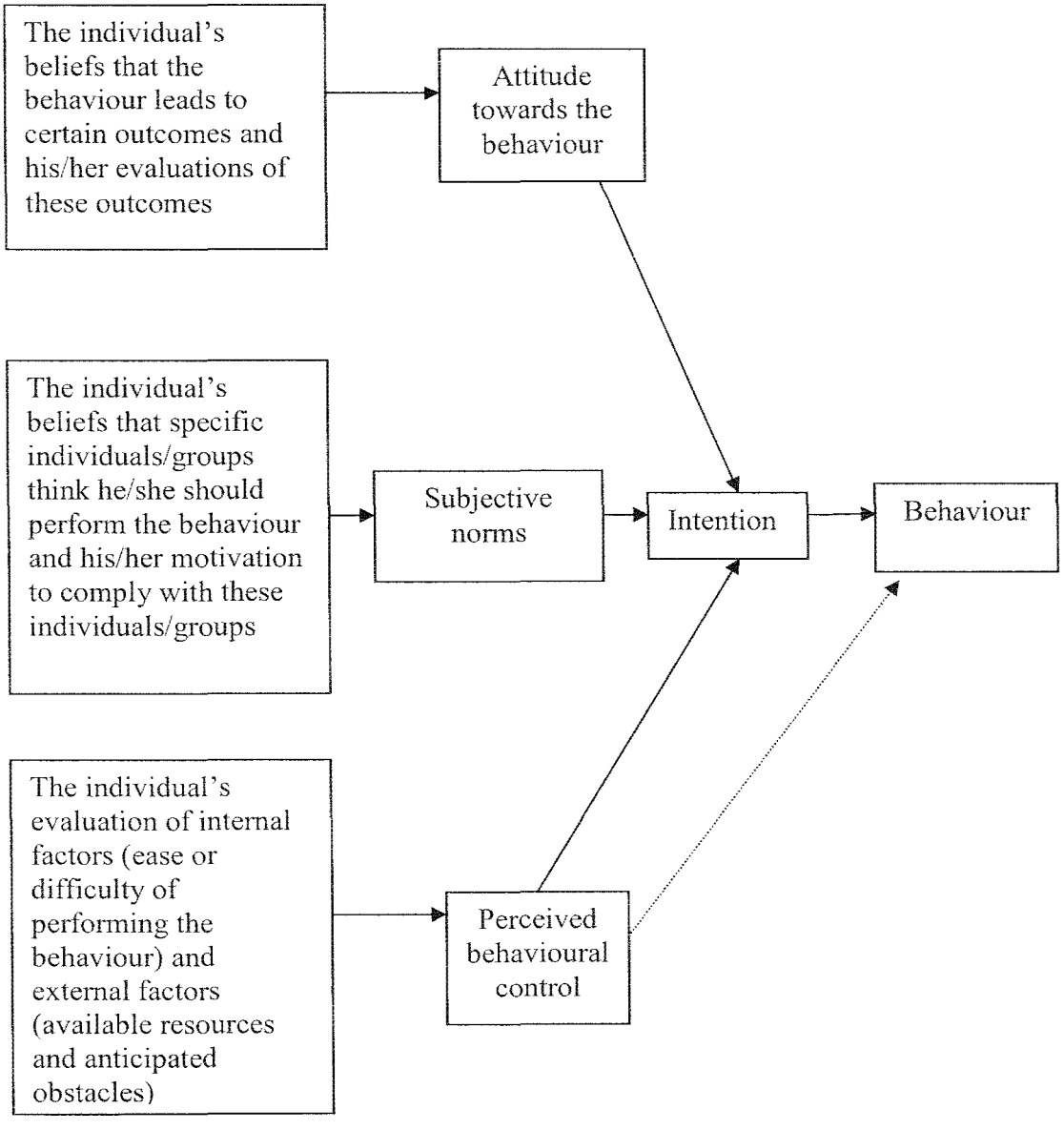

Figure 2. Components of the Theory of Planned Behaviour (Ajzen, 1988).

2.6.2 The TPB and WTP in an HIV vaccine trial

A review of the literature revealed that there is a lack of theoretical work conducted around WTP in HIV vaccine trials. Moreover, there are no studies which have incorporated the TPB as a predictive model of WTP in an HIV vaccine trial. Although the intention to receive a future HIV vaccine is vastly unrelated to participation in an HIV vaccine trial, Gagnon and Godin (2000) evaluated the acceptability of a hypothetical future HIV vaccine among adolescents using the TPB as a predictive model. The results indicated that of the 136 adolescents surveyed, 88% of the adolescents had a moderate to high intention to receive the HIV vaccine (Gagnon & Godin, 2000). Moreover, results of a multiple logistic regression analysis showed that two psychosocial variables from the TPB were significant predictors of the adolescents' intentions to receive the HIV vaccine. The two contributing factors were the adolescents' attitude toward receiving the HIV vaccine (OR = 4.80, 95% C.I. = 2.08-13.05) and the perceived behavioural control of receiving the HIV vaccine (OR = 2.52, 95% C.I. = 1.17-6.05) respectively. However, whether or not the TPB is predictive of WTP in an HIV vaccine trial among South African adolescents is uncertain and requires investigation.

2.7 Application of the TPB in the present study

The TPB has been used to assess a variety of behaviours including health-related behaviours such as testicular self-examination (e.g.: Brubaker & Wickersham, 1990), clinical glove use (e.g.: Watson & Myers, 2001), treatment adherence in various populations (e.g.: Conner et al., 1998; Povey et al., 2000), HIV preventative behaviours (e.g.: Albarracín et al., 2001; Boer & Mashamba, 2005; Giles et al., 2005; McCabe & Killackey, 2004) and intentions to receive various vaccinations (e.g.: de Wit et al., 2004; Gagnon & Godin, 2000).

There is a lack of theoretical work conducted around WTP in HIV vaccine trials. It may therefore be useful to apply existing models of health behaviour to gain an understanding of WTP in an HIV vaccine trial. Kafaar et al. (2006) address an important issue which arises from the application of a theory commonly used to understand health behaviours (such as the TPB) to HIV vaccine trial participation. Health behaviours are conventionally regarded as the maintenance of health and prevention of illness (Kasl & Cobb, 1966; Marks, Murray, Evans, & Willig, 2000; Matarazzo, 2002; Ogden, 2004). Moreover, health behaviours are

traditionally understood as acts from which individuals benefit directly. Participation in an HIV vaccine trial is regarded as a behaviour which may potentially contribute to changes in public health (by possibly contributing to the long term decline of HIV incidence). However, behaviours which contribute to changes in public health are not conventionally understood as health behaviours (Kafaar et al., 2006).

Therefore, from a traditional point of view, critics may question whether participation in an HIV vaccine trial can be regarded as a health behaviour as participation in an HIV vaccine trial poses no direct health benefits to the participants as such. Thus it is appropriate to question the extent to which a theory commonly used to understand health behaviours can be applied to behaviour such as HIV vaccine trial participation. Kafaar et al. (2006) argue that whether or not participation in an HIV vaccine trial can be regarded as a health behaviour depends on whether it is viewed from the individual's perspective or from the perspective of the researcher.

From an individual perspective, participants may benefit from participation in an HIV vaccine trial. These individuals may perceive that receiving the HIV vaccine might offer increased protection from HIV above that of an individual who does not receive an HIV vaccine. Trial participation can be regarded as a health behaviour as anticipated protection from HIV infection may follow. Moreover, participation in an HIV vaccine trial and regular visits to trial site clinics reminds individuals repeatedly of their high risk for HIV infection (Kafaar et al., 2006). In a recent study conducted by Lesch et al. (2006) respondents in fact reported that participation in an HIV vaccine trial would be a means to protect themselves from HIV infection. These factors may be seen as health-promoting behaviours.

From the researcher's perspective however, health benefits to individual participants are not a primary concern. The primary aim of developing an effective HIV vaccine is to improve public health. Investigators are primarily concerned with designing ethically, legally and scientifically valid trials. In fact, investigators may consider it inappropriate to regard participation in an HIV vaccine trial as a health behaviour as none or not all the participants may directly benefit from HIV vaccine trial participation (Kafaar et al., 2006).

Researchers investigating HIV vaccine trial participation may use traditional health promotion models such as the TPB and others due to an absence of tested theoretical models (Kafaar et al., 2006). Given the uncertainty of the applicability of such models to research in this area, this presents researchers with the challenge of moving beyond the limited focus on such theories and engaging in a process of theory-testing and theory-building. This process of theory-testing and theory-building allows including and testing the suitability of existing theoretical models. It may also promote understanding of the multifaceted nature of HIV vaccine trial participation and the eventual development of robust theoretical models for explaining this construct.

Due to the fact that WTP in an HIV vaccine trial is hypothetical in nature, no overt behaviour was tested using the TPB in the present study. The intention to participate in an HIV vaccine trial was regarded as synonymous to WTP in an HIV vaccine trial. As stated by Albarracín et al. (2001) an individual's overt behaviour is determined by the individual's intention/or willingness to perform the specific behaviour. Previous research has therefore regarded the intention to perform a behaviour and willingness to perform a behaviour as synonymous constructs. For the purpose of the present study then, whether or not an individual will be willing to participate in an HIV vaccine trial is influenced by three determinants, namely: an individual's positive or negative evaluations towards participation in an HIV vaccine trial, the perceived social pressure to participate or not participate in an HIV vaccine trial and lastly, the individual's self-efficacy with respect to participation in an HIV vaccine trial, despite difficult circumstances (see Figure 3).

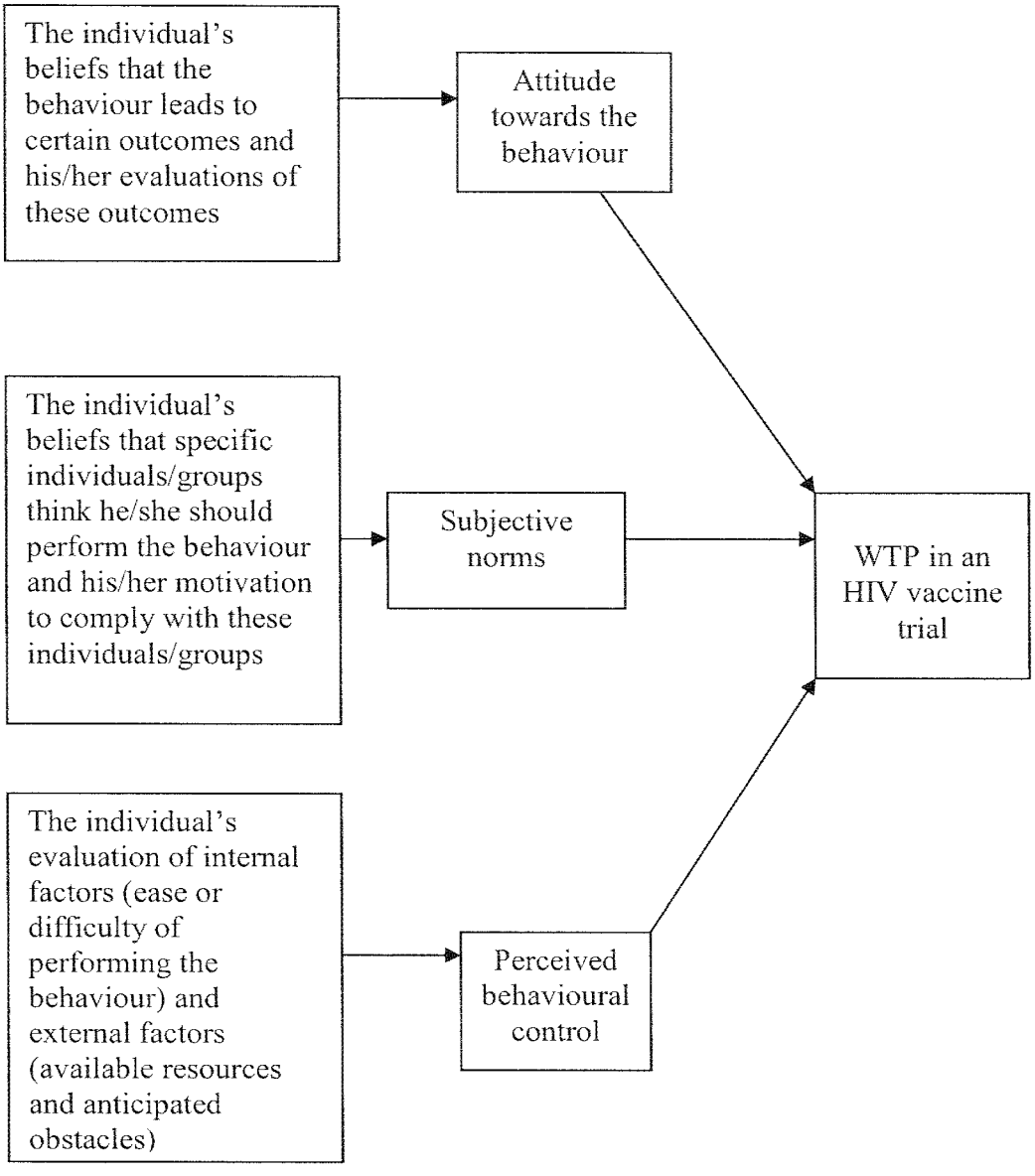

Figure 3. Use of the Theory of Planned Behaviour (Ajzen, 1988) in the present study.

CHAPTER 3

RESEARCH METHODOLOGY

3.1 Research design

The present study was a research survey with a cross-sectional design.

3.2 Participants

A total of 224 grade 10 and 11 learners were selected by means of convenience sampling from two secondary schools located in an African township on the Cape Flats.

3.3 Procedure

Permission to conduct research in the above schools was first obtained from The Western Cape Education Department and subsequently, ethical clearance and permission was obtained from the University of Stellenbosch' Internal Review Board.

The researcher met with the school principals in order to make the necessary arrangements and gain permission to conduct the relevant research. Subsequently, the researcher and a research assistant carried out the data collection. Groups of grade 10 and 11 learners were brought together in the school hall or classrooms where the researcher was introduced to them. The researcher carefully explained the study to the participants and subsequently, the participants were asked to sign an informed consent form (see Appendix A). The researcher presented a short pre-test workshop in which the HIV vaccine and the HIV vaccine trial were explained to the participants. Participants then completed the battery of instruments. Once the data collection was complete, the participants were thanked for their time and received crisps and sweets in gratitude of their participation.

3.4 Measuring instruments

All questionnaires were administered in English and Xhosa.

3.4.1 Demographic variables

Gender, age, grade and ethnicity were assessed using a self-administered questionnaire (Appendix B).

3.4.2 Perceived risk of HIV infection

To measure participants' self-perceived risk of HIV infection, a visual analogue scale was developed by the researcher (see Appendix B). A visual analogue scale (VAS) is an instrument which is used to measure constructs and attitudes or opinions about specific stimuli, which range across a continuum and cannot be directly or categorically measured easily. A VAS is usually a 10cm horizontal line and is anchored by descriptive words on each end of the line. The participants mark on the line the point they perceive to represent their current state or feeling toward that which is being measured (Gould, Kelly, Goldstone, & Gammon, 2001). The participants were requested to indicate with a cross on the continuum ranging from "very low risk" (0 cm) to "very high risk" (12 cm), how much at risk they thought they were of contracting HIV. Higher scores indicated a higher perceived self risk of HIV infection.

3.4.3 Willingness to participate (WTP) in an HIV vaccine trial

To measure participants' WTP in an HIV vaccine trial, a visual analogue scale was developed by the researcher (see Appendix B). The participants were requested to indicate with a cross on the continuum ranging from "very unwilling to participate" (0 cm) to "very willing to participate" (12 cm), how willing they were to participate in a hypothetical Phase III HIV vaccine trial. Higher scores indicated a greater WTP in an HIV vaccine trial.

3.4.4 Knowledge of HIV vaccines and HIV vaccine trials

In order to measure participants' knowledge of HIV vaccines, HIV vaccine trials and related concepts, an instrument was developed by the researcher and members of the Socio-behavioural working group, SAAVI, Stellenbosch University (see Appendix C). The instrument consisted of 23 items (with a two-option response format consisting of "true" and "false"). Examples of items which appeared in the instrument are as follows: "a placebo is a fake treatment that is similar to the real vaccine or drug", "HIV vaccines are given to help prevent someone from becoming infected with HIV" and "if you enrol in an HIV vaccine trial you will get the appropriate medication, medical tests, and HIV tests regularly all the way through the trial." The instrument was scored by giving a 1 for a correct response and a 0 for an incorrect response. Therefore, a minimum total score of 0 and a maximum total score of 23 was possible. Higher scores indicated an increased knowledge about HIV vaccines, HIV vaccine trials and related concepts. A panel of experts in the

Socio-behavioural working group, SAAVI, Stellenbosch University reviewed the newly constructed instrument before it was used. Cronbach alpha reliability coefficients were subsequently calculated and are reported in the Results chapter.

3.4.5 Attitude towards HIV/AIDS

To measure participants' attitude towards HIV/AIDS, the AIDS-related Stigma Scale developed by Kalichman et al. (2005) was used (see Appendix D). The scale consisted of nine items (with a two-option response format consisting of "I agree" and "I disagree"). However, for the present study, this two-option response format was changed to a four-option Likert response format ranging from "strongly disagree" to "strongly agree" in order to achieve continuity in participant responses. Positively worded items such as "it is safe for people with AIDS to work with children" were scored from 1 (strongly disagree) to 4 (strongly agree). Negatively worded items such as "people who have AIDS are dirty" were reverse scored from 4 (strongly agree) to 1 (strongly disagree) in order to maintain the negative response set. Higher scores indicated a more positive participant attitude towards HIV/AIDS. In order to ensure that the scale not only measured AIDS stigma but also measured positive attitudes towards HIV/AIDS, item number 7 "people who have AIDS should be isolated" was changed to "people who have AIDS should not be isolated" and item number 9 "people who have AIDS should not be allowed to work" was changed to "people who have AIDS should be allowed to work".

Research conducted in five South African communities found the scale to be internally consistent ($\alpha = 0.75$), with alpha ranging from 0.64 and 0.83 across the samples. The sample consisted of 2306 participants who were 18 years and older. The scale was found to be stable over time, both at one month ($r = 0.68$, $p < 0.01$) and three months ($r = 0.67$, $p < 0.01$). Moreover, the scale has internal consistency in English (alpha = 0.78), Xhosa (alpha = 0.88) and Afrikaans (alpha = 0.71) (Kalichman et al., 2005). Before the scale was used, the changes made were reviewed by a panel of experts in the Socio-behavioural working group, SAAVI, Stellenbosch University. Subsequently, Cronbach alpha reliability coefficients were calculated for the adolescent sample and are reported in the Results section.

3.4.6 Health-promoting behaviours

To measure participants' health-promoting behaviours, the Health-Promoting Lifestyle Profile (HPLP) developed by Walker, Sechrist, and Pender (1987) was used (see Appendix E). However, in order to avoid response fatigue, the original instrument consisting of 48 items was shortened into a 15 item instrument (with a four-point Likert-type format, consisting of four possible responses: "Never", "Sometimes", "Often" and "Routinely"). The instrument consisted of six sub-scales representing dimensions of a healthy lifestyle: Self-actualisation, Health responsibility, Exercise, Nutrition, Interpersonal support and Stress management (Walker et al., 1987). Participants were asked to indicate how frequently they performed each health-promoting behaviour. When scoring the instrument, a total score and a score for each sub-scale was obtained. Higher scores indicated more frequent performance of the healthy lifestyle behaviours. The alpha reliability coefficients for each sub-scale reported by Walker et al. (1987) are as follows: Self-actualisation: 0.90; Health responsibility: 0.81; Exercise: 0.81; Nutrition: 0.76; Interpersonal support: 0.80 and Stress management: 0.70. The total instrument was found to have an alpha reliability coefficient of 0.92. Furthermore, to establish stability, the scale was administered twice at a two week interval period. The Pearson r was 0.93 for the total scale and ranged from 0.81 to 0.91 for the subscales (Walker et al., 1987). The 48 item instrument was shortened into a 15 item instrument using the factor loadings of each sub-scale reported by Walker et al. (1987). Items with the highest factor loading were selected for the short form of the instrument. These items and their corresponding factor loadings are summarised in Table 1. Before the instrument was used, the changes made were reviewed by a panel of experts in the Socio-behavioural working group, SAAVI, Stellenbosch University. Thereafter, Cronbach alpha reliability coefficients were calculated and are reported in the Results chapter.

Table 1

Items and Factor Loadings of the Shortened Version of the Health-Promoting Lifestyle Profile (N=15)

Sub-scale and items	Factor loading
Self-actualisation	
I feel content and at peace with myself	0.72
I find each day interesting and challenging	0.71
I believe that my life has purpose	0.71
I like myself	0.70
Health responsibility	
I ask for information from health professionals about how to take good care of myself	0.75
I discuss my health concerns with health professionals	0.69
I check my blood pressure	0.60
Exercise	
I exercise vigorously for 20 minutes or more at least three times a week	0.82
I do stretching exercises at least three times per week	0.78
Nutrition	
I eat three meals daily	0.85
I eat breakfast	0.75
Interpersonal support	
I touch and am touched by people I care about	0.69
I maintain meaningful and fulfilling relationships with others	0.59
Stress management	
I relax my muscles before I sleep	0.54
I use specific methods to control my stress	0.53

3.4.7 Attitude towards participation in an HIV vaccine trial

Using questionnaire guidelines provided by Francis et al. (2004), a questionnaire with nine items was constructed by the researcher and members of the Socio-behavioural working group, SAAVI, Stellenbosch University (see Appendix F). The questionnaire consisted of a stem which defined the behaviour under investigation ("participating in an HIV vaccine trial is") followed by the use of evaluative bipolar adjectives such as "worthwhile/worthless" on a scale from 1 to 7. The scale was constructed so that the endpoints were a mix of positive and negative adjectives. Examples of items which appeared in the questionnaire are as follows: "participating in an HIV vaccine trial is worthwhile/worthless", "participating in an HIV vaccine trial is harmful/beneficial" and "participating in an HIV vaccine trial is pleasant/unpleasant". When scoring the questionnaire, items with negative endpoints were reverse coded, so that higher scores reflected a more positive attitude toward participating in an HIV vaccine trial. Subsequently, the mean of the item scores was calculated to obtain an overall attitude score. A panel of experts in the Socio-behavioural working group, SAAVI, Stellenbosch University reviewed the newly constructed questionnaire before it was used. Internal consistency of the measure was subsequently analysed and alpha reliability coefficients are reported in the Results section.

3.4.8 Subjective norms

To measure subjective norms, the researcher and members of the Socio-behavioural working group, SAAVI, Stellenbosch University constructed a questionnaire with six items (see Appendix G) using questionnaires construction guidelines provided by Francis et al. (2004). The questionnaire used a four-point Likert scale response format ranging from "strongly disagree" to "strongly agree". The questionnaire consisted of items such as: "most people who are important to me think that I should participate in an HIV vaccine trial", "it is expected of me to participate in an HIV vaccine trial" and "approval of my participation in an HIV vaccine trial is important to me". Items such as "most people who are important to me are willing to participate in an HIV vaccine trial" were scored from 4 (strongly disagree) to 1 (strongly agree). Reverse scored items such as "I feel under social pressure to participate in an HIV vaccine trial" were scored from 1 (strongly disagree) to 4 (strongly agree). Higher scores indicated a stronger perception of participation in an

HIV vaccine trial being the norm. A panel of experts in the Socio-behavioural working group, SAAVI, Stellenbosch University reviewed the newly constructed questionnaire before it was used. Internal consistency of the measure was subsequently analysed and alpha reliability coefficients are reported in the Results section.

3.4.9 Perceived behavioural control

Similar to above, questionnaire guidelines provided by Francis et al. (2004) were used to develop a scale which measured participants' perceived behavioural control (see Appendix H). This scale was constructed by a Psychology doctoral student at Stellenbosch University and members of the Socio-behavioural working group, SAAVI, Stellenbosch University. The scale consisted of seven items with a four-point Likert scale response format ranging from "strongly disagree" to "strongly agree". The scale consisted of items such as: "I am confident that I could participate in an HIV vaccine trial if I wanted to", "the decision to participate in an HIV vaccine trial is beyond my control" and "whether or not I decide to participate in an HIV vaccine trial is entirely up to me". Items such as "I am confident that I could participate in an HIV vaccine trial if I wanted to" were scored from 1 (strongly disagree) to 4 (strongly agree). Reverse scored items such as "the decision to participate in an HIV vaccine trial is beyond my control" were scored from 4 (strongly disagree) to 1 (strongly agree). Higher scores indicated a stronger perception of behavioural control over participation in an HIV vaccine trial. Before the scale was used, a panel of experts in the Socio-behavioural working group, Stellenbosch University reviewed the newly constructed questionnaire. Thereafter, Cronbach alpha reliability coefficients were calculated and are reported in the Results section.

3.5 Data analysis

All statistical procedures were performed using the Statistical Package for the Social Sciences (SPSS) with an alpha level of 0.05.

Deletion of cases with missing values was considered unsuitable because this would have reduced the sample size and in turn the statistical power of the study. Therefore, cases with missing values were included in all analyses. Firstly, frequencies (*f*), percentages (%), means (M), standard deviations (SD) and ranges were calculated for the independent variables. Secondly, the Kolmogorov-Smirnov (*D*) test of normality was

conducted in order to assess normality of the dependent and independent variable distributions. As a result of skewed distributions, the dependent variable was dichotomised in order to conduct logistic regression analyses on the data. Boxplots were requested to reveal the presence of outliers that could have exerted an unnecessary influence on the regression model. To test whether these outliers were significantly influential, standardised residuals were examined. Thereafter, Cook's distance was assessed. To test for any multicollinearity between predictor variables, the Variance Inflation Factor (VIF) statistic was assessed. Spearman's correlation coefficients were calculated to determine the nature of any relationships between the independent variables and the dependent variable. Moreover, Spearman's correlation coefficients were calculated to determine the nature of any relationships between the demographic variables and the dependent variable. Finally, two multiple logistic regression analyses were performed. Firstly a hierarchical multiple logistic regression analysis was conducted, followed by a stepwise multiple logistic regression analysis.

3.5.1 Predicting Willingness to participate in an HIV vaccine trial

At step 1 in the first multiple logistic regression analysis, a hierarchical method was used in which Attitude towards participation in an HIV vaccine trial, Subjective norms and Perceived behavioural control were entered into the analysis to determine whether the TPB could significantly predict WTP in an HIV vaccine trial. At step 2, the additional predictor variables of Perceived risk of HIV, Knowledge of HIV vaccines and HIV vaccine trials, Attitude towards HIV/AIDS and Health-promoting behaviours were added to Attitude towards participation in an HIV vaccine trial, Subjective norms and Perceived behavioural control to determine whether these additional independent variables could further explain WTP in an HIV vaccine trial.

Following the hierarchical logistic analysis, a second multiple logistic regression analysis was performed. This analysis was solely empirical and a forward stepwise likelihood ratio method was therefore used. The analysis involved one step in which Perceived risk of HIV, Knowledge of HIV vaccines, HIV vaccine trials and related concepts, Attitude towards HIV/AIDS, Health-promoting behaviours, Attitude towards participation in an HIV vaccine trial, Subjective norms and Perceived behavioural control were

entered simultaneously into the analysis to determine whether any of the above seven predictor variables could significantly predict WTP in an HIV vaccine trial.

CHAPTER 4

RESULTS

4.1 Demographic characteristics of the sample

The sample consisted of 224 participants attending two secondary schools located in an African township on the Cape Flats. Of the 224 participants, 42.9% were 10th-grade learners and 56.7% were 11th-grade learners. The participants were, on average, 17 years of age (M = 17.3, SD = 1.5). The age of the participants ranged from 14 to 21 years of age. All the participants were Black and there were more females (60.3%) than males (34.8%). These results are summarised in Table 2.

Table 2

Demographic Characteristics of the Sample

	N	*f*	(%)	M	SD	Range
School	224		(100)			
A		97	(43)			
B		127	(57)			
Grade	223		(99.6)			
10		96	(42.9)			
11		127	(56.7)			
Age (years)	222		(99.1)	17.3	1.5	14-21
Race	224		(100)			
Black		224	(100)			
Sex	213		(95.1)			
Male		78	(34.8)			
Female		135	(60.3)			

4.2 Data screening and tests of parametric assumptions

The Kolmogorov-Smirnov (D) test of normality was used to assess the normality distributions of the dependent variable and independent variables (see Table 3). The results indicate that the dependent variable violated the assumption of normality, $D(215) = 0.33$, $p < 0.01$. The normality plot revealed a nonlinear relationship with distinct categories on the left and the right of the distribution and minimal cases falling in the middle of the distribution. As stated by Field (2000) modeling a non-linear relationship using a linear model limits the generalisability of the findings. Consequently, a decision was made to dichotomise the continuous dependent variable into those unwilling to participate in a future Phase III HIV vaccine trial and those willing to participate in a future Phase III HIV vaccine trial in order to conduct logistic regression analyses on the data. Participant scores for WTP in a future Phase III HIV vaccine trial ranged from 0cm to12cm on the self-administered visual analogue scale. However, there were no participant scores ranging from 6-8cm for this variable. Subsequently, a decision was made to make the cut-off point at a score of 8cm on the visual analogue scale. Therefore, WTP was dichotomised into the following categories: those unwilling to participate in a future Phase III HIV vaccine trial (a score below 8cm) and those willing to participate in a future Phase III HIV vaccine trial (a score above 8cm). The distributions of all the independent variables were significantly skewed ($p < 0.05$). However, in logistic regression, there are no assumptions about the normality of the predictor variables and thus the predictors do not have to be normally distributed, linearly related or of equal variance (Tabachnick & Fidell, 2001).

Boxplots were screened in order to identify any outliers in the dependent variable as well as the independent variables. The boxplots revealed the presence of outliers in the dependent variable as well as all the independent variables except Perceived risk of HIV infection and Attitude towards participation in an HIV vaccine trial. Consequently, Standardised residuals were examined in order to isolate cases for which the model fitted poorly and which could have influenced the regression model. According to Field (2000) Standardised residuals with an absolute value greater than 3 are cause for concern and indicate the presence of cases for which the model fits poorly and which could exert an undue influence on the regression model.

Although the boxplots revealed the presence of outliers, the Standardised residuals did not exceed an absolute value greater than 2.5. Therefore, it was concluded that no cases were able to influence the regression model. Moreover, to consider the effects of a single case on the regression model as a whole, Cook's distance was examined. According to Field (2000) absolute values greater than one may be cause for concern and indicate that a single case may be influencing the model's predictive ability as a whole. Analyses of Cook's distance revealed no values above one. Therefore, it was concluded that no cases were able to unnecessarily influence the regression model.

Lastly, correlations between predictor variables were examined to assess whether significant multicollinearity was present. The guidelines offered by Myers (1990) suggest that a Variance Inflation Factor (VIF) statistic exceeding 10 is a cause for concern. Analyses revealed that there were no VIF values exceeding 10 in the data. Therefore, it was concluded that there was no significant multicollinearity between the predictor variables.

Table 3

Normality Test for Dependent Variable and Independent Variables

	Kolmogorov-Smirnov		
Variable	Statistic	df	p
Willingness to participate	0.33	215	0.00**
Perceived risk of HIV	0.22	192	0.00**
Knowledge of HIV vaccines	0.19	192	0.00**
Attitude towards HIV/AIDS	0.09	192	0.00**
Health-promoting behaviour	0.07	192	0.00**
Attitude towards participation	0.07	192	0.01*
Subjective norms	0.16	192	0.00**
Perceived behavioural control	0.18	192	0.00**

* $p < 0.05$

** $p < 0.01$

4.3 Internal consistency of measurement instruments used in the present study

The guidelines offered by Nunally (1978) suggest that an alpha reliability coefficient of 0.70 or higher is acceptable for scales used in beginning research. However, Reynaldo and Santos (1999) argue that lower thresholds have been deemed acceptable in existing literature. Guidelines offered by Huysamen (1996a, cited in Wolfaardt, 2001) suggest that an alpha reliability coefficient of 0.65 or higher is acceptable for decisions about groups.

4.3.1 Knowledge of HIV vaccines and HIV vaccine trials

The internal consistency analysis revealed a modest Cronbach alpha reliability coefficient ($\alpha = 0.65$) for the measure. However, once the item "people who take part in HIV vaccine trials will receive free health care at the study clinic only for trial-related medical problems" was removed from the analysis, the internal

consistency improved (α = 0.77). The internal consistency could not be further improved. After the deletion of the above item, the final instrument consisted of 22 items.

4.3.2 The AIDS-related Stigma Scale

The Internal consistency analysis of the AIDS-related Stigma Scale (Kalichman et al., 2005) revealed a Cronbach alpha reliability coefficient of 0.49. Once the item "people with AIDS must expect some restrictions on their freedom" was removed from the analysis, the internal consistency improved (α = 0.59). Moreover, when the item "it is safe for people who have AIDS to work with children" was removed from the analysis, the internal consistency improved (α =0 .60). The internal consistency could not be further improved. The instrument therefore consisted of seven items after deleting the above items.

4.3.3 The Health-Promoting Lifestyle Profile

The internal consistency analysis revealed an acceptable Cronbach alpha reliability coefficient for the measure (α = 0.70). The internal consistency could not be improved.

4.3.4 Attitude towards participation in an HIV vaccine trial

The internal consistency analysis revealed an acceptable Cronbach alpha coefficient for the measure (α = 0.75). It was therefore decided that this reliability coefficient did not require further improvement.

4.3.5 Subjective norms

The internal consistency analysis revealed a Cronbach alpha coefficient for the measure (α = 0.64). When the item "I feel under social pressure to participate in an HIV vaccine trial" was removed from the analysis, the internal consistency improved (α = 0.75). The internal consistency could not be further improved. The total number of items remaining was five.

4.3.6 Perceived behavioural control

The internal consistency analysis revealed that the measure had modest internal consistency (α = 0.52). Once the item "it would be very difficult for me to participate in an HIV vaccine trial" was removed from the analysis, the internal consistency improved (α = 0.57). When the item "the decision to participate in an HIV vaccine trial is beyond my control" was removed, the internal consistency improved (α = 0.63). Finally, once the item "I would not be able to participate in an HIV vaccine trial even if I wanted to" was

removed from the analysis, the internal consistency improved (α =0 .66). The internal consistency could not be further improved. The total number of items remaining was four.

4.4 Analysis of demographic variables

Spearman's correlation coefficients were calculated to determine the nature of any relationships between age and WTP, grade and WTP and gender and WTP in a future Phase III HIV vaccine trial. These results are summarised in Table 4.

4.4.1 Age

No significant correlations were found between age and WTP in a future Phase III HIV vaccine trial ($r = -0.05$, $p = 0.45$).

4.4.2 Grade

No significant correlations were found between grade and WTP in a future Phase III HIV vaccine trial ($r = -0.11$, $p = 0.12$).

4.4.3 Gender

No significant correlations were found between gender and WTP in a future Phase III HIV vaccine trial ($r = 0.09$, $p = 0.19$).

Table 4

Spearman's Intercorrelations Between Demographic Variables and Willingness to Participate (WTP) in a future Phase III HIV Vaccine Trial (N = 202)

	WTP	Age	Grade	Gender
WTP	1			
Age	-0.05	1		
Grade	-0.11	0.29**	1	
Gender	0.09	-0.07	-0.03	1

** $p < 0.01$

4.5 Correlations between predictor variables and WTP

Spearman's correlation coefficients were calculated to determine the nature of any relationships between the predictor variables and WTP in a future Phase III HIV vaccine trial. These results are summarised in Table 5.

4.5.1 Perceived risk of HIV infection

No significant correlations were found between Perceived risk of HIV infection and WTP in a future Phase III HIV vaccine trial ($r = -0.09$, $p = 0.22$).

4.5.2 Knowledge of HIV vaccines and HIV vaccine trials

No significant correlations were found between Knowledge and WTP in a future Phase III HIV vaccine trial ($r = 0.05$, $p = 0.51$).

4.5.3 Attitude towards HIV/AIDS

No significant correlations were found between Attitude towards HIV/AIDS and WTP in a future Phase III HIV vaccine trial ($r = 0.06$, $p = 0.41$).

4.5.4 Health-promoting behaviours

No significant correlations were found between Health-promoting behaviours and WTP in a future Phase III HIV vaccine trial ($r = 0.09$, $p = 0.17$).

4.5.5 Subjective norms

A significant positive correlation was found between Subjective norms and WTP in a future Phase III HIV vaccine trial ($r = 0.24$, $p = 0.01$).

4.5.6 Attitude towards participation in an HIV vaccine trial

There was a significant positive correlation between Attitude towards participation in an HIV vaccine trial and WTP in a future Phase III HIV vaccine trial ($r = 0.14$, $p = 0.05$).

4.5.7 Perceived behavioural control

There were no significant correlations found between Perceived behavioural control and WTP in a future Phase III HIV vaccine trial ($r = 0.12$, $p = 0.11$).

Table 5

Spearman's Intercorrelations Between Predictor Variables and Willingness to Participate in an HIV Vaccine Trial (N =194)

	WTP	Perceived Risk	Knowledge	Attitude towards HIV/AIDS	Health-promoting behaviours	Subjective norms	Attitude towards participation in an HIV vaccine trial	Perceived behavioural control
WTP	1							
Perceived Risk	-0.09	1						
Knowledge	0.05	-0.23**	1					
Attitude towards HIV/AIDS	0.06	-0.13	0.39**	1				
Health-promoting behaviours	0.09	-0.13	0.11	0.16*	1			
Subjective Norms	0.24**	0.11	0.05	0.13	0.10	1		
Attitude towards participation in an HIV vaccine trial	0.14*	-0.09	0.35**	0.19**	0.06	0.07	1	
Perceived behavioural control	0.12	0.01	0.01	0.39**	0.11	0.28**	0.09	1

** $p < 0.01$
* $p < 0.05$

4.6 Predicting Willingness to Participate (WTP) in a future Phase III HIV vaccine trial

4.6.1 Regression model 1

In the hierarchical multiple logistic regression analysis, Attitude towards participation in an HIV vaccine trial, Subjective norms and Perceived behavioural control were entered together in the first step. In the second step, Perceived risk of HIV infection, Knowledge of HIV vaccines and HIV vaccine trials, Attitude towards HIV/AIDS and Health-promoting behaviours were added to Attitude towards participation in an HIV vaccine trial, Subjective norms and Perceived behavioural control. At the first and the second step of the hierarchical multiple logistic regression analysis, the Hosmer and Lemeshow goodness-of-fit test was conducted. The Hosmer and Lemeshow test statistic was non-significant ($p > 0.05$) for both step one and step two of the analysis. These findings suggest that the model was a good fit of the data. Moreover, two additional evaluative indices were assessed, namely, Cox and Snell R^2 and Nagelkerke R^2. These indices can be treated as additional evaluative indices such as the overall model evaluation and goodness-of-fit test statistics (Peng, Lee, & Ingersol, 2002). Similar to the Hosmer and Lemeshow goodness-of-fit test, both Cox and Snell R^2 and Nagelkerke R^2 for both steps in the regression analysis were non-significant ($p > 0.05$) suggesting that the model was a good fit of the data. The Hosmer and Lemeshow goodness-of-fit test, Cox and Snell R^2 and Nagelkerke R^2 for each step are summarised in Table 6.

Table 6

Goodness-of-fit Test Statistics and R^2 for the Hierarchical Multiple Logistic Regression Analysis

Test	χ^2	R^2	df	p
Step 1				
Hosmer and Lemeshow goodness-of-fit	11.32		8	0.19
Cox and Snell		0.07		
Nagelkerke		0.11		
Step2				
Hosmer and Lemeshow goodness-of-fit	13.36		8	0.10
Cox and Snell		0.08		
Nagelkerke		0.12		

4.6.2 In the hierarchical multiple logistic regression analysis, Attitude towards participation in an HIV vaccine trial, Subjective norms and Perceived behavioural control were entered together in the first step. As can be seen in Table 7, the chi-square test of the full model with all three predictors against a constant-only model indicated an increase in the amount of information explained by the model as a result of the inclusion of the above three predictors. Moreover, the model chi-square test statistic was statistically significant indicating that the inclusion of the above three predictors significantly improved the prediction of WTP in a future Phase III HIV vaccine trial. Prediction success was high with 79.9% of cases correctly classified using the above three predictors. Subjective norms significantly predicted WTP in a future Phase III HIV vaccine trial, $\chi^2(1, N = 194) = 8.52$, $p = 0.00$. The odds ratio indicated that as the perception of participation in an HIV vaccine trial being the norm increased by one unit of measurement on the Subjective norms scale, the odds of WTP in a future Phase III HIV vaccine trial also increased, but negligibly (OR = 1.19, 95% C.I. = 1.06-1.34). Although the Wald statistic for Attitude towards participation in an HIV vaccine trial was significant, $\chi^2(1, N = 194) = 3.74$, $p = 0.05$, this finding is likely to have little practical utility.

Attitude towards participation in a future Phase III HIV vaccine trial was associated with an odds ratio of 1.32. However, the confidence interval for the odds ratio included 1 (95% C.I. = 0.99-1.73). Therefore, there was no significant relationship between Attitude towards participation in an HIV vaccine trial and WTP in a future Phase III HIV vaccine trial in this sample. Lastly, Perceived behavioural control did not make a significant contribution to the prediction of WTP in a future Phase III HIV vaccine trial ($p > 0.05$). Therefore, of the three variables from the TPB, only Subjective norms significantly predicted WTP in a future Phase III HIV vaccine trial.

In the second step of the hierarchical multiple logistic regression analysis, Perceived risk of HIV, Knowledge of HIV vaccines and HIV vaccine trials, Attitude towards HIV/AIDS and Health-promoting behaviours were added to the model in order to determine whether the addition of the above predictor variables could further explain WTP in a future Phase III HIV vaccine trial. As can be seen in Table 7, the chi-square test of the block with the additional four predictors included in the model was non-significant indicating that the additional predictors did not improve the prediction of WTP in a future Phase III HIV vaccine trial. Moreover, prediction success showed that only an additional 0.5% of cases were classified after the inclusion of the additional four predictors, with a total of 80.4% of cases correctly classified by the model. Similar to the findings in the first step, of the seven predictors included in the second step, only Subjective norms significantly predicted WTP in a future Phase III HIV vaccine trial, $\chi^2(1, N = 194) = 8.65$, $p = 0.00$ and was associated with an odds ratio of 1.19 (95% C.I. = 1.06-1.35). This finding indicated that the odds of WTP in a future HIV vaccine trial increased as the perception of participation in a future HIV vaccine trial being the norm increased by one unit of measurement on the Subjective norms scale, but negligibly.

Table 7

Summary of the Hierarchical Multiple Logistic Regression Analysis for Variables Predicting Willingness to Participate (WTP) in a future Phase III HIV Vaccine Trial (N = 194)

Predictor variable	β	SEβ	Wald's χ^2	df	p	eβ (Odds Ratio)	95% Confidence Interval
Step 1			13.58	3	0.00**		
Constant	-2.30	1.13	4.13	1	0.04*		
Attitude towards participation	0.28	0.14	3.74	1	0.05*	1.32	0.99-1.73
Subjective norms	0.17	0.06	8.52	1	0.00**	1.19	1.06-1.34
Perceived behavioural control	0.02	0.07	0.09	1	0.76	1.02	0.89-1.17
Step 2			1.86	4	0.76		
Constant	-2.51	1.75	2.07	1	0.15		
Attitude towards participation	0.27	0.15	3.44	1	0.06	1.31	0.99-1.75
Subjective norms	0.18	0.06	8.65	1	0.00**	1.19	1.06-1.35
Perceived behavioural control	0.04	0.08	0.22	1	0.64	1.04	0.89-1.20
Perceived risk of HIV	-0.06	0.06	0.94	1	0.33	0.95	0.85-1.06

Predictor variable	β	SEβ	Wald's χ^2	df	p	eβ (Odds Ratio)	95% Confidence Interval
Knowledge of HIV vaccine trials	0.09	0.07	0.02	1	0.89	1.01	0.89-1.15
Attitudes toward HIV/AIDS	-0.04	0.06	0.43	1	0.51	0.96	0.86-1.08
Health promoting behaviours	0.22	0.03	0.55	1	0.46	1.02	0.96-1.09

** $p < 0.05$
* $p < 0.01$

4.6.3 Regression model 2

As a result of the findings of the hierarchical multiple logistic regression analysis, a second multiple logistic regression analysis was conducted which did not involve theory testing, but which was entirely exploratory. Therefore, a stepwise method was deemed suitable for this analysis. In the forward likelihood ratio logistic regression analysis[2], Perceived risk of HIV infection, Knowledge of HIV vaccines, and HIV vaccine trials, Attitude towards HIV/AIDS, Health-promoting behaviours, Attitude towards participation in an HIV vaccine trial, Subjective norms and Perceived behavioural control were entered simultaneously into the analysis to determine whether any of the above seven predictor variables could significantly predict WTP in a future Phase III HIV vaccine trial. In order to assess the goodness-of-fit of the model at each step of the analysis, the Hosmer and Lemeshow goodness-of-fit test was conducted. Moreover, two supplementary evaluative indices (Cox and Snell R^2 and Nagelkerke R^2) were assessed. Although Cox and Snell R^2 for step one was significant ($p = 0.05$), the Hosmer and Lemeshow goodness-of-fit test statistic at both step one and step two was non-significant ($p > 0.05$). Additionally, Nagelkerke R^2 was non-significant ($p > 0.05$) at step one and step two. These findings suggest that the model was a good fit of the data. The Hosmer and

[2] A backward likelihood ratio method was also conducted and revealed the same results as the forward likelihood ratio method.

Lemeshow goodness-of-fit test statistic, Cox and Snell R^2 and Nagelkerke R^2 for each step of the stepwise logistic regression analysis are summarised in Table 8.

Table 8

Goodness-of-fit Test Statistics and R^2 for the Forward Stepwise Multiple Logistic Regression Analysis

Test	χ^2	R^2	df	p
Step 1				
Hosmer and Lemeshow goodness-of-fit	10.00		7	0.19
Cox and Snell		0.05*		
Nagelkerke		0.08		
Step2				
Hosmer and Lemeshow goodness-of-fit	12.89		8	0.12
Cox and Snell		0.07		
Nagelkerke		0.11		

*$p \leq 0.05$

4.6.4 Of the seven predictors entered simultaneously into the forward stepwise logistic regression analysis, Subjective norms and Attitude towards participation in an HIV vaccine trial could significantly predict WTP in a future HIV vaccine trial. As can be seen in Table 9, in the first step of the analysis, Subjective norms was the most significant predictor of WTP in a future Phase III HIV vaccine trial, $\chi^2(1, N = 194) = 9.26$, $p = 0.00$ and was therefore added to the model first. The chi-square test of the full model with the above predictor was statistically significant indicating that the inclusion of Subjective norms significantly improved the prediction of WTP in a future HIV vaccine trial. Moreover, prediction success was high, with 78.4% of cases correctly classified using Subjective norms as a predictor variable.

In the second step of the analysis, Attitude towards participation in an HIV vaccine trial was added to the model. As can be seen in Table 9, the chi-square test of the step with the additional predictor included in the model was statistically significant indicating that the additional predictor further explained WTP in a future Phase III HIV vaccine trial. Prediction success showed that an additional 2% of cases were classified after the inclusion of Attitude towards participation in an HIV vaccine trial, with a total of 80.4% of cases correctly classified by the model. Moreover, the model which included the above two predictor variables was compared to the model if the predictor variables were removed. The change in the model was statistically significant, suggesting that the inclusion of Subjective norms and Attitude towards participation in an HIV vaccine trial improved the predictive ability of the model. Subjective norms significantly predicted WTP in a future Phase III HIV vaccine trial, $\chi^2(1, N = 194) = 9.81$, $p = 0.00$. The odds ratio indicated that as the perception of participation in a future Phase III HIV vaccine trial being the norm increased by one unit of measurement on the Subjective norms scale, the odds of WTP in a future HIV vaccine trial also increased, but negligibly (OR = 1.19, 95% C.I. = 1.07-1.34). Attitude towards participation in an HIV vaccine trial significantly predicted WTP in a future HIV vaccine trial, $\chi^2(1, N = 194) = 3.88$, $p = 0.05$. The odds ratio indicated that as Attitude towards participation in an HIV vaccine trial increased by one unit of measurement on the Attitude towards participation in an HIV vaccine trial scale, the odds of WTP in a future HIV vaccine trial also increased, but negligibly (OR = 1.32, 95% C.I. = 1.00-1.74).

Table 9

Summary of the Forward Stepwise Multiple Logistic Regression Analysis for Variables Predicting Willingness to Participate (WTP) in a future Phase III HIV Vaccine Trial (N = 194)

Predictor variable	β	SEβ	Wald's χ^2	df	p	eβ (Odds Ratio)	95% Confidence Interval
Step 1			9.51	1	0.00**		
Constant	-0.84	0.73	1.33	1	0.25	0.43	
Subjective norms	0.17	0.06	9.23	1	0.00**	1.18	1.06-1.32
Step 2			3.98	1	0.05*		
Overall model			13.49	2	0.00**		
Constant	-2.15	1.01	4.55	1	0.03*	0.12	
Attitude towards participation in an HIV vaccine trial	0.28	0.14	3.88	1	0.05*	1.32	1.00-1.74
Subjective norms	0.18	0.06	9.81	1	0.00**	1.19	1.07-1.34

**$p < 0.01$

*$p \geq 0.05$

CHAPTER 5

DISCUSSION AND CONCLUSION

5.1 Predicting WTP in a future Phase III HIV vaccine trial

The first aim of the present study was to determine whether the inclusion of the TPB could significantly predict WTP in a future Phase III HIV vaccine trial among high risk adolescents in the Western Cape. The TPB is a social cognitive model commonly used to assess a variety of behaviours including health-related behaviours. For example, the TPB has been used in studies assessing testicular self-examination (e.g.: Brubaker & Wickersham, 1990), clinical glove use (e.g.: Watson & Myers, 2001), treatment adherence in various populations (e.g.: Conner et al., 1998; Povey et al., 2000), HIV preventative behaviours (e.g.: Albarracín et al., 2001; Boer & Mashamba, 2005; Giles et al., 2005; McCabe & Killackey, 2004) as well as intentions to receive various vaccinations (e.g.: de Wit et al., 2004; Gagnon & Godin, 2000).

In the present study, the inclusion of the TPB significantly improved the prediction of WTP in an HIV vaccine trial among adolescents in the Western Cape, with a high prediction success of 79.9% of cases correctly classified using the TPB as a theoretical model. Subjective norms significantly predicted WTP in an HIV vaccine trial and was associated with an odds ratio of 1.19 (95% C.I. = 1.06-1.34). Attitude towards participation in an HIV vaccine trial was associated with an odds ratio of 1.32. This finding is likely to have little practical utility as the confidence interval included 1. Therefore, there was no significant association between Attitude towards participation in an HIV vaccine trial and WTP in an HIV vaccine trial in this adolescent sample. Lastly, Perceived behavioural control did not make a significant contribution to the prediction of WTP in an HIV vaccine trial. The inclusion of the combination of the TPB variables significantly improved the prediction of WTP in a future Phase III HIV vaccine trial among this adolescent sample. However, Attitude towards participation in an HIV vaccine trial and Perceived behavioural control were not significant predictor variables individually.

The second aim of the present study was to determine whether the inclusion of the additional predictor variables of Perceived risk of HIV infection, Knowledge of HIV vaccines and HIV vaccine trials,

Attitudes toward HIV/AIDS and Health-promoting behaviours could further explain WTP in a future Phase III HIV vaccine trial among high risk adolescents in the Western Cape. Prediction success remained mostly unchanged, with merely an additional 0.5% of cases classified after the inclusion of the additional four predictor variables. A total of 80.4% of cases were correctly classified with the inclusion of the additional four predictor variables. Moreover, the chi-square test of the step was non-significant, suggesting that the additional predictor variables did not improve the prediction of WTP in an HIV vaccine trial. Similar to the first step, of the seven predictors included in the second step, only Subjective norms significantly predicted WTP in an HIV vaccine trial and was associated with an odds ratio of 1.19 (95% C.I. = 1.06-1.35) respectively. In this regression analysis, a hierarchical entry method was employed as this method is deemed to be most suitable for theory testing (Field, 2000). Although only Subjective norms was a significant predictor of WTP in an HIV vaccine trial, these findings are important and may inform future research. These findings suggest that psychosocial factors may influence adolescents' WTP in a future Phase III HIV vaccine trial.

5.1.1 Subjective norms as a predictor variable of WTP in a future Phase III HIV vaccine trial

Adolescence is a developmental stage typically associated with emotional maturity, identity development, development of a value system, independence and establishment of mature love relationships and friendships (Meyer, 2004b). The psycho-social crisis for this developmental stage is that of group identity versus alienation (Meyer, 2004b). Forming a relationship with one's peer group is therefore a developmental task at this stage (Heaven, 1994). Adolescents are typically in the process of evaluating themselves and their own actions in the context of a peer group and are pre-occupied with gaining peer group acceptance in order to be popular, loved and respected by peers their own age, who are faced with the same pressures and challenges (Kaplan, 2000). As suggested by White (1999) peer groups are a source of socialization for adolescents, and for many, more time is spent with peers than with adult counterparts or parents. The most important way in which peers influence one another is by group formation. Group norms are established, determining how members should look, act and think (Shaffer, 1993). Peer groups typically personify cultural norms and values that are of the essence to an adolescent. Moreover, among these groups,

strict norms exist and those who deviate from the norm are faced with ridicule or rejection by fellow group members (Heaven, 1994).

The peer group has consistently been regarded as a fundamental context for growth and independence and forms the basis for long term social functioning (Poole, 1989). Peer groups are well established at the high school level and membership in a peer group involves commitment, loyalty, intimacy, solidarity and adherence to group norms (Berger, 2000). Berger (2000) suggests that the social pressure to conform to peer groups (in behaviour, dress and attitude) is usually considered a negative experience. As argued by Meyer (2004b), although individuals can feel continuously pressured to conform to the group, peer groups can be constructive and strengthen self-confidence in adolescents. Consistent with this argument, Heaven (1994) suggests that the peer group plays a crucial role in providing role models and setting boundaries for behaviour as the growing adolescent deals with physiological maturity and identity formation. Newman and Newman (1999) suggest that because adolescents are aware of a variety of behaviours, roles, morals and life styles, social modelling is particularly important for self-growth and identity formation. Social modelling typically refers to the process of adolescents learning from external sources such as fellow peers. Being a member in a peer group and engaging in social modelling is a vehicle by which independence and identity are attained (Heaven, 1994).

Peer group norms and peer pressure have been shown to influence adolescent behaviour (e.g.: Sieving, Eisenerg, Pettingell, & Skay, 2006; Zwane & Mngadi, 2004). Due to the fact that adolescents spend more time with peers than adult counterparts, the way in which peers teach each other about sex and AIDS will subsequently affect the way these individuals will behave (White, 1999). Moreover, if an individual is a member of a group in which fellow peers are engaging in risky behaviours, that individual is most likely to be inclined to do the same (White, 1999). Given that acceptance in a peer group is a developmental task at adolescence, it is likely that if participation in an HIV vaccine trial is a perceived group norm, this perceived group norm may influence adolescents' decisions about future Phase III HIV vaccine trial participation. This may be the case in the present study as results showed that as participation in an HIV vaccine trial being the norm increased, so did the adolescents' WTP in a future Phase III HIV vaccine trial. Moreover, because the

present research study was conducted in the school environment where the adolescents were surrounded by their peers, the participants may have potentially been more stringent in conforming to group norms. However, as suggested by Swartz et al. (2005) peer group influence may potentially affect participation in an HIV vaccine trial in unpredictable ways. As adolescents progress through time, beliefs concerning factors such as social good may change. Therefore, group norms need to be positively influenced (Swartz et al., 2005).

Although no research has tested the ability of the TPB to predict WTP in an HIV vaccine trial, there is some evidence that subjective norms may influence WTP in future HIV vaccine trials (Lesch et al., 2006). Participants in the study conducted by Lesch et al. (2006) reported that negative reactions from family and community members would act as an inhibitor to participation in a HIV vaccine trial. Conversely, participants reported that positive family and community reactions to participation in an HIV vaccine trial, and the presence of role models would act as enablers to participation in HIV vaccine trials (Lesch et al., 2006). Participants emphasised the role that family members have in the decision making process of whether or not to participate in a future HIV vaccine trial (Lesch et al., 2006). Therefore, it is evident that an individual's perception of the social pressure put on him/her by salient individuals to participate or not participate in a future HIV vaccine trial may play a crucial role in determining WTP in a future Phase III HIV vaccine trial.

5.2 Predicting WTP in a future Phase III HIV vaccine trial (model 2)

Given the null findings of Attitude towards participation in an HIV vaccine trial and Perceived behavioural control as individual predictor variables, all seven predictors included in the present study were entered simultaneously into the model in the second logistic regression analysis. Therefore, none of the predictor variables were held constant in this analysis. Of the seven predictor variables entered simultaneously into the regression analysis, Subjective norms and Attitude towards participation in an HIV vaccine trial significantly predicted WTP in an HIV vaccine trial. Subjective norms significantly improved the prediction of WTP in an HIV vaccine trial. Prediction success was high, with 78.4% of cases correctly classified using Subjective norms as a predictor variable. Moreover, Subjective norms was associated with an

odds ratio of 1.19 (95% C.I. = 1.07-1.34) respectively. When Attitude towards participation in an HIV vaccine trial was added to the model, the chi-square test of the step with the additional predictor included in the model was statistically significant indicating that Attitude towards participation in an HIV vaccine trial further improved the prediction of WTP in an HIV vaccine trial. Prediction success improved, with an additional 2% of cases correctly classified after the inclusion of Attitude towards participation in an HIV vaccine trial. A total of 80.4% of cases were correctly classified by the above two predictor variables. Attitude towards participation in an HIV vaccine trial was associated with a negligible odds ratio of 1.32 (95% C.I. = 1.00-1.74) respectively. None of the remaining five predictor variables significantly predicted WTP in a future Phase III HIV vaccine trial.

In contrast to the first regression model which involved theory testing, this analysis was an entirely exploratory approach to predicting WTP in a future Phase III HIV vaccine trial. Consequently, a stepwise method was employed. This method is deemed suitable in situations in which no previous research exists on which to base hypotheses for testing (Field, 2000). Although the TPB has been used to assess a variety of health-related behaviours, there is a paucity of research which has incorporated the TPB as a predictive model of WTP in an HIV vaccine trial.

Demonstrating the robustness of regression analyses, the two psychosocial variables constituting the Theory of Reasoned Action (Attitude towards participation in an HIV vaccine trial and Subjective norms regarding participation in an HIV vaccine trial) proved to be significant predictors of WTP in a future Phase III HIV vaccine trial among adolescents in the Western Cape. Therefore, when none of the variables were held constant, the individual predictive ability of the above two predictors was strengthened. This suggests that psychosocial factors may play a crucial role in predicting WTP in a future Phase III HIV vaccine trial among adolescents. From the present study it is evident that isolating a theory such as the TPB may limit the prediction of WTP in an HIV vaccine trial. Instead, variables constituting an existing theory should be added to other variables, and these variables should be exposed to exploratory analyses. This process may initiate theory-testing and theory-building, as well as the eventual development of a robust theoretical model to explain the multifaceted nature of WTP in an HIV vaccine trial.

5.3 Attitude towards participation in an HIV vaccine trial as a predictor of WTP in a future Phase III HIV vaccine trial

Although there is no research that has tested the ability of the TPB to predict WTP in a future HIV vaccine trial, the findings that Attitude towards participation in an HIV vaccine trial is predictive of WTP in a future HIV vaccine trial is somewhat analogous to the findings of Gagnon & Godin (2000) and Zimet et al. (1999). Although this research focused on adolescents' intentions to receive a future HIV vaccine, which is vastly unrelated to HIV vaccine trial participation, the findings nevertheless suggest that attitude towards the HIV vaccine significantly predicted adolescents' intention to receive a future HIV vaccine. Similarly, the results of the present study indicate that Attitude towards participation in an HIV vaccine trial was a significant predictor of WTP in a future Phase III HIV vaccine trial. This finding may inform future research and suggests that positive attitudes toward participation in an HIV vaccine trial should be promoted among adolescents.

5.4 Perceived behavioural control as a predictor of WTP in a future Phase III HIV vaccine trial

The findings of the present study showed that Perceived behavioural control did not significantly predict WTP in a future Phase III HIV vaccine trial among adolescents in the Western Cape. As discussed by Ajzen (1988) perceived behavioural control is not entirely realistic in some situations, namely, if an individual has little information about the behaviour in question, when available resources have changed, or when new and unfamiliar factors have entered into the situation. Therefore, assessing perceived behavioural control in these situations may limit the accuracy of behavioural prediction (Ajzen, 1988).

Perceived behavioural control is influenced by an individual's control beliefs, namely, the beliefs about resources and opportunities available to perform the target behaviour. These beliefs may be based on past experience with the behaviour. Moreover, these beliefs will usually be influenced by information from external sources regarding the behaviour, by observing the experiences of salient others regarding the behaviour and by other factors that increase or decrease the perceived difficulty of performing the target behaviour (Ajzen, 1988). As suggested by Ajzen (1988) the TPB is a model in which the TRA is a special case. The TPB explicitly recognises that behaviours may not be under the complete volitional control of an

individual. However, when issues of control are not a fundamental consideration for an individual; the TPB reduces to the TRA (Ajzen, 1988). In cases where issues of control are not a fundamental consideration for an individual, neither intention nor actions will be influenced by beliefs of control over a specific behaviour, leaving attitudes toward the behaviour and subjective norms concerning the behaviour as the determinants of interest (Ajzen, 1988).

The findings of the present study, namely that Subjective norms and Attitude towards participation in an HIV vaccine trial were significant predictors of WTP in an HIV vaccine trial among this adolescent sample in the Western Cape provides support for the Theory of Reasoned Action (TRA) in predicting adolescent enrolment in HIV vaccine trials. Therefore, in this sample of adolescents, perceived behavioural control over participation in a future HIV vaccine trial was not a significant predictor. Instead, whether or not these adolescents would be willing to participate in a future Phase III HIV vaccine trial was influenced solely by their behavioural beliefs and normative beliefs.

A possible explanation for the support of the TRA and not the TPB as originally hypothesised is that in instances where beliefs about control over the behaviour are not primary to an individual, measuring perceived behavioural control may not be realistic and may limit the accuracy of behavioural prediction (Ajzen, 1988). Firstly, given that the present study was not aimed at recruiting participants for an HIV vaccine trial, it was clearly stipulated to the participants that the present study was merely assessing hypothetical WTP in a future Phase III HIV vaccine trial. Considering that hypothetical WTP in an HIV vaccine trial does not necessarily translate into actual WTP in an HIV vaccine trial (Buchbinder et al., 2004), issues of control over participation in a future HIV vaccine trial may not be among these adolescents' primary concerns. Preparations for future Phase III HIV vaccine trials are relatively new in developing countries such as South Africa. Moreover, research has shown that South Africans have low levels of knowledge regarding the HIV vaccine and HIV vaccine trials (Smit et al., 2006). South African communities have emphasised the need for information regarding HIV vaccines and HIV vaccine trials before being able to answer questions relating to WTP in these trials (Smit et al., 2006). This lack of information and unfamiliarity with the HIV vaccine trial may influence whether or not these individuals perceive issues of

control to be a fundamental consideration. Ajzen (1988) argues that an individual's control beliefs regarding the target behaviour are based on past experience with the behaviour, will usually be influenced by information from external sources and by observing the experiences of salient others regarding the behaviour. Once again, considering the unfamiliarity of South Africans with the HIV vaccine trial and the fact that Phase III HIV vaccine trials have not commenced in the country, these individuals have no reliable sources, information or experiences on which to base these control beliefs. Lastly, given that the majority of adolescents are still dependent on adult counterparts, these individuals are more likely to be concerned with attitudes and subjective norms regarding a hypothetical future Phase III HIV vaccine trial. As suggested by Swartz et al. (2005), there are constraints on the power and autonomy possessed by adolescents. The freedom to be in control of the behaviour in question is not likely to be determined by an adolescent but by those counterparts who they are dependent upon.

5.5 Self-perceived risk of HIV infection as a predictor of WTP in a future Phase III HIV vaccine trial

Much evidence suggests that there is a significant relationship between perceived risk of HIV infection and WTP in an HIV vaccine trial among numerous samples internationally, e.g. among Thai men (Jenkins et al., 2000), gay and bisexual men in Canada (O'Connell et al., 2002), men who have sex with men in Brazil (Périssé et al., 2000), Indian samples (Sahay et al., 2005) and Italian samples (Starace et al., 2006).

Although numerous studies have consistently reported a significant relationship between perceived HIV risk and WTP in an HIV vaccine trial in specific samples, there is a paucity of research focusing on this relationship among South African adolescents. Smit et al. (2006) found that in a South African sample consisting of 16-40 year old participants, self-perceived HIV risk was significantly associated with WTP in an HIV vaccine trial. Contrary to the findings of Smit et al. (2006), self-perceived risk of HIV infection was not a significant predictor of WTP in a future Phase III HIV vaccine trial among adolescent participants in the present study. However, the sample used in the study by Smit et al. (2006) was relatively small and consisted of participants who had already volunteered to be part of a longitudinal HIV-related study. Therefore, the finding that self-perceived risk of HIV infection was significantly associated with WTP in an HIV vaccine trial may not be generalisable to the entire community. The results of the present study indicate

that among adolescents in the Western Cape, self-perceived susceptibility to HIV infection may not influence their decision to participate in a future Phase III HIV vaccine trial. The relationship between perceived HIV risk and WTP in future HIV vaccine trials requires further investigation among South African communities.

5.6 Knowledge of HIV vaccines and HIV vaccine trials as a predictor of WTP in a future Phase III HIV vaccine trial

Although prior research has provided evidence for a significant relationship between knowledge of HIV vaccines and WTP in an HIV vaccine trial (Kiwanuka et al., 2004; Koblin et al., 2000; Sahay et al., 2005; Smit et al., 2006; Starace et al., 2006), Knowledge of HIV vaccines and HIV vaccine trials did not significantly predict WTP in a future Phase III HIV vaccine trial among adolescents in the present study. The finding that Knowledge of HIV vaccines and HIV vaccine trials is not predictive of WTP in future Phase III HIV vaccine trials is congruent with those of Halpern et al. (2001) and Priddy et al. (2006). Although logistic regression has no assumptions about the normality of predictor variables (Tabachnick & Fidell, 2001), the distribution of knowledge scores were significantly negatively skewed, indicating a pile up of scores on the right of the distribution. This is known as a ceiling effect and indicates that the majority of the participants scored high on the knowledge questionnaire. Consequently, there was limited variance in knowledge scores and this may have resulted in poor external validity which may have contributed to the null findings. Contrary to the evidence that South African's have low knowledge of HIV vaccines and limited scientific literacy to understand HIV vaccine trial methodology (Smit et al., 2006), the participants in the present study presented with high knowledge scores.

Before participants completed the battery of instruments, a short pre-test workshop was presented in which the HIV vaccine and the HIV vaccine trial methodology was presented and explained to participants. Consequently, the high knowledge levels in this sample may be an indication of participants' recall of the information presented to them regarding the HIV vaccine and HIV vaccine trial, rather than a true indication of knowledge levels in this sample. Moreover, contextual limitations associated with the data collection may have, in part, contributed to the high knowledge scores. Firstly, there were limited classroom facilities (lack

of space) and as a result, some participants were seated next to each other at the desks. Secondly, the teacher supervising the class read the questionnaires out to the participants in order to ensure that all participants finished in time for the next class scheduled to begin in that room. Given that the questionnaire assessing knowledge consisted of a true and false response option format, and that the teacher was reading to the participants, the adolescents may have regarded the process as a test or examination in which they were expected to give the correct answer to the questions being asked. Participants may have been influenced by their teacher and their peers to give the correct answer and may have easily copied fellow peers seated at the same desk as them.

5.7 Attitudes toward HIV/AIDS as a predictor of WTP in a future Phase III HIV vaccine trial

Although no prior research has directly focused on the relationship between attitudes toward HIV/AIDS and WTP in an HIV vaccine trial, in a qualitative research project conducted in South Africa, participants reported that the HIV vaccine's association with HIV/AIDS may be a potential inhibitor to participation in an HIV vaccine trial (Lesch et al., 2006). Participants in the study by Lesch et al. (2006) reported that there is a pervasive generalised negative perception of HIV/AIDS in the community. In the present study, no significant relationship was found between Attitudes toward HIV/AIDS and WTP in a future HIV vaccine trial among adolescents in the Western Cape. A possible reason for this null finding is that the AIDS-related Stigma Scale (Kalichman et al., 2005) used in the present study was not reliable in the adolescent sample. The guidelines offered by Nunally (1978) suggest that a reliability of 0.70 or higher is acceptable for scales used in beginning research. However, guidelines offered by Huysamen (1996a, cited in Wolfaardt, 2001) suggest that a reliability coefficient of 0.65 or higher is acceptable for decisions about groups.

The Internal consistency analysis of the AIDS-related Stigma Scale (Kalichman et al., 2005) revealed a Cronbach alpha reliability of $\alpha = 0.49$. After deleting two items, the internal consistency improved ($\alpha = 0.60$). However, the internal consistency could not be further improved. Following the guidelines provided by Huysamen (1996a, cited in Wolfaardt, 2001), the Cronbach alpha of $\alpha = 0.60$ for the AIDS-related Stigma Scale in the present study is not acceptable. Therefore, in the present study, the scale was not

a reliable measure of Attitudes toward HIV/AIDS in the adolescent sample and may have contributed to the null findings.

5.8 Health-promoting behaviours as a predictor of WTP in a future Phase III HIV vaccine trial

No prior research has investigated the relationship between health-promoting behaviours and WTP in an HIV vaccine trial. The findings of the present study showed no significant relationship between health-promoting behaviours and WTP in a future Phase III HIV vaccine trial among adolescents in the Western Cape. Health-promoting behaviours may not influence adolescents' decision to participate in a future HIV vaccine trial. A possible reason for this lack of association may be that the shortened form of the Health-Promoting Lifestyle Profile (HPLP) (Walker et al., 1987) used in the present study assessed solely health-promoting behaviours. Although unrelated to vaccine trial participation, Zimet et al. (1999) found that increased engagement in health-compromising behaviours (such as the use of marijuana and minimal condom use) was significantly associated with greater HIV vaccine acceptance among adolescents. It may be useful to measure a combination of health-promoting as well as health-risk behaviours. Given the lack of prior research, the relationship between health-promoting behaviours and WTP in an HIV vaccine trial requires further investigation.

5.9 Demographic characteristics

5.9.1 Age

It has been reported that younger age is significantly associated with WTP in an HIV vaccine trial (Buchbinder et al., 2004; Jenkins et al., 1998; O'Connell et al., 2002). Some evidence also suggests that increasing age is significantly associated with WTP in an HIV vaccine trial (Bartholow et al., 1997; Koblin et al., 1997; Smit et al., 2006). The results of the present study indicate that age is not associated with WTP in a future Phase III HIV vaccine trial. This finding is congruent with those of Jenkins et al. (2000), Kiwanuka et al. (2004), McGrath et al. (2001) and Viera De Souza et al. (2003). The null finding suggests that age may not influence the decision to participate in an HIV vaccine trial among this adolescents sample. Given that the sample used in the present study was an adolescent cohort, age is not likely to be a significant predictor of WTP in an HIV vaccine trial.

5.9.2 Gender

Previous studies have found males to be more willing to participate in an HIV vaccine trial (Jenkins et al., 1998; Smit et al., 2006). The results of the present study indicate no gender differences in terms of WTP in a future Phase III HIV vaccine trial. This finding is congruent with those of Kiwanuka et al. (2004) and Sahay et al. (2005). The findings of the present study therefore indicate no gender differences in adolescents' WTP in a future Phase III HIV vaccine trial. The null finding may, in part, be a result of low numbers of male participants relative to female participants.

5.9.3 Education

While some evidence suggests that high levels of education is significantly associated with WTP in an HIV vaccine trial (Jenkins et al., 2000), other studies have found that low levels of education is significantly associated with WTP in an HIV vaccine trial (Bartholow et al., 1997; Périssé et al., 2000; Viera De Souza et al., 2003). The results of the present study indicate that education was not associated with adolescents' WTP in an HIV vaccine trial. This finding is congruent with that of Kiwanuka et al. (2004). Education may not influence adolescents' decision to participate in an HIV vaccine trial.

5.9.4 Race

There is evidence that race is significantly associated with WTP in an HIV vaccine trial (Bartholow et al., 1997; Buchbinder et al., 2004; Halpern et al., 2001). Congruent with the findings of Viera De Souza et al., 2003, the results of the present study showed no significant relationship between race and WTP in a future Phase III HIV vaccine trial. However, the sample used in the present study was homogenous. Therefore the lack of racial differences contributed to the null findings.

5.10 Implications and social relevance

The findings of the present study suggest that psychosocial determinants may influence adolescents' decision to enrol in a future Phase III HIV vaccine trial. HIV vaccine preparedness programs targeting adolescents should aim to influence group norms positively, increase normative pressure and motivate adolescents to comply with this normative pressure to participate in an HIV vaccine trial. Additionally, HIV vaccine preparedness programs should aim to promote positive attitudes toward participation in a future

Phase III HIV vaccine trial among adolescents. Positive group norms and positive attitudes toward participation in an HIV vaccine trial may promote participation in a future Phase III HIV vaccine trial among young adults. Consequently, participation in an HIV vaccine trial may contribute to changes in public health and the eventual development of a safe and effective HIV vaccine to control the HIV pandemic.

5.11 Limitations

There were contextual difficulties associated with the data collected in this sample of adolescents. The lack of space and time resulted in a few participants being seated around one desk. Moreover, the questionnaires were read to the participants by the supervising teacher in order to ensure that participants finished in time for the next scheduled class in the room. These two contextual constraints may have led to a lack of variability in participant scores, specifically for the knowledge questionnaire. Participants may have been influenced by their fellow peers and social desirability responding may have been introduced. As a result of peer influence as well as the fact that the teacher read questionnaires to the participants, participants may have regarded the process as a test or examination in which they were expected to give the correct answer to the questions being read out to them. Therefore, it is a possibility that the participants may have influenced each other's responses. These contextual constraints may have resulted in poor external validity. Therefore, the extent to which the results of the present study can be generalised to the entire adolescent population is uncertain.

5.12 Directions for future research

Future research should consider implementing further quantitative research among South African adolescents in order to identify salient factors that may affect WTP in a future Phase III HIV vaccine trial. There is a paucity of research focusing on adolescents' WTP in future HIV vaccine trials, both internationally and in the South African context. Significant predictors of participation in a future HIV vaccine trial among adult samples may not be as salient for South African adolescents. Incorporating significant predictors that have been investigated in prior research studies, as well as those which have not yet been tested may initiate the process of theory-building. Future research aimed at determining the multifaceted nature of participation in a future Phase III HIV vaccine among South African adolescents awaits further investigation.

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APPENDIX A

STELLENBOSCH UNIVERSITY

Department of Psychology

(021) 808 3461

CONSENT TO PARTICIPATE IN RESEARCH

IDENTIFICATION OF FACTORS AFFECTING WILLINGNESS TO PARTICIPATE IN AN HIV VACCINE TRIAL

INVITATION TO PARTICIPATE

You are cordially invited to take part in the aforementioned research project.

AIM

The aim of this research project is to establish the factors that could affect individuals' willingness to participate in future HIV vaccine trials.

PROCEDURE

As a participant, you will be part of the study and asked to complete a questionnaire packet measuring various factors that may influence willingness to participate in an HIV vaccine trial (such as knowledge of HIV vaccines and vaccine trials, health lifestyle patterns and attitudes toward HIV/AIDS and HIV vaccines).

POTENTIAL COSTS, RISKS AND DISCOMFORT

There is no financial cost, risk or discomfort directly associated with taking part in this project.

POTENTIAL BENEFITS TO SUBJECTS AND/OR SOCIETY

There is no guarantee that you will benefit directly from the study but your participation will contribute to the research in this field and therefore eventually be a benefit to society if a safe and effective vaccine is developed to prevent HIV.

COMPENSATION

By agreeing to take part in this research study, you will receive a small token of appreciation for your participation.

CONFIDENTIALITY

Every attempt will be made to keep all information collected in this study strictly confidential, except as may be required by court order or by law. If any publication results from this research, you will not be identified by name.

ADDITIONAL INFORMATION

Your participation in this study is completely voluntary, and you are free to refuse to take part. You may stop taking part at any time without consequences of any kind. If you stop taking part in the project, you may

ask that we not use the information already given to us. You may also refuse to answer any questions you don't want to answer and still remain in the study. The investigator may withdraw you from this research if circumstances arise which warrant doing so. You are encouraged to ask questions about the study at any time as they occur to you during the programme. Any important new findings developed during the course of the study that may relate to your willingness to continue taking part will be given to you.

DISCLAIMER/ WITHDRAWAL

You agree that taking part in this study is completely voluntary and that you may stop at any time.

SUBJECT RIGHTS

If you have any questions regarding taking part in this research study, you may contact the Principal Investigator, Georgina Giocos, by telephoning 082 778 73 78 or the Research Supervisor, Professor Ashraf Kagee, by telephoning (021) 808 3442.

CONCLUSION

By signing below you are indicating that you have read and understood the consent form and that you agree to take part in this research study.

_____ Date _____

Subject's signature

_____ _____

Investigators signature Date

IDYUNIVESITHI YASE STELLENBOSCH
Isebe leSayikholoji (uBunzululwazi ngengqondo)
(021) 808 3461

IMVUME YOKUTHATHA INXAXHEBA KUPHANDO

UKWAZISWA KWEMIBA ENXULUMENE NOKUBA NOMDLA EKUTHATHENI INXAXHEBA KUVAVANYO/UKULINGWA KWEYEZA ELIKHUSELA UMNTU ANGOSULELWA YIHIV

ISIMEMO SOKUTHATHA INXAXHEBA

Uyamenywa ngobubele ukuba uthathe inxaxheba kule nkqubo yophando ekhankanywe apha ngasentla.

INJONGO

Injongo yolu phando kukufumanisa ngemiba enokuthi inxulumane nomdla wabantu ekuthatheni inxaxheba kuvavanyo /ukulingwa kweyeza elikhusela ukungosulelwa yiHIV kwixesha elizayo.

IMIGAQO

Njengothatha inxaxheba, uza kuba yinxalenye yale nkqubo kwaye uzakucelwa ukuba ugcwalise umqulu wephepha lemibuzo elivavanya iintlobo ngeentlobo zemiba enokuchaphazela umdla ekuthatheni inxaxheba kuvavanyo /ukulingwa kweyeza elikhusela ukungosulelwa yiHIV (njengolwazi lwamayeza akhusela ukungosuleleki yiHIV,kunye nokuvavanywa kwamayeza akhuselayo, iindlela zokuphila kunye nezimvo ngamayeza akhusela ukungosulelwa yiHIV/AIDS).

IINTLAWULO, UBUNGOZI KUNYE NOKUNGAKHULULEKI OKUNOKUBAKHO

Akusayibakho zintlawulo, bungozi okanye ukungakhululeki okuqondene ngqo nokuthatha inxaxheka kule nkqubo.

INZUZO KUBATHATHI NXAXHEBA KUNYE/OKANYE KULUNTU.

Akukho siqinisekiso sokuba kungakho inzuzo eqondene ngqo nale nkqubo kodwa ukuthatha kwakho inxaxheba kuza kuba negalelo kuphando ngalo mxholo ze ekugqibeleni kube luncedo kuluntu xa iyeza elikhuselekileyo nelisebenza ngokufanelekileyo lifunyaniswe ukuba linqada ukosuleleka yiHIV.

ISIBONELELO

Ngokuthatha inxaxheba kule nkqubo yophando , uza kufumana isibonelelo esingephi njengombulelo wokuthatha kwakho inxaxheba.

IMFIHLELO

Inzame yokuba ulwazi oluqokelelweyo luhlale luyimfihlelo kule nkqubo luzakwenziwa, ngaphandle kwaxa lunokufunwa yinkundla okanye ngokwasemthethweni. Xa kungakho upapasho olwenziwayo kolu phando, igama lakho alisayi kukhankanywa.

ULWAZI OLWENGEZELELWEYO

Ukuthatha inxaxheba kolu phando lolokuzinikela ngokupheleleyo, kwaye ukhululekile ukwala ukuthatha inxaxheba. Unganqumama ekuthatheni inxaxheba nanini na ngaphandle kokusengelwa phantsi. Xa uyeka ukuthatha inxaxheba kule nkqubo yophando, unakho ukucela ukuba singalusebenzisi ulwazi osinike lona. Kwakhona unakho ukwala ukuphendula nayiphi na imibuzo ongafuni kuyiphendula kwaye uhlale ukule nkqubo. Umphandi angakuyekisa kolu phando xa iimeko zinyanzelisa. Uyakhuthazwa uba ubuze imibuzo ebhekiselelele kolu phando nanini na ngendlela evela ngayo kuwe ngexesha lale nkqubo.

UKUYEKA

Uyavuma ukuba ukuthatha inxaxheba kolu phando lolokuzinikela ngokupheleleyo yaye ungayeka nanini na.

AMALUNGELO ALOWO UTHATHA INXAXHEBA

Xa unemibuzo malunga nokuthatha inxaxheba kule nkqubo yophando, ungatsalela Umphathi Omkhulu wophando, uGeorgina Giocos, ngokutsalela le nombolo 082 778 73 78 okanye Umongameli Wophando, u Professor Ashraf Kagee, ngokutsalela le nombolo (021) 808 3442.

ISIPHELO

Ngokusayina apha ngezantsi ubonisa ukuba uyifundile kwaye wayiqonda ifomu yemvumelwano kwaye uyavuma ukuthatha inxaxheba kule nkqubo yophando.

_____ _____

Usayino lomthathi nxaxheba Umhla

_____ _____

Usayino lomphandi Umhla

APPENDIX B

1. Please indicate your gender here by placing a cross (X) in the appropriate box below/ Nceda bonakalisa isini sakho ngokufaka unongxabalaza (X) kwibhokisi efanelekileyo apha ngezantsi:

Male / Ndoda	
Female / Mfazi/Bhinqa	

2. Please write your age here / Nceda bhala iminyaka yakho apha: _____

3. What grade are you currently in? / Ukweliphi ibanga ngoku? _____

4. Please indicate which population group you belong to by placing a cross (X) in the appropriate box below / Nceda bonakalisa ukuba ungummi weliphi na iqela ngokufaka unongxabalaza (X) kwibhokisi efanelekileyo apha ngezantsi:

Black / Mnyama	
Coloured / Webala	
White / Mhlophe	
Indian / Ndiya	
Asian / M-Asiya	
Other / Ezinye _____	

5. **Please note the example below / Nceda qaphela lo mzekelo ongezantsi:**

Very Low Risk / Ndisengciphekweni encinci kakhulu — Very High Risk/ Ndisengciphekweni enkulu kakhulu

|_____X_____|

Following the example above, please indicate with a cross (X) on the line below how much at risk you THINK you are of contracting HIV / Ulandela lo mzekelo ongentla, nceda bonakalisa ngonongxabalaza (X) kulo mgca ongezantsi ubungakanani bengcipheko OCINGA ungakuyo yokusuleleka yiHIV

Very Low Risk / Ndisengciphekweni encinci kakhulu

Very High Risk / Ndisengciphekweni enkulu kakhulu

|_____|

6. **Please note the example below / Nceda qaphela lo mzekelo ongezantsi:**

Very Unwilling Ndinomdla kakhulu

Very Willing Andinamdla kakhulu

|_____X_____|

Following the example above, please indicate how willing you are to participate in an HIV vaccine trial by placing a cross (X) on the line below / Ulandela lo mzekelo ongentla, nceda bonakalisa ukuba unomdla kangakanani na ekuthatheni inxaxheba kuvavanyo/ukulingwa kweyeza elikhusela ukungosulelwa yiHIV ngokufaka unongxabalaza (X) kulo mgca ongezantsi:

Very Willing Ndinomdla kakhulu

Very Unwilling Andinamdla kakhulu

|_____|

APPENDIX C

	TRUE EWE	FALSE HAYI
1. A placebo is a fake treatment that is similar to the real vaccine or drug/ Iplacebo liyeza elingelilo elifana neyeza lokukhusela okanye iyeza eliyobisayo/isiyobisi.		
2. In a clinical trial there are usually two groups of people: one group that receives the real vaccine or drug and the other group that receives a fake vaccine or drug (placebo) / Kuvavanyo lwasekliniki kudla ngokuba namaqela amabini abantu: Elinye iqela lifumana iyeza elililo lokukhusela okanye isiyobisi ze abanye bafumane iyeza elingelilo lokukhusela/isiyobisi.		
3. It is important that the individuals placed in each group in a clinical trial are similar to each other in as many ways as possible / Kubalulekile ukuba abantu ababekwe kwiqela ngalinye kuvavanyo lwasekliniki bafane kangangoko.		
4. In a clinical trial, neither the clinicians nor the participants know which group has received the real vaccine or drug and which group has received the fake medication (placebo) / Kuvavanyo lwasekliniki, akunakubakho gqirha kwaye kungenakubakho bathathi-nxaxheba abanganolwazi ngokuba leliphi iqela elifumene iyeza elililo okanye isiyobisi kunye nelo elifumene iyeza elingelilo(into efana neyeza kodwa elingelilo esetyenziswa ekukholiseni nje)		
5. Sometimes some participants in a clinical trial may recover from an illness even though they only receive the fake vaccine or drug (placebo) / Ngamanye amaxesha abanye babathathi-nxaxheba kuvavanyo lwasekliniki bangaziva bengasaguli/bephilile noxa befumene iyeza elingelilo okanye isiyobisi (into efana neyeza kodwa elingelilo esetyenziswa ekukholiseni nje).		
6. When testing a new medication or vaccine it is necessary to have a group that receives only a placebo. This will help researchers to determine whether the new medication works better than the fake medication		

(placebo) / Xa kuvavanya/kulingwa iyeza elitsha kumele kubekho iqela elifumana into efana neyeza kodwa elingelilo elisetyenziswa ekukholiseni qha. Le nto inceda abaphandi ukuba baqinisekise ukuba ingaba eli yeza elitsha lisebenza ngcono na kuneyezelingelilo (into efana neyeza kodwa elingelilo esetyenziswa ekukholiseni nje).		
7. HIV vaccines are given to help prevent someone from becoming infected with HIV / Amayeza akhusela ukungosulelwa yiHIV anikelwa ukunceda umntu angosuleleki yiHIV.		
8. HIV vaccines are given only to children, never to adults / Amayeza akhusela ukungosulelwa yiHIV anikwa abantwana bodwa, hayi abantu abadala.		
9. If a person receives a new HIV vaccine that does not work properly, he or she may not be protected from becoming infected with HIV / Amayeza amatsha akhusela ukungosulelwa yiHIV kumele avavanywe ukuze kwazeke/kubonakale ukuba ngokwenene ayasebenza ekukhuseleni umntu angosuleleki yiHIV.		
10. An HIV vaccine can never give you HIV or AIDS / Iyeza elikhusela ukungosulelwa yiHIV alingeke likunike iHIV okanye iAIDS.		
11. HIV vaccines are tested on human beings only once they have been shown to be safe in animals / Amayeza akhusela ukungosulelwa yiHIV avavanywa ebantwini kuphela xa sele kufunyaniswe ukuba akhuselekile kwizilwanyana.		
12. If you decide to participate in an HIV vaccine trial, you will receive information about the trial before you are included in the study / Xa wenze isigqibo sokuthatha inxaxheba kuvavanyo/ukulingwa kwamayeza akhusela ukungosulelwa yiHIV, uzakufumana/uzakunikwa ulwazi malunga novavanyo phambi kokuba ufakwe kule nkqubo yophando.		
13. People who want to enroll in an HIV vaccine trial will be asked to sign a form saying that they agree to participate before they are included in the trial / Abantu abafuna ukubhalisela olu vavanyo/ukulingwa kweyeza elikhusela umntu angosulelwa yiHIV bazakucelwa ukuba basayine ifomu		

exela ukuba bayavuma ukuthatha inxaxheba phambi kokuba bafakwe kolu vavanyo.		
14. If you receive an HIV vaccine it is possible that you may test HIV positive even though you are not really infected with HIV / Xa unikwe eli iyeza elikhusela ukungosulelwa yiHIV kusenokwenzeke ukuba ufunyaniswe uneHIV nangona ungosulelekanga kwaphela yiHIV.		
15. If people have unsafe sex, the HIV vaccine being tested might not protect them from becoming infected with HIV / Xa abantu besababelana ngesondo ngendlela engakhuselekanga, eli yeza elikhusela ukungosulelwa yiHIV elivavanywa kubo lingangabakhuseli ekosulelekeni yiHIV.		
16. People who take part in HIV vaccine trials will receive free health care at the study clinic only for trial-related medical problems / Abantu abathatha inxaxheba kuvavanyo/ukulingwa kweyeza elikhusela ukungosulelwa yiHIV bazakongiwa simahla/ngaphandle kwentlawulo kwikliniki eyodwa eqhuba olu phando malunga nokugula okunokubakho okudibene nolu vavanyo.		
17. If you enroll in an HIV vaccine trial you will get the appropriate medication, medical tests, and HIV tests regularly all the way through the trial / Xa ubhalisile kolu vavanyo/ukulingwa kwamayeza akhusela ukungosulelwa yiHIV uza kufumana unyango ngamayeza olufanelekileyo, ukuxilongwa, novavanyo lweHIV rhoqo lude lugqitywe olu vavanyo.		
18. If you enroll in an HIV vaccine trial, each time you visit the trial site you will be asked questions about your health and sexual behaviour / Xa ubhalisile kolu vavanyo/ukulingwa kwamayeza akhusela ukungosulelwa yiHIV, ngalo lonke ixesha usiya kule ndawo yovavanyo uza kubuzwa imibuzo emalunga nempilo yakho kunye nendlela oziphethe ngayo ngokwezesondo.		
19. People who take part in an HIV vaccine trial will be allowed to stop their involvement in the trial at any time / Abantu abathatha inxaxheba kolu vavanyo lwamayeza akhusela ukungosulelwa yiHIV bazakuvunyelwa		

ukuba bayeke ukuthatha inxaxheba nanini na.		
20. An HIV vaccine trial is a study in which an HIV vaccine is tested to see if it prevents people from contracting HIV / Uvavanyo/ukulingwa kweyeza elikhusela ukungosulelwa yiHIV yinkqubo yophando apho iyeza elikhusela umntu angosulelwa yiHIV livavanywa ukuze kufunyaniswe uba ingaba liyabakhusela na abantu ekosulelekeni yiHIV.		
21. In an HIV vaccine trial, scientists want to know whether there are fewer HIV infections in the group that receives the HIV vaccine than in the group that receives the fake HIV vaccine (placebo) / Kuvavanyo/ukulingwa kweyeza elikhusela ukungosulelwa yiHIV, iinzululwazi zifuna ukuqonda ukuba ingaba ukosuleleka kukambalwa (kukancinci) na kwiqela elifumene iyeza elililo lokukhusela ukungosulelwa yiHIV kuneqela elifumene iyeza elingelilo elikhusela ukungosulelwa yiHIV (into efana neyeza kodwa elingelilo esetyenziswa ukukholiseni).		
22. If fewer people in the group that receives the real vaccine develop HIV than those who are given the fake HIV vaccine (placebo), we can say that the vaccine is working effectively / Xa bembalwa abantu ababonakala beneHIV kwiqela elifumene iyeza elililo kunabo abakwiqela ebelinikwe iyeza elingelilo (into efana neyeza kodwa elingelilo esetyenziswa ukukholiseni), sinokuthi eli yeza lisebenza ngokufanelekileyo.		
23. In an HIV vaccine trial, all participants have an equal chance of being placed in the group that receives the real vaccine or the group that receives the fake vaccine (placebo) / Kuvavanyo/ukulingwa kweyeza elikhusela ukungosulelwa yiHIV, bonke abathatha inxaxheba banethuba elilinganayo lokufakwa/kungeniswa kwiqela elifumana iyeza elililo okanye iqela elifumana iyeza elingelilo (into efana neyeza kodwa elingelilo esetyenziswa ekukholiseni).		

APPENDIX D

	Strongly Disagree/ Andiyavumelani kakhulu	Disagree / Andivumelani	Agree / Ndiyavumelana	Strongly Agree / Ndiyavumelana kakhulu
24. People with AIDS are dirty / Abantu abaneAIDS bamdaka.				
25. People who have AIDS are cursed / Abantu abaneAIDS baqalekisiwe.				
26. People who have AIDS should be ashamed / Abantu abaneAIDS kumele babe neentloni.				
27. It is safe for people who have AIDS to work with children / Kukhuselekile ukuba abantu abaneAIDS basebenze nabantwana.				
28. People with AIDS must expect some restrictions on their freedom / Abantu abaneAIDS kumele bayilindele imiqathango ethile malunga nokuzimela/ukuziphatha kwabo.				
29. A person with AIDS must have dome something				

wrong and deserves to be punished / Umntu oneAIDS udla ngoba enze okungalunganga kwaye kumele ohlwaywe.				
30. People who have HIV should not be isolated / Abantu abaneAIDS kumele bangangabi bodwa.				
31. I do not want to be friends with someone who has AIDS / Andifuni kwenza ubuhlobo nomntu oneAIDS.				
32. People who have AIDS should be allowed to work / Abantu abaneAIDS kumele bavunyelwe ukuba basebenze.				

APPENDIX E

	Never Zange	Sometimes /Ngamanye amaxesha	Often / Kaninzi	Routinely / Ngokuqhelekileyo
33. I feel content and at peace with myself / Ndiziva ndikholisekile kwaye ndinoxolo ngam/ngesiqu sam.				
34. I find each day interesting and challenging / Ndifumanisa usuku ngalunye lunomtsalane kwaye lucela umngeni.				
35. I believe that my life has purpose / Ndinenkolelo yokuba ubomi bam bunenjongo.				
36. I like myself / Ndiyazithanda.				
37. I ask for information from health professionals about how to take good care of myself / Ndicela ulwazi kumagosa empilo ngendlela elungileyo yokuzikhathalela.				
38. I discuss my health concerns with health professionals / Ndixoxa iingxaki/iinkxalabo ngempilo yam namalungu ezempilo.				
39. I check my blood pressure / Ndiyalwenza uvavanyo loxinzelelo lwegazi.				
40. I exercise vigorously for 20 minutes or more at least three times a week (such as brisk walking, bicycling, aerobic dancing etc.) / Ndizilolonga ngamandla kangangemizuzu eyi 20 okanye nangaphezulu ubuncinane kathathu ngeveki (ngolu hlobo ukuhamba ngokukhawuleza, ukuqhuba ibhayisikile,				

ngomdaniso wokuzilolonga njalo njalo.)				
41. I do stretching exercises at least three times per week / Ndizilolonga ngokutwabulula imisipha ubuncinci kathathu ngeveki.				
42. I eat three meals daily / Nditya kathathu ngemini.				
43. I eat breakfast / Ndiyasitya isidlo sakusasa.				
44. I touch and am touched by people I care about / Ndiyabachukumisa kwaye nam ndiyachukumiseka ngabantu endibakhathalelayo.				
45. I maintain meaningful and fulfilling relationships with others / Ndiyabugcina ubudlelwane obunentsingiselo nobufezekileyo nabanye.				
46. I relax my muscles before I sleep / Ndiyekelela imisipha yam phambi kokuba ndilale.				
47. I use specific methods to control my stress / Ndisebenzisa indlela ethile ukulawula isigxiniso esimandla.				

APPENDIX F

Participating in an HIV vaccine trial will be / Ukuthatha inxaxheba kuvavanyo/ukulingwa kweyeza elikhusela ukungosulelwa yiHIV kuza kuba:

54. Harmful/ Nengozi	1	2	3	4	5	6	7	Beneficial / Luncedo
55. Good / Kokulungileyo	1	2	3	4	5	6	7	Bad / Kokubi
56. Pleasant / Mnandi	1	2	3	4	5	6	7	Unpleasant / Kungemnandi
57. Worthless / Kokungento	1	2	3	4	5	6	7	Worthwhile / Lulutho
58. Important / Kubaluleka	1	2	3	4	5	6	7	Unimportant / Kokungabalulekanga
59. Admirable / Kokuncomekayo	1	2	3	4	5	6	7	Non Admirable / Kokungancomekiyo
60. Necessary / Kokufunekayo	1	2	3	4	5	6	7	Unnecessary / Kokungafunekiyo
61. Beneficial / Noncedo	1	2	3	4	5	6	7	Non beneficial / Kokungenancedo
62. Silly / Bubuhiba	1	2	3	4	5	6	7	Clever / Bubulumko

APPENDIX G

	Strongly Disagree/ Andivumelani kakhulu	**Disagree/ Andivumelani**	**Agree/ Ndiyavumelana**	**Strongly Agree/ Ndiyavumelana kakhulu**
48. Most people who are important to me think that I should participate in an HIV vaccine trial / Abantu abaninzi ababalulekileyo kum bacinga ukuba kumele ndithathe inxaxheba kuvavanyo/ukulingwa kweyeza elikhusela ukungosulelwa yiHIV.				
49. It is expected of me to participate in an HIV vaccine trial / Kulindeleke ukuba ndithathe inxaxheba kuvavanyo/ukulingwa kweyeza elikhusela ukungosulelwa yiHIV.				
50. I feel under social pressure to participate in an HIV vaccine trial / . Ndiziva ndiphantsi kwesinyanzelo/koxinzelelo lwabanye ukuba ndithathe inxaxheba kuvavanyo/ukulingwa				

kweyeza elikhusela ukungosulelwa yiHIV.				
51. Most people who are important to me are willing to participate in an HIV vaccine trial / Abantu abaninzi ababalulekileyo kum bayafuna ukuthatha inxaxheba kuvavanyo/ ukulingwa kweyeza elikhusela ukungosulelwa yiHIV.				
52. Doing what significant people in my life think I should do is important to me / Ukwenza oko abantu ababalulekileyo ebomini bam abacinga ukuba kumele ndikwenze kubalulekile kum.				
53. Approval of my participation in an HIV vaccine trial is important to me / Ukwamkeleka kwam kolu vavanyo/ ukulingwa kweyeza elikhusela ukungosulelwa yiHIV kubalulekile kum.				

APPENDIX H

	Strongly Disagree / Andivumelani kakhulu	Disagree / Andivumelani	Agree / Ndiyavumelana	Strongly Agree / Ndiyavumelana kakhulu
63. I am confident that I could participate in an HIV vaccine trial if I wanted to / Ndikholelwa ekubeni ndingayithatha inxaxheba kuvavanyo/ukulingwa kweyeza elikhusela ukungosulelwa yiHIV.				
64. It would be very difficult for me to participate in an HIV vaccine trial / Kunganzima kakhulu kum ukuthatha inxaxheba kuvavanyo/ukulingwa kweyeza elikhusela ukungosulelwa yiHIV.				
65. The decision to participate in an HIV vaccine trial is beyond my control / Isigqibo sokuthatha inxaxheba kuvavanyo/ukulingwa kweyeza elikhusela				

ukungosulelwa yiHIV singaphaya kwamandla am				
66. Whether or not I decide to participate in an HIV vaccine trial is entirely up to me / Nokuba ndithatha inxaxheba okanye andiyithathi kuvavanyo/ ukulingwa kweyeza elikhusela ukungosulelwa yiHIV oko kuxhomekeke kum ngokupheleleyo.				
67. I would not be able to participate in an HIV vaccine trial even if I wanted to / Andinawukwazi ukuthatha inxaxheba kuvavanyo/ ukulingwa kweyeza elikhusela ukungosulelwa yiHIV nokuba bendifuna.				
68. I could easily participate in an HIV vaccine trial if I wanted to / Kungalula ukuthatha inxaxheba kuvavanyo/ ukulingwa kweyeza elikhusela ukungosulelwa yiHIV xa ndifuna.				
69. It is up to me to decide whether or not I will				

participate in an HIV vaccine trial / Kuxhomekeke kum ukwenza isigqibo sokuba ndingakwazi okanye ndingangakwazi ukuthatha inxaxheba kuvavanyo/ ukulingwa kweyeza elikhusela ukungosulelwa yiHIV.				