

**An Exploratory Study of Students' Understandings and
Experiences of Vaccination: Implications For Future HIV
Vaccine Trials In South Africa**

BY

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DECLARATION

I declare that unless specifically indicated to the contrary, this thesis is the result of my own work.

A handwritten signature in cursive script, appearing to read "Luigina".

February 2004

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ABSTRACT

As Africa faces the challenges of its renewal or renaissance, the HIV/AIDS epidemic poses the greatest potential barrier to the attainment of this vision (Makgoba, 2001 in Dorrington, Bourne, Bradshaw, Laubscher & Timaeus, 2001). The development of an HIV vaccine that is safe, effective and affordable, has been widely contemplated as a necessary supplement to already established interventions. In preparation for HIV vaccine trials in South Africa the current project aimed to assess students' understanding (knowledge and perceptions) and experiences of vaccination in general, and to explore if these were associated with demographics such as motherhood and gender. A parallel aim was to assess students' knowledge and expectations of HIV vaccination and trial participation. A sample of 33 students was recruited from university residences at the University of Natal, Pietermaritzburg. Participants were interviewed via a semi-structured interview schedule. The data collected was then coded and analysed using content analysis, while Chi - square analysis was used to evaluate if demographics such as gender and motherhood were systematically associated with various responses.

The results revealed that the vast majority of participants (97%) knew the purpose of vaccination, stating that it was to promote health and prevent illness. Most participants (67%) knew that vaccination works by mobilising the immune system (vaccination mechanism). The vast majority of participants (91%) could name at least one vaccine preventable disease. Uptake of childhood immunisation was reportedly high (88%) while adult uptake of immunisation was low (33%). A significant minority (36%) reported that they had experienced side effects but understood these to be an integral part of vaccination. Thirty percent of participants stated they were willing to participate (WTP) in a hypothetical vaccine trial, 33 % of participants were not WTP and 15% were not sure. Motivations for trial participation were reportedly influenced most by personal incentives of altruism (39%) and barriers such as perceived significant physical risk (61%). In general, knowledge and experiences of vaccination were not associated with gender or with motherhood. The results suggest that more awareness of HIV vaccine trials is needed. In this regard education should emphasise that the prospective vaccine will be preventive, that only healthy people can volunteer and that the HIV vaccine will not guarantee immunity to HIV infection. Suggestions are made for future research into motivations, barriers and incentives to facilitate an ethical process of vaccine trial participation.

1.1 Introduction

Current UNAIDS statistics on HIV morbidity and mortality rates are increasing, indicating that the HIV/AIDS pandemic is worse than the Black Death of the 14th century, the bubonic plague epidemic that killed over 50 million people throughout Asia and Europe (Makgoba, Solomon, Johan & Tucker, 2002). As South Africa embraces its relatively new democracy, after a long but victorious fight against an oppressive regime under apartheid rule, AIDS threatens the exciting prospects of life as a 'rainbow nation'. At the turn of the twentieth century the AIDS pandemic remains an unprecedented challenge for both health prevention and medical research, with approximately 42 million people living with AIDS world-wide (UNAIDS - WHO, 2002). Of this figure South Africa has the largest number of people living with HIV than any other country (Bekker & Morris, 2002; Dorrington et al., 2001). Like with many developing countries the severity of the AIDS pandemic in South Africa has expressed itself in human, public health, social and economic terms. While various strategies to control the epidemic have been implemented, behavioural interventions have been the most widely used prevention strategy against the AIDS crisis. Antiretroviral therapy¹ and drugs for infants to reduce mother to child transmission and ameliorate symptoms for HIV/AIDS sufferers have also been recognised treatments for HIV infection. However, these are not widely available in South Africa. Up until now, collective intervention efforts have not made a significant health impact (Harrison, Smit & Myer, 2000). Thus, an HIV preventive vaccine² has been widely and seriously considered as a necessary supplementary intervention to control the spread of HIV infection.

In general, immunisation³ remains one of the most cost effective and efficacious health interventions to prevent disease, saving an estimated 3 million lives each year throughout the world (Hall & O'Brien, 1998). Efforts by the Expanded Programme on Immunisation (EPI)

¹ Antiretroviral – a group of drugs, which reduce the reproduction of HIV in the body (Barrett, 1998).

² Vaccine – “Vaccines are materials derived from infectious agents which are administered in order to stimulate the immune system to produce an effective immune response similar to that produced by the corresponding infectious agent but without its associated disease” (Schoub, 2002, p. 561).

³ Immunisation – another synonym for vaccination like inoculation, often used in the context of childhood preventive health measures and also refers to the process or behaviour of being immunised.

have focussed on universal childhood immunisation from disease including polio, measles, and hepatitis (Henderson, 2000; Wright, 1995). As the third decade of the AIDS pandemic unfolds, there remains no HIV vaccine that has been demonstrated to be safe and effective. It has been widely emphasised that

“...the successful development of effective HIV preventive vaccines is likely to require that many candidate vaccines be studied simultaneously in different populations around the world. This in turn will require a large international co-operative effort drawing on partners from various health sectors, intergovernmental organisations, government, research institutions, industry, and affected populations” (UNAIDS, 2000, p. 5).

Although developing countries bear the brunt of the AIDS burden (International AIDS Vaccine Initiative [IAVI], 1998; Joint United Nations Program on AIDS in collaboration with the World Health Organisation [UNAIDS-WHO], 2002), thus far only two HIV vaccine trial initiatives have been carried out in Africa (Weidle, Mastro, Grant, Nkengasong & Macharia, 2002) of an approximate 30 HIV vaccine trials currently being run world-wide (Slack et al., 2000). Therefore it is imperative that HIV initiatives also increase in this region. During the process of HIV vaccine development and implementation, attention to ethical standards will be required to avoid exploitation of vulnerable communities – most prevalent in developing countries. Thus, the partners involved in the development of an HIV vaccine will have to address the difficult ethical concerns that arise (Makgoba, et al., 2002).

In many respects, South Africa is one ideal place in sub-Saharan Africa to conduct HIV vaccine trials, in that it meets the necessary criteria (Abdool Karim, 2002), and has been identified as such by the World Health Organisation (WHO) (Barrett, 1998). Initiatives such as the South African AIDS Vaccine Initiative (SAAVI) can therefore play a key role in facilitating the development of a local vaccine and in ensuring that the rights of potential participants are protected. Communities in the developing world have sometimes been considered good candidates for medical research because they tend to be poor, malnourished, illiterate and desperate (Moodley, 2002). “HIV in South Africa flourishes most in areas that are burdened by unemployment, homelessness, welfare dependency, prostitution, crime, a high school drop-out rate, and social unrest” (Lindegger & Wood, 1995, p. 8). The safeguarding of rights of these often vulnerable communities is therefore crucial (UNAIDS, 2000). Certain South African communities, especially those in rural areas, may also be

described as vulnerable due to the high poverty rates accompanied by a myriad of social ills including a high incidence of HIV infection. Therefore these communities must be protected from potential exploitation in research (Moodley, 2002). This is particularly poignant in South Africa where undermining fundamental human rights (through apartheid) was legitimised.

In South Africa, the relevance of psychology to the community has been questioned in the past, especially given its 'apparent silence' in the apartheid era (Lindegger & Wood, 1995). Psychology as a profession has been accused of marginalizing itself from the majority in South Africa, with psychological services being seen generally as a luxury and accessible to the wealthier minority (Heyns, 1992 in Lindegger & Wood, 1995). The AIDS pandemic in South Africa marks another historical era, posing a major challenge to the health care industry. As a behavioural science, psychology has an especially important role to play with various aspects of AIDS and its prevention (ibid). Specifically, psychologists may intervene through policy development; preventive education campaigns; education and training of lay counsellors; psychological counselling for screening (and for) HIV-affected people, their families, co-workers and carers; psychological services for the 'worried well'; assisting with training of health care workers; and conducting AIDS related research (Schneider, 1989 in Lindegger & Wood, 1995). Therefore psychology has a role to play in the preparation and implementation of trial phases for HIV trials (Abdool Karim, 2002), which are due to begin in 2003 in South Africa. In conjunction with a series of vaccination studies being carried out in the country (da Silva, 2003; Lindegger, Quayle & Slack, 2003) the current study aims to explore knowledge, perceptions of and experiences with vaccination. These results may be used to inform education campaigns and informed consent procedures (which are required for adequate preparation) for communities in preparation for vaccine trials.

1.2 Rationale for the study

The development of local HIV vaccines has been identified as an urgent need in South Africa (Abdool Karim, 2002; Bekker & Morris, 2002; Galloway, 2000; Williamson C., Morris, Rybicki & Williamson, A.L., 2000). As South Africa is in the process of commencing safety trials, the following study, in conjunction with a series of studies currently underway in South Africa, has a role to play in the general preparation of HIV vaccine trials. According to Slack et al.

“Vaccine trials may be alien or unwelcome concepts in communities from which participants for trials are drawn. A counter-view posits that, since other forms of immunisation and vaccination are already so widespread, HIV vaccine trials may be perceived as extensions of familiar health protective practices” (2000, p. 291).

The current study assumes the latter view. Therefore it is based on the premise that South Africans have a longstanding history with infant immunisation, childhood immunisation, adult vaccination and vaccination for travel purposes, as forms of preventive health practices. Therefore community attitudes to vaccination could be surveyed in preparation for HIV vaccine trials (Slack et al., 2000).

Various studies have also been carried out throughout the globe assessing people’s knowledge, attitudes and experiences toward vaccination in general and these have yielded variable results. Studies on people’s willingness to participate in hypothetical HIV vaccine trials have also been documented together with perceived barriers to participation. The findings are presented in Chapter 2. In South Africa however, information on people’s knowledge, experiences and attitudes toward general vaccination is sparse, with only a few studies having been documented. Even fewer studies have investigated perceptions of potential HIV vaccination in South Africa. Moreover, given the advent of HIV vaccine trials more studies of this nature are especially required now.

In general, vaccine development is highly technical and complex. It is important to uncover peoples’ knowledge, attitudes and experiences with vaccination in general to identify important health beliefs in different communities so as to aid researchers in the conduct of culturally sensitive research. Misconceptions and attitudes toward vaccination could also be extracted. This would help to generate ways of communicating the complex technicalities of vaccines in a more meaningful and acceptable way for the communities concerned. This is one way that communities may impact on implementation of vaccine development (UNAIDS, 2000). Therefore the current study in conjunction with two other studies being conducted at the University of Natal, Pietermaritzburg (da Silva, 2003; Lindegger et al., 2003) attempt to bridge a knowledge gap by exploring indigenous knowledge, experiences and attitudes toward vaccination in general with different samples of the South African population. A practical application of these findings would be to inform education campaigns

and informed consent procedures as part of the preparation for HIV vaccine trials in South Africa.

1.3 Aims and objectives of the study

The current study is an investigation of university students' understandings of vaccination, and their experiences. The key objectives are to assess students':

- Understandings of vaccination: Knowledge and perceptions of vaccination in general, including perceived barriers to vaccination;**
- Experiences of vaccination generally;**
- Knowledge of and expectations toward HIV vaccination and participation in a hypothetical HIV vaccine trial; and**
- To explore if particular knowledge and experiences are associated with demographics such as motherhood and gender.**

Chapter 2:

LITERATURE REVIEW

Chapter 2: Part 1: The AIDS pandemic and the urgency of an HIV vaccine

2.1 Introduction

The following chapter is made up of three parts, prefaced by an introductory definitions section. Part one contextualises the AIDS crisis and highlights the urgency of HIV vaccine development. With the advent of HIV vaccine trials, part two begins by outlining the importance of protecting the rights of participants of future vaccine trials and concludes with a discussion on the necessary preparation for an HIV vaccine trial. Finally, part three presents empirical studies reviewing knowledge, attitudes and experiences toward general vaccinations. The implications for future HIV vaccine trials are also presented.

2.2 Definition of terms

The term understanding refers to the process of grasping meaning (or fact) of a given subject, which is either present or implied (Pearsall, 1998). Knowledge can be broadly defined as the possession of explicit information pertaining to a given subject (Rooney, 1999). Perception refers to the process through which we give meaning to information we get from our senses (Louw & Edwards, 1998). Wade and Tavis (1996, p. 663) define an attitude as a “fairly stable opinion toward a person, object, or activity, containing a cognitive element (perceptions and beliefs) and an emotional element (positive or negative feelings)”. Experience refers to the condition of having undergone or been affected by a particular event (Ayto, 1991).

2.3 Context

2.3.1 The AIDS epidemic

Variable stages of the epidemic are being encountered globally. Some countries are experiencing the early stages accompanied by economic and social changes, resulting in the explosive spread of HIV. In other countries, like Uganda, the rates of infection have been significantly reduced (Masemola & Gray, 2002). According to UNAIDS – WHO (2002) statistics an estimated total of 5 million infections and 3 million AIDS related deaths occurred in 2002. Sub-Saharan African has been described as the AIDS epicentre of the world, with an approximated 48% of all new infections (Morris, Williamson, Gray & Tiemessen, 2000). Growth rates of new HIV infections have also been reported from Asia and the Pacific - with

7.2 million people living with AIDS in that region. Eastern Europe and Central Asian republics, especially Baltic states, have also been reported areas of growth rates (UNAIDS - WHO, 2002). Other growth regions include the Russian federation and several central Asian republics, and India, where almost 4 million people live with HIV/AIDS. In South Africa five million adults and children are currently living with AIDS (ibid) but the worst affected group appears to be women aged 20-30 years, with the highest incidence of new infections being amongst women between 15 – 30 years (Harrison et al., 2000).

As the third decade of the AIDS epidemic is approached, its impact is dramatic, leaving behind human, public health, social and economic ramifications, and in extreme situations the epidemic is driving some nations towards destitution (UNAIDS - WHO, 2002). In several African countries, the economic impact alone could amount to a loss of more than 10% of potential economic production (IAVI, 1998). In South Africa concern is mounting about the potential costs to companies, as a large sector of the working force has only just begun to be affected by HIV/AIDS-related morbidity and mortality rates (Rosen, Simon, Thea & Vincent, 2000). Thus, the AIDS pandemic requires that decisive action be taken to slow down its progression.

2.3.2 Interventions against the AIDS pandemic

Although extensive research has been conducted in the field of HIV/AIDS there remains no proven preventive vaccine or cure. In the following section interventions that have been the main focus of HIV prevention and treatment will be presented.

2.3.2.1 Drug therapies for AIDS

To date HIV/AIDS control efforts have focused mainly on prevention, while lagging behind in providing adequate treatment, care and support to people living with HIV/AIDS (Harries, 2002). Less than 4 % of people in need of antiretroviral treatment receive the drugs and fewer than 10 % of people with HIV/AIDS have access to palliative care or treatment for opportunistic infections (UNAIDS -WHO, 2002). The package of care for already infected people includes: screening for sexually transmitted infections, psycho-social support, clinical care for opportunistic infections (e.g. tuberculosis), palliative care for terminal illness, home based care, care and support for orphans, prevention of mother to child transmission of HIV, and possible antiretroviral drugs (Harries, 2002). In general, antiretroviral medication has been demonstrated to be the most effective treatment for slowing HIV-related disease

(UNAIDS, 2000) and has led to a major reduction of mortality rates in developed countries (Barrett, 1998). Although this has meant that AIDS has become a chronic disease in developed countries, like diabetes or hypertension, it is not the case with South Africa and other developing countries (Barrett, 1998, IAVI, 1998).

Antiretroviral drugs are not available to the majority of South Africans affected by HIV/AIDS for various reasons (C. Williamson, Morris, Rybicki & A.L. Williamson, 2000). In many countries competing national priorities constrain allocation of resources to HIV/AIDS care, support and treatment, especially in sub-Saharan Africa and Asia (UNAIDS - WHO, 2002). This is certainly the case in South Africa where poverty and economic disparities are also rife. Antiretroviral therapies are costly, complicated to administer, require close medical monitoring and can lead to significant adverse effects (UNAIDS, 2000). Furthermore, there remain several challenges to effective therapy and these include: the development of resistance to treatment, drug toxicity, the failure of therapy to eradicate the latent viral reservoir in the body and insufficient adherence to treatment regimens by patients (van Rensburg, 2002). Wood (2002) proposes that the development of an effective therapeutic vaccine could form complementary or alternative treatment for HIV/AIDS. Precedents for the use of therapeutic vaccines in other viral diseases after exposure include rabies, herpes simplex and hepatitis B (Wood, 2002).

In South Africa treatment and care of people living with HIV/AIDS has also become highly politicised, with availability and delivery of such services dominating media debate regarding public health policy. One commonly held view is that South Africa has adequate resources to control the HIV/AIDS epidemic, especially given the fact that countries with lower per capita income than South Africa, like Uganda, have already had major successes (Abdool Karim, 2000a). Yet another view, which contradicts popular perceptions, is that the cost of drugs is not the only factor involved in bringing effective treatment to AIDS sufferers but also requires fully resourced, specialised clinics and close monitoring of patients for blood viral load and levels of CD4 cells (among other factors) which will take time for the South African public health care service to provide (Lecatsas, 2000). However, most researchers from various disciplines do concur that single-course, single drug treatment to prevent mother to child transmission should be more readily available in South Africa (Abdool Karim, 2000a; Lecatsas, 2000; Soderlund, 1999 in Abdool Karim, 2000a), especially in the light of the average 25% seroprevalence rate among pregnant women (McIntyre & Gray, 2000).

2.3.2.2 Behaviour change interventions

HIV is principally transmitted behaviourally - primarily through 'unprotected' sexual intercourse. Thus, efforts to change high-risk behaviours have become a chief focus of HIV prevention. Research has indicated that certain behavioural interventions have met with a degree of success (Harrison et al., 2000). These include information, education and communication programmes, condom promotion and behaviour change initiatives to decrease number of sexual partners and delaying the age of sexual initiation and promoting abstinence. In South Africa women between ages 15 and 30 years tend to be the most vulnerable to HIV infection. This may be attributed to various reasons including poverty, limited access to society's resources, and inequalities both within their public and private relations (Barrett, 1998). Thus, for any potential behavioural strategy to be rendered relevant and effective it needs to address these disparities. Increasing women's access to female condoms (Barrett, 1998) and empowering young women with skills to successfully negotiate condom use (Harrison et al., 2000) are some possible ways of how these issues may be addressed.

There is both empirical evidence and theoretical support for the efficacy of various behaviour change interventions in reducing high-risk behaviour and increasing condom use. Several empirical studies have found that behaviour interventions increased knowledge of HIV/AIDS, improved participants' attitudes, increased both the intention to use and the use of condoms, and reduced the number of sexual partners, although these have not had a significant impact on the incidence of HIV infection (Harrison et al., 2000). This alludes to the fact that knowledge alone does not necessitate change. Nonetheless, common elements in interventions that led to positive outcomes have been identified (see table 2.1). In South Africa many behavioural programmes have been carried out over the past ten years. Three areas of major action include Information, Education and Communication (IEC), peer education and behaviour risk reduction (Harrison et al., 2000). IEC programmes are particularly relevant early in an epidemic, when focus must be on raising awareness and conveying accurate knowledge. In South Africa a high level of awareness exists among the general population, with the aid of mass media efforts on television, radio, youth magazines (such as *Laduma* and *Lovelife*) and billboards and newspaper advertisements. Thus, the emphasis of policy makers, researchers and programmers needs to shift toward actions that will lead to an increase in preventive behaviours (ibid).

Theoretical support for the effectiveness of behaviour change interventions is most prominent in cognitive behaviour theories. These theories emphasise the individual as a rational instigator of change. Thus, the view that knowledge, attitudes, and beliefs determine AIDS related practice (the KABP paradigm) is a component of this theory. The KABP paradigm, which dominates social scientific AIDS research and prevention programmes, also encapsulates the Theory of Reasoned Action (TRA) and the Health Belief Model (HBM) (Jaffe, 1996). The assumptions of the KABP paradigm and its proponents have been challenged for their emphasis on the individual as a rational actor in altering behaviour (Jaffe, 1996). Recent theoretical contributions emphasise the importance of group norms and collective change (ibid). Thus, while knowledge is a necessary precedent to behaviour change it is not sufficient to initiate such a change but rather interventions that impart skills, target specific risk groups and take into account the socio-cultural context of community are most effective (Harrison et al., 2000).

Systematic reviews of behaviour interventions with a positive influence show that successful interventions have addressed:

Outcomes: aim for effect on timing and frequency of sexual intercourse, numbers of partners, and use of condoms or other contraceptives

Design: positive association between intervention design and outcomes

Objectives: include a narrow focus with behavioural goals

Theoretical basis: based on social learning or other cognitive-behavioural theory

Content: include basic, accurate information on risk; repeat essential messages

Normative process: strengthen group norms

Skill-based focus: include experiential activities, especially the modelling and practice of communication and negotiation skills; interpersonal negotiation and communication skills found to strengthen behavioural outcomes

Duration: interventions that increased condom use and involved fewer partners tended to be longer in duration; sufficient time for 3-5 intensive sessions needed for skills acquisition and retention

Community emphasis: focus on community and cultural aspects; design culturally appropriate/relevant and language-appropriate interventions; embed AIDS intervention in broader contexts; promote integration into community

Participation: create forums for open discussion; solicit participation involvement

Table 2.1 Elements of successful behaviour intervention programmes (Adopted from Harrison et al., 2000, p.285)

In sum, AIDS is a humanitarian crisis (Makgoba, et al., 2002). Various interventions have been employed in South Africa. These have been predominately preventive with less attention paid to care of already infected people. These efforts have made a modest impact on the overall crisis. Therefore these interventions need consolidation and an exhaustive care package implemented more vigorously (Harries, 2002). Furthermore, there is dissension in political ranks with regards to how and what needs to be done to curb the pandemic. “ South Africa is experiencing an unprecedented, explosive AIDS epidemic ... To defeat this epidemic, however, the greatest challenge is for South Africans to act with common purpose” (Abdool Karim, 2000b, p. 262).

It is a commonly held view among AIDS researchers that an HIV preventive vaccine even with low efficacy could have a significant impact on the epidemic. However, these efforts would still be rendered insufficient without permanent behaviour change in the population - despite the best intentions of a prospective vaccine (Schoub, 2002). Therefore, while the need for an HIV vaccine is both compelling and urgent (UNAIDS, 2000) it should complement current interventions targeting behaviour change. Finally, any meaningful challenge to the AIDS epidemic requires increased and concerted support from the international community, both for antiretroviral drugs and for basic prevention and care packages (Harries, 2002).

2.3.3 HIV preventive vaccines for sub-Saharan Africa

From a number of perspectives it would be advantageous for sub-Saharan Africa to develop HIV preventive vaccines. Firstly, an HIV vaccine, in conjunction with existing interventions, would help to significantly reduce the high seroconversion rates in sub-Saharan Africa (Williamson et al., 2000). Secondly, the high rates of infection typical of the sub-Saharan region would enable phase II trials to be conducted, which require larger numbers of people at high risk in order to test vaccine efficacy (Makgoba et al., 2002). In addition, the heavy AIDS burden, and limited access to treatment in this region strongly suggest that countries in sub-Saharan Africa would benefit from conducting trials locally (Galloway, 2000).

Traditionally most HIV vaccine trials have taken place in developed countries, where HIV-1 subtype B is more prevalent, and therefore vaccine development has been geared towards that particular clade⁴ (Morris, Williamson, Gray & Tiemessen, 2000). However, in many

⁴ Clade – also referred to as subtype or strain.

developing countries, especially in sub-Saharan Africa, HIV –1 subtype C is more prevalent (Galloway, 2000; Morris et al., 2000; UNAIDS – WHO, 2002; Williamson, et al., 2000).

South Africa is an ideally situated sub-Saharan African country to carry out the task of developing candidate vaccines for HIV-1 subtype C (Abdool Karim, 2002; Bekker & Morris, 2002; Galloway, 2000). At a workshop held in 1998 in South Africa, participants decided that sub-Saharan Africa cannot rely solely on vaccine development being conducted elsewhere focusing on a different clade but rather that South Africa should take responsibility for clade C strain of HIV-1 (Galloway, 2000). HIV-1 subtype C is emerging as the most significant virus in the global epidemic, accounting for over 55% of all HIV-infections globally (Esparza & Bhamarapravati, 2000). While HIV-1 subtype B has been more prevalent in the United States and Europe, subtype C viruses are predominant in high prevalence countries in sub-Saharan Africa such as South Africa, Zimbabwe, Zambia, Botswana and Malawi (Williamson et al., 2000). The responsibility of South Africa would therefore involve the development of a vaccine that addresses country-specific health problems, while simultaneously keeping up with progress in other countries and on vaccines developed for other clades. South Africa is also well placed to develop and run clinical vaccines trials of HIV because it has well-established clinical trial infrastructure and capability (Abdool Karim, 2002). The South African AIDS Vaccine Initiative (SAAVI), established in 1999 to coordinate the pursuit of local HIV/AIDS vaccine, has been working towards clinical safety trials that were scheduled to begin in 2002, and were delayed and subsequently scheduled for mid-year 2003.

It is important to note that there is no ‘quick fix’ solution to the AIDS crisis. Even after an effective vaccine is found it may take some time before communities that desperately need it access it. It has been previously noted that vaccines have typically reached developing countries on average twenty years after being approved in developed nations (Mirken, 2001). One example is the Hepatitis B vaccine that was only available in Africa over ten years after it was licensed in developed countries (Ijsselmuiden & Faden, 1992). According to a public address by the General Secretary of the United Nations (2002), Africa is affected by multiple crises including; HIV/AIDS, poverty and in security, and political instability. Thus the expedient and efficient development of an HIV vaccine requires a conducive environment informed by rigorous science and ethics, and characterised by governmental commitment, public and private partnerships, and international collaboration.

2.4 Development of global immunisation programmes

2.4.1 Introduction

In general vaccination has proven to be one of the most affordable and effective health interventions and prevention strategies against disease. The following section presents a short review of the history and development of vaccination programmes as they are known today.

The origins of vaccination can be traced back 200 years ago to the work of Jenner. In 1796 Jenner successfully used the cowpox virus to protect a person from smallpox disease. Jenner succeeded in inducing a 'primed' state by sufficiently infecting the patient thereby heightening the response of the immune system to secondary infection leading to prevention of disease (Pless, n.d.; Trika, Ma Man Lei, Yani & Juarso, n.d.). Since Jenner numerous vaccines have been developed and mass immunisation efforts promulgated through the Expanded Programme on Immunisation (EPI). Success of vaccination includes the eradicating of polio and smallpox by 1975 and 1977, respectively. In addition, infant vaccination has been made mandatory in many countries.

2.4.2 The Expanded Programme on Immunisation (EPI)

In 1987 a sector of the World Health Organisation (WHO) targeted the year 2000 for the global eradication of poliomyelitis giving leverage to the EPI. For years now the global community has been close to achieving universal childhood immunisation against childhood diseases. These include tuberculosis, diphtheria, pertussis and tetanus. Through the efforts of the EPI highly successful vaccines that have been able to protect from disease include polio, measles, and hepatitis (Henderson, 2000; Wright, 1995).

The EPI developed global immunisation policy, which has been extended by Ministries of Health into their respective countries. Among other things, two large strides toward eradication of poliomyelitis have made. The first was the establishment of immunisation schedules, networks of immunisation clinics that made vaccines accessible, and the specification of conditions that represented contraindications to immunisation. The second was surveillance of program success with regards to dosage, adverse effects and disease reduction attributable to immunisation. Thereafter, a global schedule of immunisation for BCG and polio, DTP and polio, and measles was adopted. To date this schedule is still the norm though it has been tailored to each country (Wright, 1995).

The public health gains due to vaccination are unquestionable. Such efforts have led to the eradication of diseases such as smallpox and polio, and likewise measles, tuberculosis, diphtheria, pertussis and tetanus are following suit. Once incurable, life-threatening diseases have now been abated through global immunisation efforts. Extensive research in the field of vaccine development is currently being conducted in different parts of the world.

In the same way that a concerted effort and commitment has aided the cause of the EPI, individual countries and the various regions will have to act with common purpose if an HIV vaccine is to be developed. Nationally this translates into collaboration between different stakeholders including government and key decision-makers, researchers, ethicists, and local communities. Internationally this implies sharing new knowledge and resources. These efforts to develop an HIV vaccine will not by themselves alleviate the crisis but should supplement ongoing strategies, e.g. behavioural interventions.

2.5 HIV vaccine development and clinical trials of HIV vaccines

2.5.1. The development of HIV vaccines

Since the initial discovery of HIV in the 1980's there have been significant scientific and social challenges. While it may be argued that decisive action to moderate the epidemic has on the whole been slow it may also be said that stated motivation to do so has not wavered (IAVI, 1998).

Conventional vaccines may be categorised as either live attenuated vaccines, which are a weakened form of the original virus, or killed inactivated vaccines (see Table 2.2). Both types have been demonstrated to be safe, provide sterilising immunity and have led to the eradication of disease such as smallpox (van Rensburg, 2002). In the case of HIV/AIDS however, both options are not practical or plausible. Vaccines can be further categorised by their outcomes into preventive or therapeutic vaccines, both of which have specific functions and strategies. Vaccination can be universal or target particular individuals, and can control, or eradicate disease respectively (see table 2.3).

Preventive vaccines are given to uninfected persons in order to elicit immune responses for protection against possible exposure to the infectious agent (Schoub, 2002). Thus, the most desirable outcome for HIV vaccines would be the prevention of infection, also known as sterilising immunity. However, most researchers concur that sterilising immunity through

candidate HIV vaccines is presently not feasible. Nonetheless, other significant results may also be derived. Thus while a vaccine may not prevent infection, it may prevent disease, delay progression of disease and decrease transmission of infection by significantly inhibiting viral replication (van Rensburg, 2002). Therapeutic vaccines on the other hand are administered to already infected individuals in order to elicit an immune response to accelerate recovery (Schoub, 2002). It is hypothesised that post-infection therapeutic vaccination may ameliorate disease by augmenting specific HIV immune mechanisms and simultaneously lead to a down-regulation of HIV replication in the body, although this still remains to be demonstrated (van Rensburg, 2002). The current study focuses on the prospects of a preventive vaccine rather than a therapeutic one.

Live vaccines	Killed (inactivated) vaccines
Trivalent oral polio (TOPV)	a) <u>Whole organism</u>
Measles	Diphtheria
Mumps	Pertussis (whole)
Rubella	Tetanus
Yellow fever	Trivalent inactivated polio (TPIV)
Varicella	Influenza (whole)
BCG	Hepatitis A
	Rabies
	b) <u>Subunit</u>
	Haemophilus influenzae
	Pneumococcal conjugate
	Influenza (split-product & subunit)
	c) <u>Recombinant</u>
	Hepatitis B

Table 2.2. Classification of vaccines (Adopted from Schoub, 2002, p. 562)

Although extensive research has been underway for over 15 years and despite the successful history of effective vaccines against other viral infections there is still no effective HIV vaccine. HIV poses complexities in structure and the pathogenesis⁵ of infection that have made the development of a HIV preventive vaccine a mammoth task (Van Harmelen & Williamson, 2002). There is also much genetic diversity of HIV found world-wide, with over

10 genetic subtypes, or clades, of HIV-1 that have been characterised (IAVI, 1998), thus potentially limiting the applicability of a candidate vaccine from one region to another. Despite the challenges to vaccine development, increasing knowledge about HIV has benefited vaccine development and many of these challenges may be addressed in clinical trials over the next few years (Van Harmelen & Williamson, 2002). Furthermore, variability of HIV is being addressed through an expanded effort to develop vaccines for different subtypes, or to develop vaccines that may be effective across different subtypes.

	Universal immunisation	Selected/targeted immunisation
Purpose	Epidemiological modification Control Elimination Eradication	Personal protection
Strategies	Routine immunisation –EPI Supplementary immunisation Mass immunisation Mop-up immunisation	Travellers' immunisation High-risk immunisation Occupational immunisation
Examples	Polio Measles Mumps Rubella Diphtheria Pertussis Tetanus Haemophilus influenzae b Hepatitis B	Hepatitis A & B Influenza Yellow fever Rabies

Table 2.3. Immunisation strategies (Adopted from Schoub, 2002, p. 562)

HIV vaccine efforts have been underway since 1987. Significant scientific progress has been made, with both public and private sectors adding to the achievements (IAVI, 1998). In general government agencies play varied roles in vaccine research and development, including support of both basic and targeted biomedical research on the disease in question, development of clinical infrastructures, conduct clinical trials and train researchers (IAVI, 1998). In South Africa the South African AIDS Vaccine Initiative (SAAVI), established by the government, has played an important role in coordinating the development of a local

⁵ Pathogenesis – refers to the cause, development, and effects of disease (Rooney, 1999)

vaccine. SAAVI is essentially a multicentre multi-disciplinary programme managed by the Medical Research Council tasked with the goal of developing a safe, effective, affordable and accessible vaccine for South Africa by 2005. In addition, the initiative has a role to play in advocacy and education, and ethical considerations in vaccine development. SAAVI employs two primary approaches in executing its goals. The first is to produce a local more affordable vaccine for South Africa that would be country-specific and therefore, hopefully, more effective than products developed in other regions. The second approach entails active international collaboration. Researchers are working in earnest and it is planned that phase I trials with one or more subtype C candidates will start in 2003 (Galloway, 2000).

2.5.2. Challenges to the development of HIV vaccines

In the search for an effective HIV vaccine numerous challenges have been encountered. Some of these are discussed below.

2.5.2.1 Science and stages of testing

The development and testing of a vaccine is a long and laborious task entailing complex biotechnology, research design, and complex ethical issues. While much scientific progress has been made the HIV virus provides challenges for researchers. These include: antigenic variation, the integration of viral genome into the host cells, correlates of protection are unknown and lack of a good animal model (van Rensburg, 2002). Nevertheless, this has not minimised hopes that an effective HIV vaccine will eventually be found. Traditionally, science has moved slowly and cautiously but the in the case of HIV vaccines there is pressure to move urgently but with diligence (Makgoba et al., 2002).

In general, the goals for HIV vaccines are: to prevent infection, prevent or, delay progression of disease, and decrease transmission of infection (Abdool Karim, 2002). A preventive vaccine is tested on healthy human volunteers and conducted through successive phases (Esparza & Bhamarapravati, 2000). In a phase I trial a small number of healthy volunteers (10-20) is exposed to the candidate vaccine for the first time. In this phase the safety, maximum dose that can be tolerated, vaccination schedule, route of vaccination and immune responses are all investigated (Abdool Karim, 2002). Phase II trials usually enrol a few hundred volunteers. The objective in this phase is to assess the safety and immunogenicity, or optimal dose of the candidate vaccine - obtained in phase I using an 'at risk' population. Phase III studies involve thousands of volunteers and test the efficacy of the vaccine using

the safe and immunogenic dose, route of administration and administration schedule obtained in phase I and II studies (ibid). Careful attention is also paid to possible side effects in this phase. In the final phase the vaccine reaches the market and its impact on the epidemiological pattern of HIV is measured. Post-marketing surveillance to identify adverse events present only in much larger numbers of people, would also be employed. Any vaccine has to go through this vigorous process before it can be considered effective. Thus, it may be at least ten years before an effective vaccine is developed and widely used in South Africa (UNAIDS, 2000).

2.5.2.2 Political challenges

Vaccine development is affected by both national and international politics. In a public address by the United Nations general secretary (2002) many African countries experience political instability, which often takes precedence over other important national issues, with HIV/AIDS de-prioritised. AIDS affects various regions differently. For efficient progress to be made all regions, regardless of socio-economic status, are obliged to work together. On the one hand, developed and rich countries have the expertise and experience to develop and test HIV vaccines but may not have large enough numbers of patients to conduct efficacy trials (Makgoba et al., 2002). On the other hand, most developing and poor countries do not have adequate infrastructure and resources to conduct large-scale trials (ibid). Therefore collaboration is appropriate. However, proper steps should be taken to ensure that ethical standards are upheld in these collaborative international research initiatives. A number of such initiatives have already begun to form. These include the Declaration of Commitment on HIV/AIDS, International AIDS Vaccine Initiative (IAVI) and its affiliated projects, the South African AIDS Vaccine Initiative (SAAVI), already discussed earlier, public-private partnerships, and many others.

Furthermore, Makgoba et al. (2002) assert that most countries lack the political will and commitment to develop an HIV vaccine. This is reflected in inadequate relevant investment. In South Africa national government's stand appears to be equivocal, proclaiming support for the fight against AIDS and simultaneously entertaining dissident views. The salient issue of treatment for HIV infected people and AIDS sufferers' remains contentious, as there are currently no therapies being widely used in South Africa. Politicians have aired concerns about the long-term safety of antiretroviral drugs such as AZT and have questioned whether

adequate resources to control the epidemic are indeed available in South Africa. Conversely, many local AIDS activists and opposing political affiliates have voiced strong dissatisfaction with governments seemingly lack of urgency and decisive action in this regard.

2.5.2.3 Economic challenges

Developing countries bear the brunt of the AIDS burden. Poverty, poor infrastructure and poor access to basic health care services are typical of these countries. These countries are also affected by unemployment, crime, domestic violence, homelessness, and low education rates. AIDS is therefore a national priority among other competing needs.

Thus, despite the challenges facing the development of an HIV vaccine, progress has been and continues to be made. Small-scale clinical trials of HIV-1 vaccines have been conducted since 1987 (Esparza & Bhamarapavati, 2000). Subsequently, larger-scale HIV-1 vaccine trials have been conducted in Europe, North America, Brazil, China, and Thailand. Phase I trials have been recently completed in Uganda and Kenya (Mugerwa et al., 2002). In addition, multicentre HIV phase III trial have been conducted in Canada, the U.S., the Netherlands, Puerto Rico as well as in Thailand (VaxGen⁶, 2003). The multicentre phase III trials were completed at the end of 2002 and in February of this year (2003), VaxGen announced that the particular vaccine used did not prove effective in the trials conducted in North America and Europe. That is the study did not show a statistically significant reduction of HIV infection within the population as a whole, although statistically significant reduction of HIV infection in certain vaccinated groups (i.e. Black and Asian volunteers) was reported. Criticism in the media ensued about the statistical analysis of the non- Caucasian data. Subsequently, VaxGen presented further analyses of the phase III data and stated that differences in vaccine efficacy observed between Caucasian and non-Caucasian volunteers could not have been due solely to chance (ibid). In South Africa preparations are well underway for a number of phase I trials. A concerted effort both nationally and internationally is paramount if South Africa is to succeed in this regard.

In summary, the inadequacy of current interventions and high prevalence rates, limited treatment and preventive options, compel the need for an effective, safe and affordable

⁶ VaxGen – a pharmaceutical developing prophylactic vaccines against HIV-1 consisting of two recombinant gp120 surface proteins from different HIV-1 strains.

vaccine in collaboration with already established interventions. Schoub (2002) concludes that even vaccines with low efficacy could have a significant impact on the epidemic, although it is likely to be insufficient without permanent behaviour changes in the population. In addition, HIV has to be recognised as a health priority reflected by the finance and resource allocation by government, other stakeholders, and sponsors. A conducive environment for the development of an HIV vaccine should be enhanced by simultaneously targeting other social ills like poverty and access to basic health care services.

2.6 Summary: Part 1

The AIDS pandemic is increasing at a rate unmatched by any other pathogen (UNAIDS, 2000). Although various interventions have been utilised to try and control it, these have proven inadequate (Harrison et al., 2000) and need to be further consolidated. In general, vaccination has been shown to be a safe, efficacious and affordable health intervention (Hall & O'Brien, 1998). The need for an HIV vaccine to complement current interventions has been recognised as both urgent and compelling (Barrett, 1998; IAVI, 1998; UNAIDS, 2000). There has been growing support for the development of HIV vaccine initiatives in sub-Saharan Africa. Through the efforts of SAAVI, South Africa has emerged as a major role-player in this regard and is due to begin with HIV safety trials later this year. However, the process involved in the development of an HIV vaccine is proving to be lengthy and challenging. Therefore the success of this project requires that good partnerships between various South African stakeholders as well as international collaboration be established, and that the numerous social, behavioural, and ethical challenges of trials be addressed.

Chapter 2: Part 2: Ethical requirements for HIV preventive vaccine trials

2.7 Protection of research participants

2.7.1 Introduction

While the need to develop a HIV vaccine is unquestionable, an equally important challenge is the protection of research participants who are enrolled in trials to test safety and efficacy. In general, clinical research aims to contribute to the social good by developing generalisable knowledge to improve health while minimising possible exploitation of research participants (Emanuel, Wendler & Grady, 2000). It is imperative therefore that ethical principles and standards are upheld during the process of vaccine testing. Complex social and ethical issues

associated with such trials are presented in the following section. However, before this discussion, it is important to recount the particular context from which biomedical research and ethics specifically has emerged.

2.7.2 Cultural sensitivity within universal ethical principles

In general, biomedical research on humans raises many ethical, legal and human rights concerns (UNAIDS, 2000; Wright, 1995). Over the years the application of biomedical ethics has developed as a field of study and various international ethical codes have been established. Noteworthy ethical references include: the Nuremberg Code of 1947, the Declaration of Helsinki of 1964 (revised in 2000), the World Health Organisation (WHO) and Council for International Organisations of Medical Sciences (CIOMS) guidelines drafted to confront transcultural⁷ issues and inequalities in research, and more recently a guidance document which specifically addresses international HIV preventive vaccine trials (UNAIDS, 2000) and a discussion document which provides culturally sensitive guidelines for obtaining informed consent in HIV vaccine trials (Richter, Lindegger, Abdool Karim & Gasa, 1999).

Developing countries have, on occasion, been the targets of ethical misconduct by researchers from more developed countries. Biomedical research in Africa has at times been characterised by an 'insensitivity' to the indigenous concerns of African countries, which has implications for future cooperation between western countries and developing countries (Lurie et al., 1994). For example, research conducted by French HIV vaccine researchers in Zaire in 1987, led to a perception that Africans served as "guinea pigs", and that "Western science often comes to Africa with "dirty hands" for clinical trials that would not be allowed in more developed countries (Christakis, 1988, p. 142). An AIDS vaccine trial in Africa should therefore be informed by ethical norms and cultural considerations prevailing in African settings (Christakis, 1988), and accommodate the social and economic realities therein (Abdool Karim, 2000b). This is a complex task, however, as there may be tension between international ethical principles versus those norms and practices present in an individual cultural setting. Therefore it remains the responsibility of all partners involved in the development of an HIV vaccine to address the ethical dilemmas that arise (Makgoba et al., 2002).

⁷ Transcultural – " Transcultural research refers to clinical biomedical research that involves subjects and investigators from different cultures" (Christakis, 1996, p. 261, in Vanderpool, 1996).

South Africa has emerged from a particular political history that legitimised the systematic undermining of fundamental human rights, which has implications for HIV prevention vaccine research in South Africa. For example, many South Africans live under conditions of abject poverty and unemployment and this makes them vulnerable to abuse and exploitation. Researchers therefore have an obligation to protect the rights of 'vulnerable communities' (UNAIDS, 2000). Secondly, a distrust of 'modern' medicine may exist and African traditional medicine may be utilised. In particular, traditional healers are known to command a significant amount of support both in urban and rural black communities in South Africa, providing an alternative to the western medical paradigm. Conversely, idealisation of modern medicine may also exist.

2.7.3 Ethical principles relevant to clinical research

In essence ethics is a decision-making process about what is wrong or right (Abdool Karim, Q., 1997). Guidelines have been established in the form of codes of ethics (some mentioned earlier, e.g. The Nuremberg Code). Central to these guidelines are three universal principles namely, justice, beneficence/non-maleficence and autonomy (Slack et al., 2000). Justice refers to the fair distribution of research burdens/risks and benefits of which there are several widely accepted formulations (The National Commission of human subjects of biomedical and behavioural research, 1979). Formulations include: to each person an equal share, to each person according to individual need, to each person according to individual effort, to each person according to societal contribution, and to each person according to merit (ibid). With regards to research this has implications for the 'just' selection of participants. Beneficence is about maximising possible benefits of participation while non-maleficence refers to minimising possible harms. Autonomy refers to an individual's right to freedom of choice based on informed decision making. These fundamental principles are crucial to the conduct of all research.

In addition, informed consent has remained a foundational principle of ethical research practice in clinical trials, since the publication of the Nuremberg Code (Lindegger & Richter, 2000). However, the practice of requiring informed consent from research subjects has not always been adequately implemented. Despite the establishment of ethical codes in the 1940s and 1960s it was not until the 1970's that the practice of informed consent became conventional in the West (Ijsselmuiden & Faden, 1992). Generally, informed consent is usually seen as incorporating four essential components (Lindegger & Richter, 2000):

- Disclosure of all relevant information about the research
- Comprehension by prospective participants of this information to make an informed decision
- Freedom from all coercion of the prospective participant
- Explicit and formal consent by the participant, usually in written form.

2.7.4 Ethical issues relevant to HIV preventive vaccine trials

It is complex to apply ethical principles in a standardised manner. For one, ethical guidelines could be interpreted differently across various situations. It has been argued that the numerous cultures exist globally for which certain principles may be culturally insensitive or inappropriate. Discrepancies in health care service and delivery in developed and developing countries may pose additional ethical challenges – the standard of care for example, may significantly differ. In this way while codes like the Nuremberg code, Declaration of Helsinki and Belmont Report have played a significant role in the west these may not be uniformly applicable for research in developing countries (Emanuel, Wendler, Killen & Grady, 2002). Research in developing countries must provide more than broad principles but must also confront unanswered ethical questions and stark disagreements (Emanuel et al., 2002). In 1982, WHO in collaboration with CIOMS, drafted guidelines on how biomedical ethical principles could be applied more effectively in developing countries, taking into account culture, socio-economic circumstances, national laws, and executive and administrative arrangements. Similarly, another ethical guideline is the UNAIDS code of ethics, specifically for HIV vaccine trials.

Although informed consent is necessary in most cases for clinical research to be deemed ethical informed consent is never sufficient on its own (Emanuel et al., 2000). Other ethical requirements comprise; that clinical research must be valuable, scientifically valid, selected subjects fairly, have a favourable risk-benefit ratio, must be subject to independent review for social accountability, and respect participants who have enrolled (ibid).

Selection of participants in clinical trials must be fair and informed by predetermined criteria for inclusion and exclusion (Emanuel et al., 2000). According to UNAIDS (2000) guidelines for HIV vaccine research, Point 8, the choice of study populations for each trial phase should be determined and justified in advance by the scientific requirements and ethical challenges of each phase. As stipulated in 2.6.2.1 in phase I and phase II of HIV vaccine trials the goal is

to test the safety and dose optimisation, respectively. Therefore, generally participants are fewer and less vulnerable in the earlier phases (UNAIDS, 2000). However, in phase III trials as the aim is to test the efficacy of the vaccine, a larger sample of people who are at risk is selected (UNAIDS, 2000), as this group of people would best answer the scientific question regarding the efficacy of the vaccine (Emanuel et al., 2000). Therefore while the participants are in a position to benefit if the research provides a positive result (e.g. if the vaccine is partially effective) they also bear the risks and burdens of the research.

The fact that communities and individual participants qualify for phase III trials on the basis of their HIV risk raises complex ethical considerations. Although the degree of risks and benefits is inherently uncertain in research, a favourable risk-benefit ratio needs to be consistently and carefully applied by endeavouring to minimise risks and enhance benefits (Emanuel et al., 2000; Emanuel et al., 2002). Furthermore, in keeping with the scientific aims of research fair selection of participants should ensure that benefits and burdens are distributed fairly (ibid). There is a potential conflict of interest for researchers in HIV preventive trials between reducing risk and measuring efficacy, and this necessitates that protective mechanisms for potential participants be put in place (Lurie et al., 1994). The interests of participants should always prevail over the interests of science and society, and this includes providing risk counselling and access to barrier methods to trial participants (Barrett, 1998). Community advisory boards need to be appointed and play an integral part in ensuring the rights of community members are protected, throughout the preparatory stages and trial phases (Abdool Karim, 2002). In addition, as prospective participants are also vulnerable to social discrimination and stigmatisation, should they seroconvert during the trial, participants need to be assured of confidentiality and other measures need to be put in place to minimise psychosocial risks.

In South Africa HIV preventive vaccine trial sites have already been identified in kwa Zulu-Natal and Gauteng (Tucker, 2002). In accordance with UNAIDS (2000) South Africa is justified to conduct its own HIV vaccine trials for the following reasons:

- The high seroconversion rates in South Africa, which has made AIDS the biggest cause of death
- Inadequacy of current HIV interventions coupled with poor access to antiretroviral therapies
- The HIV-1 subtype C prevalent in South Africa and sub-Saharan Africa

- The resources and infrastructure South Africa has to host its own trials
- The presence of a coordinated initiative (SAAVI) to ensure that South Africa has the scientific, ethical and logistical capacity to run its own HIV preventive trials.

2.8 Preparation for HIV vaccine trials

2.8.1 Introduction

Preparation of host communities can be a challenging task, entailing detailed education campaigns and informed consent procedures. This is evident in the Ugandan experience of the first African safety trials where, despite elaborate preparations undertaken, myths and concerns arose among the general public and potential participants. Widespread rumours and conflicting media reports about the vaccine led to most of the confusion. Misconceptions included some mistaken beliefs that the vaccine was therapeutic and not preventive, a belief that the vaccine would protect against unsafe sex, fear that the volunteers would be injected with HIV, and fear that volunteers would be deliberately exposed to people infected with HIV (Mugwera, et al., 2002).

Therefore before vaccine trials can take place extensive preparation is necessary to minimise the potential for confusion (described above). In general, vaccine preparedness encompasses the trial sites themselves and the broader community including prospective participants. Thus, the following section begins with what adequate preparation of the general public involves. A section follows it on meaningful and sustained community involvement of host communities. Finally, a section on adequate informed consent of prospective participants will be presented.

2.8.2 Adequate preparation of general public

From the onset the public needs to be informed about trials in a way that will not create high expectations of trial successes. For example, inadequately informed sources could sensationalise the process. A thorough widespread public information campaign however could attract potential participants and provide them with an opportunity to be educated and allay local concerns about the trial (Lurie et al., 1994). When dealing with mass media, it is essential not to exaggerate news or give ambiguous information. Such publicity could lead to polarising of public opinion, which could lead to a 'false sense of security' (Barrett, 1998; da Fonseca & Lie, 1995) on the one hand and scepticism on the other hand. False sense of security sentiments could encourage misguided beliefs that the vaccine is a cure for AIDS,

thereby leading to an increase in risky behaviour (Lurie et al., 1994). On the other hand, there is already a degree of stigmatisation surrounding AIDS (Department of Health, 1997, in Barrett, 1998) and sceptic sentiments could lead to decreased willingness to participate in trials. Both outcomes could impinge on the vaccine trial process. It is important that education campaigns and informed consent procedures be informed by both rigorous science and sound ethics. The media is also an invaluable partner in educating of the public.

2.8.3 Meaningful and sustained community involvement

As discussed in 2.7.4.2 community preparation is vital for HIV preventive vaccine trials. Accordingly, Point 5 of the UNAIDS (2000) guidance document alludes to three important considerations for community involvement in the preparation stages. Firstly, the involvement of community representatives should be based on an equal partnership. This implies that power should be shared between the community representatives and the extended research team, whereby both parties engage in a process of mutual education. Researchers have a significant role in explaining vaccines, how it may work and the trial process. Likewise, the community can inform researchers regarding health beliefs and cultural practices in the context of that particular community. The equal partnership also entails active involvement of the community representatives in the review, approval, and monitoring of HIV vaccine research. Secondly, the code suggests that open communication between the partners should be sustained in order to promote problem solving. Finally, community representation should be relevant and legitimate. That is, representatives should be determined through a process of broad consultation and appropriate representation.

2.8.4 Preparation of host communities from which trial participants will be drawn

Point 3 of the UNAIDS (2000) guidelines for HIV vaccine research reads:

Strategies should be implemented to capacitate host countries and communities so that they can practice meaningful self-determination in vaccine development, can ensure the scientific and ethical conduct of vaccine development, and can function as equal partners with sponsors and others in a collaborative process.

Similarly, Richter et al. (1999) suggest that volunteers should not only play an active role in the development of trials but should share in the decision making process with researchers, as well as community leaders (Abdool Karim, 2002). A community advisory board to represent

the interests of the community is also considered of paramount importance (ibid). Preparation of the host community includes education of the target population from which volunteers will be selected and preparing the community for large-scale HIV voluntary counselling and testing programmes (ibid). In educating the target population, researchers must ensure the appropriateness of the information, the method of presentation to enhance understanding, and must take into account demographic factors (such as age, gender and education) and attitudes toward the process (Silva & Sorrell, 1984). To facilitate this process of community preparedness adequate clinical infrastructure is also imperative (Abdool Karim, 2002; UNAIDS, 2000).

2.8.5 Adequate informed consent

Communities in developing countries are likely to be characterised by poverty, limited health care services, illiteracy and limited understanding of the nature of science which places these communities at increased risk of exploitation (Emanuel et al., 2002). Conducting research in developing countries makes the process of informed consent complex because of different languages, social traditions and practices (Emanuel et al., 2002). For example, in South Africa eleven official languages are recognised, which are accompanied by varied social tradition and practice. In general, informed consent is complex and sometimes an idealised process and often only fully understood by specialists (Lindegger & Richter, 2000). This has implications for HIV preventive vaccine trials given the complex information that must be transmitted. The question then becomes what constitutes “adequate informed consent” in developing countries.

According to Emanuel et al. (2000) informed consent serves two purposes. Firstly, it serves to ensure that individuals control whether or not they enrol in clinical research. Thus, informed consent should be independent and steps should be taken to ensure that participants continue to understand and participate freely throughout the trial (WHO- CIOMS, 1993). Secondly, individuals may participate only when the research is consistent with their values, interests and preferences (Emanuel et al., 2000). Furthermore, informed consent should be based on complete, accurate and appropriately conveyed and understood information (WHO, 1993). However, in reality many subjects are either incapable or limited in their capacity to give informed consent, including children, adults with severe mental or behavioural disorders, and many who are unfamiliar with modern medical concepts. In such cases special measures should be taken to protect these vulnerable individuals, which includes obtaining

proxy consent of a properly authorised representative and approval from an independent ethical review body (ibid).

Furthermore, in practice there are many barriers to informed consent. Richter et al. (1999) summarise some of these barriers. Firstly, obtaining informed consent may be difficult because lay people often have problems remembering and understanding the details of scientific design and biomedical treatment comparisons. Secondly, prospective participants may experience defensive psychological forgetting of threatening information, especially about risks. Thirdly, obtaining informed consent may be difficult due to communication barriers emanating from cultural and class differences, including illiteracy, language differences, competing models of disease, and presumed differences in the construction of personhood. Fourthly, situational pressures, including a feeling of obligation may also complicate the process of obtaining informed consent. Fifthly, implicit forms of coercion may further complicate the process of obtaining informed consent by threatening voluntariness and the right to withdraw. Finally, health professionals have to exercise restraint as they too have “vested interests”.

Emanuel et al. (2002) provide five benchmarks for fulfilling the principle of informed consent in developing countries:

- Active community involvement in recruitment procedures and establishing incentives to facilitate appropriateness of the recruitment strategy.
- Dissemination and disclosure of information should be sensitive to the local context and emphasise the role of collaborative partnership. This process must therefore take into account the language and cultural idioms, literacy and education levels, social practices, customs and culture of prospective participants.
- Researchers must seek approval from the “spheres of consent” ranging from village elders to leaders of the extended family to heads of family. However, individual consent should not be supplanted by family or community consent.
- Researchers should employ creative methods for documenting informed consent which could be verified by an independent observer and simultaneously culturally sensitive to the local context.
- Researchers should give careful consideration to methods of ensuring that participants are able to refuse or withdraw from research without retribution.

2.9 Summary: Part 2

“What is essential is not that the research meet the same ethical standard world-wide. What is essential is that the research manifest a culturally sensitive and ethically sophisticated concern for the well-being of subjects throughout the world” (Christakis, 1988, p. 142).

In general, the planning and implementation of HIV preventive vaccine trials necessitate that due consideration be given to ethical standards and requirements. Although the establishment of ethical codes and guidelines has been extensive, in practice their implementation is challenging. Historically, three basic ethical principles have guided human research namely: justice, beneficence (non-maleficence) and autonomy (Slack et al., 2000). Informed consent has also been regarded as a foundational principle to clinical research and as such has received much attention (Lindegger & Richter, 2000). Increasingly though, researchers have recognised that informed consent on its own is insufficient and that clinical research further requires that: it be valuable, scientifically valid, select subjects fairly, have a favourable risk-benefit ratio, be subject to independent review, and respect participants who have enrolled (Emanuel et al., 2000). Furthermore, extensive preparation of trial sites and participants is also required (Abdool Karim, 2002). At a community level, meaningful and sustained community involvement is essential to adequate preparation (Lurie et al., 1994; UNAIDS, 2000). At an individual level, researchers must strive towards adequate informed consent for each trial participant. Psychologists have a role to play in informing both levels as well as in researching the expectations and perceptions of community members (Lindegger & Wood, 1995). The current project for example, aims to explore knowledge and experiences with vaccination in general, and knowledge and expectations toward vaccination and participation in a hypothetical vaccine trial. The findings can then be used to inform education campaigns and informed consent procedures for HIV preventive vaccine trials as well as identifying areas for future research.

Chapter 2: Part 3: Empirical review of knowledge, attitudes and predictors of immunisation behaviour

2.10 Introduction

To locate the current study within a body of literature the following section begins by describing vaccination as a health behaviour. This will be followed by a review of empirical studies of immunisation practices. A summary of studies that have looked at understandings and perceptions of vaccination is presented. Then studies investigating peoples' attitudes

toward vaccination are presented. In the final sub-section, peoples' willingness to participate in HIV vaccine trials, perceived barriers and incentives to participation, and social harm monitoring are discussed.

In general vaccination programmes target specific subgroups of the population such as children, travellers and seniors although most extensive programmes have targeted children (Marks, Murray, Evans & Willig, 2000). Adult vaccinations usually encompass three types: work-related precautions (e.g. hepatitis B vaccination), vaccinations for 'at risk groups' (e.g. influenza vaccine) and vaccinations for overseas travel. A vast amount of research has been conducted in the field, the majority of which has focused on infant and child immunisation. Historically, mothers have had a significant role with regards to care giving in the home. Thus, mothers' knowledge and attitudes towards vaccination have been investigated widely. Predictors of vaccination compliance and completion, and barriers to vaccination have also been investigated to enhance immunisation programme implementation.

Despite the relatively high uptake of immunisation programmes through the efforts of EPI there is a discrepancy in compliance rates with vaccination regimens. This is partially evident in the high rates of pneumonia and influenza deaths among the elderly and the increasing numbers of under-immunised pre-school children in the rural areas of the United States (Pruitt, Kline & Kovaz, 1995).

Assuming that HIV vaccine trials may be seen as extensions of preventive health practices, as earlier mentioned in section 1.2, an investigation of general vaccination attitudes and experiences could prove helpful to the preparation for HIV vaccine trials (Slack et al., 2000). "The extent to which village and urban populations value being vaccinated can be understood only by determining their interpretations of disease and immunity, and past experience with vaccination..." (Greenough, 1995, p. 606). The current study explores knowledge and experiences of local students with vaccination.

2.11 Immunisation as a health preventive behaviour

Immunisation, which is administered to lessen susceptibility to debilitating and fatal disease (Gore et al., 1999) has been described as preventive health behaviour or a health protective practice (Gochman, 1998; Gore et al., 1999; Marks et al., 2000; Pitts, 1996; Slack et al., 2000). Although therapeutic vaccines work differently, that is, they are administered after

exposure to the pathogen (Wood, 2002), the focus of the current study is on preventive vaccines in general and implications for HIV preventive vaccine trials. Preventive health behaviour can be defined as “those actions undertaken by persons who believe they are well, and who are not experiencing any signs or symptoms of illness, for the purpose of remaining well” (Gochman, 1988). Specifically, childhood immunisation is a preventive health behaviour that is directed toward the child by the parent (Gore et al., 1999).

As one of the most successful methods of primary prevention of disease (Marks et al., 2000) immunisation is of great relevance to health psychology (Pitts, 1996). Despite immunisation’s proven efficacy, its uptake varies over time and place (Marks et al., 2000). Psychology offers models that aim to understand the various social and psychological factors associated with uptake, and yet psychologists have little to say about this particular health behaviour (Pitts, 1996). However, an understanding of preventive health behaviour is becoming increasingly important to health care providers in general (Gore et al., 1999). Health psychology researchers have posited numerous frameworks to study and intervene in preventive health behaviour. The frameworks used have been primarily based on decision-making theory and attitude theory, with an emphasis on socio-behavioural components (ibid). These frameworks include: the health belief model, the theory of reasoned action, illness representation model, protection motivation model, the transtheoretical model and the precaution adoption process model (Pitts, 1996). While these models generally explicate the factors involved in developing and changing people’s health behaviours, these models have also been criticised for focusing on the individual, at the cost of other factors (ibid). For example economic, social, political and environmental factors also have an impact on health behaviours, such as immunisation uptake.

Pitts (1996) posited the following about the psychosocial aspects of vaccination. Firstly, he identified a clear link between health knowledge and the likelihood of vaccination. Secondly, demographic variables, particularly in developing countries, also add to understanding vaccination behaviour. Finally, perceptions of risk, including on behalf of others, are also important predictors of immunisation uptake, strongly influenced by media campaigns and personal experience (ibid). In the current study knowledge and experiences with vaccination are explored and their association with particular demographics.

2.12 Knowledge and perceptions about vaccination

2.12.1 Introduction

The following sub-section begins with a summary of empirical studies investigating knowledge about vaccination, followed by misconceptions about vaccination. A review of literature in this field indicates that knowledge is defined and measured differently. Formal measures, like knowledge of EPI, have been consistently used to identify various components of knowledge across different studies. The scope of the current review is not exhaustive.

2.12.2 Studies investigating knowledge of vaccines

In Italy a study was carried out with 841 mothers through self-administered questionnaires. The mothers of 841 infants were randomly selected from a representative cross-section of various kindergartens (which their children attended) from two towns. Among other things, the study evaluated the knowledge of mothers about vaccine-preventable diseases. The results showed that both age and education levels were significantly related to knowledge about four mandatory vaccinations for infants. In general, mothers who were older at the time of the child's birth were more knowledgeable than younger mothers about vaccination. Similarly, mothers with higher education levels knew more about vaccination than mothers with lower education levels. Mothers knew most of the mandatory vaccinations and rightly reported vaccinations for hepatitis B (87.5%), poliomyelitis (79.9%), tetanus (74.4%) and diphtheria (66.3%), respectively. About half of the sample (45.2%) correctly believed that the undesirable side-effects of vaccinations are an important determinant of their value. Reported sources of information about vaccination were from paediatricians (70.2%), mass media (30.3%), pamphlets (24.1%), and family physicians (19.7%), respectively. Most of the mothers (81.5%) wanted to learn more about various aspects of vaccines and the diseases they prevent (Angelillo et al., 1999).

In China, Zhang, Wang, Zhu & Wang (1999) conducted a vaccination survey to provide baseline information for a health education program. Thus, the care-takers of 2520 children were randomly selected from 12 counties. Although the vast majority of the parents (98.4%) believed that immunisation plays a role in preventing diseases the results revealed that the level of EPI knowledge in general was poor. Only 58.2% had knowledge about measles infections. Most parents had also had to be reminded by the health providers to vaccinate their children. All parents had confidence in their providers and 92.7% had received health knowledge from their providers. The mothers' EPI knowledge was strongly associated with

mothers' educational level, family socio-economic status, health insurance schemes for immunisation services and the frequency of watching TV or listening to radio. It was also found that the level of EPI knowledge among parents was positively associated with their attitude to and practices of vaccination.

In Africa, another study was conducted in Ethiopia on immunisation uptake and identification of problems associated with vaccination delivery (Gedlu & Tesemma, 1997). A cluster-sample survey of 1269 households in Gondar town was undertaken. The care-takers of 213 children aged 12-24 months were sampled. Again most of the respondents (91.7%) reported that immunisation protects against diseases. These findings were similar to those reported from research conducted in Keffa, south west Ethiopia, and India (ibid). No significant differences were found between the level of knowledge and demographics. In addition, despite the level of knowledge of protective nature of vaccines, uptake of immunisation was low. The authors concluded "that both knowledge and motivation to return regularly with the child are vital in increasing immunisation coverage" (Gedlu & Tesemma, 1997, p. 241).

In another study in eastern Zimbabwe seven focus group discussions were conducted with 43 mothers in Chimanimani District after a measles outbreak in 1986 (Razum, 1993). All mothers had at least one child under the age of five years and were selected with the assistance from either local teachers or village workers. In addition, mothers waiting at the district hospital were also recruited for one session. The focus group discussions ran in parallel with a survey of the Expanded Programme on Immunisation (EPI). Six leading questions directed the focus group discussions. Questions investigated knowledge, beliefs and perceived consequences of immunisation. These included questions around mothers' perceptions of vaccination in general as well as questions on perceived side effects of vaccination. Results revealed that mothers were informed about immunisation but low uptake of services was mainly due to the poor quality of EPI services. No demographic characteristics were explored in this particular study; except that the sample was drawn out of a rural population.

In a local study conducted in Cape Town, Van Staden, Langenhoven, Dhansay, Laubscher & Benade (1995) investigated mothers' knowledge about immunisation and other child health care promotion processes. A cross-sectional study was done on a random sample of 267 mothers with children aged 0-24 months attending a child health clinic (CHC). A questionnaire was administered comprising of questions on socio-demographic information

and other child health care prevention packages. Most mothers (92%) stated that immunisation was to prevent diseases while 8% were unsure. Mothers' knowledge about which diseases their children were being immunised against was as follows: measles relatively high (77%) and TB moderate (43%). Few mentioned polio and chicken pox, and none knew about polio while 9% could not name any disease. The researchers concluded that mothers' knowledge about the diseases for which immunisation were given was inadequate. In particular, single mothers who were younger than 25 years and who delivered a low birth-weight baby, had the poorest knowledge levels.

In Hlabisa , kwa Zulu-Natal, South Africa, a study on maternal and child health indicators in the rural South African Health District was carried out on 480 mothers (or carers) of children aged 12-35 months (Wilkinson, Cutts, Ntuli, & Abdool Karim, 1997). Cluster sampling was used to select participants. A questionnaire on antenatal care attendance and the child's immunisation status was used. It was found that overall immunisation uptake was high (80-98 %). However, from this number, only 76% had received all the vaccines needed for a 12 - month old child, and only 88% of these had received all doses by 12 months of age. Up to 83% had neither experienced nor heard of an adverse reaction to immunisation (ibid).

2.12.3 Misconceptions about vaccination

Immunisation has been frequently demonstrated, in both research trials and in measurements of efficacy made in the field, to be one of the most effective available medical interventions to prevent disease. It has been approximated that immunisations currently save three million lives per year throughout the world while remaining one of the most cost effective health preventions, providing high levels of protection against certain diseases and consequent disability and death (Hall & O'Brien, 1998).

Despite these obvious benefits there are those who have reservations about immunisation and its efficacy. These objections include religious or philosophical reasons. Furthermore, misconceptions exist about the safety and efficacy of vaccines. Six common misconceptions about vaccination are listed below (Hall & O'Brien, 1998; Pless, n.d.).

One misconception that exists is that human survival rates have improved due to better nutrition and other treatments such as antibiotics, and that vaccines are proving to be increasingly redundant and unnecessary. A second misconception is that vaccines are not

effective and that most vaccinated persons contract the disease despite being previously vaccinated. Another related misconception is that vaccines are not safe, causing harmful side effects including death. Fourthly, another myth is that vaccines actually cause illness and possible long-term effects. Yet another belief is that vaccines are no longer needed as the respective disease have been eliminated. A final misconception is that the giving of various combinations of vaccines simultaneously increases the risk of harmful side effects and compromises the immune system. Angellilo et al.(1999) reported in their study some misunderstandings about which vaccinations were mandatory and some participants overestimated the requirements for their children. Gedlu & Tesemma (1997) in their study found that certain participants were under the misconception that disease is better than vaccination, while others believed that vaccines actually cause illness.

In summary, measurement of knowledge has varied across studies, allowing for many knowledge components to be investigated. These different measures include: knowledge of and correct use of vaccine regimens (Angelillo et al., 1999; Van Staden et al., 1995; Wilkinson et al., 1997), adverse and side effects of vaccines (Angelillo et al., 1999; Wilkinson et al., 1997), the purpose of vaccination (Gedlu & Tesemma, 1997; Van Staden et al., 1995; Zhang et al., 1999), reported sources of information (Angelillo et al., 1999; Zhang et al., 1999), and confidence in health providers (Zhang et al., 1999). The distinction between general and specific knowledge has not been explored across the various studies. For example, while general knowledge about how vaccines work has been explored specific knowledge about the role of the immune system and how it works has not been widely explored. This is important because it has implications for what constitutes an adequate level of knowledge in education campaigns and informed consent procedures for future HIV vaccine trials.

In general, however it would appear that knowledge of vaccination systematically varies according to age (Angelillo et al., 1999; Van Staden et al., 1995), education (Angelillo et al., 1999; Zhang et al., 1999), socio-economic status, access to health insurance schemes, and exposure to information sources (Zhang et al., 1999). However, other studies have found no significant differences between the level of knowledge and demographics of the participants (Gedlu & Tesemma, 1997; Razum, 1993). It would further appear that knowledge on its own is not a reliable determinant of vaccination practice. The latter appears determined also by other factors, for example motivation to vaccinate (Gedlu & Tesemma , 1997), quality of

immunisation service (Razum, 1993), and attitude toward vaccination and practices of vaccination (Zhang et al., 1999). It is also evident that misconceptions or 'negative' knowledge about vaccines are present (Hall, 1998; Pless, n.d.) and studies support this (Angelillo et al., 1999; Gedlu & Tesemma, 1997).

2.13 Attitudes toward vaccinations

2.13.1 Introduction

Literature on attitudes toward vaccines indicates that attitudes tend to be associated with a value component, on a continuum of positive and negative attitudes. Thus, these studies often utilise various Likert scales. Attitudes also appear to play a mediating role between knowledge and experience. That is, peoples' attitude towards vaccines appears to be related to their level of knowledge and previous experiences with vaccines. In this section, the results of studies that have investigated attitudes toward vaccination will be discussed.

2.13.2 Studies on attitudes toward vaccination

In Kerala, India a study was carried out by Raman Kutty (1989) in which 78 rural mothers were interviewed. The purpose of the study was to find out the relationship between women's education and its influence on attitudes to various aspects of childcare; including child health status awareness, breast-feeding, and immunisations. All mothers were given 50 statements to which they responded 'agree', 'disagree' or 'don't know'. The results showed a general positive attitude toward vaccination. However, stronger positive attitudes toward traditional aspects of childcare (such as breast-feeding) were found than toward immunisation. That is, although people generally held vaccinations in a favourable light, the more traditional aspects of childcare were more favoured. No significant differences between educated and less educated women in terms of attitudes toward vaccination were reported. One interesting finding from the former study was that husband's education was found to have positive impact on women's attitudes toward vaccination (Raman Kutty, 1989). That is, in households where husbands were more educated, their wives tended to hold more positive attitudes toward vaccination than those with less educated husbands.

In a study with 841 mothers who completed self-administered questionnaires, Angelillo et al. (1999) also assessed mother's attitudes toward vaccinations of infants. All questions about attitudes were scored on either a three-point Lifetreescale with options for "agree," "uncertain," or "disagree" or on a 10-point Likert scale for attitudes on the utility of

vaccinations. They found that in general attitudes toward the use of vaccinations for preventing infectious diseases were very favourable. No significant differences in attitudes were found for socio-demographic characteristics. However, low education of parents was associated with non-adherence to vaccination.

In another study in Ile-Ife, Nigeria, 200 mothers were interviewed (Odebiyi, & Ekong, 1982). Initially, an areal probability sampling technique was used in which areal units were defined by grid squares superimposed on a map of Ile-Ife town. From a total of 50 grid squares, 10 squares were randomly selected from which further blocks were obtained and systematically sampled so that one out of every two blocks was selected from each square. Eligible households were selected. Mothers' concept of measles and attitudes towards the measles vaccine were investigated. The results found that the attitude of Nigerian mothers towards vaccines and other aspects of prevention are influenced by different perceptions of the cause of measles. A significant correlation between the literacy of mothers and their belief in the efficacy of measles vaccine was found. For example, eighty-one of the 103 non-literate mothers believed that the vaccine was not preventive because they claimed that some of their children who had been immunised still contracted measles. The mothers' perception of measles vaccine was also found to be a function of their socio-economic characteristics, with the lower socio-economic group favouring a supernatural explanation for measles (ibid).

In short, various studies have been carried out specifically investigating mothers' attitudes toward vaccination. These studies have examined mothers' general attitude toward vaccine safety, efficacy and service delivery in an open-ended manner while others have focused on particular attitudes using Likert-type scales. In general, positive attitudes toward vaccination were reported. This would contradict research conducted by Nichter (1995) that identified negative attitudes toward vaccination. Opposition to vaccination in the latter study included suspicion of hidden political agendas, and perceptions that poverty relief, delivery of basic services and other important health needs could be sidelined or given less attention as a result.

2.14 Predictors of, and barriers to, immunisation

Other predictors to immunisation have also been reported. These are enumerated below.

Greenough (1995) purports that the acceptability of or non-compliance with vaccination is non-random. In developing countries non-compliance reportedly varies mainly according to sect and ethnicity, although class, caste, gender, age, geography and literacy are also notable sources of differentiation (Greenough, 1995). Numerous vaccination studies have been conducted which have explored both predictors and barriers to vaccination, depending on the researchers interest. It can be deduced that predictors and barriers are 'two sides of the same coin', and are therefore discussed simultaneously.

Positive health beliefs have been positively related with vaccination. For example, Markland and Durand (1976) reported that adequately immunised populations have been shown to possess a high perception of disease seriousness and risk of disease. Adequate knowledge of vaccine efficacy, adequate knowledge of length of protection afforded by vaccine, and greater media exposure have been shown to be positively related with immunisation (Markland & Durand, 1976). Demographic factors such as: rural dwelling (Akesode, 1982; Edpuganti, 2000; Zurayk & Gangarosa, 1982), bigger families (Markland & Durand, 1976), low socio-economic status (Odebiyi & Ekong, 1982; Streatfield & Singarimum, 1988), low education (Akesode, 1982; Edpuganti, 2000; Zurayk & Gangarosa, 1982), younger parental age (Markland & Durand, 1976) have been identified as potential barriers to vaccination. Cultural and religious beliefs and practices also have an impact on immunisation behaviour (Odebiyi & Ekong, 1982). These practices have been used in conjunction with immunisation (Eng, Naimoli, Parker, Lowenthal, 1991; Odebiyi & Ekong, 1982). Finally, Greenough (1995) also points out despite the effective vaccine technology, style and continuity of vaccination service is also important.

2.15 Participation in HIV preventive vaccine trials

2.15.1 Introduction

In this section, the results of selected studies that have looked at health beliefs and attitudes toward HIV vaccination and participation in trials of HIV preventive vaccines will be presented.

2.15.2 Understandings of trial participation

Assessment of willingness to participate (WTP) in hypothetical HIV preventive vaccine trials can help identify educational issues necessary for adequate informed consent procedures and, in addition, provide information on the level of recruitment needed to achieve adequate trial enrolment. In a guide prepared for UNAIDS MacQueen (1999) puts forward several informational requirements including: basic elements of trial design, vaccine concepts, medical risks, social risks, behavioural risk reduction, benefits of participation and trial sponsorship.

Numerous studies on WTP and related subjects have emerged since the early 1990s (MacQueen, 1999). These studies have yielded differing degrees of understanding of HIV vaccines and clinical trials among the participants (Bartholow et al., 1997; Koblin et al., 1998; McGrath, George, et al., 2001; McGrath, Mafigiri, et al., 2001; Ross, Jeffords & Gold, 1993). In Uganda, where the first safety trials in Africa were conducted, McGrath, George, et al. (2001) and McGrath, Mafigiri, et al. (2001) found that participants in a vaccine preparatory study were familiar with vaccines but did not clearly distinguish the use of vaccines for prevention or curing, trial procedures were unfamiliar (e.g. placebos, randomisation, and blinding) and knowledge about trial procedures increased incrementally over follow-up. This again highlights the importance of appropriate dissemination of information repeated over time as this has direct implications for education campaigns for host communities and informed consent procedures for potential trial participants.

2.15.3 Attitudes: Willingness to participate (WTP)

WTP in a preventive vaccine trial is hypothesised to be a complex interaction of different factors in a person's life including: perceived risk of HIV infection due to behavioural and environmental factors; perceived risks of participating in the trial; perceived benefits of participating in the trial; comprehension of how the trial works; trust in those implementing and supporting the trial; altruistic motivations; and peer influence (MacQueen, 1999). The many studies conducted on WTP have been among female commercial sex workers and STD patients in northern Thailand (Celentano et al., 1995), injecting drug users in the United States (MacQueen et al., 1999; Fureman, Meyers, McLellan, Metzger & Woody, 1997, in MacQueen, 1999) heterosexual men and women in San Francisco (Chesney, Chambers & Khan, 1997, in McGrath, George, et al., 2001) and in Kenya (Jackson, Martin, Bwayo et al., 1995, in McGrath, George, et al., 2001), men who have sex with men (MSM) (Koblin, et al.,

1998) and male soldiers in Uganda (Hom, Johnson, Mugenyi et al., 1997, in McGrath, George, et al., 2001).

MacQueen (1999) presents a systematic review of literature of studies conducted in America and Thailand from 1990s to 1998. MacQueen (1999) deduced the following from the various studies:

- WTP ranged from 20% to 50%,
- Those not WTP ranged from 3% to 9%,
- The primary incentives for participation were altruism and opportunities for reducing one's personal risk for HIV infection, and
- Potential barriers to trial participation included concerns about vaccine side effects, the potential for vaccine-induced HIV infection and accelerated progression to AIDS, duration of the trial, distrust of researchers and government, and social consequences of vaccine-induced seropositivity and trial participation.

In the following section, two studies that have explored acceptability of an HIV vaccine specifically among students will be presented.

A study of 125 undergraduate students from an urban Midwestern University in the USA who volunteered for research as a means of fulfilling requirements of introductory psychology courses was conducted (Zimet, Liau & Fortenberry, 1997). Self-administered questionnaires were distributed. The purpose of the study was to evaluate the relationship of health beliefs to the intention to accept an HIV vaccine. Health beliefs such as perceived susceptibility to HIV, perceived severity of AIDS, benefits associated with receiving hypothetical HIV vaccination and barriers to performance of health behaviour were assessed. The questionnaire also elicited socio-demographic information such as age, gender and race. Intention to get vaccinated was not significantly related to gender or race. These results would appear to contradict studies that have shown that African-Americans are particularly distrustful of science and policy as they relate to AIDS. While intention to vaccinate was marginally associated with age, the relationship between intention to vaccinate and age was not a significant one. Results revealed that higher levels of perceived susceptibility, perceived severity, benefits and lower levels of barriers (such as fear of the vaccine and fear of needles) were related to greater willingness to get an HIV vaccine. Thus, it may be concluded that

intention to accept or reject an HIV vaccine is not universal but depends on a number of factors, including context (Zimet, et al., 1997).

Zimet, Fortenberry & Blythe (1999) conducted a study with 318 adolescents in Indianapolis, USA. The study evaluated associations of health beliefs and health behaviours with attitudes to HIV immunisation. The sample of adolescents was recruited from urban community health clinics when they were receiving healthcare. All participants were given an anonymous self-administered questionnaire, which they completed in a waiting room of the medical clinic while awaiting an appointment. Demographic variables included age (13-18), gender, race/ethnicity (African American, non-Hispanic, White, Hispanic and other). The results indicated that adolescents who practised less health behaviours were more open to the idea of an HIV vaccine than those who engaged in more health protective behaviour. More specifically, those people that used condoms less frequently, and were therefore at higher risk, were more accepting of HIV immunisation than people who exercised health protective behaviours. Several beliefs associated with non-acceptance were: low perceived vulnerability to infection, doubts about vaccine efficacy; worries about vaccine safety; and fears about getting injections (Zimet, et al., 1999). Such health beliefs were important in informing participants' attitudes to HIV vaccination, and impacting on their hypothetical intentions to vaccinate or not. These findings highlight the importance of health beliefs in influencing the acceptance of HIV immunisation.

2.15.4 Behavioural studies: Social harm monitoring

HIV preventive vaccine trials have the potential for psychosocial risks (UNAIDS, 2000). For example, volunteers may test positive on standard HIV tests and subsequently face stigmatisation and prejudice by those who mistakenly consider these volunteers to be either HIV infected, as having AIDS, or identifying the volunteers as being in a risk group (MacQueen, 1999; UNAIDS, 2000). Thus, it is important that social harm is monitored during and after vaccine trials. In one study (Allen et al., 2001) 1516 AIDS Vaccine Evaluation Group (AVEG) volunteers were questioned about trial-related discrimination (TRD). From this total seventy-six participants (5%) reported TRD events. Of these the most cited incidents were negative reactions of friends, family, and co-workers while a few were related to HIV testing. Furthermore, the majority of events were ultimately resolved while 40% were not. On the whole the findings indicated that TRD was neither widespread nor

severe. It is therefore important that researchers ensure that social harm is monitored in prospective trials as TRD may vary across different studies and contexts.

In summary, numerous studies have been carried out specifically looking at attitudes towards HIV vaccine trials and participation therein on different groups of people, including commercial sex workers. This field of research has come to be known as willingness to participate (WTP). In this field of research an educational component precedes formal assessment of WTP, which is considered as both imperative and a more valid way of assessing WTP (MacQueen, 1999). WTP in a HIV preventive vaccine trial has been regarded as a complex process, which needs to be adequately measured (ibid). In general the findings across the different studies have varied with WTP ranging from 20 % to 50%, those not WTP ranged from 3% to 9%, primary incentives for participation were altruism and opportunities for reducing one's personal risk for HIV infection. Potential barriers to trial participation included concerns about vaccine side effects, the potential for vaccine-induced HIV infection and accelerated progression to AIDS, duration of the trial, distrust of researchers and government, and social consequences of vaccine-induced seropositivity and trial participation.

2.16 Summary: Part 3

Immunisation, which has been described as a preventive health behaviour (Gochman, 1988; Gore et al., 1999; Marks et al., 2000; Pitts, 1996) is becoming increasingly important to health providers including Psychology (Gore et al., 1999; Pitts, 1996). Health psychology has posited various models to study and intervene in preventive health behaviour, primarily drawing on decision-making theory and attitude theory (Gore et al., 1999). Numerous studies have been conducted that have explored various aspects of immunisation, the majority of which have focused on childhood immunisation. As a result mothers knowledge and attitudes towards vaccination have been widely investigated and were of main focus of the current empirical review. In general, measurement of knowledge has varied across studies, allowing for many knowledge components to be investigated. These different measures include: knowledge of and correct use of vaccine regimens (Angelillo et al., 1999; Van Staden et al., 1995; Wilkinson et al., 1997), adverse and side effects of vaccines (Angelillo et al., 1999; Wilkinson et al., 1997), the purpose of vaccination (Gedlu & Tesemma, 1997; Van Staden et al., 1995; Zhang et al., 1999), reported sources of information (Angelillo et al., 1999; Zhang et al., 1999), and confidence in health providers (Zhang et al., 1999). Generally, it would

seem that knowledge of vaccination varies according to age (Angelillo et al., 1999; Van Staden et al., 1995), education (Angelillo et al., 1999; Zhang et al., 1999), socio-economic status, access to health care insurance schemes, and exposure to information sources (Zhang et al., 1999). Generally, mothers reported positive attitudes toward vaccination (Angelillo et al., 1999; Raman Kutty, 1989). Regarding HIV preventive vaccine trials WTP has been said to involve a complex interaction of different factors in a person's life and has been reported to range from 20% to 50% (MacQueen, 1999). Although research conducted on 1516 Vaccine evaluation Group (AVEG) volunteers on trial-related discrimination (TRD) has suggested that on the whole TRD was neither widespread nor severe, this may vary across different studies and contexts. In South Africa, social discrimination on the basis of HIV status is known to be high (Department of Health, 1997 in Barrett, 1998) and therefore monitoring of social harm of potential participants is imperative.

2.17 Summary: Literature review

At the turn of the twentieth century the AIDS pandemic poses a great threat to human life in South Africa, stretching limited health resources to their limits. With current interventions yielding limited results against the AIDS crisis (Harrison et al., 2000) a HIV vaccine has been proclaimed as compelling and urgent both worldwide and within Southern Africa (Barrett, 1998; LAVI, 1998; UNAIDS, 2000). An HIV preventive vaccine would complement and reinforce already established AIDS interventions and would require international and national cooperation for its effective implementation. Through the coordinated efforts of SAAVI, South Africa is due to start its first HIV safety trials this year. However, clinical trials generally require rigorous implementation and monitoring of research ethics (Emanuel et al., 2000) and extensive preparation, including education campaigns, informed consent procedures and social science research (Abdool Karim, 2002). Through the many projects coordinated by SAAVI, these issues are being addressed. Many research projects have been conducted worldwide that have explored attitudes and behaviour with regards to vaccination in general and these have yielded differing results. More recently, with the advent of HIV preventive vaccine trials WTP, perceived barriers and incentives to trial participation (MacQueen, 1999) have been increasingly the focus of study. In South Africa, however, information regarding vaccination in general is sparse.

Psychology as a discipline has a significant contribution to make towards AIDS intervention including: policy development; preventive education campaigns; education and training of

lay counsellors; psychological counselling for screening and for HIV-affected people, their families, co-workers and carers; psychological services for the 'worried well'; assisting with training of health care workers; and conducting AIDS related research (Schneider, 1989 in Lindegger & Wood, 1995). In conjunction with a series of studies (da Silva, 2003; Lindegger, et al., 2003) the current study set out to investigate knowledge and experiences of vaccination in general, and knowledge of and expectations toward HIV vaccination and participation in a hypothetical vaccine trial, among students, as part of the national preparation for HIV vaccine trials in South Africa.

Chapter 3:

METHODOLOGY

3.1 Introduction

The following chapter presents the methodology used in the study. The study set out to explore local students' knowledge and experiences with vaccination in general, and attitudes toward possible participation in HIV preventive vaccine trials as part of national preparation for HIV safety trials in South Africa. This chapter presents with a description of the research design, which provides a framework for the rest of the chapter, where the different research design components are described sequentially in the following order: key objectives, sampling procedure, measures and data analysis.

3.2 Research design

Research design can be described as the coherent framework between the research aims and questions, strategic methods used including sampling techniques, measures and data analysis (Terre Blanche & Durrheim, 1999). Applied research is mostly atheoretical, in that it is not necessarily guided by an established paradigm or model (Denzin & Lincoln, 1994). In this sense the current study was not held by a specific set of theoretical assumptions, instead the study was exploratory in nature (Neuman, 2000). As mentioned in section 1.2 very little research has been conducted in South Africa on peoples' knowledge and experiences with vaccination in general contrasted with numerous studies conducted worldwide. The researcher, therefore, attempted to broadly explore these phenomena within a South African context, and specifically a student population, and in so doing formulate more precise questions for future research (Terre Blanche & Durrheim, 1999). While the research was driven by specific aims, the particular research questions were refined as the research process unfolded (*ibid*) and the researcher sought a deeper understanding of the subject matter.

3.3 Key objectives of current study

As part of a larger vaccination study (da Silva, 2003; Lindegger et al., 2003) being carried out in the country, the current study broadly set out to survey student attitudes to vaccination in general, in preparation for preventive HIV vaccine trials (Slack et al., 2000). The current study is based on the premise that given South Africa's longstanding history with vaccination as a form of preventive practice, student understandings and experiences with vaccination could be investigated. This could form part of the preparation for HIV preventive vaccine

trials by informing education campaigns and informed consent procedures. In addition this study attempted to add to the body of empirical literature locally, as information in this regard is sparse in South Africa, and to generate more precise questions for future research. Thus, the key objectives of the present study were to assess students’:

1. Understandings of vaccination: Knowledge and perceptions of vaccination in general, including perceived barriers to vaccination. Specifically the following aspects of understanding were assessed;
 - Knowledge of the purpose and mechanism of vaccination,
 - Knowledge of vaccine – preventable diseases,
 - Knowledge of various perceptions about vaccination in general, including barriers to vaccination,
2. Experiences of vaccination generally;
 - Specifically students’ experiences with vaccination and the uses of vaccination,
3. Knowledge of and expectations toward HIV vaccination and participation in a hypothetical vaccine trial; and
 - Specifically, awareness about the pending HIV preventive vaccine trials, perceived purpose and target of such trials,
 - Perceptions about participation in a hypothetical vaccine trial, and
 - Perceived incentives and barriers for participation,
4. To explore if particular knowledge and experiences are associated with demographics such as motherhood and gender.
 - Specifically, the association between certain aspects of knowledge and experiences, and demographics such as gender and motherhood was explored.

In terms of objective 4 it was assumed that mothers would be more knowledgeable and provide more information and rich explanations, having had more recent and continued contact with vaccination.

This research was part of a larger study, which aimed to assess: i) local or popular understandings, perceptions and barriers to vaccination; ii) culturally and traditionally based

images, metaphors and beliefs surrounding vaccination, and the impact of these on attitudes to vaccination; iii) Knowledge about potential HIV vaccines and attitudes to participation in HIV vaccine trials among a number of sub-samples, including clinic attenders (da Silva, 2003) and members of a local community (Lindegger et al., 2003).

3.4 Sampling procedure

The sample was made up of a total of 35 participants. Ultimately, only 33 participants' data was used in the analysis due to the fact that one tape was in-audible and therefore impossible to code and in the other case one participant kept on switching between Zulu and English during the interview. After careful consideration the latter was dropped from the data corpus to maintain consistency. Demographic variables included: gender, age, first language, religion, degree of study and motherhood (further described in chapter 4). Ideally, participants would have been stratified equally along these demographic variables but due to the practical constraints it was not possible to achieve random sampling. As an exploratory study the aim was not to have generalisable results, as indicated by the both the sample size and the non-random sampling employed, but rather to extrapolate the results.

The sampling procedure employed in the study drew on a number of sampling techniques, primarily convenience sampling. The sample used in the study comprised of university students mainly from residences. The choice of students was largely influenced by the fact that students are an accessible sample. The researcher was also enrolled at the university, which facilitated negotiation of access onto site, especially given the time constraints (Silverman, 2000). Although this may have its disadvantages, researcher pleasing or social desirability for example, the benefits were estimated to outweigh the risks. It could be argued that it also provided the researcher a unique and privileged position of understanding of possible 'in-group' dynamics. In addition, steps were taken by the researcher to minimise potential disadvantages and conduct research ethically (discussed in section 3.8). Research in the field has investigated various groups of people, with a few focusing on student experiences. As an exploratory study the current study was also interested in students as a sub-group of the population. Furthermore the researcher knew that university students have been targeted for recruitment programs for HIV vaccine trials in Gauteng, South Africa (see section 5.4) and therefore the results of the current study could inform a subset of the population which will be targeted for HIV preventive vaccine trials.

The exploratory nature of the research project also enabled flexibility in the data collection. After initial analysis of the first few interviews it appeared that mothers and non-mothers within the student population may have different experiences with vaccination. Purposive snowball sampling was used to identify cases of interest, namely mothers (Patton, 1990). These participants told their friends about the research and so data collection snowballed.

Following consultation with either residence administrators or assistants, four university residences were identified for data collection. Two of these were undergraduate residences and the latter postgraduate residences. From the undergraduate residences one was a female residence, another a male residence while the postgraduate residences were both co-ed. Residence administrators or assistants advertised the study in the four residences through house meetings and by word of mouth. Prospective participants would leave their names and contact details with their resident assistant, who would pass on the information to the researcher. The researcher would then independently contact the prospective participants and arrange a suitable time to conduct interviews, which were audiotaped to allow for subsequent referral to rich text quotes from participants.

While the researcher thought that data collection would go very quickly, given the setting, in practice data collection proved to be lengthy. This can be partially attributed to the sensitive and confidential nature of AIDS research (Melton, Levine, Koocher, Rosenthal & Thompson, 1988). Despite attempts to reassure students that the research was a study of perceptions and attitudes to general vaccination and not an 'AIDS' study and that their identity would remain anonymous, many were dissuaded and chose not to participate. However, from those who volunteered, no resistance or apathy was noted.

3.5 Measures

3.5.1 Interview procedure

Interviews were conducted in a pre-arranged room designated by the respective residences, in a conducive environment for taping. At the start of each interview the aims of the study were described to all participants, who were then given an information sheet on the study (see Appendix A). An opportunity for participants to ask any questions or clarify any concerns was then afforded to all participants. All participants were required to give written informed consent for participation, and to audio tape the interview (Appendix B). Participants were informed beforehand that the interviews were confidential and anonymous and that if they

were not comfortable with audio taping detailed written notes would be taken instead. Once informed consent had been obtained, all participants initially filled in a form with their demographic details before proceeding with the interview. In the interview participants were asked open-ended questions with occasional close-ended questions, each interview spanning approximately 30 to 45 minutes. After that interview participants were again given an opportunity to ask questions. All participants were then thanked for their participation and given a refreshment as a token of appreciation for their volunteering.

On occasion environmental disturbances such as lawn mowers, or students playing their radios loud, were encountered. In such incidences interviewing proceeded if the noise was tolerable. Otherwise, interviews were temporarily suspended and reconvened once conducive for taping again. Notably, this was very rare and only occurred once or twice.

3.5.2 Interview schedule

Face to face semi-structured interviews were conducted in English by the researcher. The interview schedule consisted of two parts. The first part elicited demographic information. The researcher was particularly interested in whether or not demographics, particularly gender and between mothers and non-mothers, were associated with perceptions of vaccination. The second part of the interview schedule explored participants' understandings and experiences of vaccination, predominately using open-ended questions. The open-ended nature of questioning fitted in with the exploratory nature of the study. That is, while the interview schedule provided a useful structure to ensure consistency between interviews, it also allowed for flexibility to probe further when participants brought up interesting or new ideas (see Appendix C).

As already mentioned in section 3.3 the current study is part of a series of studies conducted by Lindegger et al. (2003) and da Silva (2003). These studies were conducted in two communities in kwa Zulu –Natal. The same interview schedule has been used across all three studies. The interview schedule was deliberately designed to elicit both diversity of opinion and details of specific viewpoints. Unlike most research in the field, which uses Likert type scales and other forms of closed ended questions the measure instrument in this study utilised open ended questions to sample diversity of opinion. Originally formulated by Lindegger et al. (2003) a subsequent study (da Silva et al., 2003) modified the questionnaire to match the community from which the participants were drawn. Also, in the current study the interview schedule was slightly modified and tailored to omit redundancy, and additional questions

according to the researcher's research interest were included. Questions were also added to explore in more detail students' perceptions of HIV preventive vaccine trials. Additional items included:

- Have you heard about an HIV vaccine?
- Who do you think should be vaccinated?
- What do you think about the vaccine? Do you think it is a good /bad thing?

3.6 Data analysis

Data analysis began after an initial set of interviews, reflecting the ongoing nature of qualitative data analysis that takes place throughout the research project (Mauthner & Doucet, 1998, in Gambu, 2000). To maximise consistency between samples in the larger study and allow future comparison between studies, the original coding schedule was maintained and the same coder was used. However, ongoing data analysis revealed that certain codes needed further refinement and in some incidences new codes were developed. See Appendix D for the coding schedule used in this study.

Traditionally, content analysis has been the most favoured method used by quantitative researchers to analyse text of different forms (Silverman, 2000). Historically, this entailed imposing predetermined categories onto the data and counting the number of instances a category came up (Neuman, 2000). In the current study content analysis was applied to the data and a level of interpretation was applied, as coding was often latent rather than manifest. Coding also entailed extracting similar and common meanings. Content analysis was ideal for the current study because it straddled the gap between qualitative and quantitative components of the study, thereby suggesting that the relationship between these two is not necessarily mutually exclusive but perhaps on a continuum. The use of counts and Chi-square helped to describe popular views and explore possible significant associations between selected codes and demographic variables such as motherhood and gender.

3.6.1 Coding system

Using content analysis, a coding system was developed in the original study. The coding schedule was designed to pick up themes as they occurred naturally in the data corpus. After an initial generation of an exhaustive coding scheme, these were abstracted and reorganised into a hierarchal coding schedule. Unlike other contemporary variations of content analysis, which advocate that categories should be mutually exclusive and exhaustive (ibid), the codes

in current study were not expected to be mutually exclusive. That is, the coding schedule was designed to allow any extract to be coded into more than one category where necessary (Weber, 1985).

The same coder from the larger study was employed in the current study. This coder was used for two primary reasons. Firstly, this facilitated a level of consistency across the three studies. Secondly, having coded all the previous data the coder had gained a level of familiarity with the coding, ensuring reliability across samples. All 33 interviews were coded and the findings were recorded onto a coding form (see appendix E). The count where each code occurred was also recorded in each interview to allow the researcher to subsequently return to original text. In addition, rich quotes were also selected and recorded on the same coding schedule to allow the researcher to illustrate themes.

3.6.2 Analysis of codes by demographic variables

Only one recording per code was made. Thus even though each code may have appeared more than once each code was only used once per interview. Each code was converted into a count for Chi-square analysis. Chi-square analysis was used to investigate the nature of relationship between certain demographics and codes. These comparisons were kept to a minimum to limit the family-wise error rate. Of the total 189 codes 64 were selected for Chi-square analysis - 18 pertained to understandings of vaccination in general, 15 to experiences with vaccination and 31 to HIV vaccine trials. Regarding understandings of vaccination the selected codes included knowledge of the purpose of vaccination, vaccine mechanism, vaccine target and specific diseases for which there are vaccines. Selected codes on experiences with vaccination referred to side effects and personal experiences. With regards to knowledge, expectations of vaccine trials and willingness to participate, selected codes related to the following: general knowledge and awareness of vaccination; willingness to participate in a hypothetical vaccine trial; perceived incentives; and barriers to vaccination.

Thus, if alpha is set at .05, all things being equal, then it would be expected that of the 64 selected codes three significant results would be expected by chance alone. Given the fact that the sample was only made up of 33 cases, which were non-randomly selected this would have the impact of reducing power and limiting the statistical generalisability of the results to other samples or populations. Therefore the results have to be considered very carefully as the chance of committing a Type II error, that is the chance of not finding a significant result

that may actually exist, can be considered quite high in the current study. Nonetheless, the aim was not to produce statistically generalisable results but rather to identify possible trends between certain responses and demographics (e.g. gender), which could be explored in future research.

3.6.3 Reliability and validity

No formal reliability and validity measures were calculated in the current study. However, attempts were made to enhance accuracy and consistency. The use of the same coder across all three samples facilitated this process. The researcher also felt it would be more constructive if the coding process were also learnt. Therefore the researcher coded a number of transcripts to aid correct interpretations of the data. While the researcher was familiar with all the interviews, five interviews were randomly selected for thorough implementation of the coding schedule.

This exploratory study did not aim to generate generalisable results but rather to extrapolate results, which was further enabled by the purposive sampling employed in the study. That is, while the findings in the current study may not be generalised to the entire population of prospective trial participants, results may apply to a subset of the population, namely students. With purposive sampling, information rich cases are selected for in-depth study (Patton, 1990). That is, while only 33 were sampled, these were considered rich with information. In addition, the researcher had reached saturation and no new themes were emerging. Thus the focus was on depth rather than quantity.

3.7 Ethical considerations

Careful consideration to ethical requirements was given in the present study. As mentioned in Chapter 2, the need for the rigorous application of ethics in South African research is paramount. Not only does it serve as “good practice” but also to foster an atmosphere of mutual respect and cultural sensitivity consistent with the South African constitution. The researcher was also a student at the university, which allowed the researcher to capitalise on an ‘in-group’ dynamic, thereby facilitating access on site. This could have raised a concern regarding the dual role of the researcher (as a student on the one hand and a researcher on the other). Deliberate attempts were made to ensure informed consent, free from coercion. Each participant was given an information sheet, briefly outlining the study (as mentioned in

section 3.5.1). This is attached as Appendix 1. All participants were also required to give written informed consent to the interview. This is attached as Appendix 2. Consent was also obtained for audio-taping (also see Appendix 2), with the option of taking intensive notes if the participants felt that the taping was intrusive. In addition, to ensure confidentiality all interviews were conducted in a closed room. Furthermore, all participants were assigned codes to ensure anonymity. The researcher also had a system, which allowed for 'cracking the code' in case further information from participants was further required. This was clearly explained to all participants.

4.1 Introduction

In the current chapter the results of the study are presented. The chapter begins with a demographic description of the sample. This is followed by a description of the results of participants' knowledge and experiences with vaccination. In the final section, participants' perceptions and expectations of HIV vaccine trials are presented.

4.2 Demographic profile of participants

Table 1 (overleaf) gives a summary of the demographic profile of the participants. Almost half of the participants (45%) were male while the remainder (55%) were female. Four age categories were present in the sample. The biggest age category was the 21-30 age group with $n = 20$ people. Other age categories consisted of 14- 20 ($n = 7$), 31-40 ($n = 4$), and 41-50 ($n = 2$), respectively. Participants came from various first language backgrounds. The five most common languages, of the eleven official South African languages, were English ($n = 9$), Zulu ($n = 9$), Sepedi ($n = 4$), Xhosa ($n = 3$), and Sesotho ($n = 2$), respectively. Thus, while only close to a third (27%) of the participants were English first language speakers, the remaining 73% were bilingual – with English being the primary medium of instruction and writing in the university. More than five religious groups were represented in the sample, while 27% of the sample stated that they had no religious affiliation. All participants were spread across three faculties. The largest grouping ($n = 15$) came from the Arts / Social Science faculty while other participants came from the Faculties of Science ($n = 10$) and Commerce ($n = 8$) respectively. In addition, from the total of eighteen females, six were mothers while the remaining twelve stated that they did not have any children.

Demographic category		N	%
Gender:	Male	15	45%
	Female	18	55%
Age group:	14 – 20	7	21%
	21- 30	20	61%
	31-40	4	12%
	41-50	2	6%
First language:	English	9	27%
	Zulu	9	27%
	Sepedi	4	12%
	Xhosa	3	9%
	Sesotho	2	6%
	Other	6	18%
Religion:	None	9	27%
	Catholic	5	15%
	New covenant ministries	5	15%
	Lutheran	4	12%
	Methodist	3	9%
	African	1	3%
	Hindi	1	3%
	Other	5	15%
Degree:	Arts/ Social Science	15	46%
	Science	10	30%
	Commerce	8	24%
Motherhood:	Mothers	6	18%
	Non-mothers (female)	12	36%

Table 4.1: Demographic profile of participants

4.3 Knowledge, perceptions and barriers to vaccination

The results presented in this section pertain to objective 1 of the study, that is, to assess students' knowledge and perceptions of vaccination. Specific questions were asked concerning the purpose of vaccination, vaccine mechanism, vaccine-preventable diseases, perceptions of health-care workers, perceptions of vaccine target populations, preferred sources of information, safety, side-effects and barriers to vaccination, alternatives to vaccination, vaccination and human rights and educational needs.

4.3.1 Knowledge of the purpose and mechanisms of vaccination

All participants displayed some level of knowledge about vaccines with no one participant stating that s/he did not know anything about vaccination. The vast majority of the participants, that is 97% (n = 32), cited that the purpose of vaccination was to promote health or prevent illness, while the remaining 3% (n = 1) said vaccines cure disease. A fairly high number of participants, i.e. 64% (n = 21), also felt that vaccines were medically helpful. Less common responses to the purpose of vaccination cited by 18% (n = 6) included the perceptions that while vaccines protect against disease they are not necessarily 'fool proof'. In the words of one mother:

"...Some children do die from measles whereas they had the injection to protect them from catching measles. So in that sense I would say even those things are not 100% perfect. But I still take my children, just as a precaution. They might get it (disease), they might not."

One mother felt that vaccines guarantee immunity and expressed disillusionment in vaccines when they did not eliminate her child's susceptibility to disease. She stated:

"Yes she got vaccinated for measles and she got it twice already. And she had all her shots in time. So I lost faith in the thing."

Of those who felt that vaccines promote health or prevent illness 9% (n = 3) also said vaccines cure disease or treat illness.

With regards to the mechanisms by which vaccines work, two participants were unsure of the mechanism by which vaccines work while 67% (n = 22) of the participants referred to the mobilization of the immune system by using terms like pathogens, T- cells, anti-bodies and

immunity. One participant had this to say in response to the question “What does vaccination do?”

“Well I think that it tries to boost immunity by producing anti-bodies that boost your immunity to certain diseases.”

A significant minority of participants, that is 27% (n = 9), used metaphors of strength and power to explain how vaccines work, stating that vaccines make one strong and able to fight diseases. One participant reported the following when asked how vaccination protects against disease:

“Um, I know in the body you have antibodies that prevent diseases. I think that it helps to fight off diseases... I think it just helps the antibodies, to give them more fighting power against the bacteria of the disease.”

4.3.2 Knowledge of diseases that are vaccine preventable

Regarding knowledge of diseases that are vaccine preventable most participants, that is 91% (n = 30), stated common vaccine-preventable diseases. Of these participants who named common vaccine-preventable diseases the majority (n = 19) mentioned more than one vaccine-preventable disease. Common vaccine-preventable diseases included measles, chicken pox, smallpox, polio, tuberculosis, BCG and influenza. However, from this same group 57% (n = 17) also mentioned other common diseases that were not in fact vaccine-preventable, the most prominent being malaria. Thus, while the majority of participants (91%) correctly mentioned at least two vaccine-preventable diseases, a significant number of these participants (57%) also incorrectly mentioned other diseases. In response to whether there were any diseases that vaccines do not prevent against 70 % of overall participants (n = 23) mentioned HIV, although 3% (n = 1) cited HIV as a vaccine-preventable disease.

Participants also alluded to the exclusive relationship between vaccines and disease (illustrated by the citations below). As one participant put it, people get vaccinated:

“...To prevent the development of the disease that you want to be vaccinated from.”

Another had this to say:

“Um, well I know that you get measles ones when you are a child to prevent from getting measles. And you get ones for polio...”

4.3.3 Knowledge of health-care workers (HCW’s) views on vaccination

In response to questions about information received from HCWs 40% of participants (n = 13) claimed to be either to be unsure or to have never heard what HCWs say (see Table 4.2 below). Similarly, 36% (n = 12) stated that HCWs do not explain about vaccination. One participant pleaded:

“Maybe they could be more tolerant, cause you get old people who are just helpless ...they are disregarded and treated with disrespect and I just think that staff at the clinics, hospitals and all vaccination centres could be more friendly...”

Another response to what HCWS explain about vaccination was as follows:

“No, they have never as far as I know about vaccination.”

Only 9% (n = 3) of overall participants stated that they believed what HCWs say. Of these, 2 participants felt that what HCWs had to say was helpful, another 2 stated that HCWs said vaccination was a way of taking proper care of children while one participant stated that HCWs said that vaccines prevent disease. With the exception of the latter and former responses no attempts were made to explain what it was that HCWs said about vaccination.

Participants perceptions of HCW’s views of vaccination	N	%
Unsure, or never heard	13	40%
HCWs do not explain	12	36%
Believe what HCWs say	3	9%
HCWs say vaccination is way of taking proper care of children	2	6%
What HCWs say is helpful	2	6%
HCWs say vaccines prevent disease	1	3%
Total number of participants who responded	28	85%

Table 4.2: Percentage of participants reporting specific views of health-care workers

4.3.4 Perceptions of vaccine target populations

Seventy percent of participants (n = 23) believed the target population of vaccination to extend to all people of all ages (refer to Table 4.3 below). One participant responded in the following way when asked whom vaccination was for:

“Everyone! It’s just that grown ups don’t really take or think of it much. It seems like it’s for kids but its for everybody.”

However, many expressed uncertainty about the specific population target. The majority of participants, that is 82% (n = 27), felt that healthy people should be targeted because they too “can get sick”. As one participant put it:

“...I don’t think you can ever be like 100% healthy. Yah, so even healthy people should get vaccinated.”

Forty two percent of the entire sample (n = 14) felt that vaccination should be mainly for the sick. Forty percent of overall participants (n = 13) believed that vaccination should target both the healthy as well as the sick. Just over a third of all participants, that is 36% (n = 12), felt that children should be the main targets of vaccination, while 12% (n = 4) felt that vaccination should target both adults and children. Fifteen percent (n = 5) of the participants stated that vaccines should be mainly for people at risk.

Target of vaccination	N	%
All people of all ages	23	70%
Mainly healthy people	27	82%
Mainly the sick	14	42%
Both healthy and sick people	13	40%
Mainly children	12	36%
Mainly adults	0	0%
Both children and adults	4	12%
Mainly people at risk	5	15%
Total number of participants who responded	33	100%

Table 4.3: Percentage of participants mentioning specific vaccine target populations

4.3.5 Actual and preferred sources of information regarding vaccination

With reference to sources of information about vaccination more than half of all participants, namely 58% (n = 19), reported clinics, hospitals and schools as their primary information resource (as illustrated in the table below). This also included posters and pamphlets therein. Twenty one percent of overall participants (n = 7) reported that they had received their information from the media while fifteen percent (n = 5) mentioned other sources like friends or neighbours.

Reported actual sources of information	N	%
Clinics, hospitals and schools	19	58%
Media	7	21%
Other sources, e.g. friend or neighbour	5	15%
Total number of participants who responded	26	79%

Table 4.4: Percentage of participants reporting actual sources of information

When asked about preferred sources of information different results were obtained (see Table 4.5 below). Media channels were the most common response, cited by 40% (n = 13). Twenty one percent of the participants (n = 7) listed medical sources, such as HCWs, as their preference. Two participants stated that anyone with credibility and knowledge would be preferred while one participant mentioned friends and neighbours as their preferred choice.

Reported preferred sources of information	N	%
Media channels	13	40%
Medical sources such as HCWs	7	21%
Anyone with credibility and knowledge	2	6%
Other sources, e.g. friends and neighbours	1	3%
Total number of participants who responded	23	70%

Table 4.5: Percentage of participants reporting ideal sources of information

4.3.6 Reported barriers to vaccination

As there is a degree of overlap between perceived safety and barriers to vaccination these are described simultaneously in the following section, as part of identifying perceived negative factors associated with vaccination (refer to Table 4.6 overleaf).

When asked to speculate on possible barriers to and difficulties with vaccination the most common response was lack of information, knowledge or education about vaccination reported by 70% (n = 23). A third of the sample, that is 36% (n = 12), believed that logistical difficulties such as cost and transport could account for people not getting vaccinated. A significant minority of overall participants, namely 27 % (n = 9), expressed concern about the physical or medical safety of vaccination as a barrier. Almost a fifth of all participants, that is 24% (n = 8), mentioned cultural or religious barriers, although when asked to expound on these only a few examples (n = 2) were forthcoming. One respondent had this to say about what may stop some people from getting either themselves or their children immunised:

“You see each person has a world view. Sometimes this is defined by culture. So someone may believe ‘vaccine no ways’. ‘Why should I have that in my body?’ You also have these totalistic people who believe that ‘God will provide for me’. ‘I don’t need a vaccine.’ You see people don’t understand that life is a bit of everything. You have a kind of totalistic viewpoint: ‘I don’t need that, God is my saviour. He will protect me.’ Those are the beliefs that people have.”

Of the entire sample 18% (n = 6) expressed fears that vaccines may directly cause illness. Several participants, i.e. 6% (n = 2), listed intrapersonal factors. Examples include claims that some just don’t care and laziness. One participant believed there to be no barriers to vaccination.

Reported barriers to vaccination	N	%
Lack of information (education) about vaccination	23	70%
Logistical difficulties (e.g. cost, transport etc.)	12	36%
Concerns about the physical or medical safety of vaccination	9	27%
Culture or religious barriers	8	24%
Fears that vaccines may directly cause illness	6	18%
Intrapersonal factors (such as laziness)	2	6%
No barriers to vaccination	1	3%
Total number of participants who responded	33	100%

Table 4.6: Percentage of respondents reporting barriers to vaccination

4.3.7 Perceived alternatives to vaccination

Regarding alternatives to vaccination the majority of participants, that is 73% (n = 24), stated that alternatives do exist; 18% (n = 6) felt that there were not any, and 9% (n = 3) were uncertain. Health alternatives were the most commonly cited by 67% of the participants (n = 22). These included adequate dietary, sanitary and exercise requirements. Only one participant explicitly mentioned cultural alternatives while no one mentioned religious alternatives, although both were stated as possible barriers to vaccination. Twenty four percent of the participants (n = 8) felt that alternatives were complementary to vaccination. Eighteen percent of the participants (n = 6) believed that alternatives were better. However, none of the participants stated that alternatives were necessarily worse or least preferred.

Reported alternatives to vaccination	N	%
Yes, alternatives exist	24	73%
Health alternatives (diet, sanitation, exercise)	22	67%
Cultural or traditional alternatives	1	3%
Religious alternatives	0	0%
No, alternatives do not exist	6	18%
Uncertain	3	9%
Total number of participants who responded	33	100%

Table 4.7: Percentage of respondents reporting alternatives to vaccination

4.3.8 Vaccination and human rights

In response to whether or not there should be a law forcing people to be vaccinated there was diversity of opinion among participants (refer to Table 4.8 on the following page). Less than half of all participants, i.e. 42% (n = 14), felt that vaccination should be enforceable by law. Of these 4 participants felt that the populations right to be protected from disease should take precedence over an individual's right to choose to vaccinate or not. Thirty six percent of participants (n = 12) believed that vaccination should be a choice, 7 of which further stated that individual human rights should be taken into account. A fair number of participants, namely 21% (n = 7), expressed uncertainty or ambivalence about whether or not there should be a law forcing people to get vaccinated. One participant voiced strong objections about this particular question, stating that it was a politically loaded question and unfair to ask in the first place. One participant had this to say:

“Because people are so diverse, some people say my culture does not allow this. My religion does not allow this. It should be a choice. But I believe people if they are told that these vaccines are helpful...I do believe you will go there willing. I don't believe there will be someone forcing you...”

Perceptions on human rights regarding vaccination	N	%
Vaccination should be enforceable by law	14	42%
Population's right to protection more important	4	12%
Vaccination should be optional	12	36%
Individual human rights more important	7	21%
Uncertain/ ambivalent	7	21%
Total number of participants who responded	33	100%

Table 4.8: Percentage of respondents reporting human right opinions regarding vaccination

4.3.9 Stated educational needs

The vast majority of participants, that is 88% (n = 29), felt that they wanted to know more about vaccination (as illustrated in the table below). Of these 18 participants mentioned that they would like more input on how vaccines work, 12 mentioned that they would like more information about vaccination in general and 6 said that they would like more information on what vaccines were actually available. A small minority, namely 12% (n = 4), stated that they had no educational needs regarding vaccination.

Educational needs	N	%
Yes, I would like to know more	29	88%
Would like more input on how vaccines work	18	55%
Would like more general vaccination information	12	36%
Would like to know what vaccines are available	6	18%
No educational needs	4	12%
Total number of participants who responded	33	100%

Table 4.9: Percentage of respondents reporting educational needs

4.4 Personal experiences and uses of vaccination

The results presented in this section pertain to objective 2; that is to assess students' experiences of vaccination in general. In the following section personal experiences and uses of vaccination will be presented together as they appeared related. Most participants in the study, i.e. 88% (n = 29), reported that they had been vaccinated (see Table 4.10 overleaf). Three of these could give a clear account by describing their personal experience of vaccination. One Xhosa student had this to say:

"Of course, I remember the experience. It was painful because they used a needle. And sometimes you used to get drops under the tongue, which was painful. And I remember at the clinic just cause they used to set one date for a certain age of babies. So, the whole community would come to that clinic and it just used to be packed. Children were crying and nurses were getting impatient. Sometimes it just used to be chaotic but you know you used to sit all day sometimes and wait for the queue, for your turn. Babies were crying and people pitched on the wrong day. And they would have to go back. Most of the people they came from the rural areas. So they travelled and it was a disadvantage and an inconvenience to them if they got the wrong date. But I was lucky, cause I was from around, in town."

Two reported that their experiences had been helpful. Eight participants claimed that their experiences had been negative and 12 reported they had experienced side effects such as: discomfort, sickness, and in one case temporary paralysis. Discomfort experienced as a result of vaccination included pain (especially from needles), swelling, fever and fatigue. In most cases participants who reported side-effects did not explicitly mention them as barriers but saw them as an integral part of vaccination. One mother put it like this:

"Um, I took my baby when she was six weeks. I took her to the clinic. She got two injections in her thigh and I was told that the baby is going to get sick. She's going to get feverish. I must try and keep her cool, don't worry about bringing her to the clinic cause there is nothing we can do about it."

Similarly, one participant said the following about pain from the needle:

"I think you sort of expect it. So sometimes it's not at all that painful but some people seem to think that different people who actually deliver the vaccine actually ... deliver it differently. So some may make it sore, some will do it in such a way that you don't feel much pain."

Another participant had this to say:

"...I remember this one time I was in the vaccination room and it was my turn to get vaccinated and I just ran out of the room. And the nurse chased me and she got me back and I got vaccinated. It was horrifying. I hated it. I just never liked it."

Of those who reported having been vaccinated before only 11 had also been vaccinated since childhood while 10 reported that they had not been vaccinated since childhood. A few participants, i.e. 6% (n = 2), stated that they had not been vaccinated at all. Six percent of participants (n = 2) also had no or insufficient knowledge about their own vaccination. Of the six mothers present in the study all (n = 6) stated that they had their children vaccinated as they felt it was obligatory. One mother had the following to say about vaccination:

“It’s a thing that’s done that when a child is young, like six weeks old. They get vaccinated for polio and such things. There isn’t any specific reason except that it’s something that has to be done.”

More than half of overall participants, i.e. 61% (n = 20), indicated that their friends and family vaccinate, and 18% (n = 6) stated that their friends and family don’t vaccinate. When asked why friends did not go for vaccination one participant said the following:

“No! They are all grown up now. They went when they were children. But their children, like my little nephews and nieces do ...you see I’m not sure what happens with a vaccine. I’m not sure whether it is long term or maybe just a couple of years that it works or what.”

Experiences and uses of vaccination	N	%
Have been vaccinated	29	88%
Clear knowledge of personal vaccination history	3	9%
Vaccination was personally helpful	2	6%
Vaccination had negative consequences	8	24%
Experienced side-effects (e.g. discomfort or sickness)	12	36%
Have been vaccinated since childhood	11	33%
Have not vaccinated since childhood	10	30%
Have not been vaccinated	2	6%
Unclear knowledge / no knowledge of own vaccination history	2	6%
Vaccinates children (answered by mothers in the study)	6	100%
Vaccinates children to protect and prevent disease transmission	4	66%
Vaccinates children for other reasons	2	34%
Total number of participants who responded	33	100%

Table 4.10: Percentage of participants mentioning specific experiences and uses of vaccination

4.5 Perceptions of HIV vaccines, and vaccine trials: perceived barriers and willingness to participate (WTP)

The following section presents results that pertain to objective 3, that is to assess knowledge and expectations toward HIV vaccination and participation in a hypothetical HIV vaccine trial.

4.5.1 Knowledge and expectations of potential HIV vaccines

Fifty two percent of overall participants (n = 17) stated that they had never heard of the possibility of an HIV vaccine while 36% (n = 12) said they heard of a possible HIV vaccine (see Table 4.11 on the next page). Of these 4 participants mentioned antiretroviral drugs such as AZT as an “existing HIV vaccine”. This may be partially attributed to the publicity given to antiretroviral drugs by AIDS activists, especially to reduce vertical transmission of HIV, in the media at the time when interviews were being conducted. One participant had this say in response to whether or not they had heard of a possible HIV vaccine:

“I’ve heard about it. But I’m really not sure whether it prevents getting infected or helps people who are already infected. But I’ve just heard about these vaccine trials all over the news. I don’t know whether it has started or whether it is going to start. They are going to take a sample of people to see if it works. So I’m not quite clear.”

Another had the following to say:

“HIV vaccine? No! Is the antiretroviral a vaccine? ... No, no! I’ve never heard of one.”

Yet another participant has this to say:

“Well I think, I don’t know if such a thing would actually occur. But if it actually did help it would probably work like the immune boosters do but not like eliminate the virus from the body. But I don’t know. Miracles have happened.”

Regardless of whether or not participants had heard of a prospective HIV vaccine or not participants were then asked whether they thought a hypothetical vaccine would be for prevention or treatment and whom would such a vaccine target. As illustrated in the table below there were varied reactions to the prospect of HIV vaccines. Forty five percent of participants (n = 15) believed that a possible HIV vaccine would be preventive in nature, and thirty nine percent of all participants (n = 13) believed that such a vaccine would be mainly for uninfected people. Although none of the participants (0%) stated that the vaccine would

be a treatment, a significant number of overall participants, i.e. 24% (n = 8), mentioned that it would be mainly for HIV positive people. Forty five percent of participants (n = 15) felt that it should be for everyone. Twelve percent of the participants (n = 4) were of the opinion that it was mainly for people at risk of contracting HIV.

Purpose of potential HIV vaccines	N	%
Never heard of possible HIV vaccine	17	52%
Have heard of possible HIV vaccine	12	36%
Prevention	15	45%
Mainly HIV negative people (uninfected people)	13	39%
Treatment	0	0%
Mainly HIV positive people (infected people)	8	24%
All people, everyone	15	45%
Mainly people at risk	4	12%
Total number of participants who responded	33	100%

Table 4.11: Percentage of respondents reporting perceived purposes and target of HIV vaccines

4.5.2 Stated willingness to participate (WTP) in potential HIV vaccine trials

In general, people expressed varied feelings about participation in a possible HIV vaccine trial (see Table 4.12 overleaf). Almost a third of overall participants, that is 33% (n = 11), reported that they would not be willing to participate in a preventive HIV vaccine trial. Thirty percent of all participants (n = 10) stated willingness to participate, all of whom stated that they would require more information about the vaccine trial. Of those willing to participate, 9 participants stated they would be willing to participate on condition that they were guaranteed that no risks would be incurred from their participation. One participant stated willingness to participate would be subject to family members being cared for in the event of a 'mishap'. Others stipulated the following conditions:

“If I would be assured that there wouldn't be permanent side effects I think I would give it a try as long as I don't die in the procedure or because of some of the complications. If it is shown to have no permanent side-effects.”

“It would have to be a fully controlled and monitored procedure, a procedure in which um, everything must be explicit to the person involved. It must be a completely genuine thing where you are made aware of the risks. So there must be complete exposure of what will happen because we are dealing with a persons life.”

“People are definitely going to want to know if they are going to die or not, the risks – what’s going to happen to you. They must be able to explain what is going to happen in your body – the process. They must be able to hypothesise...”

“Well it depends on whether I have it or not. If I don’t have it I might be afraid that they might inject me with the virus. If I do it might get my hopes up thinking it’s going to work and I might be too disappointed, in the event it doesn’t work.”

Another participant said that willingness to participate would be purely for financial benefit. Fifteen percent of the entire sample (n = 5) indicated that they were unsure whether they would participate or not.

Stated willingness to participate	N	%
Not willing to participate	11	33%
Willing to participate	10	30%
Require more information	10	30%
Need guarantee that no significant risks will be incurred	9	27%
Need assurance that family will be taken care of	1	3%
Require financial benefit	1	3%
Unsure	5	15%
Total number of participants who responded	32	97%

Table 4.12: Percentage of respondents reporting to willingness to participate

4.5.3 Personal and perceived incentives for trial participation

Personal incentives and perceived incentives for other prospective participants differed, thus they are described separately (see Table 4.13 on the next page). With regards to personal incentives altruism was the most popular response (39%) overall. As one participant put it:

“I think I would feel very happy because there is something that is happening – that is taking people I know. It’s not something like a myth anymore. Because in the past they said AIDS is a myth, it does not exist – depending where they come from. I would be honoured.”

Fifteen percent of the sample stated compensation - in the event that something should go wrong - as an incentive for their participation. In the words of one participant:

“A million bucks and a BMW and maybe a house. Seriously, what would I want? Uh, mostly what I can say is compensation for everything that could possibly happen...”

Other incentives included recognition, medical benefits (e.g. medical aid, access to treatment during the trial and access to free vaccine once available) and opportunity to reduce personal risk to HIV infection, respectively. Regarding recognition one participant had the following to say:

“What I would want! Something on my C.V. to say that I participated in such a thing. Yah, nothing much cause I don’t mind volunteering.”

Personal incentives	N	%
Altruism	13	39%
Compensation	5	15%
Recognition/ acknowledgement	4	12%
Medical benefits (e.g. access to treatment)	3	9%
Opportunity to reduce personal risk of infection	1	3%
Total number of participants who responded	25	76%

Table 4.13: Percentage of participants reporting perceived personal incentives

When asked to speculate on perceived incentives for others material benefit was stated as the most popular incentive while no mention of altruistic intentions was made (as illustrated by Table 4.14 on the following page). Opportunity to reduce risk of infection was the second most popular response. Examples included the perception that participants would be completely protected from HIV infection and that some might see the vaccine as a cure. One participant expressed the following hopes for a prospective HIV vaccine:

“... you get healed if you are infected. And if you were not infected you get something like a protective factor.”

The remaining participants reported recognition, medical benefits and counselling as incentives for others.

Perceived incentives	N	%
Compensation	5	15%
Opportunity to reduce risk of infection	4	12%
Recognition/ Acknowledgement	1	3%
Medical benefits (e.g. guarantee of medical care)	1	3%
Counselling	1	3%
Altruism	0	0%
Total number of participants who responded	12	36%

Table 4.14: Percentage of participants mentioning perceived incentives for others

4.5.4 Perceived barriers and concerns about trial participation

As there was a degree of overlap between concerns about potential HIV vaccines and perceived barriers to trial participation these are described together. The most common perceived barrier to trial participation cited by 61% of participants (n = 20) was significant physical risk (see Table 4.15). Examples include: fear of contracting HIV through the vaccine trial, other illness, side effects, as well as fear of the unknown. Two participants raised the following issues:

“Like I was saying it has never been tried on anyone else and being the first one it is quite scary, cause they don’t know what will happen. What is it going to do to you?”

‘...there may be something negative that happens to me after that vaccine trial. Maybe I’ll get some illness and I don’t even know what that would be. And being sure that I’ll be treated and maybe know who to contact should something happen to me...’

Concern about psychosocial risk was the second most popular response. Commonly cited examples included fear of stigmatisation and increased sexual behaviour as a result of a vaccine trial. In this regard here are various quotations from participants:

“ When people hear about vaccines it may have an impact on their behaviour. A person will just do as they wish with their body and sleep around, knowing that there are vaccines coming.”

“I think people would become irresponsible because there is still other things that it could lead to. For example, pregnancy, it’s not just HIV. So you could get a whole lot of unwanted pregnancies.”

“... at the moment people are afraid to stand up and say that they are HIV positive. And if they go out telling others they are going for these vaccines, what if they do not help? I think that is where most of the fear will come from. Because people are shy – not so much that they are shy, they always worry about other people – what are they going to say ...”

“One fear could be stigmatisation. Some people have weird beliefs. Some believe that now that they have got the “AIDS vaccine” they have got the AIDS virus or something...”

Another perceived barrier was concern about affordability of the vaccine. Two different participants had the following to say about a possible vaccine:

“Expensive, it would be expensive...”

“...It might work to the advantage of rich people ... and the poor people might not have access to it...”

Questionable efficacy of the vaccine was another perceived barrier to trial participation, as a third of participants, that is 30% (n = 10), feared that the vaccine might not work. In the words of one participant:

“Oh, will it work? Because there has been so much hype about there not being a cure for AIDS... It could be hard ...to be convinced that it might just work.”

Twenty four percent of participants (n = 8) were concerned that participants may become dependent on the vaccine. Twenty percent of the participants (n = 7) expressed other concerns. These included the possible danger of reused needles due to poor administration and shortage of services in rural areas. Others even claimed that HCWs deliberately injected people with HIV. As one participant said:

“Even doctors now a days go around injecting people with the virus. So people don't trust anybody who comes close to them with needles. So that is the major problem. Most people would not consent to such a thing because they are thinking that there is catch.”

Some articulated that the vaccine may be perceived as a political ploy derived from a white ideology. In the words of one participant:

“We have a very bad political situation in this continent and this country specifically. I think political history itself will drive away a lot of people from that vaccine in the same way as news about AIDS, you know turned a lot of people deaf really when it was first being announced on radios and so on, because people always thought it’s these white people again they want to control our reproduction. And now it’s worse because they’ve also heard about the vaccine that could be said to have caused the disease. So people would approach it with serious caution. I don’t think that they would really outright refuse to immunisation. But I think it will be a very slow process.”

Perceived barriers and concerns about trial participation	N	%
Significant physical risk (e.g. fear of contracting HIV)	20	61%
Psychosocial risk (e.g. stigmatisation)	16	48%
Affordability	13	39%
Questionable efficacy of vaccine (e.g. vaccine might not work)	10	30%
Concern about dependence on vaccine	8	24%
Others (e.g. possible danger of reused needles)	7	21%
Total	33	100%

Table 4.15: Percentage of participants reporting perceived barriers to WTP, and concerns

4.6 Demographic associations with knowledge and experiences of vaccination

The results based on research objective 4, which is to explore if particular knowledge and experiences are associated with demographics such as motherhood and gender, are presented below.

Knowledge of vaccination (purpose, mechanism, and vaccine target) was not associated with gender or with motherhood. Regarding knowledge of vaccine-preventable diseases mothers were significantly less likely than non-mothers ($p = .045$) to be aware that HIV is a disease for which there is currently no available vaccine (Chi-square value: 4.018, $N = 18$, $df = 1$). No significant differences were found between experiences of vaccination (uptake of vaccination and side effects experienced) and gender or motherhood.

With regards to knowledge and expectations of HIV vaccine trials, several associations were found with gender and motherhood. The results revealed an association between familiarity with a possible HIV vaccine and motherhood but not with gender. That is, significantly more

mothers than non-mothers ($p = .034$) said they had heard of a possible HIV vaccine (Chi-square: 4.5, $N = 18$, $df = 1$). Regarding WTP in potential HIV vaccine trials, results further revealed an association with motherhood. More specifically, significantly less mothers than non-mothers ($p = .034$) expressed willingness to participate in HIV vaccine trials. In fact none of the mothers (0%) said they were willing to participate in HIV vaccine trials (Chi-square: 4.5, $N = 18$, $df = 1$). A significant association was also found between personal incentives for trial participation and motherhood, with significantly less mothers than non-mothers ($p = .017$) who stated altruism as an incentive for trial participation (Chi-square: 5.527, $N = 18$, $df = 1$). Finally, an association between perceived barriers to participation in HIV vaccine trials and gender was found. Specifically, females were significantly less likely than males ($p = .022$) to be concerned about the psychosocial risks, such as increased reckless sexual activity and stigmatisation (Chi-square: 5.241, $N = 33$, $df = 1$).

4.7 Summary of results

The vast majority of participants (97%) cited that the purpose of vaccination was to promote health or prevent illness, and 64% also said vaccines were medically helpful. The majority of the participants (67%) had an understanding of vaccination mechanism, stating that vaccines mobilise the immune system. The vast majority of participants (91%) were able to state common vaccine-preventable diseases, with 63% of these able to mention more than one. However, 57% also incorrectly mentioned other diseases that are not in fact vaccine preventable. A significant majority (over 70%) were unsure, had never heard what HCWs say, or said HCWs don't explain, about vaccination. The most preferred source of information was the media (40%) followed by health-care workers (21%). Perceived barrier to vaccination most commonly stated (70%) was lack of information, knowledge or education followed by concern about the safety of vaccination. Seventy three percent of the sample perceived alternatives to vaccination, mainly health alternatives (67%). A significant majority of participants (88%) had been vaccinated as children. Thirty six percent of the participants reported side effects. However, only 9% had clear knowledge of their personal vaccination history. Thirty three percent of the participants reported that they had been vaccinated as adults. All of the mothers in the study ($n = 6$) reported that they had vaccinated their children for various reasons.

Most participants (70%) correctly stated that HIV was a dangerous disease for which there is currently no vaccine available. A majority of participants (52%) also reported that they had

never heard of possible HIV vaccines and 45% of the participants speculated that a prospective HIV vaccine would be preventive in nature. Thirty percent of the participants stated willingness to participate in hypothetical trials while 33% said they were not willing to participate. In terms of personal incentives for WTP, 39% reported altruism however no person described this as an incentive for others. Perceived barriers to WTP most commonly reported (61%) were significant physical risks followed by psychosocial risks of trial participation (48%), especially regarding fear of stigmatisation and increased sexual disinhibitions.

Knowledge, perceptions of vaccination in general and experiences, were generally not associated with demographics of gender and motherhood. However, mothers were significantly less likely than non-mothers ($p = .045$) to be aware that HIV has no vaccine. Mothers were significantly more likely to say that they had heard of a possible HIV vaccine than non-mothers ($p = .034$). Mothers were significantly less likely than non-mothers to express WTP ($p = .034$). Mothers were significantly less likely than non-mothers to identify altruism as a personal incentive for trial participation ($p = .017$). Significantly more males than females were concerned with psychosocial risks ($p = .022$) of HIV vaccine trials.

Chapter 5:

DISCUSSION

5.1 Introduction

As part of the national preparation for HIV safety trials in South Africa, the key objectives of the study were: i) to assess students' understandings of vaccination: knowledge and perceptions of vaccination in general, including perceived barriers, ii) to assess students' experiences of vaccination, generally, iii) to assess students' knowledge and expectations of HIV vaccination and participation in a hypothetical vaccine trial, iv) to explore if particular knowledge and experiences were associated with demographics such as motherhood and gender. The chapter begins with a summary of the main results followed by a discussion of the results in terms of the four key objectives of the study. Finally, limitations of the study and implications for future research and preventive HIV vaccine trials are discussed.

5.2 Central findings

The following section presents a sequential discussion of the results grouped according to the four primary objectives. Other findings related to vaccination in general have also been integrated. Discussion of each objective comprises of comparisons of results with previous empirical studies, including ones not discussed in the literature review.

5.2.1 Understandings of vaccination: Knowledge, perceptions and barriers to vaccination

Knowledge of purpose and mechanism of vaccination

Results in the present study revealed a sound general knowledge of vaccination purpose. The vast majority (97%) knew the general purpose of vaccination, stating that it is to promote health or prevent illness. Similar results were reported in China with 98.4% of participants (Zhang, et al., 1999), Ethiopia with 91.7% of participants (Gedlu & Tesemma, 1997) and Cape Town with 92% of participants (Van Staden et al., 1995) all stating that vaccines are for prevention. In general, empirical studies indicate that the understanding of the preventive notion of vaccination is common in different parts of the world (Kiwanuku et al., 2000; McCormick, Bartholomew, Lewis, Brown & Hanson, 1997; McGrath, Mafigiri et al., 2001; Tarrant & Gregory, 2001). In first world countries such as the US (McCormick et al., 1997), Canada (Tarrant & Gregory, 2001) and European countries (Angelillo et al., 1999), the

understanding of vaccination as preventive is common. In the developing world empirical studies conducted in many different countries (Gedlu & Tesemma, 1997; Kiwanuku et al., 2000; McGrath, George, et al., 2001; McGrath, Mafigiri, et al., 2001; Van Staden et al., 1995) indicate that understanding of the preventive notion of vaccination is also widespread although counter claims have been made in some countries.

Specifically, in a study conducted in Nigeria, which sampled 200 mothers, the majority of participants (56%) did not believe that vaccination is preventive, with those of lower socio-economic status and education favouring more supernatural explanations (Odebiyi & Ekong, 1982). Of these the majority believed that vaccination is not preventive because they claimed that some of their children who had been immunised still contracted measles in later years. In contrast, in the current study a small minority of participants (18%) attributed this (children subsequently contracting diseases for which they were vaccinated against) to the fact that while vaccines protect against disease they are not 100% effective (or 'fool proof'). This is consistent with the fact that no vaccine is 100% effective as the efficacy of most vaccines ranges from 85% - 90% (Pless, n.d.). Results from this study are supported by other study's findings, which revealed a common understanding of the purpose of vaccination.

When they were prompted about educational needs, many participants (55%) in the present study stated that they would like more input on how vaccines work. However, the majority (85%) offered plausible explanations as to how vaccines work when they were asked directly about vaccine mechanisms. A popular form of explanation applied by participants used metaphors of strength and power to explicate the action of anti-bodies in prevention. One participant had the following to say about vaccine mechanism: "...So I think it just helps the anti-bodies, to give them more fighting power against the bacteria of the disease." This can be likened with the use of military language to describe disease (including AIDS), which is familiar (Sontag, 1989 in McGrath, Mafigiri, et al., 2001). McGrath, Mafigiri, et al. (2001) found that antibodies were described as soldiers whose job it is to defend the body by putting out an alert to attack a specific enemy. Yet another view expressed by Odebiyi and Ekong (1982) posited that in Nigeria and in most developing countries the germ theory as a cause of disease had not yet been widely accepted. However, the findings of the current study and other more recent studies (Eng et al., 1991; Razum, 1993) do not provide support for this claim.

Results in the current study revealed that the majority (67%) knew that the vaccination mechanism was to mobilise the immune system. This would seem to be contrary to other studies, which suggested limited knowledge of how vaccines work (Angelillo et al., 1999; Tarrant & Gregory, 2001, White & Thomson, 1995 in Tarrant & Gregory, 2001). In a study conducted by Tarrant and Gregory (2001) on mothers' perceptions of childhood immunisation, results not only revealed the latter (i.e. limited knowledge of how vaccines work) but with mothers who also readily admitted that they had limited knowledge of how vaccines work. The majority of participants (67%) in this study described how vaccines work by making reference to terms like immune system and anti-bodies, at times explicitly referring to terms such as T-cells and memory cells. For example, one Science student explained it in the following way:

"How they basically work is in the body you've got the immune system and it has memory B-cells and T-cells. The memory B-cells are those that, they get produced and they've got a specific shape ... the T-cells are there and they can change shape. They are the ones that fight the infection... So once they vaccinate you... the body produces those memory B-cells which recognise the structure of that virus, so that next time the real virus comes already the B-cells will be there to attack."

On the whole participants demonstrated a fair understanding of vaccine mechanism in general and the use of medical terms would seem to suggest a slightly more sophisticated understanding however this needs to be further investigated, as mere mention of terms does not necessarily imply understanding. A plausible explanation for this finding is the level of education as participants in the sample were fairly well educated. Several studies (Angelillo et al., 1999; Greenough, 1995; Zhang et al., 1999) have found that education was positively related to knowledge about vaccination and EPI knowledge. Furthermore, being in an institution of higher learning, the students in the current study may have access to information, e.g. Science students admitted that they received lectures on vaccination as part of their course work.

Knowledge of diseases that are vaccine preventable

The World Health Organisation (WHO) has embarked on the control of six diseases: tuberculosis, diphtheria, pertussis, tetanus, polio and measles, initiating EPI for immunisation of all children of the world and promising health for all (Schoub, 1989). The vast majority of participants (91%) in the current study were able to mention at least one common vaccine-preventable disease. Similar findings were reported locally in a study conducted in Cape

Town. In the latter study 77% of the participants mentioned measles, 43% mentioned TB and a few knew about tetanus (Van Staden et al., 1995) as vaccine-preventable diseases. Similar results were also reported in two separate studies in Zimbabwe, one of which was conducted in a rural community and the other in an urban community, respectively (Razum, 1993; Woelk et al., 1986 in Van Staden et al., 1995) as well as in Ethiopia (Gedlu & Tesemma, 1997). As in other studies, in the current study, measles was the most commonly mentioned vaccine preventable disease (Gedlu & Tesemma, 1997; Razum, 1993; Tarrant & Gregory, 2001; Van Staden et al., 1995).

In the present study many participants (57%) also incorrectly mentioned other diseases that are not in fact vaccine preventable. Specifically, malaria and chicken pox were the most incorrectly mentioned, as in other studies in Canada and South Africa, respectively (Tarrant & Gregory, 2001; Van Staden et al., 1995).

Thus, it would appear that in both developing and developed countries there is a tendency to correctly mention one or two vaccine preventable diseases, with the exception of an Italian study in which participants were able to mention four mandatory vaccines (Angelillo et al., 1999). This is often accompanied by a tendency to incorrectly mention diseases that are not preventable by vaccines. In developed countries in Europe (Angelillo et al., 1999) and North America (Tarrant & Gregory, 2001), knowledge of vaccine preventable diseases has been associated with education and age of the mother. However these variables were not explored in the current study. The results in the present study would seem to suggest that education on vaccine- preventable diseases is needed. It is important for recipients of vaccination services to know which diseases are vaccine-preventable so that people feel a sense of ownership of the vaccination process and are not threatened or feeling that vaccination is something they are coerced into (Van Staden, et al., 1995).

Knowledge of HCWs views on vaccination

Perceptions of HCWs have varied across different studies. In the current study perceptions of HCWs and their views on vaccination were predominately negative and indifferent. That is, 70 % of participants stated that they were unsure what HCWs say, had never heard what HCWs say or that they don't explain about vaccination. Similar accusations have been levelled against HCWs in different parts of the world including Ethiopia (Gedlu & Tesemma, 1997), Italy (Angelillo et al., 1999) and US (McCormick et al., 2001) both directly and

indirectly. Although most participants (58%) in the current study relied on the medical system, e.g. clinics and hospitals, as their primary source of information, perceived support by the system was low.

Results reported for a pertussis vaccination study conducted by Angelillo et al. (1999) revealed that 44.2% of participants reported no advice from HCWs. However, Zhang et al. (1999) reported that participants had confidence in their health care providers and 92.7% claimed they had received information from the same source. Low uptake of adult immunisation (36%) in the current study may be partially attributed to a lack of continuous education by HCWs, but this needs further investigation. Nonetheless the results suggest that perceptions of HCWs are negative or indifferent.

Perceptions of vaccine target populations

While numerous studies have indicated that participants across different contexts are familiar with the general purpose of vaccination (prevention) there is also evidence to suggest that some participants do not clearly distinguish between prevention and cure (McGrath, George, et al., 2001; McGrath, Mafigiri, et al., 2001). In the present study a very small minority (9%) did not clearly distinguish between prevention and cure when asked about the general purpose of vaccination. Parallel results were reported by Gedlu & Tesemma (1997) in which a small minority (3.4%) also stated that vaccines cure disease. When participants in this study were specifically asked whether a vaccine was for healthy (uninfected) or sick (infected) people, 82 % responded that it would be for healthy people and a minority (42%) replied that it was for sick people. After being prompted with a series of statements, McGrath, Mafigiri, et al. (2001) reported that 81% said that vaccines prevent disease and a majority (65%) also felt that vaccines cure a person. The results in the current study suggest that the understanding of the preventive notion of vaccination prevails, but that a minority may be confused about the role of vaccination in curing. It is also possible that participants may have been alluding to knowledge of the action of a therapeutic vaccine, which needs to be explored in future research. In addition, interviewer questions may have also contributed to participants' responses.

Actual and preferred sources of information about vaccination

As in other studies (Angelillo et al., 1999; McCormick et al., 1997) the present study found that clinics, hospitals and schools (i.e. HCWs, posters and pamphlets therein) were the most

commonly reported source of vaccination related information (58%). Other sources of information reported by participants in the current study included the media (21%) and friends or neighbours (15%). In other studies, mass media, pamphlets (Angelillo et al., 1999) family members involved with medical profession and other relatives (McCormick et al., 1997) were also reported as sources of information about vaccination. In the present study media channels were the most preferred source of information (40%), followed by medical sources (such as HCWs – 21%) despite their bad review, indicating that participants still value interpersonal contact with medical personnel in being educated about vaccination. Forty three percent of participants collectively listed various interpersonal mediums for education about vaccination, namely HCWs, anyone with credibility and knowledge, and friends or neighbours. Overall the findings regarding sources of information would seem to suggest a combination of media channels and interpersonal input would be preferred. This notion is supported by other empirical studies that have focused on the impact of communication and education campaigns in changing both knowledge and coverage of vaccination (McDivitt, Zimicki & Hornik, 1997; Silva & Sorrell, 1984). As in Angelillo et al. (1999), the vast majority of current participants (88%) wanted to learn more about various aspects of vaccination. In both studies the knowledge of the general purpose of vaccination was good while knowledge of vaccine-preventable diseases was inconsistent. This suggests that more specific knowledge including knowledge of vaccine-preventable diseases is required. Research suggests that for people to effect appropriate health behaviour both general and specific knowledge is required (McDivitt et al., 1997).

Reported barriers to vaccination

Participants reported that lack of information, knowledge or education was the most common (70%) perceived barrier to vaccination, again reinforcing the need for continuous education. Several studies conducted in Africa (Gedlu & Tesemma, 1997) in Europe (Angelillo et al., 1999) and North America (Tarrant & Gregory, 2001) have demonstrated the importance of knowledge or information (such as knowledge of vaccine preventable diseases, vaccine mechanism, vaccine efficacy, general level of education, and awareness of the need for repeated vaccination visits) on vaccination compliance. Other barriers mentioned in the study included concern about the physical or medical safety of vaccines, cultural or religious barriers, fears that vaccination may cause illness and logistical difficulties which were consistent with previous empirical findings (Durrheim & Ogunbanjo, 2000; Gedlu & Tesemma, 1997; McCormick et al., 1997; Pruitt et al., 1995).

Perceived alternatives to vaccination

Results in the current study indicated that most participants, that is 73% (n = 24), believed that alternatives to vaccination do exist. Eight of these participants felt that alternatives were complementary while six felt that alternatives were better. The most commonly cited alternative (67%) to vaccination in the current study was health alternatives such as diet, sanitation and exercise, which was not found in empirical studies reviewed by the researcher. In the current study only 3% of the respondents made reference to cultural or religious alternatives, although 24% did mention culture or religion as a perceived barrier to vaccination. This was despite the fact that participants came from diverse language/ culture/ religious backgrounds. Lindegger and Wood (1995) purport that traditional healers in South Africa provide a much respected source of health related information outside of the western medical paradigm and command a great deal of support both in urban and rural black communities. Despite the fact that participants came from diverse religious backgrounds including those that might consult traditional healers, none of the participants mentioned religion as either an alternative or complement to vaccination.

In a study conducted in Zimbabwe (Razum, 1993) it was found that while health personnel thought traditional and religious beliefs were to blame for low immunisation coverage, results could be explained by poor quality of EPI services. In addition, within these traditional and religious groups attitudes of members of such groups was changing, possibly due to social pressure from other mothers who complained that unimmunised children put their children who were vaccinated at risk (ibid). A significant minority (36%) in the current study felt alternatives were complementary. Similarly, in a study with Togolese mothers, the notion of protection through vaccination was reportedly in keeping with traditional practices of ancestors - preparing infusions with herbs and leaves or using fetishes to protect a child from disease (Eng et al., 1991). Eng et al. (1991) deduced that immunisations appear to be accepted as a present day supplement to, and not as a replacement for, traditional disease prevention practices. Furthermore, Odebiyi and Ekong (1982) found the combination of the measles vaccine with the traditional therapy of keeping *tagiri* in the house was acceptable.

In summary, it is important to investigate alternatives to vaccination in order to disseminate knowledge of vaccination in a culturally sensitive manner and explore possible barriers. Results in the current study suggest more western medical alternatives such as health practices are more prevalent, possibly due to a well-educated sample such as in the current

study. As in other studies (Eng et al., 1991; Odebiyi & Ekong, 1982; Razum, 1993) the results of the current study also suggest that alternatives are perceived to be complementary to vaccination.

5.2.2 Experiences of vaccination

Various aspects of vaccination experience have been explored in empirical studies of vaccination uptake, compliance and vaccination history. In the current study responses to personal experience of vaccination were disappointing with most participants unable to clearly articulate their personal experiences. As only a minority (36%) had been vaccinated as adults in the current study it is not surprising that many could not give an adequate account of their own vaccination history. Findings in the present study suggest that uptake of childhood immunisation was high (88%). Other local studies revealed 80 –98% immunisation coverage in Hlabisa health district, kwa -Zulu Natal (Wilkinson et al., 1997) and 71.1% immunisation uptake in Mpumalanga province (Durrheim & Ogunbanjo, 2000). In a study conducted in China, immunisation coverage ranged from 89.3% in high service areas to 63.8% in low service areas (Zhang et al., 1999). In developed countries where there is a longer history of immunisation childhood immunisation has also tended to be high. In an Italian study for example (Angelillo et al., 1999), vaccination uptake for diphtheria, oral poliovirus and hepatitis B was high (94.4%)

In this study uptake of adult immunisation was reportedly low (33%). This may also be partially attributed to the fact that participants had inconsistent knowledge of vaccine-preventable diseases. In addition, when specifically asked about vaccination target none of the participants mentioned that they were for adults too with 36% specifically stating that it was mainly for children. Failure to obtain immunisation among various adult groups including healthy persons (Chapman & Coups, 1999), high- risk professional groups (Bodenheimer, Fulton & Kramer, 1986; Mckenzie, 1992; Zimet et al., 1997) patients (Fiebach & Viscoli, 1991) and elderly people (Zimet et al., 1997) has been reported in literature and reasons for this differ. The most common include perceived effectiveness of the vaccine and perceived likelihood of vaccine side- effects.

In the current study a minority (24%) reported that vaccination had negative consequences. Although 36% reported side-effects such as discomfort or sickness participants also

recognised that it was an integral part of vaccination and did not explicitly present this as a significant deterrent. Tarrant & Gregory (2001) described how participants reported that their children had experienced vaccine side-effects such as fever, irritability, pain, swelling and redness at the injection site. As in the current study most mothers were prepared for these side-effects, which did not prevent them from having their children immunised (Tarrant & Gregory, 2001). Similarly, Angelillo et al. (1995) reported that about half of the participants (45%) correctly believed that the undesirable side-effects of vaccination are an important determinant of their value.

5.2.3 Knowledge and expectations of HIV vaccination and participation in a hypothetical vaccine trial

Knowledge and expectations of potential vaccines

Assessing community knowledge about vaccines in general and clinical trials specifically is an important aspect of the preparatory phase of vaccine trials. This is important in order to meet the educational needs of potential South African participants both at a community and individual level and in ensuring adequate information campaigns and informed consent procedures. In the current study the majority of participants (70%) correctly reported that HIV was a dangerous disease for which there is no vaccine while a small minority, that is 12% (n = 4), were under the misconception that there was an already existing HIV vaccine, in the form of antiretroviral drugs. Conversely, in a study conducted in Uganda, which assessed community knowledge and attitudes to HIV vaccination in 56 communities (10 848 participants) in preparation for HIV vaccine trials, 67% of participants incorrectly believed that HIV vaccines were already available (Kiwanuka et al., 2000). Paradoxically, results in the current study indicated that participants did not have extensive knowledge of the pending HIV preventive vaccine trials and efforts to develop a safe and effective vaccine locally. Specifically, about half of the participants (52%) had never heard of possible HIV vaccine. A minority of participants in the present study (36%) had heard of a possible HIV vaccine. Similarly, Kiwanuka et al. (2000) reported that 41% of participants knew that HIV vaccines were being tested. This points to the need to increase efforts to inform the lay public about upcoming HIV vaccine trials. In contrast, in a study conducted in Thailand to determine the WTP in a HIV vaccine trial including, female commercial sex workers (n = 215), men attending sexually transmitted disease clinics (n = 219), conscripts in the Royal Thai Army (n

= 1453) and men discharged from the army (n = 293) who had returned to civilian life, revealed a common awareness of AIDS vaccine development efforts (62% – 77%) (Celentano et al., 1995).

In the current study general awareness of efforts to develop HIV vaccination was fairly low (36%), with as many as 45% of the participants who speculated that it would be for prevention and 39% of participants believed it would be for mainly HIV negative people (uninfected people). None of the participants (n = 0) explicitly stated that it would be for treatment although a small minority (24%) believed it would be mainly for HIV positive people (already infected people). This is in keeping with a key assumption of the current study, which is HIV vaccination would be seen as extensions of other familiar vaccination or health protective practices (Slack et al., 2000) that could be surveyed. This may be considered good news for researchers involved in the pending HIV trials, which are preventive in nature. In contrast, McGrath, Mafigiri, et al. (2001) reported that when participants were asked an open-ended question regarding who should participate in a vaccine trial, 35% of participants stated that infected persons should participate. In the latter study, when specifically asked if a vaccine was for infected or uninfected persons a significant minority (38%) said it was for infected persons, the primary reason being that infected persons could benefit from a vaccine (ibid). Moreover, the results in the current study suggest that more vigorous community awareness needs to be created and the specific nature of preventive vaccines reinforced.

Stated WTP in potential HIV vaccine trials

Assessments of willingness to participate (WTP) in different communities could provide researchers with an indication of level of recruitment required, and informational requirements needed for adequate education campaigns and informed consent procedures. Although the results in the present study are not generalisable to all persons likely to be recruited, or the wider South African population (see section 5.4) and the assessment of WTP did not include all necessary elements, the results still have implications for future research into WTP in South Africa. The 'stated' WTP in this study may provide preliminary data from which more formal WTP can be assessed.

In the present study WTP was measured as a dichotomous outcome (willing or not willing). In this respect 30 % of participants stated they were willing, 33% of participants were not and

15% were unsure. These findings compare with other studies, where assessment of WTP did not include an informational or educational component on HIV vaccines and trials. For example, locally in the Western Cape where 20% stated WTP (Moodley, Barnes, van Rensburg & Myer, 2002), in Northern Thailand where 25% of participants stated WTP (Celentano et al., 1998 in MacQueen, 1999), and New York America where 27% of participants stated WTP (Koblin et al., 1998 in MacQueen, 1999). Other empirical studies that collected data from diverse as well as homogenous groups in Northern and Southern Thailand and different parts of America indicated that those definitely WTP ranged between 20% and 50% at baseline. Results less than 20% may suggest poorly defined motivations, incentives or benefits for participation in the community (Koblin et al., 1997; MacQueen, 1999). Those not at all willing to participate ranged from 3% to 9% of people surveyed. Results greater than 10% may indicate significant underlying barriers that need to be identified and addressed prior to attempting an efficacy trial (ibid). More recently, in Uganda where the first African trial of a candidate vaccine was conducted, much higher levels of WTP (69% - 79%) were recorded and those not willing to participate ranged from 13% to 22% while those not sure ranged from 4% to 14% (McGrath, George, et al., 2001; McGrath, Mafigiri, et al., 2001). The high level of WTP in the latter studies is particularly interesting considering the history of clinical research conducted in Africa in general (as discussed in section 2.7.2) and more specifically the initial ethical concerns raised by the Uganda network on law, ethics and HIV regarding the informed consent process, possible coercion of volunteers, reimbursement and volunteer' confidentiality (Mugerwa et al., 2002). Participants in the current study fell within the range 20% to 50%, as 30% of participants stated willingness to participate even though their level of awareness of the pending HIV vaccine trials was fairly low (36%). On the one hand this may be good news for researchers in the field as this suggests that local results on WTP may be consistent with those in other communities surveyed for HIV vaccine trials. On the other hand it raises ethical questions regarding informed consent if people are 'willing' to participate despite being ill informed. Either way the results of the current study are not generalisable but point to avenues for future research.

Paradoxically, it was anticipated that WTP would be higher in the current study because information about HIV vaccines was not given and most participants had never heard of possible HIV vaccine before being interviewed. This assumption was based on the fact that empirical studies have shown that with additional information (and time) WTP decreases -

but stabilises about a year after first introducing the idea of vaccine trials (Bartholomew et al., 1997; Jenkins et al., 1995; Koblin et al., 2000, Moodley et al., 2002). Thus, seeing as most participants were hearing about possible HIV vaccines for the first time, the researcher expected that WTP would border on the upper limit of the range 20% -50 %. A possible explanation could be that other intervening variables, which were not measured in the current study, contributed to the results. That is, the decision whether to participate or not is a complex function of a number of factors in a person's life, including among other things perceived risk of HIV infection due to behavioural and environmental factors, comprehension of how the trial works, peer influence, and trust in those implementing and supporting the trial (MacQueen, 1999), which were not explored in the current study.

WTP was not adequately explored but rather general issues (perceived barriers and incentives) were raised with the intent of providing more specific questions to be explored with a more generalisable sample in future research. These general issues included most importantly perceived incentives, barriers and concerns about trial participation.

Perceived incentives for trial participation

As in research conducted by Jenkins et al. (1995) the current study differentiated between personal incentives and perceived incentives for others. Although most of the incentives between the two categories were consistent, their prioritising differed. Most markedly, altruism was the most commonly stated personal motive while none of the participants mentioned altruism as a perceived incentive for others. The possibility of social desirability by the participants cannot be out-ruled. That is, participants may have stated what they perceived would be a socially desirable motive to the researcher, in order to please the researcher with their personal 'unselfish' motives. Jenkins et al. (1995) found that perceived benefits to self were associated with WTP, while altruism items were not related to WTP.

As with US, Thailand and African settings, altruism and opportunity to reduce personal risk for HIV infection were popularly cited incentives for participation in vaccine trials in the current study (Koblin, et al., 1998; MacQueen, 1999). McGrath et al. (1997) reported a 'desire for cure' if respondents became infected as the second most common reason for WTP in their vaccine study. The other incentives in the present study were also common to other empirical studies such as recognition or acknowledgement, compensation and medical

benefits - e.g. guarantee of medical care or counselling (Celentano et al., 1995; Koblin et al., 1998).

Perceived barriers and concerns about trial participation

The concerns and barriers associated with possible vaccine trial participation also parallel those found locally (Moodley et al., 2000) and elsewhere (Celentano et al., 1995; Jenkins et al., 1995; Koblin et al., 1998). The most common included significant physical risk (Celentano et al., 1995; Jenkins et al., 1995; Koblin et al., 1998), psychosocial risk such as social discrimination or stigmatisation (Jenkins et al., 1995; Koblin et al., 1998) and questionable efficacy of vaccination (Koblin et al., 1997). Unlike other empirical studies reviewed by the researcher, a significant minority of participants (39%) felt that affordability may be another possible barrier. In the words of one participant: *"I'm aware it has to do with class. Some people will afford it and others won't. But maybe as time goes on everyone should get access..."* This is a poignant point considering the economic imbalance that apartheid has caused on health issues in South Africa. Both the incentives and barriers to participation need to be addressed in order to enhance the level of WTP but also to ensure adequate informed consent.

5.2.4 Demographic variables associated with knowledge and experiences of vaccination

Results in the present study revealed that knowledge of vaccination (purpose, mechanism, and vaccine target) was not associated with gender or with motherhood. In addition, no significant differences were found between experiences of vaccination (uptake of vaccination and side effects experienced) and gender, and between experiences and motherhood. In general, knowledge has been shown to differ along the following demographic variables: age (Angelillo et al., 1999; Van Staden et al., 1995); education (Angelillo et al., 1999; Zhang et al., 1999); socio-economic status (Odebiyi & Ekong, 1982; Zhang et al., 1999); access to health insurance; and exposure to information sources (Zhang et al., 1999). Thus, it could be argued that the present results are not necessarily startling, as gender has not been clearly demonstrated to impact on knowledge of vaccination while motherhood per se has not been widely investigated. One can possibly deduce that while knowledge has been shown to differ along demographic lines, this trend is not necessarily universal but context specific. This may

also indicate that in a 'well' educated sample such as this, there might be more homogeneity with regard to certain aspects of knowledge and experiences with vaccination, but not all.

Specifically, results in the current study indicated that regarding knowledge of vaccine – preventable diseases, mothers were less likely than non-mothers ($p = .045$) to be aware that HIV has no vaccine. This may suggest that mothers were more likely to hope for an existing HIV vaccine. Perhaps this can be partially attributed to the fact that traditionally mothers have been caregivers and therefore have a vested interest in the health of their offspring. This is particularly interesting considering that mothers were more likely than non-mothers ($p = .034$) to say that they had heard of a possible HIV vaccine.

Significantly less mothers than non-mothers ($p = .034$) expressed WTP in HIV vaccine trials. In the words of one mother: “... *It's never been tried on anyone I know of and I don't know how it works. I don't want to be the first...*”. One possible explanation could be that with the uncertainty of risks involved most mothers would be unwilling as it might impact on their 'mothering' (if they got sick for example). Significantly less mothers than non-mothers ($p = .017$) were likely to report personal feelings of altruism. A possible explanation is that humanitarian feelings to future generation may be precluded by need to focus on their children and the status quo. This is consistent with the fact that most mothers were not WTP. This also suggests that most mothers were less likely to be influenced by social desirability regarding their participation.

Significantly less females than males ($p = .022$) were concerned about psychosocial risks, such as increased reckless sexual activity and stigmatisation. This suggests that females were less likely to perceive themselves to be at psychosocial risk, which needs to be explored in future research.

5.3 Limitations of the study

The results of the current study sampling 33 participants non-randomly cannot be generalised to the general population of persons likely to be enrolled in trials, or the South African population in general. However, the results may be extrapolated to one subset of the population being targeted for trials. University students from the University of the

Witwatersrand have been recruited for HIV vaccine trials in South Africa (C. Slack, personal communication, October 16, 2003).

The general aims of the study were exploratory in nature, and set out to explore knowledge, perceptions and experiences of vaccination. In so doing more precise questions for future research and education could be identified. The aim of the current study was therefore not to produce generalisable findings. However, in the future the findings of this study may be compared to similar studies currently being carried out in different South African communities (da Silva, 2003; Lindegger et al., 2003) in order to assess the generalisability of specific results.

Sampling was expedited by convenience sampling due to time constraints and a small number of participants were recruited. Even though the sample size was small, a degree of purposive sampling (which selects information rich cases) was utilised and the researcher stopped data collection after interviewing reached a point of saturation. That is, no new information was yielded.

The current research was not interested in the incidence of responses but also in the quality of responses given by participants. Due to the small sample size the power of Chi-square test can be considered as fairly low in the current study. However, Chi-square test was used to complement the predominately interpretive content analysis and investigate possible relationships between certain demographics and codes, which may be significant in a more generalisable sample.

The value of the research design in the current study is that it used open-ended interviews to identify perceptions inductively (and not just merely reduce participants' responses to numbers), complemented by the use of quantitative methods, which were used to assess how widespread perceptions were.

Interviewer bias cannot be ruled out in the current study. Specifically, when the researcher introduced the project to participants as part of the 'HIV vaccines' ethics group, this may have oriented responses in a certain direction. In addition, some of the questions may have introduced bias. For example, 'Do vaccines prevent or treat illness? Is vaccination for infected or uninfected people'?

In the current study, informational provision consistent with robust measures of WTP in a hypothetical HIV vaccine trial, were not fully met. In addition, WTP was predominately measured as a single dichotomous outcome (willing or not willing) whereas some studies have used a combination of dichotomous and scaled (e.g. definitely willing, probably willing, probably not willing, not willing at all) outcomes. Therefore direct comparison with these studies is limited. Instead in the current study general issues were explored with the intention of providing more specific questions for future research in South Africa.

5.4 Implications in HIV vaccine trials

5.4.1 Implications for education

Results in the current study revealed sound knowledge of vaccination in general. However, it was also apparent that there is a need for continuous education. Specifically, data from this study suggests the following components be included:

Vaccination in general

- The purpose of most vaccines is to prevent disease.
- Healthy people receive preventive vaccines.
- Vaccines prevent disease by mobilising the body's defence system, better known as the immune system.
- Vaccines sometimes cause side-effects, which are an important determinant of their value.
- Vaccines do not cause illness or death.
- Vaccines do not guarantee immunity but significantly reduce susceptibility to disease.
- Vaccines sometimes fail.
- Vaccines are disease specific and therefore any given vaccine targets a specific disease.
- Examples of vaccine-preventable diseases include: polio, measles, mumps, rubella, diphtheria, pertussis, tetanus, haemophilus influenzae b, hepatitis A & B, influenza, yellow fever and rabies.
- Not all diseases have a vaccine.
- There is currently no vaccine for malaria, chicken pox and HIV.
- Although most vaccines are given to children, vaccines are also given to adults.

Vaccine trials

- A preventive HIV vaccine is going to be tested in South Africa on (different) volunteers.
- The trial will be a controlled trial and therefore some volunteers will receive the vaccine while others will receive an inactive substance called a placebo.
- Some people will become HIV positive during the trial for the same reasons that other people would, e.g. from unprotected sex.
- More infections in persons who received the placebo would indicate that the vaccine is working.
- Participants will have to be available to receive injections throughout the study.
- Only healthy people who are HIV negative will be able to volunteer.
- The HIV vaccine will not guarantee immunity to HIV infection.
- A preventive HIV vaccine may prevent disease, delay progression of disease or reduce transmission of infection.

As the current study was interested in general issues, WTP was not adequately assessed. Future research conducted on a more generalisable sample therefore requires more formal assessment of WTP. The most useful assessment of potential WTP would include comprehensive education, which would be available during actual recruitment for trial (MacQueen, 1999). In a guide for assessment of WTP in preventive HIV vaccine efficacy trials prepared by MacQueen (1999) for UNAIDS, the following informational requirements are suggested: basic elements of controlled clinical trials, vaccine concepts, medical risks, social risks, behavioural risk reduction and benefits of participation and trial sponsorship.

5.4.2 Implications for future research

The results from the current study suggest the following are important issues to be explored and further researched as perceived barriers and incentives for trial participation:

Incentives

- By participating you will be helping your community (altruism).
- If you participate you will receive compensation for research- related injury.
- By participating you will receive acknowledgement (recognition).

- If you participate you will receive free HIV tests at a time that is convenient to you (medical benefits).
- By participating you will receive counselling to reduce risk (opportunity to reduce personal risk).

Barriers

- The long-term side effects of a possible HIV vaccine are not known (significant physical risk).
- Your family and friends might think it is a bad idea for you to be in a HIV vaccine trial (psychosocial risk).
- It is not clear how expensive the vaccine will be (affordability).
- The vaccine is experimental and it is not clear if it will work (questionable efficacy of vaccine).
- If you participate you will have to be vaccinated with a needle and bloods taken at every visit for a number of years (fear of re-used needles).

It is also imperative that in future WTP research, all participants not only receive adequate information but that the elements that impact on their decision are properly measured.

According to MacQueen (1999) the following elements should also be included in an assessment of WTP, some of which were not included in the present study:

- Sociodemographic characteristics of participants, which at a minimum should include: age, sex, race/ethnicity, religion, marital status, employment or occupation, income, education or literacy, residential stability and information on HIV-related risk behaviours.
- Comprehension of key concepts of a trial.
- WTP that is either a dichotomous outcome (willing or not willing) or scaled responses (e.g. definitely willing, probably willing, probably not willing, not willing at all). The latter allows for researchers to understand the amount of ambiguity and direction (positive or negative) of responses.
- Statements of incentives and barriers that are either conditional measures of WTP or independent measures.
- Motivations, incentives, and barriers that reflect realistic perceptions and do not mislead prospective participants in anyway.

- **Social networks and community context of prospective participants that may impact on an individual's decision-making process.**

As the current study was exploratory and used a small non-random sample, the generalisability of the results was limited. MacQueen (1999) suggests that a sample size of 200 is sufficient to complete a statistically valid assessment of WTP for a relatively homogenous population – with regards to factors that are likely to influence WTP such as sex, sexual orientation, risk behaviour, age, socio-economic class, ethnicity, race, education and sources of income.

Chapter 6:

CONCLUSION

In preparation for HIV vaccine trials in South Africa, the current study had four primary objectives. Specifically, the study set out to assess students' knowledge and perceptions of vaccination in general, including perceived barriers to vaccination. Secondly, students' experiences with vaccination were assessed. Thirdly, and more specifically the study assessed students' knowledge of, and expectations toward HIV vaccination and participation in a hypothetical vaccine trial. Finally, the study explored if particular knowledge and experiences are associated with demographics, such as motherhood and gender. In accordance with the objectives of the current study and despite design limitations, the following conclusions can be drawn.

The results of the current study revealed that the vast majority of participants knew the general purpose of vaccination and nearly half of the sample speculated that a prospective HIV vaccine would be preventive in nature. This indicates that the purpose of vaccination was familiar amongst students, which is good news for HIV vaccine researchers.

However, the results of the present study showed that besides infant and childhood immunisation, other forms of preventive practices (such as adult vaccination) were unfamiliar practices among the participants. This is contrary to a position put forward in Chapter 1, which posited that given South African's longstanding history with vaccination in general, HIV vaccine trials might not be seen as an alien concept in communities but rather as extensions of familiar health practices. These results suggest that more extensive awareness of the HIV vaccine trials is required.

Another pretext of the current study was to identify important health beliefs that might aid local researchers to conduct further research in a culturally sensitive manner. Although culture and religion were stated as perceived barriers (by a minority) no personal examples were forthcoming. Instead the majority of the sample reported perceived alternatives to vaccination indicating that more western medical health practices were more prevalent, which may be attributed to the urban setting and well-educated student sample status. These results suggest that culture and/ religion may not be significant barriers to HIV vaccine trials. This needs to be investigated further in future research.

Given that similar numbers of participants stated that they were either WTP or not WTP in a hypothetical vaccine trial, motivations for participation will need to be further explored in future research in order to ensure that sufficient numbers of volunteers are recruited on the one hand but also that the process of recruitment is ethically sound.

The results imply that a number of concepts are important for education including: there is currently no vaccine for malaria, chicken pox and HIV; vaccines are for both adults and children; a preventive HIV vaccine is going to be tested in South Africa, and only healthy people who are HIV negative will be able to volunteer. The results also imply that participants' motivations for participation in a HIV trial will have to be assessed as they impact on the decision to participate or not. Finally, the results of the current exploratory study are not only important because they relate to an area of research that may lead to a possible breakthrough in HIV pandemic, i.e. the advent of HIV vaccine trials, but it also highlights the need to be continually ethical. This is especially important in South Africa where undermining of human rights was legitimised in the 'not so' distant political past.

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APPENDIX A

INFORMATION SHEET

Vaccination study: An exploratory study of students' knowledge, experiences and attitudes toward vaccines

Information sheet

1. Description of study

A. Purpose

This study broadly aims at exploring the knowledge, experiences and attitudes of South African students toward vaccines. It aims to elicit information on students' understandings of vaccines and how they work. It also examines students' attitudes and subjective experiences of vaccination.

B. Background

In general there appears to be scarce information on indigenous knowledge, attitudes and experiences with vaccinations generally. It is hoped that this study will better inform us about people's understandings on how vaccines work.

C. Specific location of study

This study is part of a larger vaccination study conducted by a project based at the school of Psychology at the University of Natal, Pietermaritzburg. Interviews will be conducted in designated rooms at the School of Psychology and university residences.

D. Probable duration of project

All interviews will take place after July 23, 2001 and prior to April 31, 2003.

E. Research plan

Data will be gathered through semi-structured interviews, conducted with diverse South African students from Natal University. These interviews will focus on the students' knowledge, experiences and attitudes toward vaccines. Data will be analyzed using content analysis and qualitative data analysis methods such as thematic coding.

II. Human participants

A. Subject population, recruitment

Volunteers will be gathered from various faculties and residences at the University of Natal. Both males and females will be targeted. The sample will comprise of approximately 50 students. Sampling will be used to ensure a representative sample reflective of the gender and race variables. Attempts will be made to include a diverse range of students.

B. Risks

The study has minimal risks. It is perceived that stigmatization as a result of participation will be insignificant in this study as it is a general vaccination study as opposed to an AIDS survey in which stigmatization may occur. A possible risk is inconvenience and loss of time.

C. Informed consent procedures

Each participant will be required to have read this information sheet before interviewing can begin. The prospective participants will be allotted time to ask questions about the nature of the study in order to ensure full comprehension. Participants will be further required to give written permission acknowledging that they have been adequately informed about the study and the conditions thereof. Participants will be requested to sign a separate consent to the interview being tape-recorded. In the event that the subject does not consent to tape-recording, extensive notes will be made with reference to the participant's responses. Participants are also free to abandon the interview at any point.

D. Protection of participants

Interviews will be conducted in the privacy of a closed room. Each participant will be assigned a code, and all interview schedules will remain anonymous. Each tape-recorded interview will be identified only by the participant's code, and no names or identifying characteristics will be used during the interview. Participants will be fully informed that the goal of this research project is not to evaluate the adequacy of their knowledge and/or relative experience with vaccines. All data, including tapes of recorded interviews and transcripts, will be securely stored.

E. Potential benefits

The study will provide the participants with an opportunity to explore their own understanding of vaccines.

F. Costs to subject

Other than time, the participants involved in the study will incur no financial costs.

APPENDIX B

INFORMED CONSENT FORM

INFORMED CONSENT FOR INCLUSION IN THE VACCINATION STUDY

I, (Name).....
hereby consent to be interviewed and to participate in this vaccination study.

I acknowledge that I have been informed by:
.....
concerning the possible advantages and possible adverse effects, which may result from
the abovementioned interview.

I agree that the above interview will be carried out by

I acknowledge that I understand the contents of this form and freely consent to the
abovementioned interview being conducted on me.

I agree that this interview will be treated with strict confidentiality and anonymity. I only
agree for the information I give to be published and used in advancing other peoples'
knowledge.

I acknowledge that I may leave this interview any time I feel like doing so.

Signed (participant): Date:
.....

Signed (researcher): Date:
.....

I agree to the fact that this interview will be tape-recorded.

Signed (participant): Date:
.....

Signed (researcher): Date:
.....

[Liziwe Masina -(033) 260 6708]

APPENDIX C

INTERVIEW SCHEDULE

B. VACCINATION QUESTIONS

Question 1 (general)

- 1.1 Please tell me what you know about vaccination.
- 1.2 Why do people get vaccinated? What is the purpose of vaccination?
- 1.3 Where have you heard about vaccinations?
- 1.4 Have you been vaccinated?
 - 1.4.1 If so, what for and when?
 - 1.4.2 What do you remember about your experience of vaccination? Was it helpful, helpless, painful, worth taking, etc?
 - 1.4.3. Have you been vaccinated since childhood? Why?
If so, for what were you vaccinated? What was your experience? (Optional)
- 1.5 Have your children been vaccinated?
 - 1.5.1 If yes, how did it come about that they were vaccinated?
 - 1.5.2 What sort of experience did they have of being vaccinated?
- 1.6 Do your friends and family go for vaccination? Why?
 - 1.6.1 Do any of them not go? For what reasons?
- 1.7 What do nurses/ doctors say about vaccination?
 - 1.7.1 Do you believe it? Why?

Question 2 (vaccination function and mechanism)

- 2.1 What does vaccination do?
 - 2.1.1 What can it prevent? What can it protect against?
 - 2.1.2 Can you tell us how the vaccine works? (How do vaccines work? / What does it do in the body?)
- 2.2 Do you think that vaccination can prevent infection or disease?
- 2.3 Can you name any diseases that you think vaccines protect against?
- 2.4 What dangerous diseases do you think they do not protect against?
- 2.5 Do you think vaccination can also be used as treatment? Why is this?
- 2.6 Do you think a vaccine can cure the illness? How would it help already infected people?

Question 3 (vaccination recipients)

- 3.1. Who do you think should be vaccinated? Why?
- 3.2 Is vaccination for adults or children or both? Please explain your answer.
- 3.3 Should healthy people be vaccinated? Why?

3.4 Should already infected people be vaccinated? Why?

Question 4 (vaccination problems/ barriers)

4.1 What do you think are some of the problems of immunization? (Why people would not go?)

4.2 What things may stop some people from getting vaccinated or having their children vaccinated? Why do you think this is the case?

4.3 We have heard some people say that vaccination can cause illnesses, or difficulties, what do you say about this? Have you heard such things? What exactly have you heard? (How do vaccines cause illness?)

4.3.1 What would you suggest should be done to eliminate such difficulties? Why?

Question 5 (alternatives)

5.1 Are there any other ways of stopping yourself and / or your family from getting sick?

5.2 If yes, can you tell me about these?

5.3 Are these measures better or worse than vaccines? Why?

Question 6 (immunisation services and health care workers)

6.1 Are immunization services offered at your nearest clinic?

6.2 How do the staff and nurses there encourage you to be vaccinated?

6.2.1 What do nurses explain about how vaccines work?

6.3 What do you think would make it easier for people to get vaccinated?

Question 7 (vaccination and the law)

7.1 Do you think that there should be a law forcing people to be vaccinated?

7.2 If yes, why should people be forced to vaccinate? What about their human rights?

7.3. If no, why is this? Please explain.

Question 8 (information needs)

8.1 Would you like to know more about vaccination?

8.2 If yes, what would you like to know more about?

8.3 Why do you think this is important to know about?

8.4 How would you like to receive this information (probe i.e. nurses, community leaders, other members of the community disseminating information etc)?

Question 9 (HIV vaccination)

9.1 Have you ever heard of an HIV vaccine? Please tell me what you know about it.

9.2 Who will it be for? Will it be for healthy people (9.2.1 prevention) or HIV infected people (9.2.2 treatment)?

9.2.1 If it will be for healthy people, what will it prevent, infection or disease?

9.2.2 If it will be for HIV infected people, what do you think vaccines do to already infected people?

9.4.1 If you were asked to participate in research on H IV vaccines, how would you feel about this?

9.5 What do you think prospective participants would want to know before volunteering?

9.5.2 What do you think prospective participants would want in return for participating in such research?

9.5.3 What would be some of their fears?

9.6 What would you want individually as a participant? Please elaborate.

APPENDIX D

CODING SCHEDULE

Coding schedule for vaccination study

Format:

- An X indicates that the line is a heading, not a code.
- Any number of codes may apply to a single sentence.
- In certain instances, a higher- level code should be used if you cannot glean sufficient information from the text to use a lower level code. E.g. If participants have heard rumours of negative effects, but do not indicate whether those claims are believed or not, then code at 3.2.2.
- Code 20 if any important information cannot be coded according to this scheme at your discretion.

1. X Understandings of official views

1.1. X What do people say that medical practitioners (health care workers) say?

- 1.1.1. Unsure of what medical practitioners say
- 1.1.2. Never heard what medical practitioners say
- 1.1.3. What medical practitioners say is helpful
- 1.1.4. Medical practitioners say vaccines preventative
- 1.1.5. Medical practitioners say vaccines required for proper care for children
- 1.1.6. Medical practitioners say; are a way of taking care of lives, are helpful, good for you
- 1.1.7. Medical practitioners say that people have a right to be protected
- 1.1.8. Medical practitioners say that vaccinated people are strong and healthy
- 1.1.9. Medical practitioners just want to know children's vaccination schedule (don't explain)
- 1.1.10. Medical practitioners say vaccines are compulsory
- 1.1.11. Medical practitioners don't explain/ don't say anything

2. X Do people believe what medical practitioners say?

- 2.1. Yes, believe what medical practitioners say.
- 2.2. The advice of medical practitioners is trustworthy
- 2.3. No, do not believe what medical practitioners say
- 2.4. Personal experience confirms health-care worker's view
- 2.5. Important to confirm official views
- 2.6. Dissatisfied with what health care workers say (e.g. because no-one explains)
- 2.7. Distrust anything that is free
- 2.8. Unsure/ Ambivalent

3. X Attitudes towards vaccination (Positive/Negative)

3.1. X Vaccination helpful

- 3.1.1. Vaccinations medically helpful
- 3.1.2. Facilitates admission to school
- 3.1.3. Other ways of vaccination being helpful.

3.2. X Rumours of Negative effects

- 3.2.1. Have not heard claims of negative effects
- 3.2.2. Have heard claims of negative effects
 - 3.2.2.1. Heard claims of negative effects and believe them
 - 3.2.2.2. Heard claims of negative effects but do not believe them

- 3.2.3. Rumours/Claims of negative effects - Other
- 3.3. X Side-effects
 - 3.3.1. None (vaccines don't have side effects)
 - 3.3.2. Yes, vaccines have side effects
 - 3.3.2.1. Discomfort (pain, swelling, fever, fatigue)
 - 3.3.2.2. Loss of appetite
 - 3.3.2.3. Sickness
 - 3.3.2.4. Other
 - 3.3.3. Side-effects show that vaccine is working
 - 3.3.4. Side-effects due to pre-existing infections
 - 3.3.5. Side effects show that vaccination is making illness worse
 - 3.3.6. Side-effects signal problems with vaccines
 - 3.3.7. Side-effects - other
- 3.4. Interferes with traditional measures of disease treatment and prevention
- 3.5. Unhelpful (e.g. because disease caused by spiritual factors)
- 3.6. People who fail to vaccinate are careless/ reckless/ stupid (negative attitude towards people who do not vaccinate)
- 4. X Vaccine target
 - 4.1. All people
 - 4.2. X Specific categories
 - 4.2.1. Target: Children (mainly)
 - 4.2.2. Target: Adults (mainly)
 - 4.2.3. Target: Children or adults
 - 4.2.4. Target: Unsure about adults
 - 4.2.5. Target: Women (mainly)
 - 4.2.6. Target: Sexually active people (14-25)
 - 4.2.7. Target: Men (Mainly)
 - 4.2.8. Target: HIV+ people only
 - 4.2.9. Target: Healthy people
 - 4.2.10. Target: Unhealthy people
 - 4.2.11. Target: People at risk (From HIV, local epidemics etc.)
- 5. X What do vaccines do?
 - 5.1. Vaccines prevent illness
 - 5.2. Vaccines maintain or promote health
 - 5.3. Vaccines treat illness
 - 5.4. Vaccines treat & prevent illness
 - 5.5. Vaccines are not a treatment
 - 5.6. Protect against disease, but are not necessarily full proof (e.g. might still get sick, not 100%)
 - 5.7. Cures disease
 - 5.8. Does not cure disease
 - 5.9. Vaccines have no purpose
 - 5.9.1. Protects against infection (not disease)
 - 5.9.2. Protects against both infection and disease
- 6. X Vaccination Mechanisms
 - 6.1. Unsure of vaccination mechanisms
 - 6.2. Vaccines make you strong
 - 6.3. Vaccines fight Disease
 - 6.4. Vaccine myths (e.g. vaccines cleanse the blood)
 - 6.5. Vaccination Mechanisms – Other

- 6.6. Trigger and stimulate immune system
- 7. X Specific Diseases that vaccines prevent
 - 7.1. Vaccines prevent: Common vaccine-preventable diseases (measles, smallpox, polio, flu etc.)
 - 7.2. Vaccines prevent: Other specific diseases (e.g. cancer, malaria, arthritis, bilharzias etc...)
 - 7.3. Vaccines prevent: All or any diseases
 - 7.4. Vaccines prevent: HIV
 - 7.5. Vaccines do not prevent: common vaccine-preventable diseases (measles, smallpox, polio, flu etc.)
 - 7.6. Vaccines do not prevent: Other specific diseases (e.g. cancer, malaria, arthritis, bilharzias etc...)
 - 7.7. Vaccines do not prevent: All or any diseases
 - 7.8. Vaccines do not prevent HIV (prevention)
- 8. X Personal Experience of Vaccination
 - 8.1. Yes have been vaccinated
 - 8.2. No has not been vaccinated
 - 8.3. Clear knowledge of own vacc. history
 - 8.4. Unclear, or no knowledge of own vacc. history.
 - 8.5. Personal experience of Vaccination: Vaccination Helpful
 - 8.6. Personal experience of Vaccination: Vaccination unhelpful
 - 8.7. Personal experience of Vaccination: Vaccine had side effects
 - 8.8. Personal experience of vaccination: Negative consequences (effects) of vaccination
 - 8.9. Participant vaccinates children
 - 8.9.1. Participant vaccinates children : To protect
 - 8.9.2. Participant vaccinates children : To prevent disease transmission
 - 8.9.3. Participant vaccinates children : Unsure
 - 8.9.4. Participant vaccinates children : Other reasons
 - 8.10.1. Children's experiences of vaccination: Vaccination Helpful
 - 8.10.2. Children's experiences of vaccination: Vaccination unhelpful
 - 8.10.3. Children's experiences of vaccination: Vaccine had side effects
 - 8.10.4. Children's experiences of vaccination: Negative consequences (effects) of vaccination
 - 8.11. Participant does not vaccinate children
 - 8.12. Participant has been vaccinated since childhood
 - 8.13. Participant has not been vaccinated since childhood
- 9. X Concerns
 - 9.1. Concerns: Vaccines cause HIV (NB: Please make notes so we can tell whether people are scared of HIV infection through *needles* or from the vaccination itself.)
 - 9.2. Concerns: Vaccines cause other diseases
 - 9.3. Concerns: Vaccines cause difficulties
 - 9.4. Concerns about normal vaccines
 - 9.5. Concerns about potential HIV vaccines
 - 9.5.1. Concerns about affordability
 - 9.5.2. Concerns: Psycho-social (e.g. disinhibition, stigmatisation etc)
 - 9.6. Other concerns
- 10 X Barriers to vaccination
 - 10.1. No Barriers to vaccination
 - 10.2. Barrier to vaccination: Knowledge/Education
 - 10.3. Barrier to vaccination: Logistics (e.g. transport, money, time etc...)

- 10.4. Barrier to vaccination: Intrapersonal factors (e.g. laziness)
- 10.5. Barrier to vaccination: Concern/Fear of risks/safety
- 10.6. Barrier to vaccination: Culture/religion
- 10.7. Other barriers to vaccination (e.g. resources, poor community etc)
- 11. X Suggested measures to remove barriers
 - 11.1. Education to increase vaccination
 - 11.2. Other means to increase vaccination
- 12. X Alternatives to vaccination
 - 12.1. No Alternatives to vaccination
 - 12.2. Yes, alternatives exist
 - 12.2.1. Sanitation as alternative
 - 12.2.2. Religious alternatives
 - 12.2.3. "Cultural" alternatives
 - 12.2.4. Health alternatives (adequate sleep, exercise, diet, vitamins)
 - 12.3. Alternatives are complementary to vaccination (i.e. they work together)
 - 12.4. Alternatives are better
 - 12.5. Alternatives are worse
 - 12.6. Uncertain
- 8.10. Uncertain
- 13 X Possible HIV vaccine
 - 13.1. Never heard of possible HIV vaccine
 - 13.2. Have heard of possible HIV vaccine
 - 13.3. Participant mentions an existing HIV "vaccine".
 - 13.4. HIV vaccine will be useful for prevention
 - 13.5. HIV vaccine will be useful treatment
 - 13.6. HIV Vaccine target – healthy people
 - 13.7. HIV Vaccine target – HIV infected people
 - 13.8. HIV Vaccine target – All people, everyone
 - 13.9. HIV Vaccine target – People at risk
- 14 X Participation in HIV vaccine trials
 - 14.1. Willing to participate in HIV vaccine trials
 - 14.2. Not willing to participate in HIV vaccine trials
 - 14.3. Animals should be used in trials instead of people
 - 14.4. Unsure
 - 14.5. X Requirements before participating
 - 14.5.1. Require more information before participating in HIV vaccine trials
 - 14.5.2. Only participate if no significant risks
 - 14.5.3. Only participate if family cared for after any consequent problems.
 - 14.5.4. For financial benefit
- 15 X Perceived barriers to HIV vaccination trial participation
 - 15.1. Trial participation barrier: Significant physical risk
 - 15.2. Trial participation barrier: Significant psycho-social risk (e.g. stigmatisation, disinhibition etc.)
 - 15.3. Trial participation barrier: Fear of injections
 - 15.4. Trial participation barrier: Other
- 16 X Perceived incentives for trial participation:
 - 16.1. Trial participation incentive: Altruism (e.g. to help people who are dying)
 - 16.2. Trial participation incentive: Counselling
 - 16.3. Trial participation incentive: Material benefits (jobs, houses, cash etc...)
 - 16.4. Trial participation incentive: Education

- 16.5. Trial participation incentive: Other
- 17 X Sources of information about vaccination
 - 17.1. Information source: School/University²⁵
 - 17.2. Information source: Clinics/hospitals
 - 17.2.1. From doctors/ nurses at clinics
 - 17.2.2. From notice boards or posters at clinics
 - 17.3. Information source: Media
 - 17.4. Information source: Other
- 18 X Preferred sources of information
 - 18.1. Preferred sources of information: Nurses/Doctors/clinics
 - 18.2. Preferred sources of information: Anyone who is well-informed
 - 18.3. Preferred sources of information: Media
 - 18.3.1. Radio
 - 18.3.2. TV
 - 18.3.3. Newspaper
 - 18.4. Preferred sources of information: Trained community members
 - 18.5. Preferred sources of information: Informal à friends and neighbours
- 19 X Specific Educational needs
 - 19.1. Educational need: None
 - 19.2. Educational need: Not sure
 - 19.3. Educational need: General HIV
 - 19.4. Educational need: General vaccination info
 - 19.4.1. How it works (mechanisms)
 - 19.4.2. What vaccines are
 - 19.4.3. What vaccines are available
 - 19.5. Educational need: HIV vaccine info
- 20 QUERY CODE: ANYTHING THAT IS NOT CLASSIFIABLE UNDER THIS CODING SCHEME
- 21 X Friends and family and vaccines
 - 21.1. Friends and family go get vaccinated (Why? Code under code 5)
 - 21.2. Friends and family don't go get vaccinated (WHY? Code under code 10)
- 22.X Vaccination and human rights:
 - 22.1. There should not be a law forcing people to get vaccinated
 - 22.2. There should be a law forcing people to get vaccinated
 - 22.3. Uncertain, ambivalent as to whether there should be a law forcing people
 - 22.4. Human rights of the population are important in this case
 - 22.5. Human rights of the individual are important in this case
- 23.1 Would like to know more about vaccination
- 24 X Personal incentives for trial participation:
 - 24.1 Trial participation incentive: Altruism (e.g. to help people who are dying)
 - 24.2 Trial participation incentive: Counselling
 - 24.3 Trial participation incentive: Material benefits (jobs, houses, cash etc...)
 - 24.4 Trial participation incentive: Education
 - 24.5 Trial participation incentive: other
- 25 X HIV Vaccine Mechanism
 - 25.1 Stimulating the immune system

APPENDIX E

CODING FORM

Code	Counter number & (quote reference, e.g. Q1, Q2)
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QUOTES	
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