WILLINGNESS OF ENTEBBE MUNICIPALITY RESIDENTS TO PARTICIPATE IN FUTURE PHASE III HIV VACCINE TRIALS

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DECLARATION

This is to declare that the work presented in this book is my original work. It has never been presented wholly or partially for any award and/or publication and will never be presented for any other award. I do hereby present it to Makerere University School of Graduate Studies in partial fulfillment for the award of the Degree of Master of Public Health of Makerere University.

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DEDICATION

I dedicate this work to my parents Mr. James Galiwango and Ms. Teopista Nakitende and to my dear husband Mr. William Lwasa Bakaluba.

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I acknowledge the Almighty God through His Son Jesus Christ for giving me wisdom, good health and strength to successfully complete this research and write this book.

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Acronyms and Abbreviations

AIDS	Acquired Immune Deficiency Syndrome
ART	Antiretroviral therapy
AVAC	AIDS Vaccine Advocacy Coalition
CAB	Community Advisory Board
DNA	Deoxyribonucleic acid
FGD	Focus Group Discussion
GCP	Good Clinical Practice
HIV	Human Immunodeficiency Virus
HVT	HIV Vaccine Trials
IAVI	International AIDS Vaccine Initiative
IEC	Information, Education and Communication
JCRC	Joint Clinical Research Centre
KII	Key Informant Interviews
MSM	Men who have sex with men
MUWRP	Makerere University Walter Reed Program
MVA	Modified Vaccinia Ankara
PLWHA	People Living with HIV/AIDS
UNAIDS	The Joint United Nations Program on HIV/AIDS
UVRI	Uganda Virus Research Institute
W.H.O	World Health Organization
WTP	Willingness to Participate

Operational definitions

Participation: In this study referred to an individual volunteering to take part in an HIV vaccine trial.

Willingness to participate: An expression of readiness to volunteer in future phase III HIV vaccine trials.

A household: A group of people staying together under the same roof.

Household head: The person who headed a household or their designee.

Married: Any one who had a customary, civil or church marriage. In addition, people who were in a cohabiting relationship for more than a year were considered married.

Community: A territorial unit of society or a unit of social organization based around common interests with a shared living situation typically characterized by a sense of belonging with a high degree of cooperation in pursing common goals. Entebbe community is the planned location for phase III HIV vaccine trials and where research participants will be recruited.

Entebbe Municipality Resident: A person who had stayed in the Entebbe Municipality for more than one month or one who intended to stay for good.

Abstract

Background: Although Phase III HIV vaccine trials are being planned, availability of information is limited on willingness to participate (WTP) among residents in urban areas.

Objectives: To determine the level of and factors associated with willingness of Entebbe Municipality residents to participate in future Phase III HIV vaccine trials, and to establish their knowledge, beliefs and attitude towards participation.

Methodology: A descriptive cross-sectional study conducted among residents aged 18-50 years. Five research assistants collected data using 5 Focus Group Discussions, 8 Key Informant Interviews and 398 semi structured questionnaires. Two stage cluster sampling was used to obtain the study unit for the quantitative aspect of this study while purposive sampling was done for the qualitative aspect.

Results: Just about half of the respondents, 53% (212/398) expressed willingness to participate in future efficacy trials. Prevention from HIV (51%) and the desire to have a protective vaccine (36%) were the main reasons for WTP. WTP was associated with "the need to conduct HIV vaccine trials [ARR 0.28, (95% CI 0.13 – 0.64)]", "community support for trials [ARR 0.39, (95% CI 0.24 – 0.65)]" and "importance accorded to getting an HIV vaccine [ARR 0.49, (95% CI 0.27 – 0.90)]". Unwillingness to participate was attributed mainly to unknown side effects of the trial vaccines (51%), the fear of getting infected by the vaccine (48%) and the long study duration (22%).

Conclusion: The level of WTP in efficacy trials, in this urban study population is low compared to that from rural settings. Education particularly on HIV vaccine safety will be required before the efficacy trials begin.

Chapter One

1.0 Introduction and Background

1.1 Introduction

HIV/AIDS is a global threat to mankind and its devastating impact is felt in the health, social, economic and political sectors. Since the beginning of the epidemic, almost 60 million people have been infected with HIV and over 25 million people have died of HIV-related causes (UNAIDS, 2009). In 2009, there were 33.3 million people living with HIV worldwide, 2.7 million new infections and 2 million AIDS-related deaths.

Sub-Saharan Africa where resources to undertake prevention efforts and provision of care are limited is home to 68% of all people living with HIV worldwide with 91% of all new infections among children. An AIDS free world therefore, can only be realized through collaborative prevention and control efforts that are fully inclusive of Africa.

In Uganda, an estimated 940,000 people are living with HIV and there are an estimated 82,000 AIDS deaths each year (UAC 2009). The 2004-2005 Uganda Sero-Behavioral Survey found that 6.4% of Ugandans aged 15-49 were HIV positive. HIV prevalence was significantly higher among women than men (7.5% compared to 5.0% among men) and among urban residents than their rural counterparts (10% compared to 5.7% among rural residents). While considerable achievements have been made in responding to the problem, there is still an overwhelming need for an AIDS vaccine. Uganda was the first country in sub-Saharan Africa to register a drop in adult national HIV prevalence rates from about 18%

in 1992 to 6.4 % in 2002, alongside evidence of substantial behaviour change that inhibited the spread of HIV (Asamoah-Odei et al., 2004). Of recent, the prevalence has been noted to increase to 6.7% (UAC 2009). Even as national programs to prevent and treat HIV and AIDS are expanded, 132,500 new infections occur each year. The epidemic remains a major development problem in the country and its impact on national development and household economies has compounded a whole range of challenges that require solutions (MOH, 2006).

1.2 Background

As the HIV/AIDS pandemic continues to spread, it is becoming increasingly clear that existing biomedical and behavioral interventions alone cannot control it. Whereas antiretroviral therapy is becoming more widely available; access to treatment is still limited because of cost, infrastructure, limited treatment options, access to HIV testing and stigma (UNICEF, 2007). Because the vast majority of people throughout the world have not been infected, prevention remains an urgent priority to help people stay uninfected so as to protect future generations.

Prevention approaches such as condom promotion have had limited success due to social factors that strongly influence behaviour coupled with insufficient resources (AVAC, 2004). Incorporating new prevention tools like HIV vaccines that are safe, affordable and effective into a comprehensive response that includes other prevention options, as well as treatment, care and support for those already infected will be key to ending the HIV/AIDS pandemic (Mugisha, 2002).

Historically, vaccines have been the most effective public health tool for controlling or eradicating diseases. Smallpox for example, has been eradicated worldwide while

poliomyelitis has almost been controlled through vaccination. The high HIV prevalence in many developing countries like Uganda, combined with such countries' inadequate resources for purchasing antiretroviral medications, makes them ideal testing sites for candidate vaccines (Mugerwa et al., 2002).

Even though, safe, effective and affordable HIV vaccines are being developed and investigated through various clinical trials around the world, recruitment of study participants remains a major challenge (Burton and Moore,1998). Phase I and II trials classically involve individuals at lower risk for HIV infection while Phase III HIV vaccine trials target specific populations known to be at high risk for HIV infection such as commercial sex workers (CSW), intravenous drug-users (IDU), men who have sex with men (MSM), clients of CSW, those who exchange sex for drugs or other gifts, those who have sexually transmitted diseases and those who have had or currently have a sexual partner with any of the above risk factors.

The first HIV Vaccine trial was conducted in the United States of America in 1985 and has given way to multiple trials of different preventive HIV candidate vaccines the world over. In Sub Saharan Africa, Uganda was the first African country to conduct an HIV Vaccine trial in 1999 (Phase I trial of ALVAC vcp205) by the Joint Clinical Research Centre (Mugerwa et al., 2002). This was followed by the first UVRI-IAVI HIV vaccine trial (Phase I trial of HIV 1 Clade A, DNA/MVA vaccine) which was conducted in 2003. Another UVRI-IAVI HIV vaccine study (Phase II trial with tgAAC09 candidate vaccine) was conducted in 2006. The Makerere University Walter Reed Project based at Mulago hospital conducted its first Phase I HIV vaccine trial (multi-clade recombinant DNA) in 2004 and it’s second using

DNA/ adenovirus vectored HIV vaccine in a prime-boost strategy in 2006. The candidate vaccines tested to date in Uganda and elsewhere have been found to be safe, well tolerated with varying degrees of immunogenicity.

The first phase III HIV vaccine trials began in the United States in June 1998 and in Thailand in March 1999. To recruit hundreds of at risk individuals, thousands had to be approached and sensitized hence making the recruitment process expensive and laborious to the researchers. As more candidate vaccines become eligible for testing in Phase III clinical trials, a closer look at knowledge and attitudes, as well as barriers and motivators to participate in these trials from communities where study participants will be recruited is needed in order to give the researchers a picture of how much sensitization will be required before the communities can embrace these trials.

Chapter Two

2.0 Literature Review

2.1 Introduction:

We are confronted with one of the worst pandemic in history, a pandemic that threatens to ravage societies around the world. With more than 16,000 new people infected daily throughout the world, HIV/AIDS is clearly an illness of public health importance (UNAIDS, 2009). An effective, safe, efficacious and affordable preventive HIV vaccine is urgently needed as part of a broader prevention effort to help control the pandemic. However, according to Mugisha (2002) such a vaccine would have to be tested in human subjects in the absence of a suitable animal model. Recruiting volunteers for these trials is critical to the success of the endeavor, yet it is fraught with scientific, social, political and ethical concerns (Keymanthri, 2002). According to O'Connell et al., (2003), the decision to participate in research is likely to be influenced by a wide range of factors including the importance people accord to HIV vaccine research in general.

2.2 HIV and Participation of women in HIV vaccine trials

According to UNAIDS (2009) some 7,000 women become infected with HIV every day. Globally, just under half of all adults living with HIV are female. In most regions, women and girls make up an increasing proportion of the population living with HIV, and rates of female infection continue to rise particularly in Africa, Eastern Europe, Asia and Latin America.

AIDS has so far affected women most severely in sub-Saharan Africa and the Caribbean. In sub-Saharan Africa, women and girls account for almost 57% of adults living with HIV. A survey by Gregson (2002) revealed that in South Africa, Zambia and Zimbabwe, young women (aged 15-24) were five to six times more likely to be infected than young men of the same age.

Olenja et al., (2006) noted that biological differences in the risk of infection and viral load may lead to differences in effect of the vaccine on women and men. However, AIDS vaccines are rarely viewed through the lens of women's vulnerability, yet they hold tremendous promise for women, particularly young women, who often lack the power to negotiate the terms and conditions of safer sexual relations. A vaccine has the potential to be used with or without the partner's knowledge, and since it is not linked to the sexual act, it may be much more acceptable in cultural settings where dominant ideologies dictate that young women should be protected from information regarding sexuality and HIV/AIDS. In the past, recruitment of females has been a challenge in most of the HIV vaccine trials.

In a study by Dylan et al., (2010) about inhibitors and facilitators of willingness to participate (WTP) in an HIV vaccine trial, the factors which accounted for 45.93% of the variance in WTP were personal costs, safety and convenience, stigmatization, personal gains and social approval among the females. Kapoor & Becker (2004) noted that in order to ensure that AIDS vaccines work for both women and men, that they meet women's needs, and that women, especially young women, eventually have access to them, gender issues must be considered in the planning, implementation of clinical trials and preparations for access and use. Compelling biological, scientific, social and ethical arguments call for inclusion of

significant numbers of women and men in trials. Unless a vaccine is tested in women, it will not be clear whether it is efficacious or harmful for them and it may not be able to determine whether the vaccine works differently for men than for women. Therefore, women's participation must be a key consideration in AIDS vaccine development and advocacy efforts.

2.3 Knowledge and Attitudes about HIV Vaccine Research

Mugisha (2002) pointed out that in Uganda, awareness about the magnitude of AIDS and its impact is high and the need for a vaccine was urgent. However since the second trial in Uganda in 2002, several other trials have taken place and due to changing times in the socio-behavioral, economic and cultural arenas it is possible that the knowledge and attitudes people have about HIV vaccine trials could have changed.

Giami (1996) pointed out that negative attitudes towards HIV vaccine research include fear of being infected with HIV through a contaminated vaccine. Despite great educational efforts being made, potential participants are frequently concerned of being wrongly identified as HIV infected. This leads to stigma and discrimination by relatives and friends. In such situations, individual and group discussions are necessary to clear misunderstandings and ensure an informed community. The above situation however may differ significantly from country to country and indeed depends on the education efforts conducted in different settings as well as the prevailing cultural norms.

In their study about Willingness to participate in preventive HIV vaccine trials in a community-based cohort in South Western Uganda, Ruzagira et al., (2009) found that knowledge about HIV vaccines was one of the limiting factors to participation in HIV vaccine research. Attitudes and perceptions towards participation in future HIV vaccine trials in populations where no HIV vaccine trial was conducted at the time were found to be influenced by the knowledge people had about HIV vaccines. Kiwanuka et al (2004) found that vaccines were considered appropriate for children and women (99 and 88%, respectively), but not for adult men. In the same study, 60.2% of the participants thought that HIV-positive persons were eligible for HIV vaccine trials. With more sensitization and awareness about HIV and HIV vaccine trials, it is possible that the knowledge gap has reduced especially in the areas where HIV vaccine research is being conducted.

2.4 Willingness to participate in HIV preventive vaccine trials:

For phase III HIV vaccine trials to be feasible, thousands of high risk individuals must endorse and be willing to participate in such trials (O'Connell et al., 2002). However, reported WTP in phase III HIV vaccine trials have varied greatly between studies and countries. In America, WTP in future efficacy trials ranged from 91% in MSM to 27% in a mixed group of MSM, IDU and high-risk women (Hays and Kegeles, 1999; Koblin et al., 1998). Among the army, 25 to 30% were willing to participate in a Thailaind study by Celentano et al., (1995 and in similar studies by Jenkins et al., (1995) and Jenkins et al., (2000). However, according to McGrath et al., (2001), 80% endorsed such trials in Uganda.

Kiwanuka et al., (2004) and Mac Queen et al., (1999) conducted studies to explore how individuals felt about being research subjects in HIV vaccine trials by examining the factors contributing to their knowledge and willingness to participate. These studies revealed that between 77% -83% of the people were willing to participate in future HIV vaccine trials. According to these studies, the main reasons given for willingness to participate were altruism and potential protection from contracting HIV. Individuals who were less willing or not willing at all stated concerns about vaccine safety, social consequences resulting from vaccine-induced sero-positivity, and distrusting research personnel.

In another study about WTP in HIV vaccine trials among men who have sex with men in Rio de Janeiro, Brazil by Périssé et al., (2003), of the 815 initially HIV-seronegative participants, 569 (69.8%) reported willingness to participate in an HIV vaccine trial. In this study, factors indicative of high-risk of HIV infection were associated with a higher willingness. The data demonstrated that the high-risk homosexual male cohort had a high willingness to participate in HIV vaccine trials. On the other hand, a Ugandan study by Ruzagira et al., (2009), found that the requirement to delay pregnancy in women reduced willingness to participate from 97% to 23%. A study in Canada by O'Connell et al., (2002) found that only 48.6% of the participants were willing to participate and enroll in a phase III preventive HIV-1 vaccine trial despite the benefits. This shows that the factors which influence WTP may vary in different study populations. There is therefore need for more studies from different cultural and social settings on willingness to participate in efficacy trials especially from the developing countries to establish factors associated with such willingness.

2.5 Potential barriers to participate in HIV preventive vaccine trials:

The side effects of the candidate vaccine either actual or presumed may be barriers to participation. A study conducted in Thailand among high risk populations to assess willingness to participate in HIV vaccine trials found that vaccine side effects were considered to be important barriers to trial participation (Celentano et al., 1995). More particularly with an HIV vaccine as noted earlier, potential participants are likely to be concerned about acquiring HIV from the vaccine (O'Connell et al., 2003). Unknown to most of the potential participants is the fact that these vaccines are genetically engineered and this risk is unlikely. Participants' fears need to be allayed through continuous sensitization and educations before trials begin.

The existing news of HIV vaccine failure may deter people from participation in future HIV vaccine research. As of 2008, only one candidate HIV vaccine had reached large scale Phase III trials, the final phase of clinical trial before an experimental vaccine can be approved and licensed for general use. This trial was completed in 2003, and the vaccine being tested known as AIDSVAX consisting of recombinant gp. 120, which is a protein unique to HIV's surface, was found not to be efficacious in preventing HIV infection or in modifying the progression of infection.

Another large scale trial, known as a phase IIb test-of-concept trial which was the most promising HIV vaccine trial, was prematurely halted in September 2007 when an interim analysis showed that the vaccine was not efficacious in preventing infection (STEP and Phambili trial). Such news may be discouraging to the potential participants who may

be willing to participate in future HIV vaccine trials. The prophylactic use of ARVs in mother to child transmission of HIV and their availability for use in situations where there is occupational exposure (PEP) may offer potential alternatives to prevention of further HIV spread there by rendering the discovery of an HIV vaccine not a priority to some community members. Studies to explore people's attitudes and perceptions towards such findings may be beneficial in assessing WTP.

Various social harms may influence willingness to participate in future vaccine trials. For example in a study conducted in Thailand by Celentano et al., (1995), it was found that 24-49% of participants believed that their partners would refuse to have sex with them after immunization. While it is possible to distinguish between a natural HIV infection from a positive HIV result due to vaccine induced antibodies many potential participants might be unaware of this, so testing HIV positive after participation in an HIV vaccine trial may deter people from participation.

Public misconceptions and media misinformation are other potential barriers to participation and should be demystified. Mugerwa et al., (2002) noted that despite elaborate preparations for the first Ugandan HIV vaccine trial, misconceptions arose about the trial's purpose among the general public and potential volunteers. Between 20 and 30 people infected with HIV, who mistakenly thought that the vaccine was therapeutic, asked to be enrolled in the study. Three themes recurred during focus group discussions held for the benefit of potential volunteers: belief that the vaccine would protect against unsafe sex, fear that volunteers were to be injected with HIV, and fear that volunteers would be exposed

deliberately to people infected with HIV. Most of the confusion was due to widespread rumours and conflicting media reports about the vaccine. Many media writers, reporters, and editors seemed not to understand concepts such as the difference between drugs and candidate vaccines. One report in a Ugandan newspaper (*New Vision* 22 September 1996) referred to ALVAC-HIV vaccine as a "candidate drug"; some journalists confused the vaccine with the newly introduced combination of anti-HIV drugs. The latter error led to false hopes of treatment and to demands that ALVAC-HIV vaccine be given to as many people as possible. Entebbe community members' perceptions of risks and benefits related to trial participation need to be assessed compared to studies conducted in the past.

For those who have participated in these trials before, the possibility of being included in a control group in the trial, where a placebo will be used instead of the HIV vaccine, might be another barrier to willingness to participate. Researchers in Philadelphia reported that interest in participating in a vaccine trial dropped from 47% to 24% when the possibility of using a placebo was mentioned (Jenkins et al., 1995).

2.6. Motivators to participate in HIV preventive vaccine trials:

In a study by MacQueen et al., (1999) it was found that persons who were at greater risk of infection or who perceive themselves to be at greater risk were expected to be more likely to be willing to participate in HIV vaccine research. Other reasons that were reported to motivate willingness to participate included, getting transport money, getting free condoms and free medical care services. In a study by Périssé et al., (2003), 69.8% of the participants reported willingness to participate in an HIV vaccine trial giving altruism as the primary

reason for wanting to participate. This study investigated the WTP in HIV vaccine trials of initially HIV sero-negative homosexual men enrolled in an HIV sero-incidence cohort. In a similar study by O'Connell et al., (2002) which evaluated willingness to participate and enroll in a phase 3 preventive HIV-1 vaccine trial, those willing to participate were the disadvantaged, sexually risky who had a high-perceived HIV risk. These findings need to be compared with findings on WTP in HIV vaccine trials from general population studies particularly in developing countries like Uganda.

Despite some disappointments in HIV vaccine research, recent developments in the HIV vaccine field may be encouraging not only to the scientific fraternity but to the potential participants as well and this may be a major motivating factor towards participation in future efficacy trials. Results from an AIDS vaccine trial known as RV 144 which involved more than 16,000 participants from Thailand who received (ALVAC HIV (vCP1521) and AIDSVAX B/E (gp120) vaccine component) demonstrated that the vaccine regimen was safe and lowered the rate of HIV infection by about 31%. While the efficacy was modest, this study gave a positive signal of efficacy in a human HIV vaccine trial which was an exciting result in a field that had been characterized by many disappointments for more than two decades. It provided the evidence that a safe and effective HIV vaccine is possible, and the results should accelerate research efforts towards a more effective vaccine. Such news gives researchers and potential participants hope that an HIV vaccine is possible. Research is therefore needed to further explore the effects of such positive findings on future participation in HIV efficacy trials.

Chapter Three

3.0 Problem statement and Justification

3.1 Problem statement

HIV vaccine research has been ongoing in Entebbe Municipality since 2000 but trials conducted have only been Phase I and II trials. Plans are now under way to conduct phase III HIV vaccine trials and there is no data researchers can rely on to predict the numbers that will be achieved during enrolment. Where as Phase I and II trials require fewer people and last a shorter duration, Phase III trials take a much longer duration and require thousands of people that are representative of the population for which the vaccine is to be used.

Willingness to participate (WTP) has been found to be the best predictor of actual enrollment in research (Buchbinder et al., 2004). Data on WTP in such large scale trials for Entebbe community is not known since no studies on WTP have been conducted there. Additionally, studies in Uganda to assess community's WTP in HIV vaccine trials were in rural areas with high HIV disease burden, and relatively low literacy levels (Kiwanuka et al (2004) Ruzagira et al. (2009). These studies revealed that misconceptions about HIV vaccines and HIV vaccine research greatly hindered WTP. Although Phase III trials are planned, the extent to which mobilization and sensitization will be required to inform and recruit thousands of HIV negative but at risk populations for HIV in an urban setting with low HIV burden is not fully known.

3.2 Study Justification

Successful implementation of efficacy trials requires thousands of subjects that are freely willing to participate in these trials. Five candidates have reached phase III testing in

humans worldwide and WTP in most of these studies was never really assessed before the studies begun. This study will establish the community's WTP so as to predict the numbers that will participate in future efficacy trials. It is required that communities are well informed about efficacy trials in order for them to make an informed decision to participate. Findings from this study will help researchers establish the knowledge Entebbe residents have about HIV, HIV vaccines and HIV vaccine trials and the gaps in knowledge that need to be bridged before the efficacy trials begin. The study will identify myths and misconceptions about HIV and HIV vaccine research which may impact WTP. Information gained will be used by researchers to tailor messages that will improve understanding.

Most WTP studies have been conducted in selected populations of gay men, injection drug users and commercial sex workers. A WTP study on heterosexual individuals will generate information that is generalizable to the population which is mostly affected by HIV. In Uganda, studies to assess community's WTP in HIV vaccine trials have been conducted in areas with high HIV disease burden but where no HIV vaccine research was ever conducted. A WTP study from an area which has a relatively low HIV disease burden and where HIV vaccine research has been conducted will help researchers determine if disease burden and prior conduct of HIV vaccine research in a given location impacts WTP.

This study will generate baseline information on knowledge, attitudes and perceptions towards participation in future efficacy trials. Findings will inform future community education activities, volunteer recruitment strategies and policy. Information gained will foster successful conduct of future phase III HIV vaccine trials and contribute to the development of an HIV vaccine.

Chapter Four

4.0 Research questions and Study Objectives

4.1 Research Questions

1) To what extent are Entebbe Municipality residents willing to participate in future Phase III HIV vaccine trials?
2) What knowledge do Entebbe Municipality residents have about HIV, HIV vaccines and HIV vaccine trials?
3) What attitudes and beliefs do Entebbe Municipality residents have towards participation in phase III HIV vaccine trials?
4) Which other factors are associated with willingness to participate in future Phase III HIV vaccine trials?

4.2 Study Objectives

4.2.1 General Objective

To determine the level of willingness to participate in future Phase III HIV vaccine trials and the factors associated with such willingness in order to inform future community education activities and volunteer recruitment strategies.

4.2.2 Specific Objectives

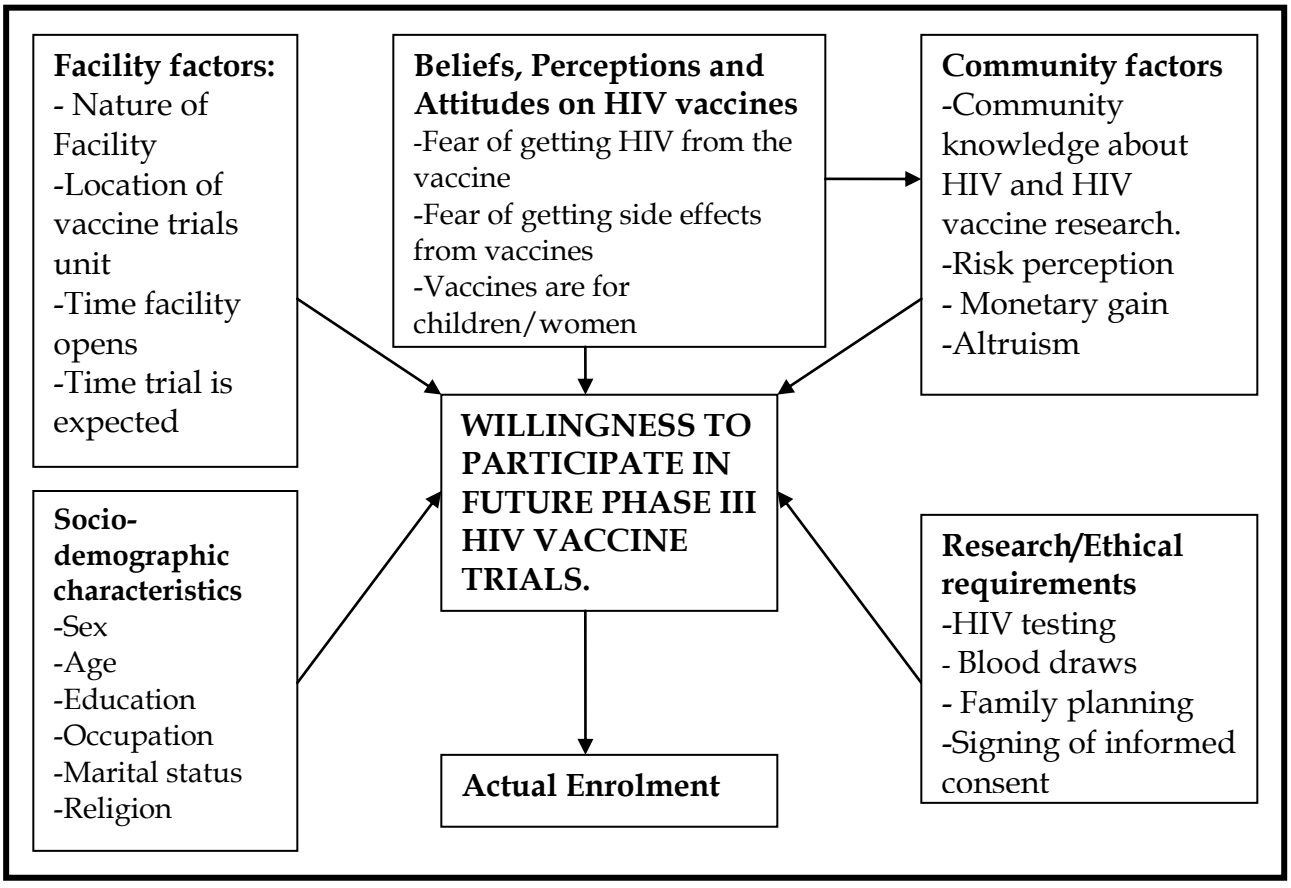
1. To establish the level of willingness to participate in future Phase III HIV vaccine trials of Entebbe Municipality residents.
2. To determine the knowledge of Entebbe Municipality residents about HIV, HIV vaccines and HIV vaccine trials.

3. To determine attitudes and beliefs of Entebbe Municipality residents towards participation in phase III HIV vaccine trials.
4. To identify the other factors associated with willingness to participate in future Phase III HIV vaccine trials.

4.3 Conceptual Model and conceptual Framework

4.3.1 Conceptual Model:

Factors influencing willingness to participate in future phase III preventive HIV vaccine trials



4.3.2 Conceptual Frame work

Social Demographic factors:

Reports from HIV vaccine trials conducted so far revealed that more males than females participated even though females were more willing to participate (Mugerwa et al, 2002). Majority of the participants were youth aged between 19-24 years. People with low educational status were more likely to lack knowledge about HIV vaccine research and its requirements. They often had myths and misconceptions about HIV being spread from HIV vaccines which hindered them from participation. Some married women especially those who were uneducated were not empowered to take on personal decisions to participate in HIV vaccine research. They depended on relatives or male partners to give them consent to participate in HIV vaccine research activities (Mugerwa et al, 2002). The people who have formal employment tend to be busy and hence have no time for research activities. Some religions are particularly hesitant about invasive procedures such as blood draws which may impact on WTP.

Facility factors:

Negative staff attitudes, location of vaccine trial's unit and the time the facility opens may impact on willingness to participate.

Research/Ethical requirements:

Some people are still stigmatized about knowing their HIV status and because people know that VCT is one of the requirements to participate in HIV vaccine research, their willingness may be influenced. Ethical requirements like signing of informed consent may influence willingness to participate for those who are illiterate.

Beliefs, perceptions and attitudes on HIV vaccines:

The fear of getting HIV-infection, the perceived or actual side effects from the vaccine and the belief that vaccines are for particular people such as the young and women may all influence willingness to participate in efficacy trials.

Community factors:

The knowledge people have about HIV and HIV vaccine trials may influence people's willingness to participate in efficacy trials. Where by those who are less knowledgeable may be stigmatized. Others may be willing to participate in efficacy trials because they perceive themselves to be at risk of acquiring HIV. Some people may be willing to participate because of monetary gain while others may want to participate purely due to altruistic reasons.

Chapter Five

5.0 Methodology

5.1 Study site

This study was conducted in Entebbe Municipality, an urban setting where the international airport is found. It is situated in Wakiso District, approximately 37 kilometers (23 miles), Southwest of Kampala (Uganda's capital). The Municipality is located on a peninsula into Lake Victoria covering a total area of 56.2 square kilometers (21.7 square miles), out of which 20 square kilometers (7.7 square miles) is water. During the 2002 national population census, Entebbe's population was estimated at 55,086 people. In 2008, the Uganda Bureau of Statistics estimated the population of the Municipality at 70,200 of which 51% are females with an estimated HIV prevalence of approximately 7%. Entebbe Municipality hosts the Uganda Virus Research Institute where the HIV vaccine trial's unit is located. There has been a lot of sensitization and awareness about HIV vaccine research in Entebbe by the International AIDS Vaccine Initiative (IAVI) in collaboration with Uganda Virus Research Institute (UVRI). Even though HIV vaccine research has been conducted in this area since 2000, there hasn't been any assessment on knowledge, attitudes and beliefs the Entebbe Municipality residents have about HIV vaccine trials making it a suitable study site for this research.

5.2 Study Population

The study targeted household heads and influential community members that were resident (by birth) of Entebbe, males and females aged 18-50 years, who were willing to provide

written informed consent; this being the age bracket for would be volunteers. Non Ugandans and staff of UVRI-IAVI HIV Vaccine Program were excluded from the study.

5.3 Study design

This was a descriptive cross-sectional study that employed both qualitative and quantitative research methods to achieve its objectives. Data was collected in order to have a quantifiable analysis of the level of willingness to participate in future phase III HIV vaccine trials and to establish factors associated with such willingness.

5.4 Sample size

The sample size was calculated based on the Kish Leslie formula (Kish, 1965) as follows;

$$N = \frac{Z^2 Pq}{e^2}$$

Where;

N = Number of respondents needed

Z = Standard normal deviate at 95% (1.96)

P = Percentage of those willing to participate in HIV vaccine trials from a baseline survey conducted by Kiwanuka et al, 2004 (77 %)*

q = 1-P

e = the maximum acceptable error (6 %)

Substituting:

$$N = \frac{1.96^2 \times 0.77 \times 0.23}{0.06^2} = 189$$

This value was multiplied by 2 in order to take care of the design effect due to sampling errors; Hence, N=189 x 2= 378

A non response rate (x) of 5% was assumed basing on a WTP study conducted in the past to calculate the Adjusted sample size (N^*) *

N^* was calculated as; N/ (1-x%)

Substituting:

N^* = 378/ (1-0.05) = 378/0.95

N^* = **398 respondents**

Bennett's formula was used to calculate the number of villages from which the 398 respondents were selected.

$$C = \frac{P(1-P)D}{S^2 b}$$

Where

C = Number of villages needed

D = Design effect (2)

P = Estimated percentage of those willing to participate in HIV vaccine trials (77%)*

S = Level of precision (6%)

b = Number of households that will be covered in each village (10)

* Kiwanuka N et al (2004) Knowledge about Vaccines and Willingness to Participate in Preventive HIV Vaccine Trials. *A Population-Based Study, Rakai, Uganda.*

Substituting:

$$C = \frac{0.77 \times 0.23 \times 2}{0.06 \times 0.06 \times 10} = 10 \text{ villages}$$

5.5 Sampling Procedure

For the qualitative aspect of the study, participants in Focus Group Discussions (FGDs) and Key Informant Interviews (KIIs) were purposively selected. I used a two stage cluster sampling method to obtain the study unit for the quantitative aspect of this study. Villages from the two divisions of Entebbe Municipality i.e. division A and B were listed using the 2002 National population Household census findings. Using Bennett's formula, 10 villages each with approximately 1,000 households out of those identified were randomly selected. A list of 10,023 households in these villages was obtained from Uganda Beaural of Statistics (for the year 2000) to provide a sampling frame. After the villages were listed in alphabetic order, 40 households were sampled from each of the first eight villages while 39 households were sampled from the remaining two villages in order to get the required 398 households. Systematic random sampling method was used to get the actual households that were interviewed where by every k^{th} household was selected until the required number of households per village was attained (k = 25 i.e. total number of households divided by sample size). The study unit was purposively selected as the household head (An adult resident aged 18-50 years who was willing to provide consent) or designee who happened to be the person next in command from the 398 selected households. Semi structured questionnaires were administered to the household head/ designee.

5.6 Study Variables

5.6.1 Dependent variable

- The dependent (outcome) variable for this study was the proportion of respondents who were willing to participate in future phase III HIV vaccine trials.

5.6.2 Independent Variables

The Independent variables for this study were;

a) Socio-Demographic factors (Age, Sex, Education, Occupation, Marital Status and Religion).
b) Facility factors (Nature of Facility, location of vaccine trials unit and time trial is expected).
c) Community factors (knowledge people have about HIV and HIV vaccine trials, Risk perception, monetary gain and Altruistic reasons).
d) Beliefs, perceptions and attitudes on HIV vaccines and HIV vaccine trials
e) Research/Ethical requirements (blood draws, signing of consent forms and HIV testing).

5.7 Data Collection

Primarily, the data collected was descriptive. A team of four research assistants and the Principal investigator collected data from community participants. Background information on HIV vaccine trials was provided by the interviewers before respondents were interviewed. Five FGDs each comprising of 8-14 members were conducted to establish

community's knowledge, attitudes and beliefs towards HIV vaccines and participation in HIV vaccine trials.

Five FGDs were conducted in different age categories and gender (One female or male FGD of adolescents aged 18-24 years, one mixed FGD of those aged 18-24 years and one female or male FGD of adults aged 25-50 years). A focus group discussant was any eligible member who was in the age and sex category that was desired for a given FGD. These discussions yielded information relevant to study objectives 2, 3 and 4.

Eight KIIs using a Key informant interview guide were conducted with one CAB member, two political leaders, one religious leader, one media representative, one medical personnel, one former HIV vaccine trial volunteer and one representative of the high risk groups. A Key informant was a community resident who was in a position to know the community well. They had a broad knowledge of the community, its services, and its people. KIIs helped to explore further and clarify some of the opinions that were garnered from the FGDs. The interviews also yielded information relevant to study objectives 2, 3 and 4. Local leaders helped in identification of Key informants and FGD members.

The research assistants conducting the discussions and interviews used tape recorders in addition to taking notes to record responses for verbatim transcription. Consent was sought and obtained for both interviews and tape recording.

Quantitatively, 398 Semi-structured questionnaires were administered by the research team (Research assistants and the Principal investigator) to establish the social demographic factors and other contributing factors that influence willingness to participate in future HIV vaccine efficacy trials. The Household head/designee was interviewed for consistency. In

case no eligible respondent in a household was found at home on the first visit, an average of at least three call backs were allowed to get them when they were more likely to be at home. Data generated from the questionnaires yielded information relevant for objectives 1, 2, 3 and 4.

5.8 Data Management and Analysis

Qualitative data from KIIs and FGDs were ordered and statements were categorized for each objective. A summary that reflects the findings from the sessions was prepared. Key statements that emerged, ideas, opinions and attitudes expressed were listed. The data was sorted according to instrument used i.e. KII or FGD and according to groups of respondents i.e., adult females, adult males and adolescents. The data were then coded, merged and analyzed manually using a master sheet with integrated common themes.

Quantitative data were coded and edited before entry in Microsoft Access. Double data entry was done for validation purposes. Statistical analysis was conducted using Stata 10.0 (StataCorp, College Station, USA)

Before analysis, data was cross checked for completeness and accuracy. At univariate analysis data were summarized into meaningful descriptive statistics i.e. frequencies, appropriate proportions and percentages to present categorical variables.

At bivariate level, different independent variables were cross tabulated with willingness to participate in future phase III HIV vaccine trials as the primary outcome variable for the study to find out if any associations existed that were later tested for statistical significance.

Chi square tests and their respective p-values were obtained to assess for the associations using p=0.05 (2-tailed) as a cut-off point for statistical significance.

Appropriate Prevalence Rate Ratios (PRR) with their 95% confidence intervals (CI) were obtained.

At multivariate level, Log-binomial regression models were used to estimate the Adjusted Rate Ratios (ARRs) and the 95% CIs of factors associated with WTP. Models were adjusted for age, gender (potential confounders), statistically significant ($p<0.05$) covariates identified in bivariate analyses, and from findings of other WTP studies.

5.9 Quality Control

To ensure the quality and integrity of the data, the study tools were pre-tested and piloted in Entebbe community before the research was conducted. Supervision of field staff and data entry officers was done. At the end of each day, verification of the data for completeness and consistence was done. Members of the research team had a scientific and research background. The research team was trained prior to commencement of the study on basic HIV vaccine information, HIV vaccine trial requirements and how to complete the study tools.

5.10 Ethical Considerations

Approval process: Permission to conduct this study was obtained from Uganda National Council for Science and Technology through Makerere School of Public Health Higher Degrees Research and Ethics committee (MSPH-HDREC). Permission was also obtained from the District Local Government through the Office of the Mayor, Mr. Kabuye Steven.

Informed Consent: Informed consent was obtained for each participant before they were interviewed. Participants were informed that participation was on a voluntary basis. Participants were also informed of the potential risks and benefits from the study.

Only those aged 18-50 years participated in the study and they each signed a consent form before they were asked any questions. The consent form was either in English or Luganda, the languages commonly used in the area. To ensure confidentiality, study numbers instead of names were used to link information to study participants.

5.11 Study Limitations

a) Non response and concealment of sensitive information as evidenced from previous studies (Kiwanuka et al., 2004) were study limitations. This was however adjusted for in calculation of sample size.

b) This being a Cross sectional study design casual inference is limited.

c) Respondent understanding of different phases was not assessed.

5.12 Dissemination of findings

Study findings will be submitted to Makerere University School of Graduate Studies in form of a dissertation for the award of a master's degree of Public Health. Findings will be disseminated to UVRI/IAVI HIV Vaccine Program and other HIV vaccine research centers in Uganda like Makerere University Walter Reed Program (MUWRP) and Joint Clinical Research Centre (JCRC) in preparation for future HIV efficacy trials. Findings will be submitted to scientific conferences both locally and internationally whenever applicable. Attempts will be made to publish the findings in peer reviewed journals.

Chapter Six

6.0 Results

Eight KIIs and five FGDs were conducted to explore the determinants of willingness to participate in future phase III HIV vaccine trials, the knowledge, attitudes, beliefs and perceptions towards participation in these trials.

Table 1: Description of Key Informants

Category of respondent	Sex	N
Local Political leader	Female	1
Former HIV vaccine trial participant	Male	1
Women representative/Political leader	Female	1
Fisher man/ Representative of High risk groups	Male	1
Religious leader	Male	1
Media representative	Male	1
Community Advisory Board member	Female	1
Medical Officer/Medical representative	Female	1
Total		**8**

Table 2: Description of Focus Group Discussion respondents

Age of respondent	Village	Sex	No. in FGD
25-50 years	Nsamizi	Female	12
25-50years	Kasenyi	Male	12
18-24 years	Lugonjo	Female	8
18-24 years	Nakiwogo	Male	8
18-24 years	Kasenyi	Female and Males	14
Total			**54**

Additionally, semi structured questionnaires were administered to 398 residents of Entebbe aged 18-50 years to further explore the determinants of willingness to participate in future phase III HIV vaccine trials.

Table 3: Socio-demographic characteristics of the 398 respondents

Characteristic	Total number of participants (N)	Proportion (%)
Overall	398	100
Sex		
Male	198	49.8
Female	200	50.3
Age-group (years)		
18-24	81	20.4
25-30	109	27.4
31-39	136	34.2
40+	72	18.1
Schooling level		
None	28	7.0
Primary	152	38.2
Secondary	135	33.9
Tertiary/Other	83	20.9
Currently employed		
Yes	264	66.3
No	134	33.7
Marital status		
Never married(single)	116	29.1
Married	222	55.8
Separated/Divorced/ Widowed	60	15.1
Faith/religion		
Catholic	104	26.1
Anglican/Protestant	132	33.2
Moslem	71	17.8
Born again	91	22.9

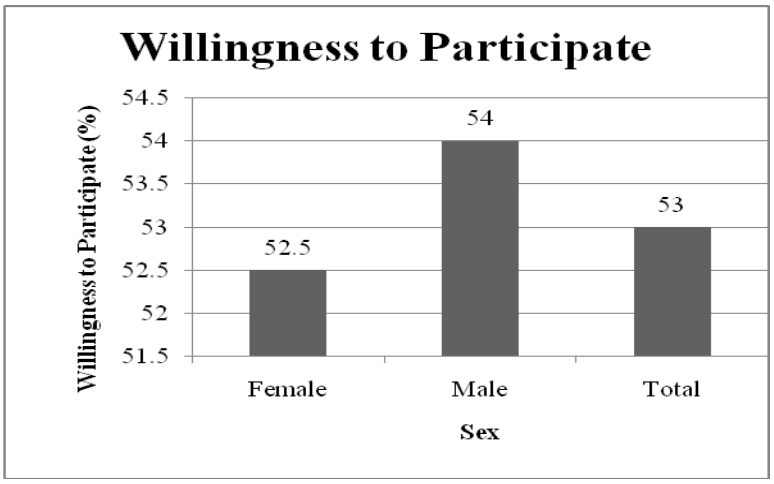
6.1 Socio-demographic Characteristics of respondents (N=398)

Table 3 shows the socio-demographic characteristics of all the 398 respondents. The questionnaires were administered to about the same number of males and females, 198 and 200 respectively. Majority of the respondents (136, 34%) were aged between 31-39 years. The mean age of respondents was 31.7 years (Standard deviation 7.7) while median age was 31 years. Majority (132, 33%) of the respondents were Anglican. Of those interviewed, 222

(56%) were married customarily or religiously. Eighty three (21%) had attained tertiary education, 135 (34%) secondary education, 152 (38%) primary education while only 28 (7%) had attained no education. Majority 264 (66%) of the participants where employed either formally or informally.

6.2 Willingness to participate (WTP) in future phase III HIV vaccine trials

Figure1: Willingness to participate in future phase III HIV vaccine trials



On average, just about half of the respondents (212, 53%) expressed willingness to participate in future phase III HIV vaccine trials where by 54% of males and approximately 53% of females expressed willingness to participate in these trials. There was no significant statistical difference in willingness to participate between males and females (p=0.793).6.2.1 Reasons for willingness to participate

Table 4: Reasons for willingness to participate in future Phase III HIV vaccine trials

Reason	Total number of participants (N)	Proportionate distribution (%)
Prevention from HIV	108	50.9
Get an HIV vaccine	76	35.8
Free medical care	61	28.28
At risk of HIV	48	22.6
Monetary gain	42	19.8
Know my HIV status	40	18.9
Be an example	29	13.7
Get Condoms	8	3.8

As shown in table 4, the most commonly stated reason for WTP in phase III HIV vaccine trials is prevention or protection from HIV ,51%. Meanwhile 36% wanted to help get an HIV vaccine, 28% to get free medical care, 23% considered themselves at risk of getting HIV, 20% wanted to get money, 19% to know their HIV status, 14% to be an example to the rest and 4% wanted to get condoms.

6.2.2 Factors associated with willingness to participate

At bivariate level, willingness to participate, the dependent variable was cross tabulated against different explanatory variables, and a pearson Chi-square test statistic was run at a 95% confidence interval as shown in Table 5.

Table 5: Factors associated with willingness to participate in future Phase III HIV vaccine trials

Sex	Willing/total	Proportion willing (%)	Unadjusted PRR (95%CI)	Adjusted RR (95%CI)	P-value
Overall	212/398	53.3			
Sex					*0.812*
Male	107/198	54.0	1	1	
Female	105/200	52.5	0.97 (0.81,1.17)	0.97 (0.81,1.16)	
Age					*0.948*
18-24	46/81	56.9	1	1	
25-30	58/109	53.2	0.94 (0.72,1.21)	0.94 (0.73,1.21)	
31-39	73/136	53.7	0.95 (0.74,1.21)	0.97 (0.76,1.23)	
40+	35/72	48.6	0.86 (0.63,1.16)	0.88 (0.65,1.19)	
Whether employed					*0.462*
Employed	145/264	54.9	1	1	
Unemployed	67/134	50.0	0.91 (0.74,1.11)	0.90 (0.74,1.09)	
Marital status					*0.921*
Single	65/116	56.0	1	1	
Married	115/222	51.8	0.92 (0.75,1.14)	0.94 (0.77,1.16)	
Separated/divorced/widowed	32/60	53.3	0.95 (0.71,1.27)	0.99 (0.75,1.31)	
Education level					
<Primary	15/28	53.6	1	1	*0.727*
Primary	89/152	58.6	1.09 (0.75,1.58)	1.05 (0.74,1.50)	
Secondary	71/135	52.6	0.98 (0.67,1.44)	0.96 (0.66,1.39)	
Tertiary	37/83	44.6	0.83 (0.55,1.27)	0.85 (0.56,1.27)	
Definition of HIV infection					*0.45*
Correct	164/315	52.1	1	1	
Incorrect	48/83	57.8	1.11 (0.90,1.37)	1.13 (0.93,1.39)	
Heard of HIV vaccines					*0.744*
Yes	65/128	50.8	1	1	
No	147/270	54.4	1.07 (0.88,1.31)	1.05 (0.86,1.28)	
Use of HIV vaccine					*0.638*
Prevention	143/258	55.4	1	1	
Cure	24/46	52.2	0.94 (0.70,1.27)	0.91 (0.68,1.22)	
Don't know	45/94	47.9	0.86 (0.68,1.10)	0.86 (0.67,1.09)	
Existence of HIV vaccine today					*0.089*
Yes	5/17	29.4	1	1	
No	116/197	58.9	2.00 (0.95,4.22)	1.99 (0.95,4.18)	
Don't know	91/184	49.5	1.68 (0.79,3.57)	1.57 (0.74,3.32)	
Heard of HIV vaccine trials in community					*0.606*
Yes	33/69	47.8	1	1	
No	179/329	54.4	1.14 (0.87,1.48)	1.10 (0.85,1.43)	
Ever participated in trial					*0.413*
Yes	8/13	61.5	1	1	
No	204/385	53.0	0.86 (0.55,1.34)	0.73 (0.49,1.10)	
Should conduct Phase III HVT					*0.001**
Yes	207/365	56.7	1	1	
No	05/33	15.1	0.27 (0.12,0.60)	0.28 (0.13,0.64)	
Important to get HV vaccine					*0.027**
Yes	204/366	55.7	1	1	
No	08/31	25.8	0.45 (0.24,0.82)	0.49 (0.27,0.90)	
Community support for HVT					*0.001**
Yes	158/236	66.9	1	1	
No	12/49	24.5	0.37 (0.22,0.60)	0.39 (0.24,0.65)	
Don't know	42/113	37.2	0.56 (0.43,0.72)	0.57 (0.44,0.74)	

* *Statistically significant (p<0.05), CI= Confidence Interval)*

It was found that there was no significant statistical difference in willingness to participate between males and females as shown in table 5 (p=0.793). Respondents aged 18-24 years

were more willing (56%) to participate in these trials as compared to the older respondents but the difference was also not statistically different. WTP for the married was higher than that for those not-married (single, divorced/separated and widowed) but the difference was not statistically significant (PRR 0.92 (95% CI 0.75,1.14)) The other socio-demographic variables that were explored and did not show any significant statistical differences in relationship to willingness to participate included, education level attained and employment status($p>0.05$).

Variables that indicated significant statistical differences in relation to willingness to participate in HIV vaccine trials included religion, perception that Phase III HIV vaccine trials should be conducted, that it is important to get an HIV vaccine and that the community would support Phase III HIV vaccine trials.

At multivariate level, Log-binomial regression models were used to estimate the adjusted risk ratios (ARRs) and the 95% CIs of factors associated with WTP as shown in Table 4.

After adjusting for confounding, age, employment , marital status and education level still did not have significant statistical difference in relation to willingness to participate in vaccine trials ($p >0.05$). At first, religion seemingly had a significant influence on willingness to participate in phase III HIV vaccine trials ($p=0.002$). Catholics seemed to be more likely to be willing to participate compared to Anglicans, Born-Agains and Muslims. After adjusting for sex and residence, this was later found to be no longer statistically significant. Attitudes towards conduct of phase III HIV vaccine trials remained statistically significant factors that influence willingness to participate ($P<0.05$). Respondents who said that phase III HIV

vaccine trials should not be conducted were less likely to be willing to participate in future phase III HIV vaccine trials as compared to those who thought that they should be conducted [ARR 0.28, (95% CI 0.13 – 0.64)]. Similarly, those who believed that it was not important to get an HIV vaccine were less likely to be willing to participate in these trials compared to those who thought it was important to get an HIV vaccine [ARR 0.49, (95% CI 0.27 – 0.90)]. Also those who thought that people in their community wouldn't support the conduct of phase III HIV vaccine trials were less likely to be willing to participate in these trials compared to those who thought that people in their community would support the conduct of phase III HIV vaccine trials[ARR 0.39, (95% CI 0.24 – 0.65)].

6.2.3 Reasons for unwillingness to participate

Table 6 shows reasons for unwillingness to participant in phase III HIV vaccine trials. A total of 186 respondents were unwilling to participate in a phase III HIV vaccine trials. Majority, (105, 57%) were unwilling due to fear of side effects; due to fear of getting HIV/AIDS from the vaccine, 93 (50%) while 23% were concerned about the long study duration and 16% feared to talk about their sex life. Of those interviewed, 30 women (16%) feared that their husbands wouldn't allow them to participate while 18 (10%) were not willing to be on any family planning method. Other reasons for non participation included not wanting to know ones' HIV status (14%), not willing to be on FP (10%), site not being accessible (5%), concern about stigma and discrimination (4%**).**

Table 6: Reasons for unwillingness to participate in future Phase III HIV vaccine trials

Characteristic	Total number of participants (N)	Proportionate distribution (%)
Total Unwilling to participate	186	46.7
Reasons for unwilling to participate		
Fear side effects	105	56.5
Fear to contract HIV from vaccine	93	50.0
Long study duration	42	22.6
My husband may not allow	30	16.1
Fear to talk about my sex life	30	16.1
Don't want to know HIV status	26	14.0
Not willing to be on FP	18	9.7
Site not accessible	10	5.4
Stigma and discrimination	7	3.8

Similarly, some FGD respondents (34%) didn't want to know their HIV status and thus were not willing to participate in the trials. One respondent said; "*…… I was once contacted by a person to participate in the trials, at first I accepted but when she told me that I had to test for HIV I feared. I am sure many people will opt out because of similar fears……*"

FGD participate – Entebbe – Nsamizi

Women concerns included gender roles, pregnancy, family planning and the potential adverse effects a candidate vaccine may have on a fetus. One FGD respondent said,

"*…….. women often carry additional responsibilities of child birth, childcare, care of the elderly and the sick in addition to housework, so as a woman I may not be able to get time for frequent clinic visits……*" ***FGD participant –Kasenyi***

Still among the women lack of empowerment, limited decision-making and low education status reduced willingness to participate in efficacy trials. It was evident from the FGDs and KIIs that many married women do not have the freedom to make their own decisions about

HIV testing or participating in research. One respondent who happened to be a married woman commented: *"……. if I am to participate in those trials, I will require consent from my husband who must fully understand what receiving a candidate HIV vaccine does or does not do to my health'. For the men, once they've decided, it's done. They may choose to inform their wives or partners, but the decision is theirs....."* ***FGD participant –Nsamizi***

Overall, 91 (49%) of those who were not originally willing to participate said they would change their minds to participate if their concerns were addressed.

6.3 Knowledge about HIV/AIDS

Efforts were made to document knowledge about HIV. Table 7 shows the respondent's knowledge of HIV in regard to what it is, how it is spread and how it is prevented. Accordingly, 315 (79%) correctly defined HIV infection. Almost all participants, 389/398 (98%) mentioned that HIV was spread through having unprotected sexual intercourse with an infected person while 149 (37%) were aware that it could be spread via transfusion with infected blood and 242 (61%) through contaminated sharp instruments including accidents. Very few 91 (23%) reported HIV spread from an infected mother to her child through breastfeeding. Despite high literacy levels noted, 18 (5%) respondents reported that HIV can be spread via kissing, mosquito bites, witchcraft and sharing cooking utensils with those infected. In regard to HIV prevention, 263 (66%) respondents knew that HIV could be prevented through abstinence, 219 (55%) through faithfulness and 267 (67%) through consistent and correct use of condoms. Very few, 25 (6%) knew about PMTCT and the role of circumcision in prevention of HIV infection. Only 48 (12%) knew that HIV could be prevented by avoiding sharing sharp unsterile instruments.

Table 7: Knowledge about HIV/AIDS

	Willing to participate		P-value	Unwilling to participate		Total
	n	%		n	%	N
Overall	212	53.3		186	46.7	398
HIV definition						
correct definition	164	52.1	1	151	47.9	315 (79.1%)
incorrect definition	48	57.8	0.349	35	42.2	83 (20.9%)
How HIV is spread						
Unprotected Sex	209	53.7	1	180	46.3	389 (97.7%)
Breast feeding	39	41.8	0.030	53	58.2	91 (22.9%)
Blood transfusion	73	49	0.186	76	51	149 (37.4%)
Sharing sharp instruments	143	59.1	0.004	99	40.9	242 (60.8%)
Kissing, Mosquito bites, witchcraft	12	66.7	0.070	6	33.3	18 (4.5%)
How HIV is prevented						
Abstinence	140	53.2	1	123	46.8	263 (66.1%)
Faithfulness	103	47	0.006	116	53	219 (55%)
Consistent & correct condom use	155	58.1	0.005	112	41.9	267 (67.1%)
PMTCT and Circumcision	15	60	0.486	10	40	25 (6.3%)
Not sharing sharp instruments	30	62.5	0.172	18	37.5	48 (12.1%)

Information gathered from FGDs and KIIs revealed that community members are knowledgeable about HIV/AIDS however; there are many false beliefs that still exist concerning spread and prevention of HIV. In one of the FGDs, one respondent said;"…….*If a woman sleeps with a man who is infected with HIV and she bathes thoroughly with a lot of emphasis on her private parts, she cannot get HIV especially if the bath is before 24 hours from the time of sexual intercourse…"* ***FGD participant –Kasenyi***

Another respondent said; "…..*If a commercial sex worker sleeps with different men without using a condom but uses coca-cola to thoroughly wash her private parts every after sexual intercourse, she can't get HIV…"* ***FGD participant –Kiwafu.***

Another respondent said; "……*Commercial sex workers swallow two tablets of septrin before having sex. They believe that this is enough even if they don't use condoms because the septrin swallowed can burn down the HIV the moment it enters the body……."* ***FGD participant –Kasenyi***

Another respondent said; "…..*If one uses two condoms at ago, he gets better protection than the one who uses a single condom….."* ***FGD participant –Nsamizi.***

Another respondent said; "….*When one uses withdraw method during sexual intercourse, one cannot catch HIV even when sleeping with an infected partner; because HIV is only in the fluids the partners produce when they climax but when the man withdraws and climaxes from outside, then there is no harm…."* ***FGD participant –Nakiwogo***

Of the fifty four people who attended the FGDs, Sixteen (30%) believed that anyone with blood group O is resistant to HIV. One respondent in that regard commented that, *"……HIV/AIDS has its customers it kills and the non-customers. Customers are those who are very afraid of it, do their best to prevent it but only make one mistake of exposure to infection and they are infected. Non customers are not afraid of it, they take no measure in preventing it and in the end they stay free from HIV…."* ***FGD participant –Nakiwogo***

6.4 Perceived sense of personal risk

Table 8 shows the perceived sense of personal risk of the respondents. More than half 247(62%) of the respondents perceived themselves to be at risk as opposed to 95 (24 %) who perceived themselves not at risk of acquiring HIV and 56(14%) who didn't know their risk status. Several reasons were given for those who thought were at risk for HIV and these included; (74%) for not using a condom at all sexual encounters, (44%)due to mistrust of the safety of condoms, (16%) due to uncertainty about a spouse's sexual behavior, and (48%) due

to uncertainty of the safety measures during delivery. Reasons cited for not being at risk for HIV included not having had sex with other partners other than regular sex partner (40%), trusting the spouse for the married participants (23%) and abstaining from sex or using condoms for the non-married (37%).

Table 8: Perceived sense of personal risk

Risk perception for HIV	Characteristic	Number of participants	Proportionate distribution (%)
Considered them selves at risk(n=247)			
	Male	127	51.4
	Female	120	48.6
	Over all	247/398	62.1
Reason why at risk			
	Not using a condom at all sexual encounters	94/127	74
	Mistrust of the safety of condoms	56/127	44.1
	Uncertainty about a spouse's sexual behavior	40/247	16.2
	Uncertainty of the safety measures during delivery	57/120	47.5
Considered them selves not at risk (n=95)			
	Male	62	65.3
	Female	33	34.7
	Overall	95/398	23.9
Reason why not at risk			
	Not having had sex with other partners other than regular sex partner	38/95	40
	Trusting the spouse	22/95	23.2
	Abstaining from sex or using condoms	35/95	36.8
Do not Know (n=56)			
	Male	34	60.7
	Female	22	39.3
	Overall	56/398	14.1

A respondent from one of the FGDs commented; "…..*Because I am married then I am at risk since HIV is now more common among those married…..*" ***FGD participant –Nsamizi***

Overall, 56 (14%) could not tell whether they had been at risk or not. HIV risk perception did not vary with marital status as the difference in risk perception was not statistically

significant for the different marital status categories (p=0.786, 95% CI: 0.334 – 2.246). Gender differences also seemed not to influence HIV risk perception as there was an almost equal number of males and females who perceived themselves to be at risk of acquiring HIV (127 versus 120 respectively).

6.5 Knowledge about HIV vaccines and HIV vaccine trials

Table 9 shows the knowledge respondents had about HIV and HIV vaccine trials. Only 128 (32%) had ever heard about HIV vaccines before and 258 (65%) new that they were for HIV prevention as opposed to 46 (12%) who thought they were for HIV cure. Overall, 94 (24%) did not know what HIV vaccines were for. When asked whether a HIV vaccine was in existence, a very small number of respondents 17 (4%) thought that the HIV vaccine was already in existence while 197(50%) said it was not yet in existence and 184 (46%) didn't know whether or not it was in existence. The majority (329, 83%) of respondents interviewed had never heard about HIV vaccine trials being conducted in their community. Only 69 (17%) had ever heard about HIV vaccine trials being conducted in their community. Of those who had ever heard about HIV vaccine trials, majority 49 (71%) got to know from TV/Radio talk shows while the least 10 (15%) got to know from information seminars.

Table 9: Knowledge about HIV vaccines and HIV vaccine trials

	Male		Female		Total	
		Proportion distribution		Proportion distribution	Total	Proportion distribution
	N	%	N	%	N	%
Total	198	100	200	100	398	100
Ever heard of HIV vaccines (yes)	59	29.8	69	34.5	128	32.2
Use of HIV vaccines						
HIV Prevention	122	61.6	136	68	258	64.8
HIV Cure	24	12.1	22	11	46	11.6
Don't know	52	26.3	42	21	94	23.6
Existence of an HIV vaccine						
Yes	6	3.0	11	5.5	17	4.3
No	101	51.0	96	48	197	49.5
Don't know	91	46.0	93	46.5	184	46.2
Heard about vaccine trials in community						
Yes	39	19.7	30	15	69	17.3
No	159	80.3	170	85	329	82.7
How they got to know about HIV vaccine Trials among those who heard						
Total who heard about HIV vaccine trials	39	100	30	100	69	100
Newsletters/brochures	6	15.4	6	20	12	17.4
Information seminar	5	12.8	5	16.7	10	14.5
TV radio	31	79.5	18	60	49	71
Friend/relative/former participant	18	46.2	11	36.7	29	42

Information gathered from FGDs revealed that some discussants (36 %) had heard of attempts by scientists around the world, making efforts to develop and test HIV/AIDS vaccines.

One respondent said that,"… *HIV vaccine exists* in *some developed African countries and it's used by the rich; very soon it will become cheap and affordable to everyone…."* ***FGD participant– Nsamizi.***

About a quarter of the FGD discussants believed that HIV vaccine research and other researches connected to HIV were meant to infect those who are not yet infected so that Africans die faster because they are a huge population. Although 34 (63%) among the FGD

respondents thought it was important to develop an HIV vaccine, only 19 (35%) were aware that HIV vaccine trials had ever been conducted within their community. Compared to adults, adolescents were more knowledgeable about HIV vaccine trials (21% and 48% respectively). Using a Pearson correlation test, however, there was no statistically significant difference of the knowledge about vaccine trials comparing males to females (p=0.306). Of the eight Key Informants interviewed, only one respondent had ever participated in HIV vaccine trials before. All the eight key informants were aware of the HIV vaccine trials within the area and knew that there is currently no HIV vaccine. However, three of these Key informants were Community Advisory Board members (CAB).

6.5.1 How to improve knowledge about HIV vaccines and HIV vaccine trials

Five (63%) of the Key informants suggested that other innovative strategies like music, dance and drama should be used to sensitize the public prior to recruitment into efficacy trials. They recommended public addresses in schools, worship places and other public gatherings. They strongly advised scientists to involve community members in planning and implementation of these trials.

6.6 Attitudes, beliefs and Perceptions towards participation in HIV vaccine research

Table 10 shows the attitudes, beliefs and perceptions respondents had towards participation in future phase III HIV vaccine trials.

Table 10: Attitudes, beliefs and Perceptions towards participation

Attitude/Perception/belief	Total number of participants (N)	Proportion with response (%)
HIV vaccine trials recruit HIV infected people	40	74
Participation in HIV vaccine research makes people think you are HIV infected	29	54
People will participate to get free HIV-VCT services	24	44
HIV research is taking so long and it is a waste of time	20	37
HIV vaccine research leads to Promiscuity and hence increased HIV infection	17	32
Vaccines are for women and children	7	13

While discussing with the community members in different FGDs, it was noted that people had divergent beliefs and perceptions about participation in HIV vaccine research. Forty out of the fifty four (74%) people believed that HIV-infected people were appropriate for participation in HIV vaccine trials despite the notably high literacy status by majority of the community members. Some men (13%) thought vaccines were for children and pregnant females so they didn't think it was necessary for them to participate in future phase III HIV vaccine trial.

Some of the respondents (32%) believed that participation in phase III HIV vaccine trials would lead to increased promiscuity and HIV infection.

Some respondents (44%) believed that some people will participate only because they want to get free HIV Voluntary Counseling and Testing (VCT) services. To some respondents, HIV vaccine research was seen as a trial and error method not scientifically proven where by participating in the trials was perceived as risking one's life. *"…… people think the HIV vaccine is like other vaccines which contain weakened or killed organisms that cause disease. They don't know how vaccines are made ……"* ***key informant.***

Some respondents (54%) said that once one is discovered to be participating in the HIV vaccine trials, he/she is isolated in the community. This is because you are perceived as being HIV positive and thus all the stigmatization related to HIV positive people is shifted towards the participant. Some FGD respondents (37%) reported not to be seeing any success in finding the solution to HIV through vaccine trials. These respondents said the trials were taking so long. They think participating in Phase III HIV vaccine trials is such a long wait for people who want immediate results.

Chapter Seven

7.0 Discussion

7.1 Introduction:

In preparation for future Phase III HIV vaccine trials, this study set out to establish the level of willingness of Entebbe Municipality residents to participate in these trials and the factors associated with such willingness. It also assessed the knowledge residents have about HIV, HIV vaccines and HIV vaccine trials; their attitudes, perceptions and beliefs towards participation in Phase III HIV vaccine trials so as to inform future community education and recruitment strategies.

7.2 Willingness to participate in future Phase III HIV vaccine trials

The level of willingness to participate in future Phase III HIV vaccine trials in this community was relatively low (53%) compared to findings from some earlier WTP studies in Uganda which showed a higher level of WTP in HIV vaccine trials ranging from 77% to 90% (Ruzagira et al.,2009; Kiwanuka et al.,2004 ; McGrath et al.,2001). These studies were different in that they did not specifically assess WTP in phase III HIV vaccine trials and were conducted in areas with a higher disease burden. The level of WTP is however higher than that reported from Thailaind studies among the army which ranged from 25 to 30% (Celentano et al., 1995; Jenkins et al, 1995 and Jenkins et al., 2000). It was also higher than that from a study conducted in British Columbia in Canada which assessed the extent to which HIV-negative cohort study participants would be willing to participate (WTP) in future HIV

vaccine trials, explored enrollment into an ongoing phase 3 HIV vaccine trial and assessed changing WTP in such trials over time which revealed a WTP level of 48.6% (O'Connell, 2002). More WTP studies may be required to assess WTP in phase III HIV vaccine trials especially since the requirements of a phase I/II trial are different from those of a phase III trial. Findings from the first trial of the HIV-1 vaccine in Uganda by Mugerwa et. al., (2002) revealed that adolescents participated more than adults. Similarly, this study showed that adolescents are more likely to be willing to participate in efficacy trials than adults.

7.3 Reasons for willingness to participate

Individual, community and facility factors tended to influence WTP in future phase III HIV vaccine trials where by willingness to participate were embedded within a context of scientific, cultural, emotional and cognitive factors. Consistent with findings from a WTP study conducted by McGrath et al., (2001) in Uganda, willingness to participate was mainly attributed to the anticipation that the study vaccine would prevent or protect participants from HIV. Additionally, people who perceived themselves at risk of HIV infection were highly willing to participate in efficacy trials, a finding that also reflects anticipation of protection. It is important that people understand that when participants are enrolled in these studies, it is not a guarantee that they would be protected and should therefore engage in high risk behaviors for acquiring HIV. Repeated and ongoing vaccine trial education is mandatory to achieve adequate understanding of the implications of trial participation.

The other reason given for WTP was the desire to have a protective vaccine that will save future generations from HIV infection. This is consistent with findings from earlier studies that were conducted in areas that are greatly affected by the pandemic. Effective anti-

retroviral therapy has slowed the epidemic in some industrialized countries worldwide but there are still an estimated 15,000 new HIV infections occurring daily. In addition to the vast personal suffering, the loss of young adult parents, caretakers, and wage-earners, HIV has created an unprecedented strain on the social and economic aspects of many developing countries, particularly in Sub-Saharan Africa. It is in fact not surprising that the magnitude and impact of the pandemic is a driving force for participation in HIV vaccine research in countries where the disease burden is great.

As earlier noted, adolescents were among those who were willing to participate in future efficacy trials. However, participation of adolescents in research may require them to first seek consent from their parents and or guardians. Some of the school going adolescents even though willing to participate may be limited by the fact that they may not be able to keep their appointments due to lack of time. Therefore, while planning for efficacy trials, adolescent issues and concerns shouldn't be neglected by researchers.

Vaccine trial participation may also be influenced by perceived benefits. In a 1995 study in Thailand, health-related benefits, including enrollment in health insurance plan, were the most valued incentives (Celentano et al., 1995). In this study, 20% of the respondents cited monetary gain as the reason for willingness to participate in these trials. This finding is dissimilar to findings from studies conducted in more developed countries like Brazil and USA whose social economic status is higher (Périssé et al., 2003; Koblin et al., 1998). Where as in developed countries the biggest concern may be health, in developing countries resources to cover basic needs are limited. It is therefore not surprising that people from these regions tend to embrace any opportunity where financial gain is anticipated.

The opportunity to know one's HIV status was found to be another factor influencing WTP. This is in agreement with findings from other WTP studies conducted in Uganda by Ruzagira et al., (2009) and Kiwanuka et al., (2004). HIV testing services in Uganda are not yet widely accessible by the public and any opportunity for people to access such services at no cost would be embraced. Other benefits that were noted to influence WTP included free condoms and free medical care which further points to the inadequate health services in the country. The desire to be a role model in the fight against HIV/AIDS was expressed by some respondents as the reason they would be willing to participate in efficacy trials.

7.4 Reasons for unwillingness to participate

Risk of getting unknown side effects had the largest impact on WTP. This was similar to findings in a study conducted in Thailand where concerns about long-term vaccine side-effects such as fear of disability and death were important barriers to participation in 36-58% of participants (Celentano et al., 1995). Potential participants need to know that by the time vaccine candidates reach phase III, researchers have substantial knowledge about safety of the candidates. Potential participants should also be informed that when trials are being conducted, volunteers are compensated in case they suffer life long injuries due to the study vaccines or following any procedure related to participating in research.

Vaccine-induced HIV infection was another reason that was given for unwillingness to participate. Although current trials are conducted on synthetic/recombinant candidate vaccines that pose no risk of HIV infection, a study conducted in USA also showed that majority of U.S. adults believe that HIV vaccines may cause HIV infection (Allen et al., 2005). A similar trend was observed in a study in Brazil where the main reason (40%) for not

participating in vaccine trials was being afraid of getting infected by the vaccine (Greco, 2000). Because HIV vaccine research is a new concept in Uganda, it's not surprising that some community members are not aware that the candidate vaccines pose no risk of HIV infection.

Gender issues play a role in hampering the levels of WTP where in most cases married women envisage first seeking consent from their spouses before they can decide to participate. According to the 2008 UNAIDS report, females are disproportionately more infected with the HIV/AIDS pandemic. This study shows that some married women are unwilling to participate in HIV efficacy trials because they are afraid their husbands will not allow them to participate. On the other hand, research requirements may not favor some married women because research dictates that women should not be pregnant, breast feeding or conceive for a specified period while in a trial. In a cultural setting where a woman's perceived worth is often tied to her fertility, it is inevitable that trial requirements that she avoid pregnancy during the course of the trial affect willingness to participate and actual participation of some women (Kapoor & Becker 2004). In order to ensure that AIDS vaccines work for both women and men, that they meet women's needs, and that women, especially young women, eventually have access to them, gender issues must be carefully planned for to foster implementation of efficacy trials. Biological differences in the risk of infection and viral load may lead to differences in effect of the vaccine on women and men (Kapoor & Becker 2004). In order to distinguish such trends, significant numbers of women and men have to be included in efficacy trials.

Stigma and discrimination was another reason why some people were not willing to participate in future Phase III HIV vaccine trials. These findings are indeed in agreement with findings from an Indian study which assessed perceptions of a community sample about participation in future HIV Vaccine Trials where 34% of the participants cited concerns about discrimination following participation in HIV vaccine research (Nyamathi et al., 2007). As with other AIDS interventions, participation in HIV vaccine research may lead to stigma and discrimination because some people think that HIV vaccine trial participants have to be HIV positive before they are recruited. Willingness to participate in such trials will be reduced for some individuals for fear of being tagged HIV infected. Some respondents fear that if they participated, they would be stigmatized as high risk and therefore face discrimination and stigma or social isolation by fellow community members. Stigma may also explain why WTP was hampered in some participants who feared to talk about their sex life and those who feared to know their HIV status. To counter such fears, researchers have to sensitize the public about research inclusion criteria and the aspect of confidentiality during conduct of clinical research.

7.5 Knowledge about HIV/AIDS

The HIV pandemic has grown to become one of the greatest infectious disease threats to human health. Nearly 60 million persons are living with HIV infection and more than 25 million people have already died from HIV related causes world wide (UNAIDS, 2009). Sub-Saharan Africa bares the biggest burden of HIV- AIDS. HIV/AIDS awareness levels in this study population were found to be high which is consistent with findings from a similar study conducted in south western Uganda by Ruzagira et al., (2009). The majority of

respondents (79%) correctly defined HIV infection and were aware of its different modes of spread and prevention. However, congruent to other WTP studies conducted in Uganda by McGrath et al., (2001) and Ruzagira et al., (2009) some people still hold on to negative beliefs about HIV spread and prevention causing them to neglect the behavioral and biomedical preventive measures for HIV infection. For example, despite the high literacy levels noted, a few respondents (5%) still reported that HIV can be spread via kissing, mosquito bites, witchcraft and sharing cooking utensils with those infected. Also note worthy is the fact that very few (6%) know about PMTCT and the role of circumcision in prevention of HIV infection. This highlights the need for further education about HIV spread and prevention in this community.

7.6 Perceived sense of personal risk

The perceived sense of personal risk for acquiring HIV in this population was high (62%) with risk of acquisition being mainly attributed to not using a condom at all sexual encounters. This indicates that the study population is a high risk population that may be suitable for phase III HIV vaccine trials and that there is still need to emphasize HIV prevention messages in this population. Sexually active people who are not mutually monogamous must know about condoms, know that condoms prevent AIDS, know how to get condoms, and know how to use them correctly and consistently (Denis, 1998). Risk reduction counseling and HIV preventive approaches need to be vigorously pursued in this community.

7.7 Knowledge about HIV vaccines and HIV vaccine trials

In recent years, significant progress has been made towards development of safe and effective HIV/AIDS vaccines. Several candidate vaccines, now in development, have shown promise in preliminary human clinical trials and non human primate studies and there is now a greater focus on the development of vaccines applicable for use in developing countries. The concept of HIV vaccines and HIV vaccine research is still new to Ugandans. In this study, respondents were told what the different phases in HIV vaccine research entailed and were helped to understand the difference between the phases. Generally, there was low awareness of HIV vaccines within the studied community. In an effort to find out the level of awareness about HIV vaccines, participants were asked if they had ever heard about HIV vaccines before. Accordingly, majority (68%) had never heard about HIV vaccines and 24% did not even know what HIV vaccines were meant for. It was surprising to find that much as HIV vaccine trials had previously been conducted in the Municipality, majority of the respondents (83%) were not aware of the research undertakings in their community. A similar trend was observed in a study in Brazil where the participants reported not having enough information (23.8%) about HIV vaccines and HIV vaccine trials (Greco, 2000). The main source of knowledge for the few who had heard about previous HIV vaccine research was reported to be electronic media. Since a big percentage is employed, it is possible that not many get the time to watch television and listen to radio.

Adolescents were slightly more knowledgeable about HIV vaccine trials compared to adults mainly due to school HIV awareness seminars normally organized by researchers like International AIDS Vaccine Initiative (IAVI). The Community Advisory Board members

(CAB) were also knowledgeable about HIV vaccine trials. CAB members play a vital role of linking the researchers to communities by advising on recruitment, culture and ethics. They are usually informed about research proceedings or undertakings. This most likely explains why their knowledge about HIV and HIV vaccines was higher than the other respondents. In preparation for upcoming efficacy trials, HIV vaccine research education needs to be prioritized so as to ensure informed consent.

The best study participants are those who understand the research, the possible risks involved, the procedures that will be followed, and their rights if they decide to enroll. The communities from which study participants are recruited require knowledge about the process, benefits and risks of study participation to enable potential participants to make knowledgeable decisions to participate in efficacy trials. The difference between how an HIV vaccine is made in comparison to the routine vaccines has to be emphasized by the researchers to avoid confusion. Since the knowledge people have about these trials may greatly influence their willingness to participate, improving community and individual knowledge through continuous education about phase III HIV vaccine trials will help ensure informed consent and improve willingness to participate in these trials.

To obtain valuable socio-cultural and behavioral information, community representatives and key stakeholders need to get involved in extensive dialogue with the researchers about pertinent HIV vaccine research (Vasquez et al., 1993). Community representatives and key stakeholders are highly respected by the community members and may at times be consulted by them before participation in research, its therefore important that they get the

right information on HIV vaccine research. If they are well informed and engaged, they can help dispel some myths and misconceptions.

7.8 Attitudes, perceptions and beliefs towards participation

Although the main interest in conducting phase III HIV vaccine trials is the desire to get a vaccine that will control the pandemic, community members had different attitudes and perceptions towards this initiative. Similar to findings from other WTP studies conducted in Thailand, the attitudes and beliefs towards participation in future efficacy trials are influenced by the individual and community knowledge that exists about HIV, HIV vaccines and HIV vaccine research in general (Celentano et al., 1995; MacQueen et al., 1999). The fact that the AIDS pandemic has infected and affected many in the country, explains why many people are willing to support endeavors that will lead to prevention of further spread of HIV. However, for some individuals conducting HIV vaccine research in developing countries raises concerns about the motives behind such research and whether the trials would be beneficial or harmful to them. The belief that Africans are being used by whites for research as guinea pigs could be a major hindrance to participation in future efficacy trials. To counter such beliefs, it is important that researchers work closely with communities and other stakeholders to emphasize that HIV vaccine trials are held to the highest international ethical standards. It is also important to ensure that communities and stakeholders are aware that trials are closely reviewed and monitored through out their progress.

Misconceptions regarding the nature of experimental vaccines used are seen to greatly influence WTP in these trials. This points to the need of emphasizing safety issues of the vaccines used to community members as these may influence WTP in future phase III HIV

vaccine trials. The public must be aware that HIV vaccine trials cannot be commissioned by national and international regulatory bodies if they were to expose participants to HIV infection or other devastating side effects. When experimental vaccines cause adverse effects to volunteers, these effects are managed accordingly by researchers. Entebbe community members believed that HIV vaccine trials enroll HIV infected people a finding that was similar to findings from a WTP study in south western Uganda (Kiwanuka et al., 2004). The false belief that HIV vaccine trials enroll HIV infected individuals clearly shows that there is still a gap in knowledge about the eligibility criteria used for trials. This lack of awareness on eligibility criteria for the vaccine trials is a key issue affecting WTP that researchers will have to address in order to influences attitudes, perceptions and beliefs towards participation in these trials.

The belief that HIV vaccine research leads to promiscuity and hence increased HIV infection in 32% of respondents was similar to findings from an Indian study which assessed perceptions of a community sample about participation in future HIV vaccine trials (Nyamathi et al., 2007). This shows that there is a gap in knowledge regarding the concept of research. Communities need to be aware that before a phase III clinical trial is completed and the data analyzed, no one knows whether any experimental AIDS vaccine is protective and volunteers cannot assume that they are protected against HIV. Education and counseling about the dangers of engaging in risky behavior during and after participating in phase III HIV vaccine trial will be necessary before the trials begin.

Chapter Eight

8.0 Conclusion and Recommendations

8.1 Conclusion

This study shows that willingness to participate (WTP) in future phase III HIV vaccine trials is low in this urban study population compared to that from rural settings in Uganda. WTP however, does not vary substantially by socio-demographic characteristics. Therefore, future phase III HIV vaccine trials may not require targeting of population subgroups.

Willingness to participate is embedded within a context of scientific, cultural, social and cognitive factors where by people who think efficacy trials need to be conducted, those who believe it is important to get an HIV vaccine and those who think people in the community will support the conduct of these trials are more likely to be willing to participate. Safety concerns, unknown benefits and risks of participation and lack of awareness of the eligibility criteria for participation greatly influence the decision-making process. Gender disparities also play a role in hampering WTP especially among married women.

The knowledge residents have about HIV/AIDS and their perceived sense of personal risk are high. However, the existence of misconceptions about HIV spread and prevention highlights the need for further education on HIV pathogenicity. The knowledge about HIV vaccines and awareness about HIV vaccine trials are low despite prior conduct of HIV vaccine research in this community. There are divergent attitudes, beliefs and perceptions towards the effects of experimental vaccines used and the rationale for HIV vaccine research in general.

8.2 Recommendations:

1. Researchers need to conduct ongoing and comprehensive HIV vaccine education which is culturally sensitive to address key trial concepts such as vaccine safety, benefits and risks of participation in order improve and promote knowledge about HIV vaccines and phase III HIV vaccine trials. This knowledge will counter misconceptions that exist and improve willingness to participate.

2. Myths and misconceptions about HIV pathogenicity underscore the need for further education of the communities by researchers.

3. In order to target many potential participants who are required for efficacy trials, researchers will need to employ several community sensitization methods like community meetings, electronic media (Radio &Television), door to door sensitization, music, dance and drama, print media including use of fliers, posters and banners.

4. To counter negative attitudes, perception and beliefs, researchers need to involve community gate keepers (political, religious and other leaders) in the planning and implementation of efficacy trials. This will enhance their credibility and help identify and address cultural, gender and ethical issues that may hamper willingness to participate.

5. Since this is the very first study about Willingness to participate in efficacy trials in Uganda, more extensive WTP studies will be required to explore other factors that may influence the willingness to participate in these trials from different social settings before the trials begin.

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APPENDIX A: INFORMED CONSENT FORM

Study title: **'Willingness of Entebbe Municipality residents to participate in future phase III HIV vaccine trials'**.

Principal Investigator

Annet Nanvubya, Student of Makerere University School of Public Health

What is the purpose of this study?

The purpose of this study is to determine the level of willingness to participate in future Phase III HIV vaccine trials and the factors associated with such willingness. The findings from this study will be used in the planning and preparation for conduct of future phase III HIV vaccine trials.

How do you join?

In order to join the study, you will sign your name or put your mark (thumb print) on the consent form. If you are unable to read the consent form, you will be asked to get a person who is not part of the study team to help you understand the study and he/she will sign the consent form as well as a witness.

Inclusion/ Exclusion criteria

Respondents aged 18-50 years who give their consent for participation in this study will be included. Non residents of Entebbe Municipality, non Ugandans and staff of UVRI-IAVI HIV Vaccine Program will be excluded in the study.

Study procedures

You will be asked some questions that you will answer according to your best knowledge. You are free to express your opinion and to ask for clarifications where you don't understand.

What are your rights?

Your participation is voluntary. If you do not participate in this study, none of your rights will be withheld, and you will not lose any benefits which you would otherwise have.

Risks and/or Discomforts

There are no health risks expected from participating in this study however, some of the questions may be of a personal nature.

Benefits of study participation

There are no direct benefits to your participation in this study other than receiving some information about HIV and HIV vaccine trials. Your answers and views however, will help us understand more about how people of Entebbe Municipality feel about future phase III HIV vaccine trials which will help us to plan for them appropriately.

Confidentiality

Your participation in the study and all personal information collected about you will be kept confidential. Study numbers rather than names will be used to link you to data collected. It will not be possible to link your name with your study number. Your identity will not be given out in any publication or presentation without your consent.

Cost to You: This study will be conducted at no cost to you.

I agree to take part in the research project entitled **'Willingness of residents of Entebbe Municipality to participate in future Phase III HIV vaccine trials.'**

I have been told what the study is all about and I know what is required of me. I understand that my participation is entirely voluntary and that I may withdraw from the research study for any reason, and this will not affect the legal rights I may otherwise have.

Participants name: ……Signature/Thumbprint: … ……

Date: |__|__|/|__|__|__|/|__|__|__|__|

Person Obtaining Consent:

I have explained the nature and foreseeable risks of the above study to the volunteer and answered his/her questions:

Print Name: ……Signature: …….……..

Date: |__|__|/|__|__|__|/|__|__|__|__|

Impartial Witness: *(only necessary if volunteer was not able to understand the Consent Information Sheet and Informed Consent Document in English).*

I affirm that the consent form has been read to the volunteer and he/she understands the study, had his/her questions answered, and I have witnessed the volunteer consent to study participation.

Print Name: …….……..

Signature/ Thumbprint: …….……..

Date: |__|__|/|__|__|__|/|__|__|__|__|

APPENDIX B: STUDY QUESTIONNAIRE

INTRODUCTION.

I am called ----------a student from Makerere University, School of Public Health. I'm conducting a study about '**Willingness of residents of Entebbe municipality to participate in future Phase III HIV vaccine trials".** Before a new HIV vaccine is made widely available, it has to go through tests to determine its safety and its ability to work well. These tests when performed in humans are what we refer to as HIV vaccine trials.

An HIV vaccine trail comprises of three phases, Phase I, II and Phase III. **Phase I vaccine trials** are studies conducted in a small number of low risk but healthy individuals (20-50) to evaluate the vaccine's safety in humans. This phase lasts a short duration (a few months upto 2 years).

Phase II vaccine trials are similar to Phase I vaccine trials but comprise of more people (up to 100) who may be at low or high risk of acquiring HIV. Phase I and II HIV vaccine trials last a short duration (a few months up to 2 years).

Phase III vaccine trials are clinical trials conducted among high risk individuals to determine the ability of a vaccine to prevent HIV infection. These Phase III vaccine trials also gather additional information about safety. These trials usually enrol several hundred to several thousands individuals and can last up to 5 years. I am using this questionnaire to collect information which I will use to make conclusions about this study. The questionnaire has questions about you, the knowledge, attitudes and perceptions you have about HIV vaccines and HIV vaccine trials. It also has questions about willingness to participate in

future phase III HIV vaccine trials. Your answers will be kept strictly confidential and your responses will be linked to a study number.

Questionnaire ID number_____ **Date of Interview** |__|__| |__|__| |__|__|__|__|
DD MM YYYY

SECTION 1: BACKGROUND INFORMATION
First I would like to ask you some questions about yourself (circle where appropriate)

			SKIP
101	Sex of the respondent	Male 1 Female 2	
102	Where do you reside?	Lunyo 1 Lugonjo 2 Banga 3 Kitubulu 4 Manyago 5 Kitoro 6 Kiwafu 7 Nsamizi 8 Katabi 9 Namate 10	
103	When were you born?	|__|__| |__|__|__|__| Month Year Do not know (Estimated) 99	

104	How old are you now?	Age in completed Years ☐☐ Do not know (Estimated) 99	
105	What is your religious affiliation?	Catholic 1 Anglican/Protestant 2 Moslem 3 Seventh Day Adventist 4 Born again Christian 5 Orthodox 6 Other (specify) 7 _____	
106	Are you currently employed?	Yes 1 No 2 _____	
107	What is your current marital status?	Single 1 Married 2 Separated 3 Divorced 4 Widowed 5	
108	What is your highest level of Education?	< Primary School 1 Primary School 2 Secondary School 3 Tertiary/Institution 4 Other (specify) 7 _____	

SECTION 2: Knowledge about HIV, HIV vaccines and HIV vaccine Trials, Barriers and Motivators to participation in HIV vaccine trials (Circle all that apply)

201	What is HIV infection?	---------- ----------	Correct 1 Incorrect 2

202	How is HIV spread?	Unprotected Sex with an infected partner 1 Through Breast feeding if mother is infected 2 Blood transfusion with infected blood 3 Sharing sharp instruments contaminated with infected blood 4 Don't know 5 Other (specify) 7 _____	
203a	How is HIV prevented?	Abstinence 1 Being faithful to your partner 2 Consistent and correct condom use 3 Circumcision 4 Use of antiretroviral drugs 5 Don't know 6 Other (specify) 7 _____	
203b	Do you think you are at risk of getting HIV?	Yes 1 No 2 I don't know 3	
203c	Give a reason for your answer above	…….	
204	Have you ever heard of HIV vaccines before?	Yes 1 No 2	
205	What do you think HIV Vaccines are for?	Prevention of HIV 1 Cure of HIV 2 Don't know 3	
206	Is there an HIV vaccine today?	Yes 1 No 2 Don't know 3	
207	Have you heard about HIV Vaccine trials being conducted in your community?	Yes 1 No 2	→209

208	How did you get to know about these HIV vaccine trials?	News Letters/Brochures 1 Information seminar 2 CAB member told me 3 TV/Radio 4 A friend/relative told me 5 A former participant told me 6 Other (specify) 7 _____	
209	Have you ever participated in an HIV vaccine Trial?	Yes 1 No 2	
210	If there was a phase III HIV vaccine trial, would you be willing to participate?	Yes 1 No 2	→211 →212
211	If Yes, why?	Will be prevented from getting HIV 1 Want to help get an HIV vaccine 2 Want to get money 3 Want to get free medical care 4 Want to get condoms 5 Want to know my HIV status 6 Want to be an example to the rest 7 I consider myself at risk of getting HIV 8 I know of friends who have ever participated 9 Other (specify) 10 _____	→301

212	If Not, why not?	The study duration is so long 1 The study site is not easily accessible 2 I do not want to know my HIV status 3 Fear to talk about my sex life 4 Fear to contract HIV from vaccine 5 Fear side effects of the vaccine 6 Not willing to be on Family planning 7 My husband may not allow 8 Other (specify) 9 _____	
213	If your concern to participate in a Phase III HIV vaccine trial is addressed, would you change your mind to participate?	Yes 1 No 2	

Section 3: Attitudes, Beliefs and perceptions about participation in future phase III HIV vaccine trials (Circle all that apply)		
301	Do you think Phase III HIV vaccine trials should be conducted?	Yes 1 No 2
302	If Yes, why?	We need an HIV vaccine 1 Free medication 2 Free Condoms 3 Free VCT 4 Free money 5 Other (specify) 7 _____

303	If not, why not?	HIV vaccines cannot be found 1 It is a waste of time 2 Knowing ones HIV results leads to stigma 3 We are being used as Guinea pigs 4 No compensation 5 Other (specify) 7 _____
304	Do you think it is important to get an HIV vaccine?	Yes 1 No 2
305	Explain your answer in 304 above	…… …… ……..… ……
306	Do you think the people in your community would support the conduct of Phase III HIV vaccine trials?	Yes 1 No 2 I don't know 3

307. Please tell me what people in your community would want to know about volunteering to participate in a phase III HIV vaccine trial.

……
……
……

308. Please suggest ways through which awareness about HIV vaccines and HIV vaccine trials can be improved in your community.

……..…
……..……
…….

THANK YOU VERY MUCH FOR YOUR TIME

APPENDIX C: FOCUS GROUP DISCUSSION GUIDE

Introduction.

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Phase II vaccine trials are similar to Phase I vaccine trials but comprise of more people (up to 100) who may be at low or high risk of acquiring HIV. Phase I and II HIV vaccine trials last a short duration (a few months up to 2 years)

Phase III vaccine trials are clinical trials conducted to determine the ability of a vaccine to prevent HIV infection. These Phase III vaccine trials also gather additional information about safety. These trials usually enrol several hundred to several thousands individuals and can last up to 5 years.

1. What is HIV infection and how is it spread and prevented?
2. How serious do you think the HIV/AIDS epidemic is, right now, in Uganda?
3. Do you think an HIV vaccine could reduce the spread of HIV in Uganda? Why/why not?
4. Do you think phase III HIV vaccine trials recruit HIV infected or uninfected individuals?
5. Do you think the people in your community would be willing to participate in a phase III HIV vaccine trial in the future?
6. What are the benefits or good outcomes people might expect from participating in a phase III HIV vaccine trial?
7. What are the risks or problems people might expect from participating in a phase III HIV vaccine trial?
8. What would people in your community want to know about phase III HIV vaccine trials.
9. How can awareness about HIV vaccines and Phase III HIV vaccine trials be improved in your community?

APPENDIX D: KEY INFORMANT INTERVIEW GUIDE

Introduction.

I am called ----------a student from Makerere University, School of Public Health. I'm conducting a study about"**Willingness of Entebbe municipality residents to participate in future Phase III HIV vaccine trials".** Before a new HIV vaccine is made widely available, it has to go through tests to determine its safety and its ability to work well. These tests when performed in humans are what we refer to as HIV vaccine trials. An HIV vaccine trail comprises of three phases, Phase I, II and Phase III. **Phase I vaccine trials** are studies conducted in a small number of low risk but healthy individuals (20-50) to evaluate the vaccine's safety in humans.

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1. What is HIV infection and how is it spread and prevented?
2. How serious do you think the HIV/AIDS epidemic is, right now, in Uganda?
3. Do you think an HIV vaccine could reduce the spread of HIV in Uganda? Why/why not?
4. Do you think phase III HIV vaccine trials recruit HIV infected or uninfected individuals?
5. Do you think the people in your community would be willing to participate in a phase III HIV vaccine trial in the future?
6. What are the benefits or good outcomes people might expect from participating in a phase III HIV vaccine trial?
7. What are the risks or problems people might expect from participating in a phase III HIV vaccine trial?
8. What would people in your community want to know about phase III HIV vaccine trials.
9. How can awareness about HIV vaccines and Phase III HIV vaccine trials be improved in your community?