

EXPECTATIONS AND EXPERIENCES OF HIV VACCINE TRIAL
PARTICIPANTS AT THE MBEYA MEDICAL RESEARCH
PROGRAMME IN MBEYA, TANZANIA 2006-2007.

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Key words:

Human Immunodeficiency Virus

HIV Vaccine trials

Trial Participants

Participants Expectations

Participants Experiences

Participants Challenges

Community Misconception

Vaccination

Vaccine induced positivity

Mbeya Medical Research Programme



LIST OF ABBREVIATIONS

AIDS -Acquired Immuno Deficiency Syndrome
CAB -Community Advisory Board
CIA -Central Intelligence Agency
GDP -Gross Domestic Product
HBM -Health Belief Model
HCI -Health Care Industry
HIV -Human Immunodeficiency Virus
HVT - HIV Vaccine Trial
MRH - Mbeya Regional Hospital
MMRP-Mbeya Medical Research Programme
NIAID - National Institute of Allergy and Infectious Diseases
SSA - Sub Saharan African
TACAIDS- Tanzania Commission for AIDS
VRC - Vaccine Research Centre
UNAIDS- United Nation AIDS
USMHRP- United States Military HIV Research Programme
WHO - World Health Organization.

ABSTRACT

Recruitment and retention of participants in HIV vaccine trials has been challenging compared to other studies conducted by the Programme at Mbeya Medical Research Centre. The purpose of this study was to gain a deep understanding of the experiences and challenges faced by volunteers who participated in a HIV vaccine trial in the town of Mbeya in 2006 - 2007. There have been many misconceptions regarding HIV vaccine trials. Some of the concerns to participants were safety of the vaccine, fear of becoming infected by the vaccine and the amount of blood drawn for laboratory tests.

A qualitative descriptive study approach was used to gather the required information. The sample for this study was drawn from an existing group of volunteers who participated in the vaccine trial at Mbeya Medical Research Centre in 2006-2007. A purposive sampling method was used to select respondents because they had had experience of being participants in a HIV vaccine trial. Twenty audio recorded in-depth interviews were conducted. The interviews were conducted at the clinic during their routine follow up visits. An open ended interview guideline was used to guide the discussion to elicit the required information from the respondents. The data was transcribed, translated and then analyzed by both content and thematic approach. Ethical procedures were observed, including getting permission from the local ethical committee in Mbeya region and participants were given an informed consent form to read and sign before starting the interview.

Based on findings from the study, it was noted that most of people who participated in the vaccine trial had participated in other cohort studies which were previously conducted

at the research centre. It was found that respondents felt that participation in the trial would be their contribution to the global effort in fighting against HIV. They also felt that should the vaccine be successful it would be a benefit to many people in future.

It was noted that long waiting time at the clinic, blood draw and the vaccine induced positivity were among of the frequently mentioned concern regarding clinic procedures. On the other hand it was revealed that some of the respondents had nasty experiences at home due to rumors and misconceptions which were circulating in the community regarding the vaccine on trial. It was reported that the vaccine induced positivity was directly related to being injected with a real HIV virus. The vaccine did not cause any serious side effects to the participants apart from mild fevers, headaches and a pain at the site of injection. Respondents appreciated the close monitoring of study participants and the health care provided by the staff when they fell sick.

The information gained from the study will assist the research team to improve the educational seminar package for volunteers during participant recruitment in future trials based on the areas of concerns reported by participants of the HVT. There is the need for the research team to provide more information and clarification of unfamiliar terms (randomization, placebo and vaccine induced positivity) during educational seminars.

DECLARATION

I declare that, expectations and experience of HVT participants at Mbeya Medical Research Programme, is my own work and that all sources that I have used have been acknowledge by complete references.

Signed

Erica S. Sanga

Date



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CHAPTER ONE: INTRODUCTION

1.1 HIV/AIDS

HIV/AIDS remains the main public health problem worldwide due to its large impact in people's lives (WHO, 2006). Since the discovery of the disease in the 1980's HIV/AIDS has claimed more than 25 million people's lives globally and is responsible for marked demographic changes among heavily affected countries (UNAIDS, 2008). In heavily affected countries especially in the sub Saharan African (SSA), the disease has reduced life expectancy by more than 20 years (UNAIDS, 2008). The disease has slowed economic growth and development and thus increasing poverty in these countries (WHO, 2006). In 2007 it was estimated that there were 33 million people living with HIV worldwide and 67% of them were from the sub-Saharan African countries (UNAIDS, 2008). The epidemic caused between 1.8 to 2.3 million deaths in 2007 worldwide with 75% of the deaths occurring in SSA countries (UNAIDS, 2008). Despite all international efforts and campaigns to reduce the HIV epidemic for example HIV/AIDS education, behavioral change education programs on abstinence, faithfulness and use of condom the epidemic's future is still uncertain (WHO-UNAIDS, 2002).

HIV Vaccine

A vaccine is a substance introduced to the body to create resistance or immunity against disease or infection (Cichocki, 2006). A vaccine is one of the most cost effective health interventions when compared to treatment. Sub Saharan African countries need a HIV vaccine urgently because the impact of HIV /AIDS is huge (UNAIDS 2008). Currently there are no HIV vaccines approved for use, considerable research and clinical trials are

necessary before a vaccine is approved (Cichocki, 2006). However recently there has been news of a promising HIV vaccine from the trial conducted in Thailand to 16,000 volunteers from 2003 to 2009. The trial found that the vaccine was safe and modest effective in preventing HIV by 31.2% although there is still some work to be done for the vaccine to be approved (Relly, 2009). In order to accelerate the development of HIV vaccine Esparza and Bhamarapravati (2000) pointed out that it was important to address the challenges experienced during the process of developing an effective vaccine and then to find solutions to them so as to increase the acceptability of the vaccine in future.

Mbeya Medical Research Programme

Mbeya Medical Research Programme (MMRP) is a nonprofit organization dealing with research activities on HIV/AIDS, Tuberculosis and malaria since 2000. The research programme also referred to as the research centre has been conducting HIV cohort studies in high-risk population as well as general population with valuable findings about HIV prevalence and incidences to the Tanzanian Ministry of Health (MOH)

1.2 BACKGROUND

Tanzania is estimated to have 2 million people living with HIV. HIV accounts for 29% of deaths in the country (WHO, 2006). In Tanzania the first case of HIV was noted in 1983 at Kagera region in the northern part of the country bordering Uganda. By 1986 all 26 regions in the country reported HIV cases despite of all efforts to control the epidemic (THIS, 2008). In 2007 the prevalence in Tanzania was 6.2% (about 2 million people were living with HIV) this trend of infections shows that the disease is progressing in the country despite of HIV preventive education, behavior change strategies, voluntary counseling and testing plus treatment care and support interventions being in place. The increasing rates of HIV infections in Tanzania has compelled the Ministry of Health and other scientific institutions to work hard towards developing additional biomedical tools such as preventive HIV vaccines and microbicides to complement ongoing efforts to the fight against HIV/AIDS (TACAIDS-Tanzania Commission for AIDS, 2008). It was reported that women are more infected than men; male to female ratio of infection is 1:1.22 (THIS, 2008; TACAIDS, 2008). HIV prevalence seems to be increasing by age and sex; most people affected are in the ages of between 30-34 for women and 35-39 for men. In 2007 there were 96,000 HIV related deaths recorded, urban areas have higher levels of HIV infection than rural residents (THIS, 2008; CIA, 2009; Tanzania National website). HIV vaccine is urgently needed in Tanzania because the disease has serious consequence to the country's social economic and health situation. Treatment, care and support for HIV/AIDS including access to ART, is not yet available to all affected people in the country (TACAIDS, 2008). TACAIDS (2008) pointed out that developing an effective and safe vaccine will be a powerful tool in the fight against HIV.

Mbeya region is among the top three leading regions with high number of AIDS cases; in 2005 there were 34,300 AIDS cases compared to 28,474 cases in Dar-es Salaam and 13,817 cases in Kilimanjaro which holds the third position (THIS, 2008). In the study done by Mbeya Medical Research Programme (MMRP) in general population in 2002 the prevalence was found to be 16.6% (Arroyo *et al.*, 2005). Although in the survey conducted by the National AIDS Control Programme (NACP) in 2003/04 HIV prevalence in Mbeya was estimated to be 14% but still it remains high (Lyamuya, 2007). Incidence was high (7%) in women than male (5%) whilst the infection was 21% in urban and 11.5% in rural areas (THIS, 2008; Arroyo *et al.*, 2005). AIDS related diseases are among the top three leading causes of deaths in Mbeya region (Mbeya Regional Hospital (MRH) Report, 2006). The region has consistently ranked high for several years for instance in a survey conducted from 2007 to 2008 reported that Mbeya ranked second with prevalence of 12.3%, after Iringa region with 16% prevalence (THIS, 2008).

1.3. THE MBEYA HIV VACCINE TRIAL

In 2005 MMRP was selected by the Ministry of Health and Social Welfare to become one of the sites to conduct HIV vaccine trials in Tanzania. The first vaccine trial to be conducted by the centre was a “A phase I/II double blinded, randomized placebo controlled clinical trial to evaluate the safety and immunogenicity of a multiclade HIV-1 DNA plasmid vaccine (VRC-HIVDNA016-00-VP) boosted by a multiclade HIV-1 recombinant adenovirus-5 vector vaccine (VRC-HIVADV014-00-VP) in HIV uninfected adult volunteers in East Africa” (RV 172 Protocol, 2004). This was part of a multi centre trial with other centres in Kenya and Uganda. The trial started in July 2006 was

sponsored by the U.S. Military HIV Research Program (USMHRP). This trial involved inoculation of the vaccine (on trial) into the participants and subsequent following up and monitoring of participants for immunogenic changes. These procedures required high frequency of clinic visits compared to other studies where there was no investigational drug on trial. For instance in the two HIV cohort studies (mentioned earlier), participants were coming every three months for follow up at the clinic while in the vaccine trial they were supposed to visit the clinic every two weeks in the first two months then later it was every month for the next six months, there after participants were coming to the clinic every four months for safety monitoring and vaccination for 14-16 months. Participants in the HIV Vaccine Trial (HVT) were invited to attend information seminars where the study was introduced to the community and would be participants. Issues on aims and objectives of the study, duration, eligibility criteria were discussed. Some of the eligibility criteria were the participant has to be a legal resident of Mbeya aged between 18 and 50 years. Should be available for appointment at the clinic for about 18 months from screening and must be in good general health. Also he/she must be HIV negative and at low risk for HIV. In addition the volunteer should be able and be willing to sign an informed consent form.

Interested volunteers were registered to attend further briefing sessions where detailed information about the study (repeat of the above mentioned information plus all procedures that will take place, for example number of visits, vaccination, blood draw, HIV counseling and testing and medical examination). The study enrolled 60 participants in total. The study comprised of 14 visits including four vaccination days three DNA shots on day 1 day 28 and day 56 followed by Adenovirus-5 on day 168. Vaccination

schedule started in July 2006 and ended in October 2007. Until now November 2010 the participants are still being followed up by the study team following an extension of study time frame for safety and immunogenic monitoring. Participants who joined the study and attended the clinic for study procedures were compensated with 15,000 Tanzanian shillings (US\$ 10) for transport and time spent at the clinic. During information seminar and briefing session there was no compensation only soft drinks were offered.

This qualitative study was conducted at MMRP clinic involving twenty volunteers who participated in the HIV vaccine trial conducted by MMRP from 2006 to 2007.



1.4. PROBLEM STATEMENT

The recruitment and retention of HIV vaccine trial participants have imposed greater challenges to the MMRP study team compared to the other cohort studies. Our experience with the HIV vaccine trial during recruitment activities showed that only half of the volunteers who attended information seminars consented to participate in the vaccine trial. The main reason for that included the nature of the study itself where a trial vaccine was to be administered to study participants.

There were lots of misconception and myths about the vaccine. Some of the concerns were the fear of being inoculated with a live HIV virus vaccine, that there was a hidden agenda concerning the safety of the vaccine and another concern was the trial being conducted in African countries (the idea of Africans being used as guinea pigs). These concerns were mainly heard from people who came to attend educational seminars but did not want to take part in the trial and also from people who were screened out in the early stages due to being ineligible for the study. Another concern from the volunteers was that too much blood drawn for laboratory purposes. It was noted that there was a stigma attached to trial participation, for instance some of the people did not feel free to talk about their participation in the vaccine trial because community members were closely following up their health status. When a trial participant encounters any health problem it was directly linked to the vaccine administered to them. Unfortunately information regarding these concerns about study participation (valuable information for vaccine trial research) was not systematically collected nor well documented during the trial. The MMRP research team felt that understanding the experiences of those who

participated in the trial would be essential for future community engagement in order to improve the relationship and to support further HIV vaccine activities.

1.5. PURPOSE OF THE STUDY

This study will give the research team an insight into what the challenges are and if possible find solutions to them to improve the level of participation in future vaccine trials.



1.6 AIM AND OBJECTIVES OF THE STUDY

1.6.1 AIM

The aim of this study was to explore the expectations and the challenges of HIV vaccine trial participants at Mbeya Medical Research Centre in Mbeya, Tanzania.

1.6.2 OBJECTIVES

- ❖ To explore the expectations of HVT participants regarding participation in the study.
- ❖ To describe the personal experiences of participants' being on the trial.
- ❖ To describe the challenges experienced by volunteers whilst participating in the study.



CHAPTER TWO: LITERATURE REVIEW

2.1 INTRODUCTION

The idea and excitement of developing an effective HIV vaccine in human beings started in the early 1980's soon after the discovery of the virus causing HIV (Pitisuttithum, Francis, Esparza and Thongcharoen, 2006). Now more than 25 years later there is still no approved vaccine for human use due to a lack of knowledge about the virus and also because vaccine research is a long process that needs to be tested on healthy humans to ensure its safety and effectiveness after having been tested in animals (Pitisuttithum *et al.*, 2006; Cichocki, 2006). On the other hand misconceptions and the varied beliefs of people towards vaccine trials poses the biggest challenges in the recruitment and retention of volunteers participating in HIV vaccine trials in different areas which are conducting these type of trials (Esparza and Bhamarapavati, 2000). Esparza and Bhamarapavati also argued that the development of an effective HIV vaccine would offer the best long term hope to control the HIV/AIDS pandemic, especially in developing countries which are hit on hard with the epidemic and thus there is a greater need for the vaccine.

2.2 EXPECTATION AND WILLINGNESS TO PARTICIPATE IN HIV VACCINE TRIAL

Lesch, Kafaar, Kagee and Swartz (2006) conducted a study in South Africa on community members' perceptions of people participating in HIV vaccine trials. They noted that general mistrust of researchers and a lack of adequate information about HIV

vaccines were inhibiting factors in trial participation. Other concerns were the fear of becoming infected with HIV through vaccination and the negative reaction of family members and the community (Lesch *et al.*, 2006).

A study conducted in India by Sahay *et al.* (2004) explored the willingness to participate in HIV vaccine trials among low and high risk populations in Pune. This study reported an overall willingness to volunteer for HIV vaccine trials of approximately 48%. Health insurance and monetary incentives were among the factors mentioned that motivated volunteers to take part in the trial. In addition the authors pointed out that women and men at risk of HIV infection participated in the trial because they were aware of current HIV vaccine development efforts. It was reported that participants expected to benefit from the vaccine by being prevented from HIV. However peer and family pressure against volunteering and discrimination by community members against participation in the trial were some of the major concerns reported (Sahay *et al.*, 2004).

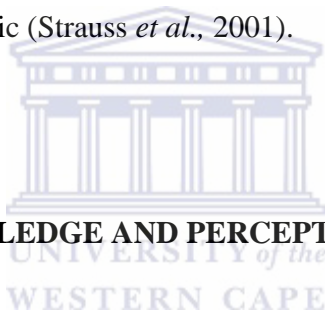
In another study on willingness to participate in an up coming HIV vaccine trial in South Africa by Paker (2006) altruism, medical incentives and hopefulness of being protected from HIV were among the facilitators to participation in HVT. However distrust to the research team, stigma and discrimination were mentioned as barriers to participation. In addition factors inhibiting willingness to participate were fear of safety and vaccine-induced antibodies and misconceptions and myths about the vaccine itself (Paker, 2006).

2.3 BENEFITS OF PARTICIPATION

Insurance and monetary incentives were among the factors mentioned to motivate volunteers and were perceived benefits of taking part in the trial. Sahay and others (2004)

pointed out that women and men at risk of HIV infection wanted to participate in the trial because they expected to benefit from the vaccine (Sahay *et al.*, 2004).

In one study examining community and individual perceptions of research related to HVT it was revealed that perceived benefits of participants were thought to be incentives for example financial compensation for participation. In another by Strauss *et al.*, (2001) it was found out that participants thought the vaccine would build up their immune system against HIV infection, while others felt the vaccine will help other people in future by preventing them from acquiring HIV. Furthermore participants in this study believed that the vaccine on trial would be effective and thus would protect their communities from HIV epidemic (Strauss *et al.*, 2001).



2.4. VOLUNTEERS' KNOWLEDGE AND PERCEPTIONS OF HIV VACCINES AND SAFETY

Knowledge and proper information about HIV vaccine and its safety is among the important factors which influences volunteer's decision to take part into the study. In the first vaccine trial in Africa which was conducted in Uganda by Mugerwa and the colleagues (2002) it was found that the community had fears that volunteers would be injected with HIV and that the vaccine might undergo dangerous mutations that could lead people to develop strange abnormalities in future. The authors pointed out that some participants in Uganda believed that the vaccine manufacturers chose poor countries for trials with the motive of spreading HIV among uninfected Ugandans to eventually wipe out the African race. In a study conducted in South Africa by Stadler, Delany &

Mntambo (2007) it was revealed that a history of human right abuses under the apartheid regimen allowed the use of black South Africans due to their vulnerability, showing that there is distrust and negative attitude towards human research in African countries. In Congo Olin *et al*, (2006) found out that the dangers of an experimental vaccine and the stigma attached to vaccine induced positivity were the major concerns which inhibited willingness to participation. MMRP experienced the same concerns during recruitment and hence the researcher planned to interview the participants about their experiences on this matter to ascertain what information may help participants in future trials better understand the difficult issues like vaccine induced positivity. In a study by Strauss and others (2001) in the united state it was noted that people were unsure of the negative side effects that might occur as a result of participating in the trial. For instance there were concerns about the safety of the vaccine on trial, like would the vaccine harm them during the trial or in future! Vaccine induced positivity was such a big challenge experienced in the study conducted in Uganda. The volunteers who tested positive due to vaccine antibodies had to be offered special participation cards to protect them from being discriminated against for immigration, insurance and employment or other social issues (Mugerwa *et al.*, 2002). The risk of contracting HIV from the vaccine was one of the concerns in one of the preparedness studies for HIV vaccine trial (Strauss *et al.*, 2001).

2.5. CHALLENGES EXPERIENCED BY PARTICIPANTS IN HIV VACCINE TRIALS

A randomized placebo-controlled trial known as Vax004, conducted in the United States, Canada and Netherlands in cities with high HIV prevalence in 1998 by Health Care Industry (HCI) showed that one in every five volunteers in HIV vaccine efficacy trials reported that they had at least one negative social impact in the three-year period of their participation in the trial (Hollander, 2008). 18% of volunteers experienced at least one negative social impact of trial participation while 3% experienced two or more. The majority 14% reported negative experiences and difficulties in interpersonal relationships such as negative reaction from partners, family members, relatives and friends. Unintentional disclosure of participation in the trial was a second common event and problems with insurance or employment were rare (Hollander, 2008). Furthermore 95% of the volunteers who became infected during the trial reported negative social impacts after infection. Some reported that friends and relatives had blamed the vaccine for the infection or for increasing the participant's susceptibility to infection (Hollander, 2008). In addition the study showed that reporting negative experiences was higher among men who were young and had had multiple partners shortly before entering the study than among those who had none or one partner (Hollander, 2008).

2.6. ETHICAL CONSIDERATION IN HIV VACCINE TRIALS

In Tanzania the Ministry of Health and Social Welfare released the National HIV vaccine strategic framework which was developed by Tanzania HIV vaccine research institutions, WHO-UNAIDS and The African AIDS Vaccine Programme (TACAIDS, 2008).

The framework is to provide guidance in the development and evaluation of candidate HIV vaccines by providing clear rules on regulatory approval, scientific and ethical reviews plus bio-safety and monitoring guidelines (TACAIDS, 2008). World Health Organization (WHO) and the Council for International Organizations of Medical Sciences (CIOMS) developed guidelines for human subjects' research to ensure safety of study volunteers (Christakis, 1988). The guideline observes human rights and safety of the participant for instance before approval of the study a protocol for a vaccine trial involving details on safety of the candidate vaccine in terms of quantity and purity, being tested in animals or nonhuman primates to establish the ability and safety of the vaccine has to pass through the necessary regulatory authorities (Christakis, 1988). Also in the study of Ethical considerations in AIDS vaccine trials countries by Mahendele (2000) it was noted that the key cross cutting ethical issues were community engagement, ancillary care obligations, care and treatment of study participants, informed consent and confidentiality. These factors are very crucial in ensuring human rights and safety of the volunteers (Mahendele, 2000).

CHAPTER THREE: METHODOLOGY

3.1 INTRODUCTION

This chapter explains the process and methods used to conduct the study, the design of the study, the researcher's role in the research centre, the study population and sample size, the sampling method, the data collection tools, the data analysis, the rigour and ethical considerations (general approach of the study).

3.2 STUDY DESIGN

The study was an explorative and descriptive qualitative study underpinned by a phenomenological approach to describe the experiences of volunteers who participated in a HIV vaccine trial at Mbeya Medical Research Centre. The reason for choosing this approach is that qualitative research is the most appropriate method in studying a phenomenon in its natural setting when the aim of the study is to understand people's opinion, feelings or experiences and to make sense or interpret a certain phenomenon based on the meanings brought by people exposed to the phenomenon (Greenhalgh & Taylor, 1997). A descriptive study design was chosen because little is known about the phenomenon and the research seeks to describe the phenomenon. The design is relatively less time consuming and inexpensive compared to other designs (Beaglehole, Bonita & Kjellstrom, 1997).

3.3. STUDY SETTING

Tanzania is located in the eastern part of Africa it has an area of 946,658 sq. km with population of 37.6 million (Census - 2002) about 80% of the population lives in rural areas (CIA, 2009; Bureau of African Affairs, 2007). Tanzania is among the poorest countries in Africa its GDP in 2004 was valued at \$10 billion while the average income per capita was 300 USD and poverty is high. It is estimated that 36.1% of the population is living below the poverty datum line (Bureau of African Affairs, 2007). The economy of the country depends heavily on agriculture which employs about 80% of workforce. Swahili and English are both official languages with 69.4% Tanzanians being literate this was in 2002. The country is divided into 26 administrative regions/provinces including Mbeya (Bureau of African Affairs, 2007).

Mbeya region lies in the southern part of Tanzania; it is on the highway from Dar-es salaam (capital city of Tanzania) to Zambia, Malawi and Congo and thus subjected to high interactions and mixture of people leading to increased risk to HIV infection. The region (province) is about 800 km from Dar-es- Salaam. The population of the Mbeya Region was 2,070,046 (2002-Census). The region has eight districts with urban, semi urban and rural areas. Most people in the region are small scale farmers (peasants) with some people employed by government or private sectors and some engaged in business (Bureau of African Affairs, 2007). Health services in Mbeya region consists of one consultant hospital, 17 hospitals, 154 health centers or intermediate hospital with capacity of conducting HIV testing and counseling plus 265 dispensaries these figure includes both public and private facilities combined (MRH 2005).

3.4. AN INSIDER APPROACH (THE RESEARCHER)

The researcher was an assistant medical officer working at Mbeya Medical Research Programme as community outreach officer since 2000. She worked as a recruitment and retention officer to most of the studies conducted in this centre (HIV related studies in high risk population as well as general population). She participated in previous studies focusing on recruitment and retention of participants in studies. In the HIV vaccine trial the researcher's duties included organizing meetings and introducing the study to the community leaders. Also organizing and conducting information seminars and briefing sessions to potential participants together with study physicians. As a retention officer she escorted the participants at home after vaccination, the intention was to know more about participants including where they lived for follow-up purposes especially when the study team could not reach them by phone. To this end she worked closely with research participants in previous HIV cohort study and also HIV vaccine trial. It is based on the active involvement in recruiting participants, monitoring research progress and attending to participants' queries and concerns that the researcher had an understanding of experiences and challenges faced by the HVT participants. For previous studies there were not many challenges in recruiting participants compared to the vaccine trial which was a new kind of study at the MMRP and it involved inoculation of drug/vaccine in the volunteer's body. This posed the biggest challenge to the researcher in terms of recruitment, follow up and retention of participants especially due to community misconceptions. However knowledge of the participants was advantage to selection of respondents who were rich in information required for the study and the closeness to the participants was an advantage as it increased their freedom of expression.

3.5. STUDY POPULATION AND SAMPLE

The study population in this study was 60 participants who participated in the HIV vaccine trial study in 2006-2007 at MMRP in Mbeya town. Respondents in this study were both male and female ages between 19 -49 years. Most of the respondents were married with children some were single and few were students. Initially the study was planned to interview 12 participants only but during the process of data collection and analysis the researcher noted that there was still new information coming up. Therefore she decided to continue with interviews to the level of saturation and finally interviewed 20 participants.

3.6. SAMPLING PROCEDURE

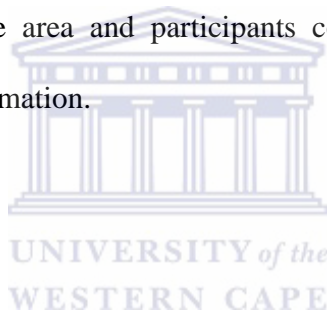
Sampling is selection of individuals or units to be closely studied as representatives of the study population since it is not practical to study everybody (Katzenellenbogen *et al.*, 1997). Purposive sampling was used in the selection of study participants. Participants were strategically selected based on their knowledge of the study phenomenon (Bryman, 2008). The selection considered participants' demographic characteristics such as age, gender, education level, marital status and the location where the participant lived within Mbeya town. With regard to age the study selection criteria sought to include participants below 25 years, those between 25-45 years and above 45 years to see if they had different points of views regarding their participation in the trial. Both sexes were included that is 11 males and 9 females both married and singles. The researcher wanted to get an insight on whether gender or marital state of the participant had any repercussion to him/herself, spouse and/or family. The sample also included those who lived near the clinic that is those living within 3km from the clinic and those living more than 3km from the clinic,

also educated and less educated participants were all part of the sample. Furthermore the interviews included three participants who became infected with HIV during the trial. The intention for this diversity in the group was to correlate and validate the information elicited from respondents. The study secretary assisted in selection of study participants, she knew them well and she is the one who dealt with their routine appointments and schedules. The participant enrollment register and follow up reports were used in selection of respondents as they contained necessary information to assist diversity in sampling (age, sex, marital status, HIV status, occupation and location). In addition the researcher and her assistant also worked closely with the participants; therefore the researcher's knowledge of the area and participants contributed to selection of best subjects with the required information.

3.7 DATA COLLECTION

3.7.1 THE INTERVIEW

Data in this study was collected by individual In-Depth Interviews (IDIs) conducted with study participants. IDI's are very good in eliciting personal feelings and experiences of people although they are time consuming (Liamputtong and Ezzy, 2005). An interview guide with open ended questions was designed starting with simple and less sensitive question progressing to more sensitive questions. The factors that were to be explored by the study were participant expectations or motivational factors for participating in the trial for instance what compelled them to take part in the study. To understand whether they foresaw any perceived benefits, whether they had to ask permission from spouses, parents or family members and whether there were any fears/concerns regarding the trial. Furthermore the study was to explore the challenges faced by respondents at the clinic for



example study visits with regard to their personal plans, waiting time, the randomization issue like wanting to be in the vaccine group hoping that they would be protected. Likewise, the study looked at the challenges faced in the community where the participants lived for example rumors, misconceptions and the stigma attached to testing positive due to vaccine. The questions focused on the lived experience of the respondents as participants in the vaccine trial. The interview started with greetings, self introduction and informal discussion about general issues like work, business (depending on what was the respondents occupation), children and giving him/her something to drink (coffee, tea, water or soda-soft drink) to build up good rapport and making the respondent relax before starting the interview. The questions asked were open ended and probing was allowed to shape the discussion/interview. (See the interview guideline attached in appendix no. 1).

3.7.2 DATA COLLECTION PROCEDURE

Permission to conduct this study was granted by the managing director at MMRP and the study community advisory board. Then during participants annual debriefing session the researcher discussed with the whole group of HVT participants about this study explained the purpose of the study, objectives, sample size and selection of respondents. There was no objection especially after explaining that they are going to be interviewed by staff in the study team. Training of the research assistant was done for two days by the researcher. The training focused on interviewing skills and ethics ensuring good quality of data. The research assistant was a nurse counselor working at the clinic who was also well known and trusted by the participants. The researcher chose her because she was an experienced counselor and interviewer and the researcher felt that respondents will be free talking to her (the known nurse counselor) than to a new person especially on

questions focusing on their HIV status. The counselor has also worked in previous studies at the research centre as an interviewer for the past four years.

With assistance of the study secretary one day before their routine visit to the clinic the selected respondent was contacted by phone. It was explained to the potential participant that he/she was requested to participate in the interview the next day when they reported for a clinic schedule. Prior appointments were made to prepare the respondent and avoid inconveniencing their daily schedules. Respondents were invited to the interview room only after finishing all procedures required for their routine visits. After creating rapport and ensuring confidentiality the information sheet was read to the participant and if willing to go on with the interview she/he was given a consent form to read and sign. Confidentiality was ensured and respondents were encouraged to ask all questions they wanted to before signing the consent form. All interviews were conducted at the clinic in a private and quiet room. The interviews were prepared in English then translated into Swahili (Tanzanian national language), all interview were conducted in Swahili although some participants could speak English. The interviews were audio tape recorded with the participant's permission. In addition the interviewers used a pen and notebook to write down important events/aspects that cannot be picked up by the recorder during the interview like sighing, any signs of uncomfortably, relaxation or tiredness. The interviews were conducted on weekdays (Monday to Friday); most interviews took 40-60 minutes (50 minutes average). Since these interviews were conducted on their routine visits bus fare and time compensation were covered as part of the trial routine compensation. In two of the extra interviews from the original planned sample the researcher had to conduct the interviews by phone because these participants had moved

out of Mbeya one for further education, while another was married in another region. The interviews conducted by phone were more expensive and time consuming in terms of tracing the respondents and persuading them to agree for an interview as the researcher felt it was crucial to understand their reasons for withdrawing from the study as they had an implication to the outcome of the study. On the other hand it was easier to clarify and paraphrase question in the face to face interview than phone interviews. However the findings from these interviews were contributive to this study and future vaccine trial at MMRP. In another situation the researcher conducted an interview in the respondent's office because she dropped out of the study she could not come for routine schedules and it was also crucial to understand her reasons for dropping out because the respondent was among the volunteers who seroconverted during the study. The research sought to understand whether her dropping out was connected to seroconversion. The interview had to be brief as she had to lock the door to avoid interruptions. This experience shows that in qualitative research sometimes appointments and interviews do not take place according to the plan therefore flexibility and adaptation to different situation is necessary.

3.8. DATA ANALYSIS

Qualitative research is not usually guided by hypothesis and each qualitative research is unique thus making the final report for each qualitative study also unique depending on the inquiries made by the researcher (Willms & Johnson, 1993). In this study all collected data were transcribed verbatim and then translated back from Swahili into English by the researcher and the research assistant within one week of interview to ensure that no valuable information was forgotten or excluded. Themes for this study were prior

formulated based on the aim and objectives of the study, exploring expectations and experiences of HIV vaccine trial participants at MMRP. There after the data collected was organized into themes and codes to facilitate analysis and interpretation.

The data was analyzed using a thematic content analysis (comparing the contents in each sentence from the respondents with the themes identified in advance by the researcher).

The themes in this study were seeking to understand the experiences of respondents to the whole process of participation in the HVT, from entering the study to the end of the study. Themes focused on education seminars, expectations, motivation and reaction of significant others plus the challenges encountered during their participation. In addition the research sought to understand participants' opinion towards HIV status and seroconversion plus participant's general opinion about HIV vaccine trials (See attached themes and codes-Appendix 2).



3.9. RIGOUR

The researcher used purposive sampling to select sample units with relevant information to the study aim/goal. The researcher knows well the participants as she works in the research centre on daily basis thus ensuring right selection of study participants which included a diversity of people in the group. For instance taking consideration of different age groups (young, middle age and elders) gender both male and female were interviewed, marital status and location based on distance from the clinic was considered to ensure trustworthiness and best triangulation of information. In addition the interviews were conducted in a private room to offer reliable privacy and freedom of expression to respondents and all interviews were audio recorded transcribed and translated to make sure that nothing mentioned by the respondent is overlooked to ensure confirm ability.

Furthermore a cross section of the participants' sex, age, distance, HIV status and education helped to ensure inclusiveness of the study population and at least two interviews were conducted in each group. In addition the researcher interviewed some participants who had relocated to other places far from Mbeya town also those dropped out of the study to ensure that none of the necessary information is missed concerning participation in the trial.

3.10. ETHICAL CONSIDERATIONS

The study was approved by the local authorities at Mbeya Medical Research Programme and the region research ethics committee. The study did not involve any threatening or invasive procedure that was likely to cause harm. However the vaccine trial counselors were always around in case the need arises as the interviews were conducted in the clinic during working hours.

Respondents were informed that participation in this study was completely voluntary. The study's aim and method were well explained to all potential study participants in the information session. Potential participants were given a study information sheet with details about the study they had to read and sign the informed consent form before taking part in the study (appendix 3). Volunteers were ensured of confidentiality and anonymity. Due to sensitivity of the study it was clearly explained that the participants that they may refuse to answer any of the questions they do not want to and they were free to withdraw from the study at any time without negative consequences or losing any rights which they were otherwise entitled to.

CHAPTER FOUR: FINDINGS

4.1 Demographic profile of study participants

Participants were purposively chosen to suit the aim of the study. Diversity in the study sample was ensured. The researcher interviewed 11 male participants and nine female participants, of these 12 were married and eight were single. Five participants were below the age of 25 years, 11 participants were between 25-45 years old and 4 participants were over 45 years. Eleven participants lived within 3 km of the clinic while 9 lived more than 3 km from the clinic. Ten participants had a primary school education level, 5 had a secondary school education and the other 5 had a college level of education (see the table below).



Table 1: Demographic profiles of the participants:

Characteristics variables	No of participants	Percentage
<u>Gender</u>		
Male	11	55%
Female	9	45%
<u>Marital status</u>		
Married	12	60%
Single	8	40%
<u>Age</u>		
Below 25 years	5	25%
Between 25-45 years	11	55%
Above 45 years	4	20%
<u>Distance from the clinic</u>		
Within 3 km	11	55%
More than 3 km	9	45%
<u>Education level</u>		
None or below Primary school	1	5%
Primary school level	10	50%
Secondary school	5	25%
College/other institution level	4	20%
<u>Occupation</u>		
Petty business	10	50%
Students	3	15%
Employed	4	20%
House wives	3	15%
<u>HIV status</u>		
Negative	17	85%
Positive	3	15%

4.2 Entering the study and clarity of educational seminars

There were mixed views about joining the study as some participants feared and others were clear, respondents pointed out that participation in the study was completely voluntary. Potential participants attended a detailed educational seminar before they decided to take part in the trial. It was also noted that most of the volunteers who participated in HVT had been participants in other cohort studies conducted by MMRP. Respondents reported that some areas of education were clear but some areas needed to be emphasized and more clarified for example, a 23 years old female participant, and college student pointed out that... *“It was not very clear when you said, we might test positive.... but we shouldn’t worry.... I guess more clarification is needed there...”*

As to the experience about entering the study the participants reported hesitating before attending educational seminars. For example a 34 years female participant married to a bus driver remarked *“initially I was not sure whether to enter the study or not... I was hesitating because I was not sure if there is completely no risk in participating in this kind of trial... However after getting detailed information I decided to join”*

Also a 42 years old male participant who is married and a father of four children also a driver in a private company remarked ... *“I asked the facilitators so many questions...”*

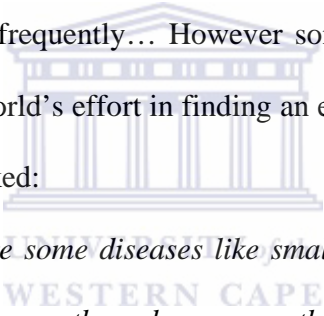
The interviewer asked him whether the questions were answered to his level of satisfaction; the response was *“ooh yes otherwise I would not participate”*

4.3 Expectation and Motivation to participation.

This part of the interview explored what compelled the volunteers to participate in the trial, also to know whether they had any concerns or worries and whether they had to ask permission from their spouses before deciding to take part in the trial.

4.3.1 Motivation factors and perceived benefits

Most of the respondents remarked that they joined the study because they wanted to check their HIV status and to receive free medical care which was part of the benefits of participating in the study. A 34 years female participant, married and mother of two working as a secretary at the university said ... I wanted to monitor my health status... I know I will be checked more frequently... However some respondents mentioned that they wanted to be part of the world's effort in finding an effective vaccine for HIV. A 44 year old male evangelist remarked:



...I know that there were some diseases like small pox which was a disaster for decades, but the vaccine was the only measure that was successful in eliminating it.... So the same with HIV, I feel that if the idea of a vaccine succeeds, it will be a savior for our nation ... adults and even youngsters are being wiped out by the disease.

Another female respondent a 45 year old married house wife explained:

My biggest motivation was medical health care... but also I thought if the vaccine will be successful it will benefit me and if not me then my children or grandchildren.

Some participants believed that they would be protected from HIV infection, for example a 25 year old single female reported... *“The vaccine must have some protective effect”*

Also a 24 years old male college student had a similar expectation he said “...if we were allowed to choose I wanted to get the real vaccine... I know it will add some immunity in the body...”

A female participant aged 33 years and married reported “... since it was the first HIV vaccine to be tried in our country... I thought it is a big achievement ... actually I’m proud to be part of this trial.

She further said “we were told that every research passes through several stages for check before approval is given to conduct the study... (Silence)... I believe our government is not asleep, it cannot allow something harmful to be introduced in the country” (this respondent also had participated in other studies at MMRP).

4.3.2 Concerns/Worries to participation on HVT

Respondents had differing views on the vaccines. Whilst some had little knowledge of the vaccine, others believed that all vaccines had some parts of the virus or bacteria in question. A 44 year old married male a street leader in one of the areas in town said “we used to know that vaccines are made from the bacteria or the virus responsible for the disease intended to be prevented... so we thought the same applies to HIV vaccine”

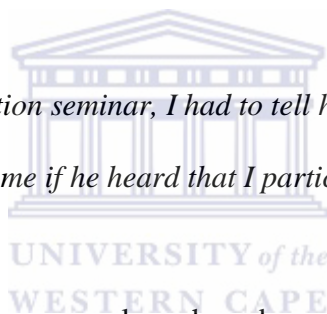
A 45 year old married female who had participated in two HIV cohort studies conducted at MMRP, pointed out that “...No, I did not have any worries, I believed what the doctors told us in the seminar and since I had been a participant at MMRP for like three years, I trust them not to do anything that will harm the participants in any way, if that was the case they would have done it long ago.”

Also a 33 years old business man said ... *Initially I was worried about the safety of the vaccine... what if it harms me or I real get sick! But the seminar was good it answered most of the questions I was asking myself*"

4.3.3 Permission from partners/spouse

Most respondents whom were either married or living together for more than two years, pointed out that, they had discussions with their partners before participating in the study. Female participants, especially, had to get permission from their husbands. A 34 year old female secretary explained:

... After attending the information seminar, I had to tell him the details of the study otherwise he would have killed me if he heard that I participated without his permission



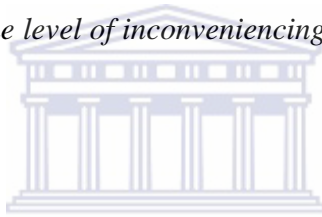
It was also reported that in some couples where by one participated whilst the other partner did not, it lead them into serious problems in their marriages. A 38 years old male participant, married and a shoe seller admitted that "... *my wife and I had a serious quarrel about my participation in this trial, especially after hearing the rumours concerning the vaccine; she would not allow me to touch her because she thought I am already infected by the virus from the vaccine...The situation got worse. We had to talk to the PI (Principal Investigator). He explained to us and together we went through the informed consent form.... she understood and things went back to normal. But I tell you it was very tough at home... (laughter).*

4.4 Personal experiences at the clinic

4.4.1 Appointments and time at the clinic

Most of the participants said they were satisfied with their appointments and other procedures at the clinic. A secondary school student aged 19 said; *“for me I was okay with the whole arrangement at the clinic and schedules, we were told from the beginning that doctors will monitor us very closely.... So how can they monitor you if you don't come here...?”*

Another participant, a 26 year old male laborer said *...yah initially appointments were like too many...though not to the level of inconveniencing my duties, but I knew it was for good intention.*



However participants who were students during the study reported that they had to adjust their routines to accommodate study appointments, for example a 24 year old male student said *“I had to change my (school) time table... especially for morning session on days of appointment ... but it was okay”* Also a secondary schools female student of 21 years said... *“at times I missed morning sessions to come at the clinic ... in the evening I had to copy notes from my classmates”*.

Some respondents felt that the time spent at the clinic to complete all procedures in a particular visit was too long, especially in the initial visits where they had to go through the informed consent process, the test of understanding, a medical examination and counseling. The evangelist said; *“ Yes ...yes...about that..., waiting time was too long in some of the visits, like in one visit I remember coming at eight o'clock in the morning*

and I left the clinic at half past three in the afternoon...this is not convenient for someone employed”.

On the other hand there were some participants who were fine with schedule and visits, for example a 33 years old business man remarked... *It was fine with me... I just live behind the clinic and am not so busy in most of the mornings.*

4.4.2 Trial procedures (Vaccination, randomization, blood draw, vaccine induced positivity)

The participants acknowledge that initially they were concerned about safety due to vaccination, particularly... A female participant 31 years old married with three children-house wife reported ...*I had some fear especially with the first vaccine shot... I thought ooh lord why did I bring my self into this...So I went home till next day... I was fine, three days later nothing wrong, and then I relaxed.*

Participants reported that it took time to fully understand the rationale and safety issues in the vaccination although they were still reporting for further doses. One respondent mentioned ...*the second one I still had some worries but the third and forth doses I was completely at ease.* Furthermore respondents reported that they did not experience any serious side effects from the vaccination, for example a 40 year old female petty trader remarked, ...*I did not feel anything like fever or any kind of shock apart from mild pain at the site of injection..*

However some participants experienced minor side effects, a married 42 year old housewife stated that, “.....*It was nothing seriousI had a headacheit lasted for like four hours”*

With regard to randomization, participants reported that they understood why they were divided into two groups (a vaccine group and a placebo group) for research purposes. A 25 years female participant who was single a vendor pointed out... *It was clear at the seminar that we have to be in two groups so that they can compare the results.*

On the other hand a 24 year old male college student stated ...*Honestly I wanted to be on the vaccine group But I was not... I believe the vaccine has some protective effects.*

Participants had different perceptions regarding vaccine induced positivity (false positive). Some accepted this situation while others were concerned. A 31 year old female secretary explained, ...*I did understand well the seminar so I thought it was just fine, so long as it is not a real infection.*

On the other hand a 49 year old business man reported, ...*I was a little skeptical and asked lot of questions on this area...at last I felt it is fine since it is a research...let it be”.*

Others felt that there was something hidden behind this positivity, for example a 24 year old young man said;

False positive mmh! ... you never know... maybe this would be for real.....honestly I was worried three months after vaccination I went to a VCT centre to test my blood , just to check if I will test positive or not” I would have also known whether I was in the vaccine or placebo arm...

Few respondents reported being uncomfortable with the amount of blood drawn for laboratory purposes, for example one food vendor, a 34 years old lady reported ... *aah! The blood taken was too much (silence)... what if someone has low levels of blood!!* (The blood drawn per visit was about 140- 150 mls).

4.5 Experiences at home with family and friends/neighbors

4.5.1 Free to tell others about their participation

Most of the participants said they were free to tell others of their participation in the trial, although some were mocked by their neighbours and friends who told them they were risking their lives for a little money. It was part of the study duties to escort participants' home after vaccinations if they wanted to. One participant, a 39 year old male participant who worked at a local garage who rejected the offer to be escorted home by a research vehicle explained,

At the beginning, I did not tell anybody..., even my wife did not know... when you (study staff) wanted to escort me home after the first vaccination.... I disappeared; actually I did not want you people to follow me home because I knew if this happens my wife will start asking questions.

The interviewer asked for the reasons not to tell his wife; he said..,

Actually in the beginning even myself I was not so much trusting what you people (the study team) told us in the seminars.... so I was in the state of let me wait and see for some time... until everything is right... when we built trust... after being vaccinated with two doses I saw nothing has happened to me or others, from there I was free to talk about the study at home and even at work.

In some areas people in the community were asking questions about the study. They wanted to know the details. A 37 years married female participant remarked,

I was free to tell my friends... they asked me questions, I answered them according to what we learned in the informational seminars... some promised to

attend information seminars, others just mocked me... but I did not care as I know what I wanted and had participated in several studies at MMRP.

4.5.2 Reactions of significant others (Spouses, family members, neighbours and friends).

Some participants admitted having a difficult time with their spouses, families and friends as there was a stigma attached to participating in the trial. They were especially skeptical about the presence of the white investigators in the trial. For instance a male tailor who was 39 years old and married summed it all:

My (relatives) and my wife had no problem and we both took part in the study...but the neighbours huh! it was hell..., especially those who were screened out at the initial stages of participation. For example one said; I tell you, those whites (European white researchers in the MMRP trial) are bad news, they are intending to inject us with the virus, they have a hidden agenda. I'm warning you... You will die for a little money.

Participants reported that most of the rumours and misconception going around in the community concerning the vaccine were coming from people who had not attended education seminars or they had wanted to take part in the trial but were filtered out during screening visits (they were ineligible). A 23 years old lady, single a college student reported that:

Friends and neighbours said we are being injected with HIV virus, we will soon fall sick, we are very stupid to involve ourselves in something very risky, why are the whites(the people coordinating the trial) not conducting this trial in their own

countries! They are coming to Africa to kill us”... but actually they didn’t know the truth about the trial.

A street leader who together with his wife participated in the trial reported the neighbors telling him ... *you and your wife are going to die due to participating in the whites’ trial.*

A male respondent 25 years a petty trader and also married pointed out;; *“I realized the people who started those rumours wanted to participate...they even attended educational seminars but they were found not to fit into the study (ineligible)... so they decided to spoil the names of those who continued with the study” For example someone at home said openly that... I listened to their (the research team) information seminars but at last I knew they have a hidden agenda.*

A lady 27 years old a housewife explained;

.....we were so much insulted by our neighbours....they said to us... You are even told not to become pregnant...but you are still blind ... it needed one to be strong to stay in the study to the end.

A 39 years old male, working at the garage narrated,

I tell you there were so many rumours in the streets, it was a big problem to many participants... some wanted to drop out of the study... It was not easy for some of the couples; they had to sleep in separate rooms.

Some respondents pointed out that they did not care much what other people thought so long as their spouses were fine with them participating in the trial. A 28 year old married male taxi driver explained:

My wife and relatives had no problems because they know and trust me that, I would not put myself into something dangerous ...and that was all that mattered to me, other people were just talking because they did not know what was exactly happening at the research centre (silence) so I just ignored them.

It was also reported by respondents that some people thought there was a hidden agenda to sell the blood to America because the study was funded by the USA military.

On the other hand respondents appreciated the health care provided by the research team when they fell sick. For instance, a 49 years old male participant, a shoe shiner who was married and a father of three children, he had some serious health problems the study team provided the necessary medical care he appreciated,

If I were not a participant in MMRP centre I would have been dead by now, because with that sickness, I would not have that amount of money needed to go to Dar-es Salaam for treatment, but with the support of research centre, look at me as you can see, I am healthy and feeling good again .

He continued,

“When I started having fits the neighbours said the vaccine has already affected me and I will soon die, even my wife was so worried”

This participant was initially well and passed all eligibility criteria during screening phase, then three months after enrolment he developed a problem of having fits which sometimes ended up with him losing consciousness. He was referred to the National Hospital in Dar-es Salaam (over 800 km from Mbeya). The research centre hired a flight for him and paid all costs for investigation and treatment. In addition he was given a

doctor from the team to escort him. He was admitted to Muhimbili National Hospital and after Computer Tomography scan it was found that he was having *Taenia solium* (cysticercosis) in the brain. He was treated and recovered fully.

Other respondents felt that the people who were spreading the rumours were being stubborn or jealous. The male street leader reported that;

Some people, who were saying bad things concerning the trial, are just being stubborn... They knew that one has to be HIV free to participate, and they can't dare go for a HIV test.... and others were just jealous because they were not benefiting from the free treatment the participants were entitled to.

4.6. HIV status, discordance and seroconversion during trial

Participants were free to discuss their HIV status. They felt that HIV/AIDS was now a common problem and people were free to talk about it. There were some participants whose partners were HIV infected while they were not (discordant couples). A female student aged 23 years explained, ... *We can discuss anything I'm so free.... even if I was positive I would have just told you, nowadays this is no longer something to hide....*

A 49 year old male participant was happy that he knew his status but the problem was his wife, he spell out *Am happy that....I'm HIV free... but I don't know my wife's state She does not want to hear anything about HIV testing....."*

Some participants were in a state of confusion they felt that may be they were infected, it was just the tests that were faulty and not giving the right results. For instance a male participant 42 years old and married also a driver explained;

...at times I do not understand what is happening in my life, because my wife is HIV positive for some years now..... but every time I come here for my appointments the counselor tells me that I'm HIV free ... so I don't know... why am I still negative ... we do not use any protection.

A male respondent 26 years old who is a laborer at the main bus stop reported; *...I guess God protects mewe found out that my wife was HIV infected during her antenatal attendance three years ago....I'm still negative... and loving my wife..... so I think am just lucky... ”*

During the two years of participant follow up in the study, some participants who were initially HIV negative, seroconverted while in the study. These respondents had different opinions for example there was a respondent who blamed the vaccine as the cause of his infection. A 28 years old male participant, married working as a clerk remarked,

What I know is that, I entered the study being HIV free and after the third vaccine they told me I was infected.... He continued “... I really wonder how come I'm infected while my wife is not and she has just delivered a baby.

The participant was bitterly complaining that it was being in the study that caused his change in status, due to its sensitivity this matter was discussed in the community board meeting, together with the study team they investigated the participant's sexual behaviour and it was found that he was at high risk of acquiring HIV due to multiple partners.

While the other infected respondents felt that they were infected because they were exposed to HIV by their partners' behaviors. For instance a 32 years old, female participant a mother of two, employed in the private sector stated;

I joined the study because I wanted to have a thorough check of my body, ... I had been doubting my husband's health for quite some time ... at the beginning they told me that I was negative..., I was so happy..... but after one year... I came to the clinic and the counselor told me that I was infected, (silence).... I was so sad but I was not surprised as I knew my husband's behaviour and he has been suffering from questionable skin infections. ... I have learned to live with the infection...I hold no grudges on him.

One married female respondent of 36 years narrated;

I was not shocked by the news because for some months my husband and I were not on good terms...he was not sleeping at home... he was going out with other women...I knew I was in danger and that's it...

All seroconverted participants are receiving supportive counseling and treatment care at the treatment centre neighboring MMRP within the Mbeya consultant hospital campus.

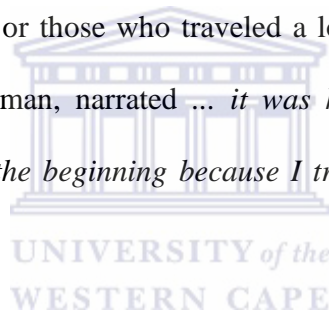
4.7. Challenges to participation and being in the study to the end

The study was quite time consuming, with numerous visits for safety purposes for instance close monitoring of participant, regarding any side effects or problems due to vaccination and the participants is well (all vital signs are normal) before allowing him/her to go home. Participants were to stay at the clinic for at least four hours in the screening and vaccination visits because they were to do informed consent papers, clinical examinations, drawing of blood, counseling and observation after vaccination. It also required the participant to come in the morning hours which were working hours for most people.

A female respondent whose business included selling spices from home explained ...*It was fine for me... I don't have much to do at home any way..., and I live just behind the clinic.* As for benefits, she remarked ... *aah! Yah! My business is small.... so with the money I received, I use to buy some basic home needs ... as it is not much...*

The participants who lived 15 km from the clinic faced the problem of transport in the morning, a lady aged 28 living with her parents explained, ...*In order to reach the clinic in time, I had to leave home very early because it is far and taxis are congested in the morning... but it was okay since it is not every day.*

Remaining in the study to the end was also a challenge to some respondents, especially to those with a busy schedule or those who traveled a lot for business purposes. A 33 years old married businesswoman, narrated ... *it was hard for me to abide with the scheduled visits especially in the beginning because I travel a lot... at times I miss my appointments...*



This also applied to students who had to miss some of their classes/sessions to attend the clinic. For example a student in one of the colleges in Mbeya who is 24 years old reported ...*my appointments were mostly on Monday or Tuesday, these days we are busy at the college... so I would come late to the clinic... or choose to miss one or two sessions...*

The study indicated that participants who dropped out for different reasons, either moving out of Mbeya town due to work, business or family reasons. None of the interviewed participants had a reason directly related to the study. A female participant

32 years old married also a secretary reported ...*I had to stop because I got a better job in Dar- es Salaam... I could not make it for all appointments because it is far.*

In another case a 26 year old female who was single at the time she joined the study said... *My fiancé lived in Arusha... he came and wanted me to go with him... So I had to withdraw from the study.... I would have continued if I was still in Mbeya.*

The constant challenge mentioned by respondents was dealing with the rumours, misconceptions and stigma of community members (relative, friends, and neighbors) regarding their participation. A 42 years old male respondent, a driver explained ... *I tell you it needed a strong heart to keep on coming here... others despaired due to what people said about this trial...*



4.8 Participant's opinion of the trial in general

Respondents acknowledged that the care provided to them at the clinic, especially when they fell ill, was of high quality. They felt safe and in good hands. This wiped away all the fears and feelings that there was a hidden agenda to this vaccine trial

A 45 year married male explained ...*the care we are getting here is not available in the public hospitals.... so I see it as a big advantage for my being in the study*".

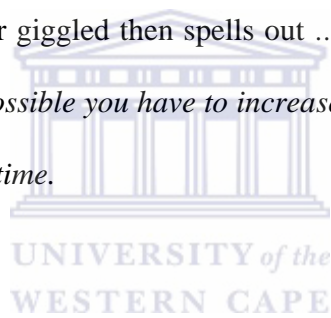
As for how to improve future HVTs most of the participant said that the order of procedures from the reception to the end of the visit was fine with them. Regarding the frequency of visits, they pointed out that it was fine since it was important to their safety.

They felt we should continue like that. For example a single female petty trader 25 year old reported,

... I feel that the whole arrangement at the clinic ...including appointments is well organized, because it is important to our health... one has to organize his/her schedule because we are given our dates to come in advance.

However an evangelist reported; *... In future you should try to minimize waiting time to allow people to continue with their daily activities.*

A 42 years old male bus driver giggled then spells out *...I am not sure whether it is the right place to say it.... But if possible you have to increase the amount of compensation... the study takes so much of our time.*



CHAPTER FIVE: DISCUSSION

This chapter discusses the findings from the study which was designed to explore expectations and challenges experienced by HIV vaccine trial participants at Mbeya Medical Research Centre. The objective of the study was to describe personal experiences and challenges encountered by the volunteers whilst participating in the trial. The key themes identified will be discussed under separate headings.

Entering the study

Most of the participants in the HVT participated in other HIV cohort studies conducted at MMRP. The study revealed that entering the vaccine trial was completely voluntary; people were invited for educational seminars. Interested individuals registered their names and were given appointments for initial procedures for enrollment (screening visits). Informed consent form was provided to all volunteers to read and sign before any procedure. According to most respondents the educational seminars were clear and understandable however some participants indicated that they wished to have more details on some areas of the study like randomization, placebo and especially the vaccine induced postivity (why this happens and how could it be differentiated from a real infection). These findings were in line with the findings by Strauss *et al.*, (2001) where the study indicated that people would require more information and assurance on these aspects before they decide to participate in a HVT. Therefore there is a need to improve the package of educational seminars to address these concerns and also giving adequate information. Also clarification of misconception before enrollment will motivate volunteers and increase enrollment uptake in future studies.

The study showed that the community develops trust in a research centre based on its previous successful research activities and the period of its existence in the community. In the study by Lesch, et al., (2006) it was noted that mistrust to the researchers was a barrier to entering the study, however the findings in this study showed that trust to the research team was an important motivating factor for participation. It was reported that some of the participants had been volunteers in other cohort studies conducted by MMRP since 2000. They reported that they knew and trusted the research centre too well to have any fears or worries concerning the vaccine on trial.

It was also noted that using the radio or television to invite or educate people on vaccine trials increased the trust of the participants to the research centre because they believed that for something to be in the trusted media it must have been approved by all important authorities. These findings are very important to the research institution to assist in building trust to the participants and research communities and thus increasing willingness of people to volunteer participation in studies. For instance in one of the studies in South Africa by Stadler and others (2007) it was noted that there was mistrust and negative disposition towards medical research. Therefore mistrust can be minimized by the use of media like television, radios and newspapers and this requires more research on how far/much does the media influence community participation in studies. However there was mistrust of the organization because it was funded by American military and white investigators. Since there is a history of colonialism in African countries there was a feeling that there is a hidden agenda behind research activities and thus having an implication to participant recruitment.

Motivation factors, perceived benefits and perceived threats

The study indicated that most respondents felt that they wanted to be part of the world's effort in fighting the HIV epidemic and some expected that the candidate vaccine would be successful in protecting their offspring in the future. The participants acknowledged the loss of their loved ones to HIV/AIDS and they really wanted to do something. They believed that a vaccine was a powerful tool in fighting serious diseases. They referred to small pox and polio as evidence. Free medical care was among the pull factors to participation in the trial. This is in line with the study conducted in the USA on preparedness to conducting a phase III vaccine trial where it was pointed out that free medical care, altruism (self-sacrifice) and expectation for the vaccine to work were some of the perceived benefits for the respondents (Strauss *et al.*, 2001).

Strauss and others (2000) noted that financial or other practical compensation were mentioned as perceived benefits for taking part in the trial. This also became evident in this study some participants reported financial compensation as part of the benefits expected. These findings has an implication on willingness of people to participate in the study it shows that people have things to consider in making decision to participate in trial based on what they believe as benefit or threat in the phenomenon in place. The participant in this study most of them participated in other studies conducted at MMRP thus they were privileged with benefits of free medical care as well as compensation. On the other hand ethical bodies are concerned with compensation or incentives to study participants. It was pointed out by Grant & Sugarman (2004) that there is a confusion regarding appropriateness of using incentives in research with human subjects; it is

considered as form of coercion or inducement especially in cases where people are not ready to participate if the amount for compensation is small.

On the other hand the study revealed that some participants took part in the study believing that they would be protected from HIV infection. This shows that there was a gap or unclear information in our educational seminars. May be the volunteers did not understand that the candidate vaccine was still on trial and it was not known whether it had the ability to protect or not. This is probably the reason some people got infected because they thought they were protected. Similar findings were pointed out from an HIV vaccine safety and immunogenicity trial conducted by Chesney, Chambers & Kahn (1997) in San Francisco to examine changes in sexual risk behavior that are associated with risk of HIV transmission. It was found that participants had participated in the trial hoping that they would be protected from HIV infection. Respondents expressed that they had some fears/worries concerning the vaccine on trial. For example they feared getting a real infection from the vaccine because they knew that most of the vaccines were made from the bacteria or virus responsible for the particular disease. Some were concerned with the safety of the vaccine; they had fear of the side effects also some participants wanted to know how long the false positive will remain in their bodies. Similar concerns were pointed out in the study by Hollander (2008) that fears of infection, mistrust of the research team and a lack of detailed information about the trial were some of the setbacks to a willingness to participate in HVT. The same findings were also noted in the study conducted in South Africa by Lesch and the colleagues (2006).

.As for family issues in relation to participating in the trial the study showed that there were some couples which experienced serious problems due to one partner participating and the other not, following rumours and misconceptions which were circulating in the community concerning the trial. It was found that participants who were married or living with partners' especially female participants had to ask permission from their partners before participating in the study.

These findings have implications to individual's freedom to decision making. In most African cultures/customs women and children are supposed to be submissive to their husbands and parents. Traditionally in Tanzania a wife has to consult or ask permission from her husband before doing anything whether is for her own or family benefit and thus interfering with one's autonomy to making decision. More education and sensitization is needed to the community to improve people's understanding of research issues and freedom to decide. In the study by Woodsong (2004) on covert use of topical microbicides in women it was revealed that a woman's decision to use the microbicides with out involving the partner was not simple especially in the context where men control house hold finances and wife is completely dependant to the husband. It was pointed out that decision to use was interfered by fear of repercussion on discovery from the partners (Woodsong, 2004).

Personal Experiences at the clinic

As for experiences at the clinic the study found that the most participants were comfortable with appointments and procedures attached to HVT. Although visits were very frequent in the beginning they understood that it was for safety monitoring purposes

and they thought that it was really important to be closely monitored. However there were some concerns over the length of waiting time also on the amount of blood drawn for tests (they felt it was too much). They had concerns on randomization and false positivity as mentioned earlier they were not able to fully understand these terms even when explained in vernacular language. This was in line with the study by McGrath *et al.*, (2001) on knowledge about vaccine trials where it was noted that most people were not familiar with the terms used in HVT for example randomization and placebo as they were difficult to understand when explained. Furthermore none of the participants had any serious side effect from vaccination apart from a slight pain at the site of the injection. Some had mild headache or fever which did not last longer than a few hours. These findings are congruent to the findings from a study conducted in Thailand where it was found that most participants experienced only minor side effects from vaccination (Pitisuttithum *et al.*, 2006). This showed that the vaccine was safe and tolerable to most participants and could be used in future vaccine trials as examples to inform potential volunteers. These findings imply to the need of improved package for educational seminar and the researchers should look for languages which are understandable to most people. Alternatively use of examples that are familiar to the research community to make sure that at the end they make an informed decision about participating in trials. In Mbeya community most people are very sensitive with blood related issue, they believe that blood is something which should not be taken by a person you don't know, it is believed that one can harm another person (superstition) by using blood products. Therefore in these kinds of studies where large amount of blood are drawn for study purposes proper and detailed explanations are needed before enrolling participants.

Experiences at home and reaction of significant others

The study revealed that respondents had varied experiences with community members. Some reported having nasty experiences with their spouses, friends and neighbors due to rumours connected to the vaccine trial. Similar findings were reported on the study by Sahay and colleagues (2004), where it was noted HVT participants experienced peers and family pressure also discrimination due to volunteering. People in the community believed that the participants were being injected with an active HIV virus and they were going to encounter a real infection which was made worse by the fact that participants may test positive in serological tests. These results are in line with the findings of the study conducted by Lesch and others (2006). It was pointed out that testing positive due to vaccine was an issue to most people as it was directly linked to real infection. The respondents reported that people who did not know the details (did not attend educational seminars) about the trial were the ones who were spreading wrong information in the community and thus increasing the negative attitude of people towards the trial and the participants. The respondents suggested we educate the whole community instead of educating only study participants.

The study showed that almost all female participants who were married or living with partners had to ask permission from their husbands to participate in the trial otherwise it may bring serious trouble at home. While there were male participants who took part in the study without wife's permission, this implies to gender power issue with regard to cultural influences over women's ability to make decision. This finding is consistence with the study by Woodsong (2004) on the use of topical microbicides where by it was

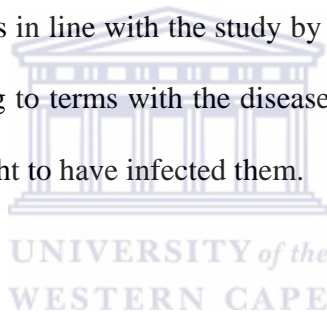
noted that based on socioeconomic status and cultural norms in African countries are likely to influence decision of women in using microbicides. It was also pointed out that men think that women should not use microbicides without informing them and receive approval (Woodsong, 2004). In another study conducted in Ghana by Tanner (2008) it was noted that relationship dynamics, power and gender roles had a great impact in the acceptability of microbicides use in women for HIV prevention. This qualitative study showed that great understanding and trust was needed among couples in Mbeya for one to continue in the trial as discouragements and de-motivators were many around the community. It also became evident that in couples where both partners participated in the study there were no problems and they supported each other in dealing with rumors and misconception.

Elsewhere in the community it was said that the research centre was benefiting by selling participants' blood to America while the participants were paid little money as compensation. These kinds of rumors had a big impact in terms of the recruitment as well as retention of participants in trials. However participants who had participated in other trials at MMRP had more knowledge on the trial procedure and had more trust to the research centre which enabled them to deal with pressure from other people (families, friends, neighbors). These kinds of rumors need to be well addressed in communities.

HIV status, discordance and seroconversion during trial

The study revealed that respondents were either not aware or they did not believe that one partner could be infected while the other was not (Serodiscordance). Some participants were denying their results based on their partners' status or a wife having a HIV free

baby, this shows that more education is needed in communities. One respondent blamed the vaccine for causing HIV infection even after being unblinded and finding out that they were in the placebo group. However the study team and community advisory board investigated his sexual behaviors and he was found to have a high risk as he was having multiple sexual partners. On the other hand respondents felt that they acquired HIV because they were at risk in one way or another. It also became evident from this study that acceptance in status change was related to partner's behaviors. It was noted that respondents did not struggle much in accepting their new status when their spouses had risky behaviors and they admitted having no grudges over them and it helped them to live with the problem (HIV). This is in line with the study by Pretorius and colleagues (2005) where it was noted that coming to terms with the disease was related to letting go of the anger/hate towards those thought to have infected them.



Challenges to participation

It became evident that respondents were aware that HIV is a problem, they perceived the risk to HIV for themselves and their generation and they felt that something has to be done to fight the disease. However they were faced by some challenges because of lacking adequate information on their safety. Most of the fears are already mentioned in the previous topics. Furthermore the study revealed that respondents faced challenges in terms of time spent at the clinic (too long), the scheduled time for clinic visits as morning hours was the time best suited for income generating activities and studies. For instance for students it was found that some had to miss their sessions to attend study visits, this has an implication in involving students and adolescents in this kind of studies as most of

them are under 18 and still in school but they are already sexually active (Villafana et al., 2006). The study on adolescents in HIV vaccine trials in Botswana showed that 1 in every 4 girls aged between 15-19 years were already infected with HIV and thus it is important to include youths in vaccine trials although is challenging due to legal implications, ethics allows participation at the age of 18 years and above (Villafana et al., 2006). Transport was a reported challenge for the participants living far from the clinic. Problems in coping with rumours and stigma attached to participation by the community members was the most frequently mentioned challenge by respondents. This is congruent with findings in the study by Hollander (2008) where it was pointed out that one in every five volunteers in HIV vaccine efficacy trials experienced at least one negative social impact. It was further noted that 14% reported negative experiences and difficulties in interpersonal relationships i.e. negative reactions from partners, family, relatives and friends. Also these findings are supported by findings from a study conducted on vaccination against Human Pappiloma virus in Twente, by Van der Berg and Westerman, (2010) which pointed out that reasons for people not participating in the vaccination programme were perceived as dangers of the vaccine, also risk for side effects of the vaccine.

Challenges to the researcher

Although the study managed to explore and explain HVT participant's expectation, experiences and challenges encountered during their participation in the trial. The research experienced some challenges during data collection and analysis. One of the challenges was to interview participants who had dropped out of the study and were unable to come at the clinic for interviews. For instance in one case the interview had to

be conducted at the respondent's office after exhaustive efforts to reach her. It was also emotionally challenging to ask the questions about HIV status especially to participants who seroconverted during the study as this was attributed to study induced seroconversion. The researcher's role in the trial and now as a researcher in this interview was therefore difficult especially in cases where participants mentioned that they seroconverted.



CHAPTER SIX: CONCLUSION AND RECOMMENDATIONS

The study has contributed to the understanding of HVT participant's experiences and challenges encountered during participating in the trial. The findings in this study are important to the research team plans for future vaccine trials. Areas of concerns were identified which needs to be addressed by the research team conducting vaccine trials at MMRP especially capacitating the research community with all the necessary information before enrollment of volunteers. The elicited information will be used in improving the educational package and other aspects of the study based on the experiences of the people who took part in the trial.

In this study it becomes evident that more and detailed information about the trial procedures and outcomes are needed during the educational and information seminars to deal with volunteers' worries and concerns with regard to their safety. Therefore we recommend improving the package of information seminars with additional information, explanations and an emphasis on aspects which are of concern to the volunteers, for instance, information on the nature of the candidate vaccine, vaccine induced positivity, randomization and placebo.

The study also revealed that participants experienced difficulties in the community due to rumours and misconceptions, as the people in the community are not well educated about the vaccine trials, therefore we recommend a continuous education program by the research centre to all communities where HVT is taking place, not only to volunteers in the trial, to help the communities understand the research and thus minimize rumors and misconceptions. In addition we recommend the use of media like television and radio

programmes for community education as it was noted that when people heard something via the media, they believed that the authorities had approved it.

The study found that there were serious family problems among couples where one was a HVT participant and the partner was not, due to misconceptions regarding the vaccine on trial. We recommend that the recruitment team should invite married couples or living together volunteers to a special session where, they have an opportunity to learn and make an informed decision together.

In addition the possibilities of discordant results in couples should be well explained by nurse counselors during HIV counseling sessions, as the study showed a lack of knowledge on this. If possible, voluntary counseling and testing should be done to both partners, even if one of them would not be participating in the trial.

The timing of visits to the clinic (morning hours and week days) was bringing some inconvenience to some participants like students, employees and other participants with busy daily schedules, therefore we recommend the research team organize some clinics/visits on weekends for participants who cannot make it on weekdays or organize for late evening clinics to accommodate the volunteers who are employed and the team should minimize the waiting time by scheduling a smaller or manageable number of participants per day.

Opinions and experiences elicited with regard to rumors and misconception about HVT in the community was only from the people participated in the study, it would be nice to conduct further studies to the community members surrounding the research centre for more understanding of issues related to participation in vaccine trials in the Mbeya community.

The amount paid (10 USD) for compensation was found to be small compared to the time spent at the clinic and other inconveniences. Therefore we recommend a rise in compensation, not necessarily in cash; it could be food, vouchers.



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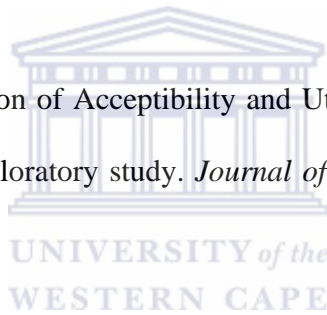
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APPENDIX 1: GUIDELINE OF THE IN-DEPTH INTERVIEW

Introduction of the interviewer and the aim of interview

Ask for permission to record the interview

Note the time of starting the interview.

Questions

1. How did you know about HVT study?
2. What motivated you into participating and what were your worries or fears?
3. What was your experience as a participant at the clinic?
4. What was the experience as a participant at home, what did the people close to you feel or say regarding your participation in the trial?
5. Were you free to tell the people at home that you are participating in the study?
Ask for reasons for whatever the answer the respondent gives.
6. What was your experience with vaccination shots i.e. the first shot?
and what about the other shots.
7. What do you think about vaccine induced positivity?(The false positive)
8. Would you like to discuss with me about your current HIV status. If yes then tell me how you feel about your status.
9. Would you please tell me what you did appreciate in the trial what do you think needs improvement?

Thank you so much for your time and cooperation, do you have any question before we close the interview?

APPENDIX 2: THEMES AND CODES

A. Entering the study

- Invitation and educational seminars
- Challenges, experiences and expectations upon joining the trial

B. Expectation and Motivation to participation.

- Motivation to participate in HVT
- Concerns/Worries to participate in HVT
- Permission from partners/spouse

C. Personal experiences at the clinic

- Appointments/schedules and procedures
- Trial procedures (Vaccination, Randomization, vaccine induced positivity)

D. Personal experiences at home (in the community)

- Spouses, family members, neighbors, workmates and friends (what did they feel, say, react)
- Free to tell others about their participation
- Misconception and rumors

E. HIV status, discordance and seroconversion during the trial

- Feelings on their current status
- Experiences and challenges of those who seroconvert

F. Challenges to participation and being in the study to the end

- Perceived threat
- Perceived benefits
- Sustainability issues/Withdraw from the study

G. Participant's opinion of the trial in general

- What went well? - Strength
- What needs improvement?- weakness



APPENDIX 3: PARTICIPANT INFORMATION SHEET (English)

Date:

Dear participant

Thank you for agreeing to listen/read to information package concerning this study. What follows is an explanation of the study, purpose and process of the interview. The study is for mini –thesis being conducted as a partial fulfillment for Masters Course in Public Health at the University of Western Cape. You are free to ask me any question or clarification regarding this study. My contacts and those of my supervisors are written at the end of this sheet.



Title of study

Expectations and Experiences of HIV vaccine trial participants at the Mbeya Medical Research Programme in Mbeya, Tanzania 2006-2007.

The Purpose of the study

This study seeks to explore expectation and experiences of participants during the HIV vaccine trial at the clinic as well as in their families/community. With intention to improve recruitment and participation in future HVT by improving educational seminar package using experience and information received from volunteers who participated in the HIV vaccine trial before.

Description of Study

The study will need you to undergo an in-depth interview of about 40-60 minutes at the clinic after finishing your routine scheduled activities. The interview will be audio recorded with your permission. The question will focus on your experiences as a HIV vaccine trial participant at MMRP.

Anonymity of respondents (Confidentiality)

At all times, I will keep the source of the information confidential and refer to you or your words by a nickname which I would like you to choose before the interview starts. I shall keep any other records of your participation locked away at all times, and destroy them after the study has been completed. The contents will be used for the purposes referred to above, but may be used for published or unpublished research at a later stage.

Voluntary participation and withdraw

Participation in this study entirely voluntary, you are free to withdraw at any point of interview if you decide to do so. The interview may touch on issues which could be sensitive to you in one way or another if there is anything that you would prefer not to discuss, please feel free to say so. I will not be offended and there will be no negative consequences if you would prefer not to answer any question. I would appreciate your guidance should I ask anything which you see as intrusive.

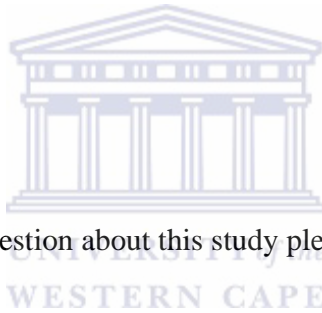
Benefits and costs

There may not be any direct benefits for you in taking part in this study, however the information received from the volunteers will help the Mbeya Medical Research team to

improve recruitment and retention of study participants in future studies and any success from these vaccine studies my benefit your future generation. There no cost for participation in this study apart from the extra time you will spend at the clinic after finishing your routine activities.

Informed consent

If you understood my explanation and you are willing to participate in this study, I will request you to sign an informed consent form before I proceed with the interview. The form is attached to this information sheet you may review the form and decide whether you want to participate or not.



Questions

Should you have any further question about this study please contact me at

Name: Erica Sanga

UWC student no: 2706872

Tel: +255 25 2503364, Fax +255 25 2503134 and cell phone: + 255 762 577041

E-mail:ericass80@hotmail.com or esanga@mmrp.org

Institution: Mbeya Medical Research Programme (MMRP)

I am accountable to Dr Leonard Maboko who is the principle investigator of the vaccine trial study and the Managing Director of MMRP, contactable at phone number + 255 25 2503364 or Fax: 025 2503134 and by e-mail lmaboko@mmrp.org

APPENDIX 4: PARTICIPANT INFORMATION SHEET (Swahili)

UKURASA WA MAELEZO KWA MSHIRIKI

Tarehe:

Ndugu Mshiriki

Asante kwa kukubali kusilikiza/kusoma maelezo kuhusu utafiti huu. Kifuatacho ni maelezo ya kina juu ya utafiti, malengo na taratibu za mahojiano. Utafiti ni kwa ajili ya tasinifu ndogo, inayoanywa kama sehemu ya kukamilisha kozi ya shahada ya uzamili wa afya ya jamii katika chuo kikuu cha Western Cape kilichopo Afrika ya kusini. Una uhuru wa kuuliza swali lolote au ufafanuzi kuhusiana na utafiti huu. Maelezo juu ya jinsi ya kunifikia na pia wakuu wangu yameandikwa mwishoni mwa hii karatasi.

Jina la utafiti

Matarajio na uzoefu wa washiriki wa majaribio ya chanjo ya virusi vya ukimwi katika program ya utafiti wa tiba za binadamu mkoani Mbeya, Tanzania 2006-2007.

Madhumuni ya utafiti

Utafiti huu unatafuta kugundua matarajio na uzoefu wa washiriki wa majaribio ya chanjo ya virusi vya ukimwi katika maeneo ya kliniki na pia majumbani, katika familia zao na jamii kwa ujumla.

Ukiwa na lengo la kuboresha upatikanaji wa washiriki wa majaribio ya siku sijazo kwa kuboresha kifurushi cha semina elimishi kutegemeana na habari tutakazipata toka kwa washiriki waliowahi kushiriki katika majaribio haya hapo nyuma.

Maelezo ya utafiti

Utafiti utakuhitaji ufanye mahojiano ya kina kwa takribani dakika 40-60 katika kliniki baada ya kumaliza taratibu zako zote za kawaida. Mahojiano yatarekodiwa iwapo utaruhusu. Maswali yatalenga kujua uzoefu wako kama mshiriki wa majaribio ya chanjo ya virusi vya ukimwi hapa

MMRP.

Usiri wa mshiriki na taarifa zake

Wakati wote nitatunza chanzo cha taarifa zangu kwa usiri na nitakutambua kwa kutumia jina bandia ambalo utalichagua mwenyewe kabla ya kuanza mahojiano. Nitatunza taarifa nyingine zozote za ushiriki wako zikiwa zimefungiwa wakati wote na zitaharibiwa baada ya utafiti kwisha kabisa. Taarifa ulizotoa zitatumika kwa madhumuni yaliyotajwa hapo juu lakini pia yaweza kutumika kwa chapisho kataka hatua za baadaye.

Hiari ya kushiriki au kujitoa

Ushiriki wako katika utafiti ni wa hiari kabisa, uko huru kujitoa wakati wowote wa mahojiano iwapo utaamua kufanya hivyo. Usahili au mahojiano yanaweza kugusa mambo ambayo ni nyeti kwako kwa njia moja au nyingine, iwapo kuna chochote ambacho hutapenda tuzungumzie, tafadhali kuwa huru kusema. Sitaudhika na hakutakuwa na shida/ubaya wowote iwapo utaamua kutojibu swali lolote. Nitashukuru kwa mwongozo wako endapo nitauliza swali ambalo unaliona ni kero.

Faida na gharama

Yawezekana kusiwe na faida ya moja kwa moja kwa wewe kushiriki katika utafiti huu, hata hivyo taarifa tutakazopata toka kwa washiriki zitasaidia timu ya watafiti kuboresha ushiriki na ukaaji wa washiriki katika tafiti zijazona pia mafanikio yatakayotokana na hizi

chanjo zinazojarihiwa yatasaidia katika kizazi kijacho. Hakuna gharama yoyote utakayotoa kwa kushiriki katika utafiti huu mbali na muda wa ziada utakaoutumia kliniki baada ya kumaliza utaratibu wako wa kawaida.

Idhini ya ushiriki

Iwapo umeyaelewa maelezo yangu na uko tayari kushiriki katika utafiti huu, nitakuomba uweke sahihi katika fomu hii ya kukubali kushiriki kabla ya kuendelea na mahojiano. Fomu imeambatanishwa na karatasi ya maelezo unaweza kuipitiana uamue iwapo utapenda kushiriki au la.

Maelezo/maswali zaidi

Endapo utakuwa na maswali zaidi kuhusu utafiti huu tafadha wasiliana nami, Naitwa Erica Sanga

Namba ya uanafunzi UWC 2706872

Simu: 255 25 2503364, Fax +255 25 2503134 na simu ya mkononi + 255 762 577041

Barua pepe: ericass80@hotmail.com au esanga@mmrp.org

Taasisi: Mbeya Medical Research Programme (MMRP)

Ninawajibika kwa Dr Leonard Maboko ambaye ndiye mtafiti mkuu wa majaribio ya chanjo ya virusi vya ukimwi na pia mkurugenzi wa MMRP, anapatikana kwa simu namba + 255 25 2503364 au Fax: 025 2503134 na e-mail lmaboko@mmrp.org.

APPENDIX 5: PARTICIPANT INFORMED CONSENT FORM(ENGLISH)

Title of the study

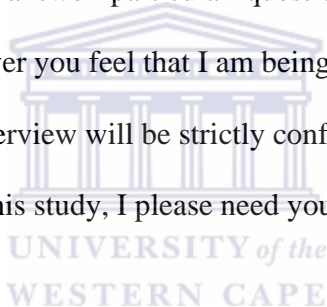
Expectations and Experiences of HIV vaccine trial participants at the Mbeya Medical Research Programme in Mbeya, Tanzania 2006-2007.

Thank you for agreeing to take part in this study. As mentioned earlier your participation in this study is entirely voluntary. You may decide not to participate or withdrawals at any point of the interview without losing any privilege or benefit you are entitled to.

You may also choose not to answer particular question asked during the course of interview be free to say whenever you feel that I am being intrusive, I wont be offended.

Information received in this interview will be strictly confidentially.

If you decide to participate in this study, I please need you to sign before we proceed with the interview.



I Agree to take part in this study. I have read and understood the participant information sheet or it has been read to me. I understand that participation is voluntary and I have the right to withdraw from interview and free not to answer any questions I do not want to answer in this interview. Also I have been assured of confidentiality of the information I give and I had the opportunity of asking questions and they were answered to the level of my satisfaction.

.....

Participants signature

Date

.....

Witness name and signature if the participant is illiterate

Date

.....

Researcher's name

.....

Researcher's signature

Date



APPENDIX 6 : PARTICIPANT INFORMED CONSENT-Swahili

IDHINI YA MSHIRIKI KUSHIRIKI

Jina la utafiti

Matarajio na uzoefu wa washiriki wa majaribio ya chanjo ya virusi vya ukimwi katika program ya utafiti wa tiba za binadamu mkoani Mbeya, Tanzania 2006-2007.

Nakushukuru kwa kukubali kushiriki katika utafiti huu, kama ilivyoielezwa hapo awali kushiriki kwako ni kwa hiari kabisa. Unaweza kuamua kutoshiriki au kujitoa katika hatua yoyote ya majadiliano bila kupoteza faida yoyote ambayo unatakiwa kuipata. Unaweza pia kuchagua kutojibu baadhi ya maswali yatakayoulizwa wakati wa mahojiano, kuwa huru kusema wakati wowote utakapoona nakuingilia sana, sitauidhika. Taarifa zitakazopatikana katika mahojiano haya zitakuwa siri kubwa, Iwapo unaamua kushiriki katika utafiti huu, tafadhali nitakuomba usaini kabla hatujaendelea na mahojiano.

Mimi.....Nakubali kushiriki katika utafiti huu.

Nimesoma/nimesomewa na kuelewa karatasi ya maelezo. Naelewa kwamba ushiriki wangu ni wa hiari na nina haki ya kujitoa kwenye mahojiano na nina uhuru wa kutojibu swali lolote nisilopenda kulijibu katika mahojiano haya. Pia nimehakikishiwa usiri wa taarifa nitakazotoa na nilipata nafasi ya kuuliza maswali niliyokuwa nayo ambayo yalijibiwa kwa kiasi nilichoridhika.

.....
Sahihi ya mshiriki

.....
Tarehe

.....

Jina la shahidi na sahihi iwapo mshiriki hajui kusoma/kuandika Tarehe

.....

Jina la mtafiti

.....

Sahihi ya mtafiti

Tarehe

