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MOTIVATIONS AND DETERRENTS TO TAKE PART IN AN HIV VACCINE TRIAL: EXPERIENCES FROM STUDY PARTICIPANTS IN DAR ES SALAAM, TANZANIA

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"...treat future trials as an opportunity to apply our best science not only to product development but to the community dimensions of clinical trial planning and implementation"- Newman, PA. 2006

ABSTRACT

Background: As HIV infection continues to be a public health problem, development of an effective preventive HIV vaccine is a priority. For the ultimate development of an AIDS vaccine, clinical trials are being conducted throughout the world. However, the process of developing the vaccine does not only depend on identification of suitable trial candidates, but also requires knowledge of incentives to participate in the community where the trial is being conducted. Therefore, the studies presented in this thesis are components of a HIV/AIDS and HIV vaccine trial project in Dar es Salaam, Tanzania to address motivations and deterrents of participating in an HIV vaccine trial.

Aim: To examine the motivations and deterrents for participating in preventive HIV vaccine trials.

Methods: Data were collected from participants and volunteers who were considered for participation or participated in a phase I/II HIV vaccine trial. Four studies with different designs were conducted. In Study I, a semi-structured interview administered questionnaire was used to assess willingness to volunteer for a phase I/II HIV vaccine trial. A convenience sample of 329 individuals from the police force cohort was recruited for the study in 2005-2006. In Study II, focus group discussions were conducted to explore factors that would influence participation in an HIV vaccine trial among members of the police force in 2006-2007. In Study III, face-to-face interviews were used to identify reasons for declining to enrol in an HIV vaccine trial among those who agreed to enrol at the start and were randomized for the trial in 2007-2009. In Study IV, we used focus group discussions to evaluate the experiences of those who participated in the phase I/II trial in 2009.

Results: Willingness to volunteer for an HIV vaccine trial was associated with intention to tell others, positive outcome of the trial, personal decision and expectation of obtaining protection against HIV infection. Participation in an HIV vaccine trial would be negatively influenced by sexual partners, friends, family members, relatives or parents (significant others) and fear of vaccine side-effects. Personal fears and negative influences from significant others were the main reasons for declining to enrol in an HIV vaccine trial. Despite the negative comments from significant others, volunteers in the HIV vaccine trial managed to stay on until the end of the trial as a result of personal decision and trial-related interventions.

Conclusion: Personal decision is both a motivation to participate in an HIV vaccine trial and a reason to stay on until the end of trial. On the contrary, significant others are the deterrents to participation in the HIV vaccine trial and the reason for declining to enrol in the HIV vaccine trial. Awareness of these issues before trial implementation may help to maximize resource use and enhance retention of those who volunteer in the HIV vaccine trials.

Keywords: Willingness, phase I/II, HIV, vaccine trial, motivation, enrolment, participation, police officers, Tanzania

LIST OF PUBLICATIONS

The following articles are included in the thesis, and they will be referred to by their Roman numerals I-IV in the text:

I. **Tarimo, EAM.,** Thorson, A., Bakari, M., Mwami, J., Sandstrom, E., and Kulane, A. Willingness to volunteer in a phase I/II HIV vaccine trial: a study among police officers in Dar es Salaam, Tanzania. Global Health Action, 2009, **2**: doi:10.3402/gha.v2i0.1953

II. **Tarimo, EAM.,** Thorson, A., Kohi, TW., Mwami, J., Bakari, M., Sandstrom, E., and Kulane, A. Balancing collective responsibility, individual opportunities and risks: A qualitative study on how police officers reason around volunteering in an HIV vaccine trial in Dar es Salaam, Tanzania. BMC Public Health 2010.**10**: 292. doi:10.1186/1471-2458-10-292

III. **Tarimo, EAM.,** Thorson, A., Kohi, TW., Bakari, M., Mhalu, F., and Kulane, A. Reasons for declining to enrol in a phase I and II HIV vaccine trial after randomization among eligible volunteers in Dar es Salaam, Tanzania. PLoS one 2011.**6**(2): e14619. doi:10.1371/journal.pone.0014619

IV. **Tarimo, EAM.,** Thorson, A., Kohi, TW., Bakari, M., Mhalu, F., Sandstrom, E., and Kulane, A. A qualitative evaluation of volunteers' experiences in a phase I/II HIV vaccine trial in Tanzania (manuscript)

All previously published articles are open access and ownership is with the author.

CONTENTS

LIST OF ABBREVIATIONS

AIDS	Acquired immunodeficiency syndrome
ART	Antiretroviral therapy
ARVs	Antiretroviral drugs
DNA	Deoxyribonucleic acid
EU	European Union
FGDs	Focus group discussions
GDP	Gross domestic product
HIV	Human immunodeficiency virus
HIVIS	Human immunodeficiency virus-I study
IAVI	International AIDS Vaccine Initiative
IHCAR	International health care research
IRB	Institutional Review Board
MNH	Muhimbili National Hospital
MOHSW	Ministry of Health and Social Welfare
MSM	Men who have sex with other men
MUCHS	Muhimbili University College of Health Sciences
MUHAS	Muhimbili University of Health and Allied Sciences
MVA	Modified vaccinia Ankara
NACP	National AIDS Control Program
NBS	National Bureau of Statistics
NIMR	National Institute for Medical Research
PASADA	Pastoral activities and services for people with AIDS in Dar es Salaam archdiocese
PYAR	Person-year-at-risk
SMI	Swedish Institute for Communicable Disease Control
SPSS	Statistical package for the social sciences
TACAIDS	Tanzania Commission for AIDS
TaMoVac	Tanzania Mozambique Vaccine trial project
TANSWED	Tanzania Sweden research collaboration
THMI	Tanzania HIV malaria indicator
UNAIDS	Joint United Nations Programme on HIV and AIDS
WHO	World Health Organization
WRAIR	Walter Reed Army Institute of Research
WTV	Willingness to volunteer

PREFACE

The choice of HIV vaccine trial as my PhD topic has a history, beginning when I met Associate Professor Muhammad Bakari in 2005. Muhammad Bakari was at that time the co-principal investigator in a large-scale HIV and AIDS project, the forerunner of the subsequent HIV vaccine trial in the cohort of police officers in Dar es Salaam. He invited me to join the project as a social scientist, and because my research interests were in HIV and AIDS, I accepted his invitation. That was my first stepping-stone to research in the social and behavioural aspects of the HIV vaccine trial project in the cohort of police officers in Dar es Salaam, Tanzania (2007-2011).

Back in 1997, when I was doing a nursing internship at Muhimbili National Hospital (MNH), I saw an emaciated female patient sleeping in a remote corner, far away from the main entrance to the ward. With compassion, I felt like asking her about her condition, but she was quite obviously suffering from AIDS. A nurse pulled me aside: 'Don't spend time in that place; it is infectious! [The nurse whispered]! I still remember the image of that patient who could be a 'mama' [mother] of somebody / sister / friend / colleague, etc.' and the whisperings of the nurse. With the little knowledge I had about HIV and AIDS, I was confused about what to do. However, my confusion was allayed by a colleague with whom I shared the situation. He put me in contact with an organization that ran counselling courses, particularly for HIV/AIDS, that were funded by the British Council in Dar es Salaam. I felt proud after acquiring the skills I was lacking when I came across the sick woman and the nurse [poorly skilled in counselling techniques].

After my internship (1998), I decided to apply my counselling and nursing skills to AIDS patients. I started working for Pastoral Activities and Services for people with AIDS in Dar es Salaam Archdiocese (PASADA) as a counsellor, community health nurse and later on as the director of home-based care services for people with AIDS up to 2002. PASADA is a non-governmental organization which has gained tremendous recognition because of its extensive non-discriminatory services to people with AIDS in Dar es Salaam and neighbouring regions. During my practice, I noted people visiting from a neighbouring region, Morogoro, partly to avoid stigma in their local district, but also to obtain quality services. My four years of working with PASADA were characterized by overwhelming challenges, especially the countless days of grieving for our clients. Premature deaths were very common because most clients showed up at a very late stage of their illness. We provided expertise in palliative care, but our services, including the provision of oral morphine to alleviate severe pain, were limited. Thanks God, today we have antiretroviral therapy (ART). Although not everyone who is eligible can get the treatment on time, I am sure that the availability of antiretroviral drugs (ARVs) has changed and prolonged the lives of many individuals.

During my work experience, I noted another category of AIDS victim - the informal caregivers whose workload was doubled and who found themselves providing basic medical/nursing care to relatives with AIDS without having the proper skills; a situation that could predispose them to HIV infection and/or inappropriate management of AIDS patients. The details of caregivers and their contribution to AIDS care are available in my Master's thesis entitled: 'Assessing the impact of HIV/AIDS on informal care: a qualitative study from an urban Tanzanian context'. These findings are also published in Transcultural Nursing Journal, Vol. 1 .2009. The above exposure was a crucial factor in me staying in the field of HIV/AIDS research. Also, I believe that the

contribution of social science to the development of an HIV vaccine is important especially in our cultural context. Although no one is sure how long the vaccine journey will take, I am confident that **P**eople **h**ave **D**reams, dreams that will eventually contribute to the development of an AIDS vaccine.

1 INTRODUCTION

1.1 BACKGROUND

For more than three decades, Human Immunodeficiency Virus (HIV) and its related disease, Acquired Immunodeficiency Syndrome (AIDS) have persisted without an effective preventive vaccine. Efforts are ongoing throughout the world to search for such a vaccine [1], but progress is hampered by both scientific [2-3] and social challenges in the recruitment of volunteers [4-8]. Scientists have discovered different forms of an HIV virus that have evolved over time. These forms are members of the same family tree with different branches known as clades (subtypes) [9], which exist in different parts of the world. The existence and distribution of different subtypes in the world [10-11] is a dilemma for scientists. Can a vaccine tested in one part of the world be used in other parts of the world? Clearly, multiple trials are needed for different subtypes in different parts of the world. Along with these trials, studies of the incentives and deterrents for participating in an HIV vaccine trial are key to understanding the acceptability of the trial in the community where it is being conducted.

In previous studies, there has been increasing demand for basic HIV vaccine education to address certain vaccine trial concepts [12-21] in order to understand the conduct of HIV vaccine trials. Moreover, willingness to participate in HIV vaccine trials and the associated motivations and barriers have been broadly documented. In high-income countries, the motivations to participate in HIV vaccine trials include: a high perceived HIV threat [17], perceived protection [5, 22], higher self-related likelihood of HIV infection [21, 23], perceived high-risk behaviour [24], monetary incentives [25-26], and feeling comfortable about participation in an HIV vaccine trial [21, 27]. The barriers towards participation in HIV vaccine trials have also been identified in these countries: mistrust of government or scientists conducting the trials and fear of being stigmatized [5, 22, 25, 28], low perceived risk for HIV infection [5, 22], fear of vaccine induced HIV sero-positive [5, 22, 25, 28-29], side-effects of the vaccine [22, 25], longer trial duration [29] and effect of participation in the trial on relationships [22].

In low-income countries, willingness to volunteer for HIV vaccine trials is positively associated with: a wish to prevent or stop the spread of HIV [16, 20, 30-31], perceived vaccine protection against AIDS and perceived family support for participation [32], helping researchers to find an effective vaccine [20], self-perception of HIV risk [12] and desire to have protective vaccine [15-16, 20, 33-34], assurances regarding stigma and confidentiality, and compensation for family in the event of poor vaccine outcome [16]. In Uganda, the high interest in a vaccine trial among participants was found to be influenced by unrealistic expectations such as being protected from HIV transmission while having multiple sexual partners or not using condoms [35]. However, a study among commercial sex workers in Kenya showed that fewer respondents would increase risk behaviour as a result of participation in an HIV vaccine trial [36]. The barriers identified in relation to participation in HIV vaccine trials in low-income countries are: possibilities of side-effects from the vaccine [15, 30], perceived risk of stigma [14, 32-33], fear of becoming HIV infected from the vaccine [15-16, 33], fear of discovering own HIV status [14], physical risk [14, 34], effect of the vaccine on participants' lives and unknown efficacy of the trial [20], requirement to delay pregnancy and low-risk behaviour [34]. In addition, a growing body of literature shows

that altruism provides universally consistent motivation for HIV vaccine trial participation [5, 13, 16, 18, 34, 37-39].

Despite the fact that many trials have been conducted, few studies have explored the experiences of the volunteers who enrol in HIV vaccine trials. Those who enrol and stay on until the end of the trial have been noted to reduce their high-risk sexual behaviour [40-41]. However, some of the volunteers have encountered negative reactions from friends and family [42-45] because of participating in the HIV vaccine trial. In addition, some studies have documented reasons for declining to enrol in HIV vaccine trials among eligible volunteers. The reasons include: trial duration [46-48], negative reactions from partner, family or friends [47], and concerns about false positive HIV test results and side-effects from the vaccine [47-48]. These studies provide unique knowledge on the uptake of HIV vaccine trials in different contexts, which may be useful even in the acceptability and uptake of a partially effective vaccine if made available.

1.2 GLOBAL OVERVIEW OF HIV VACCINE TRIALS

Increasingly, most HIV vaccine trials are performed in the United States and Europe with very few conducted in Africa [1, 11, 49]. Given the genetic variability [10], conducting HIV vaccine trials is important, both in high- and low-income countries. It is also logical to test the typical vaccine in various regions where they are likely to be used [9]. The first phase I trial was conducted in the US in 1987 [10] among 72 healthy adult volunteers and the first volunteer was immunized in February 1988 [50]. At the end of 2009, almost 200 trials, using a variety of vaccine types alone or in combination, were recorded in the International AIDS Vaccine Initiative (IAVI) Clinical Trials Database [3]. The first phase I/II vaccine trial in a developing country was conducted in China in 1993 [11]. Since then, more than 30 phases I and II trials have been completed in developing countries with several trials in Thailand, Brazil, Haiti, Botswana and South Africa, Zambia, Rwanda, Kenya and Uganda [1]. In 1999, Uganda was the first country in Africa to conduct a phase I/II HIV vaccine trial [1, 51-52]. The study evaluated safety and immunogenicity among healthy, HIV-negative, low-risk, adult male and female volunteers. None of the trial volunteers experienced significant local or systemic toxicity from the candidate vaccines tested in Uganda [51, 53-54]. HIV vaccine trials have also been performed in Kenya since 2001 [55-57]. In addition, a multi-site phase I/II HIV vaccine trial was conducted in the general population in Uganda, Kenya and Tanzania in 2003 [1, 58].

Phase III HIV vaccine trials have also been conducted to assess the protective efficacy of different versions of candidate vaccine. So far, four AIDS efficacy trials have been completed: 1) The VAX004 trial using AIDSVAX B was conducted during 1998 in the US, Canada and the Netherlands among 5 403 men who have sex with men (MSM) and among women at high risk for heterosexual transmission of HIV-1 [9, 59-60]; 2) The VAX003 trial using AIDSVAX B/E, Clades B & E was conducted in Bangkok, Thailand between March 1999 and August 2000 among 2546 injection drug users [61]. Both trials did not indicate overall protective effect of the vaccine against acquisition of HIV infection. 3) The STEP trial using Adenovirus type 5 (Ad5) vaccine was conducted in the Americas, Caribbean and Australia among MSM and at-risk women [62-63]. Unfortunately, the trial was discontinued in 2007 because there was an increase of HIV-1 acquisition in subgroups of male vaccine recipients who had pre-existing Ad5 antibody titres, and also were uncircumcised [62, 64]. Following the non-efficacy results from the STEP trial, the Phambili trial in South Africa, which was using

the similar Ad5 vaccine, was also stopped before completion [64]. 4) Recently, a sign of hope for an effective vaccine came through the RV144 trial using ALVAC-HIV plus AIDSVAX B/E, Clades B&E which was conducted among the general population in Thailand. The trial results showed that the vaccine had the potential to lower the rate of HIV infection by 31% [65-66].

(See Appendix I for stages of clinical trials and safety issues)

1.3 THE NEED FOR AN HIV VACCINE FOR AFRICA

An HIV vaccine is urgently needed for Sub-Saharan Africa because the majority of new HIV infections in the world continue to occur in selected countries in this region [67]. Similarly, it is important to conduct HIV vaccine trials in Tanzania because of a large number of new HIV infections [68].

Risky sexual behaviour in Tanzania

In Tanzania, the HIV epidemic is fuelled by an increase in the high-risk behaviour of having unprotected heterosexual intercourse with multiple sexual partners [68]. In recent years, the national response has been directed towards increasing individual and community awareness of the risk of HIV and its implications for the individual, the family and the community [69]. Even with preventive efforts such as large-scale information campaign and widespread condom distribution [70], new infections continue to occur due to people having unprotected sex with concurrent sexual partners [70-74]. In 2008, it was found that less that 50% of people aged 15-49 years old used a condom during their most recent higher risk intercourse (sexual intercourse with a non-marital or non-cohabiting partner) [68]. For both men and women, urban residents have higher levels of HIV infection than rural residents (9 and 5 percent respectively). In a previous study among police officers, the HIV prevalence was comparable to that of the general population, and condom use was low [75]. Therefore, unprotected heterosexual intercourse which accounts for over 90% of new HIV infections remains the primary mechanism for HIV transmission in Tanzania [68]. Thus, more HIV transmissions are likely to continue in some populations in Tanzania.

Although antiretroviral therapy (ART) is available in Tanzania, only 32% of people living with HIV are able to access it [67]. ART is given to people who are already infected with HIV to prolong their lives, but efforts towards development of an effective preventive vaccine for those who are HIV-negative are a priority. However, with persistent risky sexual practices and even the stigma surrounding ART use, participation in preventive HIV vaccine trials may bring a new challenge, namely that participants will be guided to practice safe sex which may not be a shared norm for many people.

Sexual behaviour, use of ART and stigma

Little research has been performed on sexual behaviour in relation to ART use or adherence to ART in Africa. In Uganda, Bunnel et al found that provision of ART, prevention counselling (including partner voluntary counselling) and testing decreased high-risk sexual behaviour and sexually transmitted HIV infection [76]. In a previous review, introduction to ART showed both an increase and decrease in high-risk sexual behaviour among clients [77]. In addition, a multivariate analysis of the relationship between ART, adherence and unprotected sex suggests that a decrease in high-risk sexual behaviour depends on adherence among enrolled patients [78]. However, in some parts of Africa, availability of ART was found to bring a new source of stigma;

those on ART were perceived as a threat to the well-being of the HIV-negative members of the community [79-82]. It is important to understand issues surrounding sexual behaviour, stigma towards HIV/AIDS and ART use in the African context. This information may guide the researchers in predicting what may happen when implementing preventive HIV vaccine trials as well as in the event of a partially effective preventive vaccine being available.

1.4 AN OVERVIEW OF HIV VACCINE TRIALS IN TANZANIA

Tanzania is among the very few countries in Africa conducting HIV vaccine trials. Consequently, a cohort of police officers in Dar es Salaam was recruited to assess its suitability for future HIV vaccine trials in 1994. Between 1994-1998, the prevalence and crude HIV-1 incidence among members of the police force was determined and was found to be 13.8% and 19.6/1000 PYAR respectively [75]. According to WHO recommendations [83], these results showed that the police officer cohort would be a potential suitable population for HIV vaccine trials. To that end, preparatory sensitization meetings with commanders and police officers of all ranks in all stations in Dar es Salaam were conducted. The meetings were intended to inform and educate police officers about the nature of HIV incidence study and the HIV vaccine trial project. In addition, information leaflets about what the study was all about were made available to workshop participants in a national language (Kiswahili).

After these preparations, HIV Vaccine Immunogenicity Study (HIVIS03), a phase I/II trial was conducted among police officers in Dar es Salaam, and the first volunteer was vaccinated on 27 February 2007. The HIVIS03 was a collaborative research programme that involved Muhimbili University of Health and Allied Sciences (MUHAS) in Tanzania, the Swedish Institute for Communicable Disease Control (SMI) and Karolinska Institutet (KI) in Sweden, the University of Munich, Germany, and the University of Cape Town, South Africa, as well as the Walter Reed Army Institute of Research (WRAIR) in the US. The study received support from the European Union (EU), the Swedish Embassy in Dar es Salaam, and the European and Developing Countries Clinical Trials Partnership (EDCTP). The HIVIS03 trial further built up on the results of an earlier phase I HIV01/02 trial that was conducted among 40 individuals in Stockholm, Sweden and which showed that the candidate Deoxyribonucleic acid (DNA)- Modified Vaccinia Ankara (MVA) vaccine caused mild and tolerable vaccine-related events [84] as well as being capable of eliciting good immune responses [85]. This study involved the experiences of recruitment and participation in the follow-up trial in Tanzania, HIVIS03. The vaccines used in the HIVIS03 trial were found to induce strong and broad immune responses among the vaccinated Tanzanian volunteers with priming with DNA and boosting with MVA [86].

Based on the results from HIVIS03, another phase II HIV vaccine trial has been started in May 2010 to further explore the best HIV-1 DNA vaccine delivery method. This is a collaborative project between Tanzania and Mozambique (TaMoVac-1). The trial sites are based in two cities, Mbeya and Dar es Salaam. In Mbeya, the volunteers are recruited from the general population, while in Dar es Salaam they are recruited from the police force, prison force and youths. All the recruited volunteers are at low risk of HIV infection. Another TaMoVac-II trial is planned to start in April 2012 in Tanzania and Mozambique to further optimize DNA delivery using novel methods like electroporation, and also to further document the immunogenicity and safety of the vaccine.

1.5 RATIONALE

In Tanzania, motivations for and barriers to participation in HIV vaccine trials have not been studied. For future HIV vaccine trials to succeed, it is important to understand the potential study participants in terms of knowledge, attitudes and their perceptions. General misconceptions about the HIV vaccines [5, 14, 20, 28, 34, 37, 39, 52] can prevent people from participating in any vaccine study. Such misconceptions may even interrupt scientific efforts towards prevention of other infections in the future as well as acceptability of a newly developed vaccine for other diseases. Therefore, studies on the existing knowledge, attitudes and perceptions towards HIV vaccines, norms, and risk behaviour are very important during phase I/II HIV vaccine trial implementation. This thesis provides contextual information to understand motivations and deterrents for participation in an HIV vaccine trial in Tanzania. Understanding this scenario is crucial to gain knowledge on the "motivations to participation in an HIV vaccine trial" among the Tanzanian's police officers who took part in the studies. The studies also provide unique information on the uptake of the current HIV prevention efforts within the police force in Dar es Salaam, Tanzania.

1.6 AIM AND OBJECTIVES

1.6.1 Aim

To examine the motivations and deterrents for participation in preventive HIV vaccine trials

1.6.2 Objectives (I-IV)

I. To determine factors associated with willingness to volunteer in a phase I and II HIV vaccine trial among police officers
II. To examine how police officers reason around their decision to volunteer for the HIV vaccine trial.
III. To explore reasons for declining to enrol in the HIV vaccine trial after randomization among eligible volunteers.
IV. To evaluate experiences of volunteers who participated in phase I and II vaccine trial.

1.7 THEORETICAL MODEL

This thesis focuses on different aspects of public health such as health promotion, disease prevention and evaluation of effectiveness of the programme intervention. Therefore, it is important to apply a model that can provide scope to analyze the knowledge, perceptions and cultural issues involved in the participation in an HIV vaccine trial in an African cultural context. In this regard, participation in an HIV vaccine trial is a health promotion issue and an important step towards prevention of HIV transmission (participating in the trial to develop a preventive vaccine). Thus, participation in an HIV vaccine trial should be examined (motivations and deterrents), evaluated and finally, the intervention points should be identified to aid the future design of clinical trials in a Tanzanian setting.

1.7.1 PEN-3 Model

PEN-3 is an acronym of the three components of each dimension (domain) in the model (Figure 1) that I will describe later. The PEN-3 model is a model that was developed and was first published in 1989 to be used in planning and evaluating culturally appropriate health interventions [87-88] in African settings. The model offers scope within which socio-cultural meanings can be cross-examined. It is also designed to put much more focus on the voices of the community, which form the basis of all

health interventions [87]. The model has been used to prioritize interventions aimed at HIV/AIDS prevention, care and support in Africa [88], HIV and AIDS-related stigma in the context of family support and race in South Africa [89], and in decision making on malaria treatment for children under five years among mothers in Nigeria [90]. The PEN-3 model is useful because it can be modified and extended as needed to fit different target cultures [91].

The model consists of three domains, each with three components. These domains are: Cultural empowerment; Relationships and expectations; and Cultural identity (Figure 1).

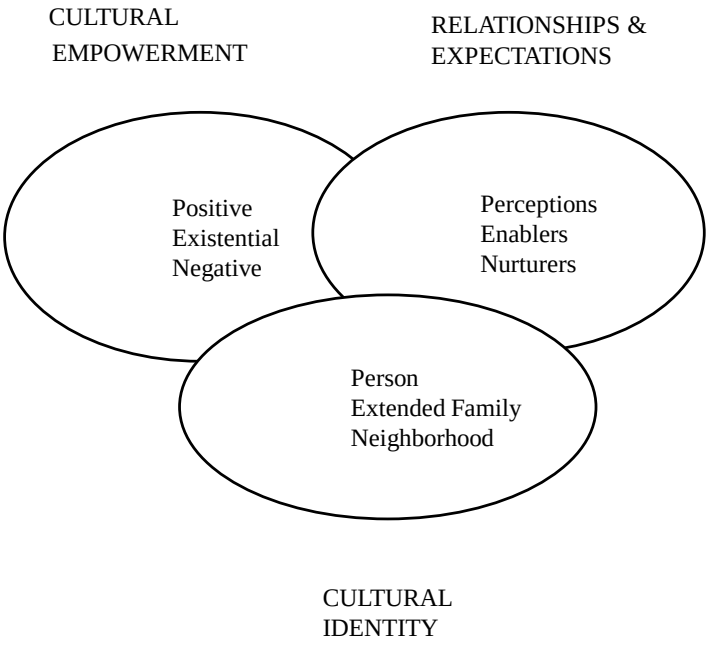

Figure 1. Pen-3 Model

Cultural empowerment
Within the cultural empowerment domain, Airhihenbuwa [87] argues that in every community, in every family, in every individual, there is tripartite entity of the following components:
Positive: values and relationships that promote the health behaviour of interest.
Existential: qualities of culture that make that culture unique; mostly ill understood by outsiders and often blamed for programme failures.
Negative: the conventional objectives of programme interventions that focus on what is wrong that should be changed.

Relationships and expectations:
According to Airhihenbuwa [87], the influence of family, kin, and friends is important in nurturing individual behaviour. This emerges from the relationships and expectations that exist in any culture. The relationship and expectation domain is influenced by the following components [87-88]:
Perception - knowledge and belief, values, in decision-making that are focused on either persons or groups, highlighting the complementarities of emotions and rationality in behaviour outcomes.

Enablers - resources and institutional support, socioeconomic status, and wealth (assets over liabilities) as measures of resources and power, and costs and availability of services.
Nurturers - supportive and/or discouraging influences of families and friends including eating traditions, community and events, spirituality and soul, values of friends (e.g. alcohol consumption), and marriage rules and expectations.

Cultural identity
The above three components of cultural empowerment (positive, existential and negative) interact and co-exist with those of relationships and expectations (perceptions, enablers and nurturers) to define the individual and his or her cultural identity. The three components of the cultural identity domain are:
Person – the degree to which the person may be dealing with the notion of double consciousness during programme interventions [87-88].
Extended family – the degree to which the family network allows different persons within the family to influence key decisions in the family. Family relationships and responsibilities form the basis for communication on which preventive health programmes should be founded [87] .
Neighbourhood – the capacity of a geographically and/or ideologically defined group (community, village, congregation, etc) to influence decisions for its collectives [87].

Cultural identity is the intervention point of entry because the question of identity is central in finding solutions to health problems [87]. The model gives scope in which the range of cultural values can be encouraged, acknowledged and/or discouraged by project implementers.

1.7.2 Application of PEN-3 model in HIV vaccine trial participation
This model has been loosely adapted in the present study to explain the phenomenon of participation in an HIV vaccine trial. The use of the PEN-3 model in the present study will help when responding to the question, "What motivates participation in HIV vaccine trials in a Tanzanian context?"

The PEN-3 model will be used to organize the main results into categories specific to the components of cultural empowerment & relationships and expectations domains. The following is a description of how the components of the Cultural empowerment domain are applied in HIV vaccine trial participation:

- *Positive* is the knowledge, values and/or beliefs that promote participation in HIV vaccine trials
- *Existential* refers to cultural values among the community members that are somehow unique and that researchers may not be aware of in relation to participation in HIV vaccine trials, for example the opinions of significant others.
- *Negative* focuses on what is wrong that should be changed in order to promote participation in HIV vaccine trials.

Moreover, the components of the relationships and expectations domain are applied to HIV vaccine trial participation as described below:

- *Perception* refers to knowledge, beliefs and values that motivate people to volunteer for an HIV vaccine trial.
- *Enablers* are institutional support mechanisms available to facilitate participation in HIV vaccine trials

- *Nurturers* are elements of support and /or discouraging influences of significant others towards participation in HIV vaccine trials.

The components from both domains are integrated in the presentation of the results in the thesis.

Appendix II summarizes the selected results from each objective.

The cultural identity is a point of intervention. In HIV vaccine trials, some of the interventions will be directed at the individual level. For example, the precise information about the phase I/II HIV vaccine trial should focus on individual volunteers while the misconceptions and rumours should be addressed at both community and individual levels. Information targeting families or close members of the family (extended family) may be used to tailor recruitment strategies. So, cultural identity domain will be discussed along with other components and will be also addressed in the recommendations.

In this way, the model constitutes a suitable framework to synthesize the findings in an understandable manner for the trial implementers, leading up to recommendations for designing future trials in a similar context. Thus, the range of cultural values can be *encouraged – (*positive responses towards participation in the trial), *acknowledged* – (existential or nurturers in the community), or *discouraged* – (negative responses towards participation in the trial) by the HIV vaccine trial implementers.

Therefore, a decision to participate in the future HIV vaccine trials in this context where this study was conducted will be based on where the intervention [education] should take place because health education can be used to reinforce long-term cultural beliefs at appropriate levels. That is, at a personal, extended family, neighbourhood or community level.

2 METHODS

2.1 CONTEXT AND POPULATION

2.1.1 Setting

All studies were carried out in Dar es Salaam, Tanzania. Tanzania is situated in East Africa, immediately south of the equator, with an area of 947 300 square kilometres and a population of 42 746 620 million people [92]. Administratively, it is divided into 26 regions. The Dar es Salaam region, in the east coast of Tanzania, has an area of 1 393 square kilometres and a population of 3.207 million according to 2009 estimates [92]. According to DSS data [93], administratively, Dar es Salaam is divided into the municipalities of Ilala, Temeke and Kinondoni. Dar es Salaam has a mixture of more than 120 ethnic groups from all parts of Tanzania but originally only one group (Zaramo) inhabited the area. The majority of the population are Muslim (70%), and the rest are Christian (30%). Kiswahili is the major language. A large portion of people in the region work for small businesses or do manual labour (both skilled and unskilled); and a few have office jobs. The region has three municipal-government hospitals, a national hospital (Muhimbili), which is also a large public university teaching hospital, private hospitals and health centres as well as not-for-profit health organizations [93].

Figure 2. Location of Dar es Salaam, adapted from DSS site map, Tanzania
Source: **http://www.idrc.ca/ev_en.php?ID=43009_201&ID2=DO_TOPIC**

Table 1. Selected health and development indicators in Tanzania

	Indicator	Figure
1	Population growth rate (%, 2011 estimates)	2
2	Birth rate (births /1000 population, 2011 estimates)	32.64
3	Death rate (death/1000 population, 2011 estimates)	12.09
4	Infant mortality (deaths/ 1000 live births, 2011 estimates)	66.93
5	Life expectancy at birth, both sexes (years)	53
6	Total fertility rate (children born/woman)	4
7	Sex ratio (male(s)/female)	1.03
8	Literacy level (%, 2002 census)	69.4
9	Population living in urban areas (%)	26
10	GDP per capital (Purchasing power parity – PPP (2010 est.))	1,500
11	GDP (PPP) (billion, 2010 estimates)	62.22
12	GDP (Real growth rate - 2010 est. %)	6.4

Source: https://www.cia.gov/library/publications/the-world-factbook/geos/tz.html

2.1.2 Health system

Tanzania has a well-developed, albeit basic health care delivery system that is organized at three levels – primary, secondary and tertiary. The primary level consists of dispensaries, health centres and district hospitals. The secondary level consists of regional hospitals with six tertiary hospitals in the country [94]. MNH is one of the tertiary hospitals based in the City of Dar es Salaam. The referral system of patients from one level to another follows the skills that are required to address the problems of the patients. HIV prevention and AIDS care and treatment services are integrated into all levels through policy and technical support from the Tanzania Commission for AIDS (TACAIDS) and the National AIDS Control Programme (NACP) respectively. TACAIDS was created by a parliamentary statute in 2001 and is mandated to provide strategic leadership, coordinate multisectoral response and perform monitoring and evaluation activities, including research, resource mobilization and advocacy. Among other activities, the NACP, under the Ministry of Health and Social Welfare (MOHSW), conducts sentinel surveillance to provide updated estimates of selected basic demographic and health indicators [68]. In 2005, the United Republic of Tanzania under the MOHSW launched a national HIV vaccine framework to guide vaccine trials research in Tanzania. This framework is comprehensive in the sense that it highlights all the essential requirements for conducting clinical trials [95]. According to this framework, emphasis has been also on socio-cultural and political challenges in conducting HIV vaccine trials.

2.1.3 The HIV epidemic in Tanzania

Similar to many other sub-Saharan African countries, Tanzania is facing challenges in controlling the HIV epidemic. Since the first cases of AIDS were recorded in Tanzania in 1983 [96], enormous efforts have been made to control the epidemic. This includes promotion of condom use and behaviour change [70]. Despite the efforts, the number of HIV-infected individuals continued to increase until 2006 when prevalence started to stabilize in most regions in the country [68].

Dar es Salaam, the region of interest in this study, has the second-highest prevalence of HIV in the country [68]. Unlike other regions of Tanzania, Dar es Salaam draws attention in respect to HIV/AIDS in various ways. Most people are exposed to HIV prevention messages through mass media; consequently, there is increased public

awareness of HIV/AIDS and attitudes are more open. Nevertheless, in this most populous city, previous studies have shown a high HIV prevalence. For instance, the sero-prevalence among hotel workers was 10.4% in 1990 [97]; and was 13% among the police force in 1995 [75]. The prevalence is still high (9.3%) in this city[68]. Women aged between 30 and 39 years had an estimated prevalence of between 9.5 and 10.4 in 2008. The overall prevalence for both men and women in the age group of 15-49 is 5.7 [68], a group that is reproductively important, and also the most economically productive.

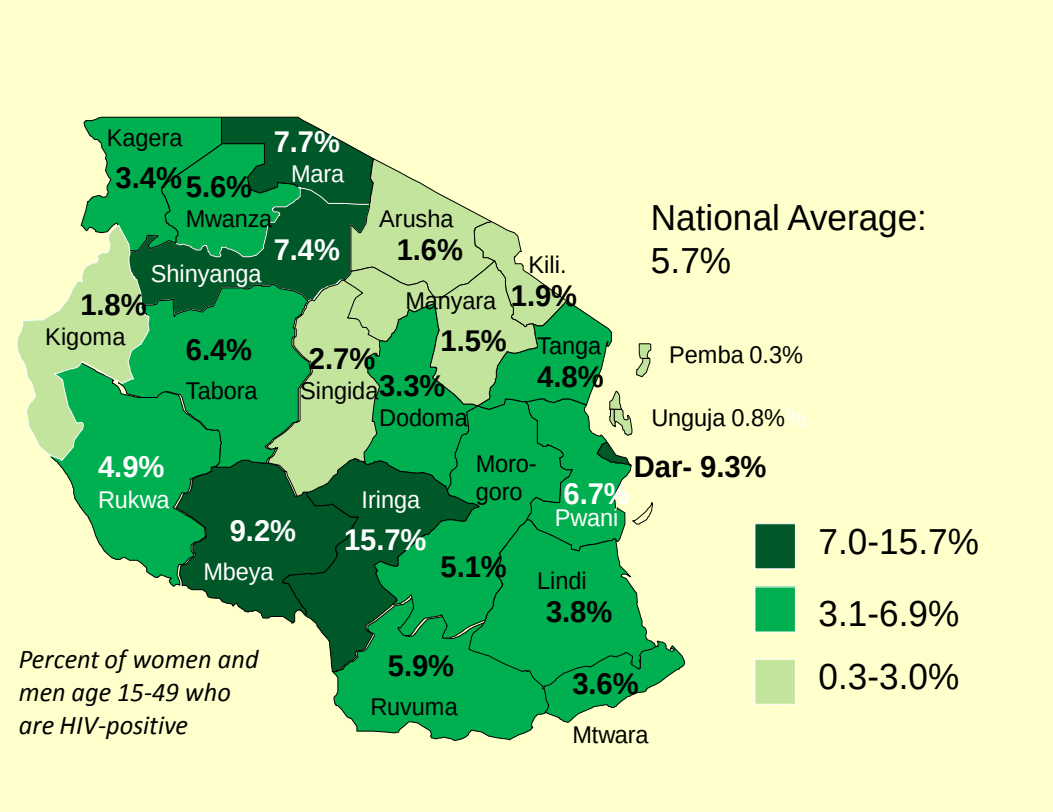

Figure 3. Distribution of HIV prevalence in Tanzania by region - 2008
Source: Tanzania HIV and Malaria Indicator (THMI) Survey – NBS, TACAIDS and Macro International, 2007-2008

Table 2. Selected HIV/AIDS indicators

1	Indicator	Tanzania	Sub-Saharan Africa	Global
2	% prevalence among adults (15/49 years)	5.6	5.0	0.8
3	Adults and children living with HIV (million)	1.4	22.5	33.3
4	AIDS-related deaths among adults and children	110 000	1 400 000	1 800 000
5	Adults and children newly infected with HIV	100 000	1 800 000	2 600 000
6	Access to anti-retroviral drugs among people eligible for treatment (Adult coverage %)	32	37	36

Source: http://www.unaids.org/globalreport/documents/20101123_GlobalReport_full_en.pdf

2.1.4 Study population

A total number of approximately 3 000 police officers, 20% of them female, made up the police force in Dar es Salaam during data collection. The region has 32 police stations, all of which were involved in the Tanzania-Sweden collaboration (TANSWED) project which recruited approximately 1 300 police officers from all stations to determine the current prevalence of HIV infection in 2005 - 2006.

The following section presents the flow of activities and series of studies from preparation to the evaluation of phase I/II HIV vaccine trials.

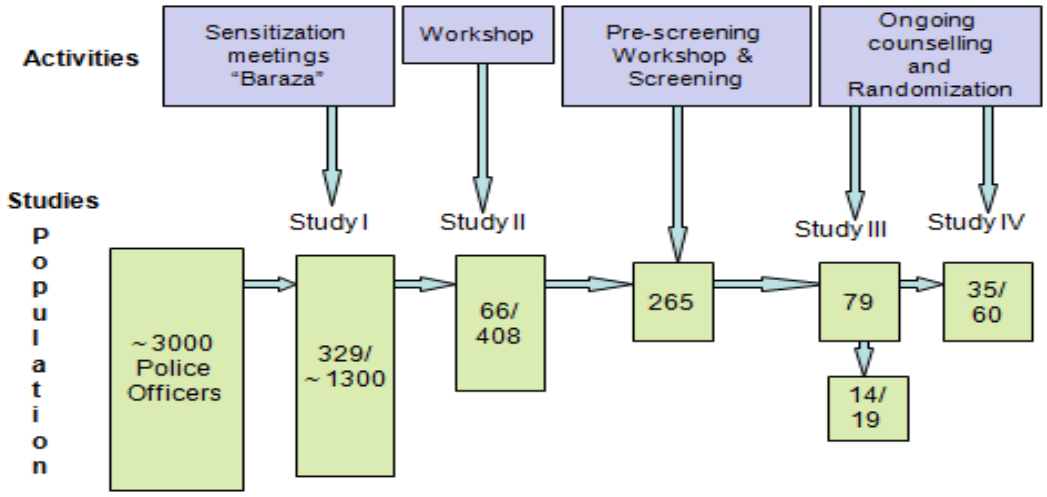

Figure 4. Activities, population and study time points

2.2 STUDY DESIGNS AND PARTICIPANTS

2.2.1 Study I

Participants were recruited from a pool of approximately 3 000 police officers (Figure 4). Approximately 1 300 of these voluntarily participated in sensitization meetings to learn basic information about HIV infection at the national and individual level. They also took part in an HIV prevalence study. These meetings were held in the police stations by a field team consisting of doctors, nurses and counsellors from MUHAS and MNH together with collaborators from the police force, a medical doctor and a nurse from the Health Unit in the police force. Questions and answers led to extensive discussion on various concerns about HIV/AIDS, which were addressed by the field team. The field team gave the police officers detailed information about the aims of HIV/AIDS and HIV vaccine trial project. During the meetings, information leaflets were distributed. After each meeting, the participants were voluntarily invited to take and read the consent form which described all the details of the studies, and get back to the nurse counsellors if they wished to take part in the studies. After understanding the details of the studies, all of them returned the forms either with the intention of participating or not participating in the studies. Those who wanted to participate in the studies signed the consent form, were interviewed on social and behavioural issues (Questionnaire 1), and then received voluntary pre-test counselling proceeded by HIV testing. In this interview, participants were also asked to indicate if they were willing to form a group of educators (core group) to educate other police officers about

HIV/AIDS and HIV vaccine trials following additional training. (A total of 408 signed for the core group membership). After two weeks, those who tested for HIV were contacted for post-test counselling and HIV test results, followed by second interview on vaccine knowledge, attitude and willingness to volunteer for the HIV vaccine trial study (Questionnaire 2). A convenience sample of 329 responded to both questionnaires, and was included in Study I.

2.2.2 Study II

Study participants were recruited from the group of participants who were interested in educating others (the 408 members of the core group) about HIV/AIDS and HIV vaccine trials after a detailed workshop. This workshop was more informative than the sensitization meetings in the sense that it was conducted in a venue outside the police stations on Saturdays, with facilities such as powerpoint presentations, and handouts about the HIV vaccine trials (frequently asked questions). The details of the magnitude of HIV/AIDS globally, regionally and nationally; historical background of the available vaccines such as polio, measles; reports of ongoing HIV vaccine trials in the world and phase I and II trial in Sweden were discussed with the workshop participants. In addition, the field team provided information on the benefits and risks of taking part in the planned phase I and II HIV vaccine trial among police officers in Dar es Salaam. Such benefits were: complete physical check-up; free medical services and referral to credited health centres if taken ill during the trial; follow-up visits and regular HIV testing. Possible risks such as unknown preventive effect of the vaccine were also discussed. The team clarified the inclusion criteria, including the age limit of between 18 and 40 years (HIVIS03 requirement) and contraceptive measures to avert pregnancy throughout the trial period. The participants were asked to share the education obtained from the workshop with colleagues at work. The workshop organizers provided the volunteers with the option of giving their contact details before leaving the venue for internal use only. (Through this process, a total of 265 participants from repeated similar workshop registered that they would like to volunteer for the HIV vaccine trial). A month after the workshop, a purposive sample was drawn from the workshop attendees for Study II. Groups of diverse membership with respect to age, sex, rank, location of the police stations, marital status and whether the participant played a care-giving role for a relative suffering from AIDS were formed for focus group discussions (FGDs). Except for the care-giving role group, stations with less than four participants who did not fit into the pre-determined characteristics of the groups were excluded from the sampling frame. A total of 66 participants were included from the stations that met the inclusion criteria.

Stepping-stones to Study III and Study IV

Special sessions about the vaccine that was being tested were organized and general information relating to the implementation of phase I and II HIV vaccine trials such as trial duration, required investigations, procedures, rules and the number of study visits including what the volunteer should expect at each visit was given to the 265 potential volunteers in groups of 50-60. Pedagogic illustrations were used to emphasize understanding, for example the amount of blood needed for the tests as compared to the total blood volume in a healthy individual. A comprehensive checklist of who was eligible for such trials was discussed. Those who considered themselves eligible for the trial according to the checklist were asked to confidentially register their contact details for future screening [complete medical and behavioural risk assessment]. On different occasions, those who met the eligibility requirements were invited for individual screening at the trial site. Before the screening took place, each individual signed part

one of the informed consent form, a prerequisite for enrolment in the trial. The screening involved: clinical history and examination; HIV counselling and testing; safety laboratory tests; screening for syphilis and hepatitis B infections; blood for haematological and clinical chemistry, and urine collection for pregnancy test among females. Potential volunteers were also interviewed by the study nurse about their risk behaviour, for example the number of sexual partners they had had in the last six months and whether condoms were used. Two weeks later, they signed part two of the informed consent form to confirm their enrolment in the HIV vaccine trial and follow-up if they skipped the planned schedules. This procedure of signing two parts of the informed consent form was stated in the original project protocol. During this second visit, all laboratory results in line with fulfilling the inclusion criteria were reviewed and the volunteer was assessed to make sure that he or she had understood the objectives of the study. A total of 79 participants were randomized into the trial. Nineteen skipped or withdrew before the first injection and were replaced to obtain a total of 60 vaccinees (Figure 4).

2.2.3 Study III

Studies III and IV were affiliated with the HIVIS03 trial. Informants for Study III were recruited from the 19 eligible volunteers for the phase I/II trial who withdrew from the trial after randomization (19/79). The sample was all-inclusive of the participants who declined to enrol in the trial. The author of this thesis, who was also part of the recruitment team, contacted the potential study participants by mobile phone, briefed them about the aim of the present study, and asked whether they were willing to share their reasons for declining to enrol in the HIV vaccine trial. Of the 19 targeted participants, 14 (74%) agreed, were accessible, chose to meet the author at their workplace and participated in the study.

2.2.4 Study IV

As stated earlier, the HIVIS03 project randomized 79 volunteers in total, but 19 withdrew after randomization (see above). The remaining 60 volunteers, 15 (25%) of them being women, enrolled fully in the trial and proceeded with the scheduled follow-up trial visits (Figure 4). Therefore, the participants in Study IV were drawn from the volunteers who enrolled and completed the trial schedules. The recruitment of these participants started towards the end of the vaccination procedures; two announcements about this study were made during regular workshops with the volunteers, telling them that they would be invited to share their experiences during the trial with the researchers. Volunteers who took part in an earlier interview after the third DNA / placebo vaccination [98] were excluded from the sampling frame because we wanted to gain the shared perspectives from those who were never interviewed. Before the actual invitation to FGDs, the first author grouped the potential participants by gender and marital status. The number of participants per group ranged from 7-11 which followed the recommended size for focus group discussions of 3-12 people [99-100]. A total of 35 participants were included in the study.

2.3 DATA COLLECTION TOOLS

2.3.1 Structured interviews [Questionnaire] (Study I)

Whereas unstructured interviews contain a number of open-ended questions, semi-structured interviews lie somewhere between the structured and unstructured types, containing elements of both, with some questions being closer to structured interviews, and others closer to unstructured ones [101].

In Study I, peer-reviewed and pre-tested questionnaires containing both close- and open-ended questions were used to collect data. The first questionnaire was used to gather basic information on knowledge, attitudes to HIV and AIDS, sexual practices and was assessed by 'yes', 'no' or 'I don't know' options. The second questionnaire comprised questions on vaccine knowledge and attitudes to vaccine trials. Knowledge about how a vaccine works was assessed by asking an open-ended question; categorized as either 'right', 'not right' or 'I don't know' by the interviewer; attitudes towards vaccines and willingness to volunteer in HIV vaccine trials were assessed by using 'yes', 'no' or 'I don't know' responses. The reasons for the given responses on willingness were further explored by using open-ended questions that were categorized accordingly. Both questionnaires were administered in face-to-face interviews by trained nurse counsellors. The nurses' expertise in health issues enabled them to give immediate counselling to the study respondents after filling in the questionnaire. The semi-structured interview was used to collect data because the nature of the study design involved knowledge facts and scope for immediate intervention (counselling/education) when required. The PhD candidate (EAMT) also took part in data collection and counselling.

2.3.2 FGDs (Studies II & IV)

Focus group is an inquiry that uses interview in groups of people who have experiences or conditions that are of interest to researchers [99]. The group interviews are stimulated by the interaction between the participants, from which researchers discover how participants think and feel about a particular issue [99, 102]. We therefore used FGDs because they are typically designed to elicit normative views and perceptions [103]. They also preserve group norms, richness of the information, and groups' perspectives in terms of collective judgements [104]. A topic guide is often used to moderate the discussion.

In study II, the number of the participants per group ranged from four to twelve. A topic guide comprising general socio-demographic background information was provided and two main research issues were asked: (1) "Can you tell me your views about the problem of HIV and AIDS in the police force?" (2) "What are the cultural norms, views and opinions among police officers that may influence willingness to volunteer in an HIV vaccine trial?" In the present study, we focus on the cultural norms, views and opinions among police officers that may influence willingness to take part in HIV vaccine trial. All FGDs were conducted in a location of the participants' own choice at the police stations. Two trained and experienced moderators interchangeably moderated the discussions, which were audio-recorded and lasted between 25 and 71 minutes.

In Study IV, the number of group participants ranged from seven to eleven, and one question was asked: "Can you tell us your opinion on changes that occurred during the vaccination period?" This question was followed by probing questions. The discussion was held in a venue at the trial site and I (EAMT) was the moderator, having been trained and experienced in moderation skills. The discussions lasted between 79 and 115 minutes.

2.3.3 Face-to-face interviews (Study III)

An interview is a data collection tool used to explore the 'insider perspective'; to capture, in the participants' own words, their thoughts, perceptions, feelings and experiences either face-to-face, over the telephone or on the Internet; and the tone of

the interview is generally informal and conversational [105]. It is informal and conversational in the sense that the researcher uses an interview guide to explore and understand the world from the participant's perspectives. A face-to-face interview was considered appropriate for data collection because it can elicit personal opinions about sensitive issues, and will reveal the topic and importantly, the research question was on personally oriented experiences.

In Study III, face-to-face interview with a semi-structured guide was used to collect data. The interview guide contained the following statements: "I understand you are among the volunteers who were randomized in an HIV vaccine trial; however, later you decided not to continue with the planned visits for the vaccinations. Can you explain to me the reasons for not continuing with the scheduled vaccinations?" This question was followed by a probing set of questions related to the responses. All interviews were audio-recorded except one due to a noisy environment. The interviews lasted for 10-30 minutes, excluding the conversations before and after the audio recording.

2.4 DATA ANALYSIS

2.4.1 Statistical analysis (Study I)

The first step was to merge the two questionnaires by using the respondents' exclusive study numbers. Frequency distribution of all social demographic variables (sex, age, marital status, religion, education, number of children, housing, ranks and work stations) and other independent variables was performed. All the social demographic variables and other dichotomous or categorical variables whose responses were represented by options of 'yes', 'no' and 'I don't know' were cross-tabulated for willingness to volunteer in an HIV vaccine trial, and Pearson Chi-square was displayed.

For the subsequent analysis, we created new variables. For example: 'single/separated' and 'widowed' were merged into 'single' and compared with 'married'. All other independent variables were also merged. For example: Do you think Tanzania should be a partner in developing HIV vaccine?: 'yes', 'no', and 'I don't know'. We repeated the cross-tabulation and test for willingness after merging and only marital status changed to non-significant in the Pearson Chi-square test. All variables that were significant with the Pearson Chi-square except marital status were significant in the final model.

We applied binary logistic regression to analyze willingness and the associated socio-demographic characteristics, knowledge, attitudes, self-perception of risk and risk behaviours. The willingness to volunteer (WTV) for the HIV vaccine trial was assessed by 'yes' and 'no' choices. Binary logistic regression was performed to estimate the odds ratio (OR) and 95% confidence interval (CI) of factors associated with WTV for the HIV vaccine trial. Missing responses were excluded and non-significant results were not reported. Statistical analysis was conducted using SPSS 15.0 for Windows (SPSS, Inc Chicago, IL, USA). Open-ended questions such as the reasons given for volunteering or not volunteering for the trial were analyzed using a content analysis approach.

2.4.2 Interpretive description (Study II and Study IV)

Interpretive description is an inductive analytic approach designed to create ways of understanding clinical phenomena that yield applications implications [106]. The method relates to other qualitative methods in the sense that it borrows from some aspects of grounded theory, naturalistic inquiry, and ethnography, drawing values

associated with phenomenological approaches [107]. As other qualitative methods of analysis, ID uses similar process such as coding, categories formation and theme(s). Primarily, ID aims to answer questions of relevance to clinical disciplines in which understanding and focus are considered crucial.

The audio-taped FGDs were listened to after each FGD to help design the probes for the next FGD; transcribed verbatim and translated from Kiswahili to English. The main author (EAMT), a bilingual speaker of Kiswahili and English, read all the transcripts several times to understand the data set and to identify ideas, patterns and codes on the margins of the transcripts. The codes were then read and compared. To increase validity and ensure quality, data were inductively coded separately and discussed between two researchers in both Study II and Study IV. Through an interpretive process, the categories were formed and compared against the FGD transcripts to ensure that interpretive analysis reflected the raw data content. The underlying meanings in the data set led to emerging themes. Finally, all authors read the analysis and agreed on the emerging theme(s). The preliminary findings were presented and discussed with the trial team and the study participants on different occasions. The discussion provided more insight on the data, leading to a review of the categories and the theme(s). In both studies, quotes were used to reflect the voices of the participants in the studies.

2.4.3 Content analysis (Study III)

In qualitative research, content analysis can be approached in either latent or manifest form. Latent analysis is the analysis of what the text talks about, relationship aspects and involves interpretation of underlying meanings of the text while manifest analysis involves analysis of visible obvious components of the text [108]. According to Graneheim and Lundman [109], both forms focus on selecting the unit of analysis, meaning unit, codes; categories and themes; the common terms used in content analysis. Meaning units, words are sentences or paragraphs containing aspects related to each other through their content and context; A code is a tool which can be assigned to a phenomenon and should be understood in relation to the context; A category refers to a group of content that shares a commonality and mainly forms a descriptive level of content and can thus be seen as an expression of the manifest content of the text. The category can be divided into sub-categories. A theme can emerge as a thread of underlying meaning through condensed meaning units, codes or categories on an interpretive level.

In Study III, content analysis was used and each interview was viewed as a unit of analysis. Statements or paragraphs that related to the same central meaning were grouped as a meaning unit. The text was reduced by condensing the meaning. Although sometimes we used different words, the essence was preserved. Codes were created and used as tools to interpret the text. Sub-categories and categories were constructed from the group of codes that had common ideas. A theme emerged through the condensed meaning unit, codes, sub-categories and categories.

Summary of studies and research questions

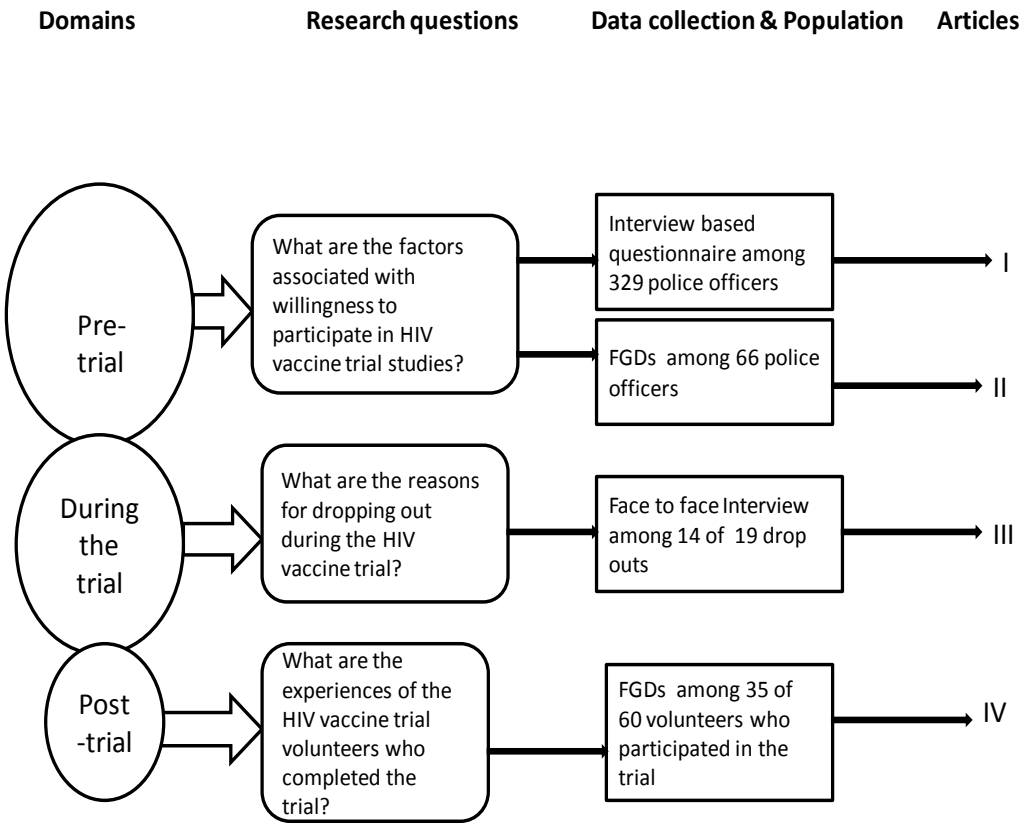

Figure 4. Domains, research questions, data collection and list of articles

2.5 ETHICAL CONSIDERATION

Ethical permits for all studies were obtained from the institutional review bodies, namely MUCHS IRB dated 11th November 2004; National Institute for Medical Research (NIMR) Ethics Committee- NIMR/HQ/R.8a/Vol.IX/410 dated 30 January 2006; and Muhimbili University Ethics Committee dated 20 April 2006. Permission letters from the police high authorities were obtained. Ethical principles were adhered to throughout the studies. Potential study participants signed informed consent forms describing all the study components before engaging in the studies.

3 MAIN FINDINGS

The PEN-3 model is used to organize the main findings into categories which are specific to the components of cultural empowerment & relationships and expectations domains. By applying the components of PEN-3 model; for example, the presence and influence of significant others in the decision to volunteer in an HIV vaccine trial are perceived from the start to the end of the HIV vaccine trial. The perception of significant others co-exists or operates separately with fear of unknown side-effects from an experimental vaccine. However, participants consistently see opportunities in the trial leading up to positive perception about the trial.

Existential nurturers: Facing resistance of significant others to participation in HIV vaccine trials (Study I, II, III, IV).

Willingness to volunteer for an HIV vaccine trial was significantly associated with intention to tell others (sexual partners, friends, family members, relatives or parents) about one's decision (OR, 36.48 (95% CI: 15.07-88.28), and the reason to share the information was to provide a safety-net should the vaccine turn out to be harmful to the volunteers (I).

On the contrary, participants speculated that telling others about their intention to volunteer in an HIV vaccine trial would be negatively received (II). Consequently, those who consulted friends about their intention to volunteer in a trial encountered resistance that forced them to weigh their decision against the friends' opinions. Others decided not to participate in the trial to avoid being abandoned:

> "Every time I told my colleague policewomen about this [the HIV vaccine trial] they challenged me. ... 'Go first and get it [the vaccine] because you are HIV positive.'… So I decided to quit…" (Young policewoman 2, Group 1) – II.

Sharing of the information within the social networks was important because of the existing social relationships and dependencies (parents expecting their children to support them in old age). However, participants said that parents have a strong influence on the lives of young people, and young people saw themselves as an asset for the future with responsibilities towards their parents. These young people, men in particular, speculated that parents would expect them not to take part in the trial since they depend on each other. The parents were said to worry that the vaccine could cause side-effects as indicated in the conversation below:

> "Some of us are taken care of by our parents. Now what would your father say if you get problems? They [parents] will query: 'Don't you know that we depend on you?" (Young policeman 6, Group 4) – II.

They further suspected that pregnancy norms would be the source of fear among the parents:

> "A parent can tell you that: 'If you are vaccinated and get married you will not get children'. He or she thinks if you get the vaccine you will not get a child…" (Young policeman 1, Group 4) – II.

These concerns emerged as realities (III**).** Those who decided to volunteer in the HIV vaccine trial had to withdraw because they did not receive approval of significant others. Simply, participants were obliged to respect the opinions of significant others to maintain the existing social relationships. Particularly, the young men realized that

enrolling in the HIV vaccine trial was counter-productive. They felt responsible and needed to 'be the insurance for their parents' despite the fact that they were interested in enrolling in the trial. The following discourse explains:

> "When I told my mother about that [vaccine trial], in brief she was shocked! … On top of that I'm the only son remaining in our family; the rest passed away… She insisted I should stop where I reached. That means I should stop. I asked her why? She said: 'that is what I am saying, if you are going against, it will be your decision and what I have told you, that is it'. So, I thought of that… That was the end of the exercise, but I was not happy to stop there" (Informant 13, man) - III.

Unlike men, women were mostly influenced by their intimate male sexual partners. One woman was indirectly warned by her fiancée and she couldn't convince him. Another woman explained that her fiancée forbad her to enrol straight away. She felt bad about it, but she could not go against him as it would spell the end of her marriage. She said:

> "…my fiancée did not accept it completely! And he warned if I enrol in the trial our relationship would end; even though he had already paid a dowry, he would postpone our marriage plans… I felt bad because I had already committed myself with that relationship and I saw there is no way to convince him" (Informant 11, woman) - III.

Similarly, those who enrolled in the trial and stayed on until the end (IV) continued to faced resistance from significant others. The family, where indeed supportive networks should be established, was instead experienced as a discomfort zone during the trial. Several participants noted that close family members such as parents, sexual partners and blood relatives demonstrated attitudes of mistrust over vaccine safety. Some men reported that their wives were distressed by comments from local people about their husbands taking part in a harmful study. Under such circumstances, the husbands tirelessly put pressure on educating their wives. Several opted to share the information with their intimate friends, but not their mothers because of the perceived notion that mothers may have difficulties in understanding the purpose of the trial:

> "I tried hard to explain to my lover but when it came to the other side, the side of the parents… I didn't tell my mother this issue because I knew it would take time for her to understand…" (Man 3, unmarried, Group 2) – IV

On the other side, those who shared their enrolment decisions with relatives felt abandoned. One man told us:

> "I tried to explain [about the trial] to my relatives. Truly, all of them threw me out of the line [discouraged me]... So, I am alone; they find its okay. When I phoned and told them that I have fever, they say: 'You wait, go ahead!' [The relatives warned]. So those are their current responses. Now even if I have mild-fever, I don't call them" (Man 7, unmarried, Group 2) – IV.

In this group, other participants sensed that the reaction from family members was more painful than the reaction from friends. For example, they noted that some parents were shocked after realizing that, without their knowledge, their sons and daughters were in the HIV vaccine trial. Overall, significant others' influence cut across all the four studies, and their influence is more negative than positive.

Existential perceptions: Sexual practices/ behaviour and reproduction concerns (Study I, II, III and IV)

In Study I, participants would volunteer for an HIV vaccine trial because they had extra sexual partners and they perceived themselves at risk of becoming HIV infected. In Study II, participants feared having an HIV test to avoid knowing their HIV status, and they felt it was okay if they got HIV infection through unprotected sexual intercourse. They reasoned that getting HIV through unsafe sex involved pleasure unlike the vaccine which would bring pain. Married policemen explained why a fear of HIV transmission by unsafe sex was different from that of the vaccine:

> "There [in sexual intercourse] you enjoy. That is what it means. It is not like when you are being vaccinated. There [sex] you know you are straightforward enjoying. So it is right if I get infected" (Married policeman 7, Group 7)- II.

Another one added:

> "You know with sex, it is imaginary. One goes thinking that he is safe and may be also my partner is safe. You see when doing sex, one does not know... That is the way it is, but sex and vaccine differ a little bit" (Married policeman 2, Group 7)-II.

Sexual relationships were important for reproduction continuity; gender power relationships were perceived in the decision whether to volunteer for an HIV vaccine trial or not. Women feared that postponing pregnancy because of enrolment in the vaccine trial could be a major concern to their husbands and boyfriends:

> "The problem is with the family [husband], that is when it becomes difficult. I get the vaccine and my husband wants a child then ... I think problems will start there" (Older policewoman 1, Group 2)- II.

> "There is a problem with girlfriend and boyfriend. For example, with the boyfriend he could stay with a woman for a long time, outside marriage lock and he wants to have a child with her ... if she postpones, of course the friendship will end" (Older policewoman 4, Group 2) - II.

They also raised personal doubts about their reproductive capacity and possibility of becoming infertile after taking part in the trial:

> "Is there any possibility for me to get a child? Won't they [the researchers] just destroy my gametes?" (Older policewoman 3, Group 2) - II.

They also feared being stigmatized by others if they participated in HIV vaccine trials.

In Study III, condom use and interference with reproduction continuity were the concerns among the drop-outs. They believed the rules in the vaccine trial were not in favour of their sexual practices. One participant expressed:

> "…they [researchers] presented it in this way: 'you are not supposed to do sexual intercourse without a condom for a certain period. Then a woman should not conceive or get pregnant…That is the main reason for us to discontinue, and saying that 'even if you will be given that vaccine will be there a feeling in your marriage relationship? It will only bring disturbance!" (Informant 3, man) - III.

In study IV, the norms of sexual practices were recognized throughout the discussion and condom use was found to be a valuable tool towards HIV prevention. Men insisted that risky sexual behaviour was part of their daily lives. Despite having multiple sexual relationships even after enrolling in the trial, the information and counselling in the trial helped them to change to safer sexual behaviour:

> "Those seminars helped us a lot because from the first vaccination, we were told that wearing a condom is really important. That one helped because some of us had multiple sexual partners… I mean, I do not have strange things [risk behaviour]..." (Man 6, married, Group 1)- IV

Participants agreed that condom use was useful for both HIV and pregnancy prevention. However, others were confused whether to use condoms consistently with stable sexual partners during the trial. In some cases, stigma was attached to the postponement of pregnancy. Women felt that their friends believed that the HIV vaccine trial would had negative consequences on their reproductive health:

> "And another person suspected that I could not give birth because of the vaccine. I mean for example at the work place, aah, truly God helped us. We have come a long way and now we are breathing… They saw us as people who are infected with the virus...waiting to die and that confused us." (Woman 1, married, Group 3)- IV

Other participants felt traumatized by negative comments from colleagues (stigma) especially during illness episodes.

Negative perceptions: Existing fear fuelled by mistrust of researchers in the trial (Study I, II, III and IV)

Willingness to volunteers for an HIV vaccine trial, however; would be hindered by fear of potential side-effects from the HIV vaccine and suspicion of why the vaccine should be tested on Tanzanians only (I**)**. Participants expressed another fear arising from the thorough medical check-ups that were a condition for inclusion in the trial (II). They feared these check-ups might reveal their HIV status or other life-threatening diseases. In addition, the fear was fuelled with the suspicion that the vaccine would have a negative impact on one's health status, such as their reproductive biology (II). Young women talked about the risk of becoming infertile after taking part in the trial:

> "There are some women without a child and other people tell them that following vaccination they will never conceive!" (Young policewoman 7, Group 1) – II.

Some men suspected the vaccine could make men impotent. They also suspected that children might be born with abnormalities because of drugs such as oral contraceptives. They reasoned that similar effects could arise from the HIV vaccine:

> "People know exactly that children are being born with abnormalities because of drugs [contraceptives]. And now an HIV vaccine has arrived!" (Low ranking policeman 3, Group 6)- II.

The fear of the vaccine was fuelled by mistrust of the researchers in this trial. Participants saw the researchers as people who were seeking to gain something from the research other than helping the research participants: They speculated that the researchers were hiding the truth about the effects of the vaccine:

> "They [researchers] are liars. They will plant virus on us! …Why don't they try with animals?" (Low ranking policewoman 12, Group 3) - II.

The attitude of mistrust seems to arise from the fact that the vaccine was imported into the country. The participants reasoned that if such a vaccine had been proven safe after testing on animals and then used on human beings elsewhere, why test it again on Tanzanian police officers? They argued that the researchers in the vaccine project might benefit financially from the trial:

> "They [the researchers] already got money from there [donors]. Now to prove they have done the job they are moving around here… A neighbour told me not to engage in the trial." (Low ranking policeman 1, Group 6) – II.

Also, fear of the vaccine's side-effect was one of the reasons for declining to enrol in HIV vaccine trial (III). For example, a newly married man decided not to continue because he was mostly concerned with the trial rules that seemed to interfere with his marriage intentions. He was worried about the effect of an experimental vaccine on his reproductive capacity even before fathering a child. He decided to postpone enrolling and gave priority to having a child. He narrated:

> "First, it was the vaccine on trial, and we were told that if we accept to participate in that programme we are not supposed to engage in penetrative sexual intercourse with any woman for a year to avoid its effects in pregnancy. At that time, I was doing another attempt in order to get a child!" (Informant 12, man)- III.

Thus, his fear was mainly connected with reproduction continuity.

In addition, informants were suspicious about the researchers' intentions. Some believed that the HIV vaccine could have side-effects that the researchers were not even aware of. One informant believed that the researchers were afraid of taking part in the trial because of uncertainty about the trial:

> "It may have negative effects in the future. You [researchers] insisted that the vaccine has no side-effects but it is not true. One day I asked one of you who facilitated the seminar that 'who gets an HIV vaccine among you?' They said 'we are not allowed to get that vaccine because we are service providers.' Don't you see that you are avoiding something?" (Informant 14, woman) - III.

Although the fear of the HIV vaccine's side-effects and attitude of mistrust of the researchers subsided among those who participated in the trial (IV), significant others played a role in convincing them that the trial was not safe. In this context, the health care providers who were not connected to the trial were the most influential. One participant narrated what he faced while interacting with one of these providers:

> "When you tell a person that you are involved in something [HIV vaccine trial], and he/she comments 'he!', in your heart you feel: 'Does it mean that I am lost?'... I met a specialist, the one they call an orthopaedic surgeon. Just by seeing my documents [HIV vaccine trial volunteer], he was shocked in such a way that shocked me too … then he called his nurse; she also looked at the documents in brief, and then they looked at each other. Things like those, we just say, let us go ahead..." (Man 9, unmarried, Group 2) - IV

Several participants encountered a similar situation and they were also confused by the attitude of mistrust among the non-trial health care providers. After interacting with

medical doctors who were poorly informed about the trial, they surrendered and place their decision in faith. Therefore, fear and mistrust from different sources emerged as a negative response towards participation in the HIV vaccine trial.

Positive enablers: Prevailing benefits & commitment of participating in an HIV vaccine trial (I, II, III and IV)

Participation in the HIV vaccine trial is seen as a personal decision; a belief that Tanzania should become a partner in the development of HIV vaccine and a high level of knowledge about HIV and AIDS (I). Additionally, participants stated that they would volunteer for an HIV vaccine trial because of the services that they would be able to access as a result of the trial interventions (II). They believed that a complete medical check-up would be a great opportunity to receive free medical services for the diseases that may be discovered:

> "Surely, I will be motivated as I think the big issue is to be checked. It's useful for me since if I am found with problems, I will be attended by experts. I will be thankful since I will be given immunity [treatment]." (High ranking policeman, group 5) – II

Although some of the eligible participants declined to enrol in the HIV vaccine trial, they still saw a benefit in having a good relationship with the trial team (III). One participant said:

> "You know what I am ashamed of is to meet such incredible people at the clinic; stating that I don't want to proceed with the trial! I remember doctors, nurses, and counsellors; the way they handled me so friendly with a cup of tea with milk …." No, but my heart doesn't encourage me to continue [proceed with the trial]…" (Informant 7, woman) – III

On the other hand, the participants who enrolled and stayed on until the end of the trial felt confident because of regular contacts with the trial team (IV). They also believed that they knew more facts about HIV and vaccine because they had attended the workshops. They benefited from HIV testing and general medical check-ups during the trial. This practice promoted confidence over their health status and they also gained courage and hope through these medical investigations:

> "Everything you [I] checked, you were [I was] told by the doctor, that you were [I was] okay … when you [I] went out, you [I] got a relief that you [I] did not have any problem. You see, because if a person had kidney problems, he was given treatment. Therefore, that gave us courage and hope..." (Man 6, married, Group 4)- IV

In addition, most of the participants agreed that participation in the trial helped them to change from risky to safer sexual practices.

Personal commitment in the trial participation was important. Respondents reasoned that they would not tell others about their intention to volunteer for an HIV vaccine trial because they believed in their personal decision (I). Further, they emphasized that personal motivation to volunteer and altruism to save others lives were the reasons that would make them volunteer for an HIV vaccine trial (II). Some quotations illustrate these:

> "I will personally see myself as a hero." (Young policeman 2, Group 4) – II.

Another group participant added:

> "I will be confident and able to say "I was among the participants" [in the HIV vaccine trial]." (Young policeman 3, Group 4) – II.

In addition participants believed that if they volunteer and make the vaccine development successful, they would have saved millions of people from HIV infection:

> "I think this [taking part in the trial] is part of motivation in my duty because if I get vaccinated and make it successful, I will save the civilians whom I protect. And to work as a police officer, there must be people to protect. No police force without people. I think this is one of the moral principles that I should do." (Low ranking policewoman 10, Group 3) – II.

Furthermore, personal decision emerged as a strong argument against the discouragement voiced by significant others (IV). Staying in the trial until the end was all about personal commitment as explained by the study participants:

> "It [discouragement] is there. Others were pressing me until I decided to tell them, 'I have decided to sacrifice myself; I have already sacrificed to rescue this world. If it is a vaccine, then it will help other people… Jesus died on the cross to save others. So, I sacrifice too." (Man 7, married, Group 4) – IV.

Through body gestures, other members of the group indicated that this was an experience to identify with especially when they interacted with their families. They felt that their work involved protecting people and their properties, but through participation in the trial, they would also promote the good health of the community. They insisted:

> "You have power and not afraid. You sacrifice yourself when you fight for your country ..." (Woman 6, unmarried, Group 3) – IV

To a large extent, participants stated that they managed to ignore negative comments from others as narrated in the earlier section because of the level of confidence they had in the trial from the start. Thus, personal decision remains a positive 'foundation' of participation in the HIV vaccine trial. Additionally, most of the participants demonstrated that the education and other services in the trial were the reason that enabled them to stay on in the trial.

4 DISCUSSION

4.1 MAIN FINDINGS

In this thesis, the discussion loosely draws from all the domains of the PEN-3 model and the interwoven findings are discussed together to strengthen the meaning and understanding of these issues.

The recognition of significant others (sexual partners, friends, family members, relatives or parents) as reliable people to share the information about the trial with (I) implies that people in this setting have strong social ties in the sense of helping or depending on each other in times of doubt. However, the significant others' reaction emerges as a major deterrent to volunteering for the HIV vaccine trial (II, III). Similar to other studies, it appears that significant others (friends, sexual partners and family) may play a significant role in influencing participation in HIV vaccine trials [13, 28, 42, 110]. In the current study, fear of breaking the dependence chain from young men to aging parents signifies the cultural aspect of insurance, which young people are expected to offer to the older generation. This also indicates the degree (in cultural identity) to which family networks can empower different persons within the family and their responsibilities [87]. The fact that some women retract their decision to enrol in HIV vaccine trials also implies that gender is becoming very central in the decision whether or not to take part. In addition, the continuous struggle to convince significant others about trial safety shows the importance of existential nurturers in the form of negotiation through information-sharing in social networks to minimize discouraging influences. Airhihenbuwa et al refer to existential nurturers as the influence of significant others and community contexts in making health decisions and choices within certain traditional values and practices [88]. In HIV vaccine trial participation, participants are obliged to make decisions in collaboration with significant others to maintain the traditional values and practices of consulting each other. However, in several of the studies (II, III, IV), the reactions of significant others may be strongly intertwined with their attitudes to HIV stigma in the community leading them to be negative to the HIV vaccine trial as well.

Moreover, understanding the sexual behaviour of potential or actual participants in an HIV vaccine trial in culturally sensitive interventions is important. People value sexual matters according to their cultural preference, and some of these preferences may not support HIV prevention interventions. The fact that potential trial participants preferred to have multiple sexual partners without using a condom, reproduction continuity and sexual pleasure implies that trial implementers need to recognize these cultural issues. The issues of becoming pregnant and fathering a child are existential perceptions that bring attention to cultural identity of fatherhood or motherhood in an African context. In Uganda, postponing pregnancy had a major impact on the willingness of women to participate in HIV vaccine trials [34]. Thus, fertility concerns and sexual practices may be a major concern in an African context. In Maasai community in Tanzania, risky sexual behaviour has been used to solve fertility problems for a long time [111], suggesting that sexual behaviour is inextricably linked to fertility issues. These are existential perceptions which Airhihenbuwa et al refer to as knowledge, attitudes and/ or beliefs that influence decisions about HIV/AIDS prevention in a manner that could be described as unique to that culture [88]. The authors further explain that such perceptions are often not positive or negative but they reflect characteristics and qualities that help to explain certain values of people [88].The risky sexual behaviour of

having multiple sexual partners may, however, interfere with the use of a partially effective vaccine and may even increase with the notion that the vaccine may be 100-percent protective. Also, understanding stigma in the broader picture of HIV/AIDS in an African context may be important in predicting the uptake of the HIV vaccine if it were made available.

Fear of an experimental HIV vaccine emerged as a major concern among the study participants. This fear was increased by the unknown effect of the vaccine. As shown in other studies, participants fear vaccine-induced HIV infection [5, 28]; negative side-effects of the vaccine [6, 23, 39]; and negative comments from others [110]. Discouragement from colleagues and friends suggests there is inadequate or poor knowledge about the safety of the trial within the community. The neighbourhood tends to influence decisions for its collectives [87]. In the present studies, the highlighted fear of the effect of vaccine on reproduction is also noted in other settings [28]. The fear of the vaccine's adverse effect on reproduction continuity implies that fertility is highly valued in Tanzania [112] and in an African context in general [113]. On the other hand, the fear of vaccine side-effects is exacerbated by mistrust of the researchers conducting trials. In previous studies, government or scientists conducting the trial were not trusted [25, 28, 114-115]. This scenario adds challenges to scientific investigations and can seriously interfere with future trials in this context, even for other vaccines. Airhihenbuwa et al refer to negative perception as knowledge, attitude and/or beliefs that negatively influence decisions about HIV/AIDS prevention [88].

Access to a free and complete medical check-up by participating in an HIV vaccine trial is perceived as an incentive (II), implying that people value free health services in this context. Although the desire to have a complete medical check-up in the trial was in the beginning tempered by a fear of discovering that one was suffering from unknown diseases (II), it was eventually seen as a reward in to the form of free access to medical services (IV). In Gambia, parents were ready to let their children participate in the trial to get free medical treatment [116]. Other studies show that getting free counselling and HIV testing are the perceived benefits of participating in HIV vaccine clinical trials [31]. Education about the vaccine is also valued as an incentive and benefit for people to participate in the trial [16]. Airhihenbuwa refers to institutional support such as medical drugs to clients as enablers [88].

The discovery of one's HIV status as a consequence of the routine testing in the trial aroused fear (II), but this fear was removed as a result of the trial interventions (IV). This change implies that trial interventions may promote understanding of and confidence in knowing one's own HIV status. The approaches to HIV prevention in Tanzania suggest that knowledge of one's HIV status can empower individuals to take precautionary measures to protect themselves against either acquiring or transmitting the disease [68]. In the present study (IV), the experienced change from risky to safer sexual behaviour is fuelled by regular monitoring of HIV status and counselling. Decrease in risky behaviour during participation in HIV vaccine trials has also been noted in previous studies [40, 117-118].

The most prevailing positive response to participation in the current trial is the self-respect and empowerment expressed by the volunteers. The ability to stand by their independent decisions with the notion of doing good for others (altruism) is crucial. This altruistic belief is universally documented as a predictor of participation in HIV vaccine trials [5, 13, 16, 18, 25, 38, 47, 119-120]. Moreover, the fact that trial

participants completed scheduled study visits implies that information or the counselling about the trial safety boosted their confidence and trust in the trial. In South Africa, the lack of information about vaccines was one of the reason for not deciding to volunteer in HIV vaccine trials [14]. The increasing demand for basic HIV vaccine trial education [12, 15, 17, 21] implies that people's understanding of the trial has an important bearing on their decision whether to participate in HIV vaccine trials or not. Thus, perhaps knowledge acquisition may motivate those who perceive the trial as an important step in helping researchers to find effective HIV vaccines [20]. Moreover, the ability to defend personal decisions was enhanced by coping strategies which human beings apply when they interact with the social climate [121]. As people deal with the notion of advantages and disadvantages during programme interventions [87-88], the decision is often in favour of one's cultural identity. Airhihenbuwa et al refer to positive perception as knowledge, attitudes and/or beliefs that positively influence decisions about HIV/AIDS prevention [88].

4.2 METHODOLOGICAL REFLECTIONS

Validity (Study I)

Internal and external validity

Study I is a quantitative study including a convenience sample of 329, since our resources and the setting did not allow us to collect a random sample. The design is not optimal since a non-random sample always generates selection bias and decreases (external) validity. Also, the study participants were self-selected after a health-related workshop. Possibly, non-participants may have affected the reported results because we have no knowledge of their characteristics. That means that there is a risk of the sample not representing the intended study population, but only a portion of this, sharing special characteristics associated with study participation. Hence, inference from this study to the general population or to the police force in Dar es Salaam is not possible. We have thus aimed to interpret and present the results in a way that makes it clear that our results only concern the actual group from which data were collected.

The previous success of conducting research within the police force [75] showed that HIV studies could ethically be conducted in such a hierarchical organization. In the present studies, the privilege of conducting HIV research among police officers in Dar es Salaam, Tanzania, is that most of them have had four years of secondary education; they come from an established organization and are easy to access. However, drawing a random sample was not possible because of emergency duties. Despite the fact that appointments were made, sometimes data collection had to be postponed for a month and so on to accommodate emergences (eg. fire or road accidents, theft incidents or robbery). Thus, most of the data were collected on a convenience basis. Access to the participants was therefore challenging at times, but the participants engaged in the study immediately after establishment of the consent process.

In the study, we used interviewer-administered questionnaires. There is in this case always a risk of individuals answering in accordance with social desirability (answer according to what they feel the researcher may want to hear). For example, revealing the number of lifetime sexual partners in a face-to-face interview was difficult for women. The nurse counsellors, including myself, noted the hesitation among a few respondents in disclosing the number of sexual partners. Hence, there is a risk that high-risk sexual behaviour is underestimated, especially among women.

Reliability
We used a questionnaire specifically designed to meet our study requirement. For example, we included open-ended questions to justify some of the close-ended questions and as an intervention tool where participants could be counselled whenever the need arose. The quality of the questionnaire [structured interviews] was reviewed and checked for its 'mechanical' structure; i.e. some questions were ruled out if they were unclear or misleading [101]. We pre-tested our interview-administered questionnaire and it was established that each time it was administered, it was understood the way we expected. Thus, the results can be reproduced using a similar tool and under similar methodology (reliability). Reliability is the consistency of the measurement or the degree to which an instrument measures the same way each time it is used under the same conditions and with the same subjects [122] . We could have used an existing standardized questionnaire on knowledge, attitudes about HIV and AIDS and sexual practices, but we opted for the designed one to meet our study requirement as stated above.

Trustworthiness (II - IV)
The studies in this thesis were designed for the research questions, and the purpose of the studies was to produce knowledge beneficial to humans while minimizing harmful effects [123]. In this thesis, participants were appropriately and carefully selected according to the purpose of each study. In order to assess trustworthiness of the studies, I have used strategies suggested in the literature, namely triangulation, member checking, peer debriefing, dependability and reflexivity [124].

Triangulation
We achieved triangulation of data in this thesis by combining quantitative and qualitative methods. Whereas quantitative research focuses on drawing inferences from particular observations, qualitative research is usually inductive and provides rich and contextual understanding of some aspects of human experience [125]. For example, the issues of significant others' influence and fear of negative side-effects of the vaccine in the trial were first pointed out in the quantitative study (I), and these issues were enriched in their actual meaning through the subsequent qualitative studies II-IV. Regarding a qualitative approach, focus group discussions and face-to-face interviews were employed, and it appeared that data from face-to-face interview in Study III complemented that of FGDs in Study II.

Moreover, in this thesis, triangulation of researchers refers to the collaboration of different disciplines to design the studies: a sociologist (JM); medical doctors and global health experts (AK and AT); qualitative expert with PhD (TWK); and medical specialists with expertise in epidemiology and clinical trials (MB, ES). Although I (EAMT) was responsible for validating the information in the audio-tapes and transcripts, the correctness of the translation from Kiswahili to English, and drafting the manuscripts, the tasks of data collection and analysis were performed in collaboration with other researchers. For example, moderation of FGDs and the analysis was carried out by two researchers to make the interpretations sound. The findings were checked by all researchers involved in the project. Thus, collaborative work added quality control throughout the stages of knowledge production.

Peer debriefing
During data collection and analysis, we debriefed the research team and our collaborators from the police force by sharing what was emerging from the study. The

feedback brought more insight into the analysis and improvement in conduct of the subsequent studies. Peer debriefing refers to the presentation of preliminary findings to colleagues to help the researcher to evaluate his or her own role in the research process [126].

Member checking

Member checking refers to a process of confirming findings with the participants to ensure that what was understood was credible [126]. The findings from Studies II and IV were presented to the study participants and their peers to gain their feedback. Most participants reacted positively to the findings and confirmed that they tallied with their own experiences and feelings, especially regarding discouragement from significant others on the HIV vaccine trial participation.

Dependability

We enhanced reliability in our qualitative data by employing a good-quality audio-recorder and transcribing the audio-tapes. The transcripts were verified by the author (EAMT) to ensure consistency of the transcribed content.

Reflexivity

Reflexivity is critical reflection on what has been thought and done in a qualitative research project and a conscious attempt by researchers to acknowledge their own involvement in the study – a form of self-reference and self-examination in relation to the research that is being carried out [99]. In a qualitative inquiry, the researcher gets involved in the process of data collection in the field, using his/her interview skills and empathetic ability to deal with different situations. As 'an instrument' in the qualitative studies, the researcher calls attention to biases. However, these biases become problematic only if the researcher is aware of them [127]. For example, listening to the participants' arguments against the HIV vaccine trial after HIV vaccine trial workshops was sometimes annoying. Perhaps, I thought the trial team was not clear in the way they delivered the message or the participants did not get the message correctly. In order to gain knowledge and perceptions from the participants, 'the knowers', it was important to be non-judgmental. Thus, being aware of my role as a researcher was important.

Multiple roles: (trial team member, researcher, PhD candidate, social scientist, lecturer, nurse, civilian, etc.)

My involvement in the sensitization sessions and recruitment workshops influenced my position as a researcher exploring social issues relating to participation in HIV vaccine trials among police officers. During data collection, study participants often referred to me as the representative from the trial team. Although I was carrying the umbrella of 'social scientist' in the HIV vaccine trial, the participants often viewed me from different angles: "a knowledgeable medical specialist and HIV/AIDS educationist", "HIV/AIDS educator", "researcher", "representative from the HIV vaccine trial team" and most often they referred to me as 'daktari' [doctor]. From all these perspectives, I feared that the participants would not be transparent about their concerns relating to the HIV vaccine trial. I was also afraid that they may refuse to discuss anything negative in relation to the trial implementers. However, once they engaged in the consent process, they became focused on the research questions and positively reacted to me as a researcher. They were also cooperative. I also tried to separate my other roles from research and remained as a researcher throughout the data collection.

Staying at the police stations after data collection was both socializing and gave me access to additional information and perceptions. At one station, a man said a joke: 'When are you [researchers] /[nurse counsellors] coming to collect our blood again? I will give you my blood, but not take part in your vaccine trial! [The colleagues around burst out laughing]. Another one added: 'You now, they [trial team] want to give us the virus [vaccine], no way! By the way when are you [research team] coming to bring the seminars again?' This discourse demonstrates how the participants viewed / perceived my role in this context, but it established a good relationship without contaminating the field environment.

During data collection, my main supervisor (AK) and I encountered different 'power' situations. Immediately after entering the police stations, we felt subservient to the police officers (We perceived the police officers like bosses). On the other hand, when the police officers came to the trial site, we felt they saw us like bosses; they looked obedient and ready to follow instructions from the health care providers/ trial team. These two power situations did not, however, influence the access to the data neither at the stations nor at the trial clinic. Perhaps the flexibility of qualitative research facilitated trust and therefore the levels of power were completely absorbed once data collection got under way.

Characteristics of the police officers

The characteristics of the police officers as an elite group can be seen in some of the quotes in this study. Possible influence of the expectation that police officers should save the nation even if this entails taking risks and their own personal views of being viewed as heroes by others may have contributed to the style of their responses. Perhaps it is their power and authority to protect the safety and welfare of the community [128] that may have contributed to their participation in HIV vaccine trial. However, we cannot base our judgement on this because participation in the HIV vaccine trial was voluntary. All steps to ensure that participation was voluntary were taken care of by the trial implementers.

The challenge of translation and analysis

Data was collected in Kiswahili, the national language and then translated into English. The benefit of two researchers (EAMT and TWK) being native Swahili speaker enhanced the quality of the translations. However, the Kiswahili language has several words which may have multiple meanings unless one reads the whole sentence or paragraph. Thus, going back and forth was part of the quality check in the translations. Sometimes, both Kiswahili and English quotes were included in the draft manuscript for final agreement in translation consistency.

Transferability

The characteristics of our participants, data collection methods and analysis are described in detail. Since all the studies were carried out among police officers, the findings can only be applied in similar settings to enhance understanding of the phenomenon [124]. However, police officers in this context may share some similarities such as relationships with significant others in the community, but may differ in terms of training, roles and responsibilities. Therefore, our findings can be transferred to a setting similar to our study setting and population. Transferability refers to the extent to which the findings of a qualitative research study can only be transferred to other contexts or settings or groups. In this perspective, transferability should rely on the one transferring and wanting to generalize the findings.

5 CONCLUSIONS

Based on the findings described in the articles and summarized in this thesis, the main conclusions are:

- Positive outcomes of the trial and expectations of getting protection from the trial were important for participants to volunteer in the HIV vaccine trial.
- Participation in an HIV vaccine trial was in this context perceived as both a family and a personal decision.
- Individuals' decisions and trial-related interventions such as counselling, free (insured) medical services were important incentives in the retention of the volunteers in the Phase I/II HIV vaccine (HIVIS03) trial.

6 RECOMMENDATIONS

6.1 PRACTICE

This study produces useful information for trial implementers regarding tentative ways of engaging the community in the scientific efforts of searching for an effective preventive HIV vaccine through clinical trials:

In line with the PEN-3 model, modification of recruitment strategies such as involving those who form close social relationships with the potential trial participants from the start of the trial is crucial. For example, in the ongoing HIV vaccine trials in Dar es Salaam, Tanzania, the presence of significant others (Extended family) is being *acknowledged* by trial implementers by actively involving them in the trial recruitment process, to share their concerns with the trial experts. Extra attention is given to potential volunteers to make sure that they understand all aspects of the trial and make independent decision on whether to participate in the trial or not. Thus, the potential volunteers (Person) are *encouraged* to make individual decisions after understanding the importance of participation in the trial. At the same time, both significant others and potential volunteers are *discouraged* from relying on rumours and misconceptions about HIV vaccine trial safety from the surrounding communities (Neighbourhood). They are also encouraged to spread positive and correct messages in their neighbourhood.

Moreover, the findings call for:

- Use of examples from this study to amend the existing AIDS educational materials or tools by incorporating positive HIV vaccine trials' information;
- Producing simple statements on the concepts that are most important to communicate to the community, especially those which are commonly misunderstood in the study, for example, the safety of the HIV vaccine trials or the fact that a volunteer can not be infected by HIV infection from the candidate vaccine;
- Developing materials for wider dissemination and such materials should be pretested among various groups (youths/students, community leaders/community groups) to incorporate their feedback in the final version;
- Involving stakeholders at higher levels from planning to the conduct of clinical trials which may be useful in maximizing trust on the clinical trials, for example:
    - Members of the Parliament, policymakers and the MOHSW are the most influential bodies. As stated in the Aids Tool kit, they have important roles at the local, national and global levels of AIDS vaccine work, and are often involved in high-level decisions. Good examples are seen in Thailand, South Africa, Kenya, Uganda, India, Rwanda and Brazil where AIDS vaccine is on the agenda [9].
    - Involving media and journalists is important because they serve as an important information source for the community and to a larger extent can be influential in shaping public opinion at all levels. However, caution should be taken to make sure that they have accurate and up-to-date

information about the respective clinical trial(s) because they may unintentionally spread misinformation that may fuel an attitude of mistrust of the vaccine trials and the involved scientists.

- The study findings direct our attention to the health care providers (doctors, nurses and other health workers) who are not directly involved in HIV vaccine trial research. These people should be correctly informed about the clinical trials because community members often consult them for health-related advice. It is therefore important to disseminate the HIV vaccine trial facts to all health care providers in setting where the trial is being conducted. In a long term, introducing the clinical trials education in medical curriculum may be useful to build up trust in clinical trials among all medical professionals.

- Also, religious leaders need to be involved in information dissemination because they have influential power in shaping the opinions of their followers including making important decisions such as participation in HIV vaccine trials.

- Liaison with the Community Advisory Boards in the respective settings is important because they can support recruitment of volunteers by disseminating correct information. and providing feedback on trial protocols (informed consent forms and processes) [9].

In summary, the Good Participatory Practice guidelines for biomedical HIV prevention trials provide a list of stakeholders which include trial participants; families of trial participants; community members residing in the neighbourhood; the research catchment area; people living with AIDS or affected by HIV; advocates and activists; non-governmental organizations; community-based organizations; religious leaders; opinion leaders; media; government bodies; national and local health care authorities; service providers; trial funders; trial sponsors and trial implementers [129].

6.2 RESEARCH

Building on these findings, further studies should be planned to examine their significance for policy formulation when conducting HIV vaccine trials with different groups in similar settings. For example, there is already an ongoing study among youths in Dar es Salaam, Tanzania to further explore the issues presented in this thesis. For example, the extent of influence of significant others on youths in participation in HIV vaccine trials is being quantitatively determined.

Moreover, longitudinal studies to monitor possible post-trial behaviour change are important. In relation to this, a study on prolonged follow-up of HIVIS03 volunteers is going on, and examination of risk sexual practices and other social issues are integrated in this follow-up project.

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9 APPENDICES

9.1 APPENDIX I

Stages of conducting clinical trials in human beings and the safety aspects

Stages

Phase I: This is a clinical trial with a small no. of ~60 healthy volunteers, at low risk, aiming at testing for vaccine's safety

Phase II: This stage involves 50-500 healthy individuals to test for immunogenicity in humans

Phase III: This is a larger controlled clinical trial with thousands of volunteers to determine efficacy of the vaccine [9].

Safety about the clinical trials

The candidate AIDS vaccines being developed and tested in humans cannot cause HIV infection for the following reasons:

- Vaccines being tested in clinical trials do NOT contain the entire virus.
- The vaccines contain either a protein that resembles the outer coat or other part of HIV, or they contain manufactured copies of small segments of genetic material resembling that of HIV; no single protein or gene could cause HIV infection.
- The genes contained in the vaccines are copies of HIV genes, meaning scientists have produced them in laboratories, so the final genes put into the vaccines have never been part of an actual virus [9].

9.2 APPENDIX II

a) Application of Cultural Empowerment components in the study results

Study's objective	Positive	Existential	Negative
I Factors associated with willingness to volunteer in an HIV vaccine trial	"Participation in a trial is a personal decision" [narrated reason]" "Tanzania becoming a partner in development of HIV vaccine: OR, 4.28" "High knowledge about HIV and AIDS: OR, 1.92"	"Intention to tell others (friends, family members, relatives or parents) about decision to participate in the trial" "Having extra sexual partner" "Not using condom"	"Fear of vaccine side-effects" "Lack of trust in vaccine trials" 'Risk behaviour"
II Reasoning around the decision to volunteer for the HIV vaccine trial	"Individual motivations (personal pride and confidence in a decision to participate in a trial)" "Altruism (obligation to protect others, and self-sacrifice to save lives of others)"	"Reproduction and pregnancy norms (desire to become pregnant)" "Responsibility for others (young ones provide insurance to the old generation)" "Influence of the significant others in decision-making" "Sex is a source of pleasure" "Stigma"	"Risk for HIV infection, myths about the vaccine's side-effects" "Fear of routine tests and follow-ups in the trial" "Mistrust of researchers in the trial"
III Reasons for declining to enrol in the HIV vaccine trial after randomization	"Personal intentions to volunteer for an HIV vaccine trial"	"Consultations within the social networks in times of doubt" "Importance of fathering a child" "Concerns about condom use in consensual relationships"	"Unknown side-effects of the vaccine in the body" "Mistrust of the researchers' intentions" "Discouragements from significant others"
IV Experiences of volunteers who participated in HIV vaccine trial	"Pride of fulfilment and self-respect by participating in an HIV vaccine trial"	"Convincing the family about the trial safety" "Pregnancy concerns" "Stigma"	"Mistrust from health care providers outside the trial"

b) Application of relationships and expectations components in the study results

Study's objective	**Perception**	**Enablers**	**Nurturer**
I Factors associated with willingness to volunteer in an HIV vaccine trial	"Positive attitude towards using an effective vaccine if available: Odds ratio (OR), 36.48 "Possible protection from HIV infection"	"High knowledge about HIV and AIDS"	"Intention to tell others (friends, family members, relatives or parents) about decision to participate in the trial"
II Reasoning around the decision to volunteer in the HIV vaccine trial	"Altruism (obligation to protect others, and self-sacrifice to save lives of others)" "Others will perceive the trial participants negatively (stigma)"	"Medical check-ups and free health services" "Researchers' assurance about the trial"	"Concerns for significant others on pregnancy norms"
III Reasons for declining to enrol in the HIV vaccine trial after randomization	"Personal decision" "Vaccine trial may interfere with sexual life"	Good relationship with the trial team	Significant others' discouragement affecting individuals' decision to enrol in the trial
IV Experiences of volunteers who participated in HIV vaccine trial	"Personal intention to volunteer in an HIV vaccine trial" "Belief in ability to change from risky to positive behaviour"	"Follow-ups: Routine check-ups, education and counselling in the trial" "Condom use"	"Convincing the family about the trial safety"