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Motivators to Participate in a Non-HIV Experimental Study among HIV-Infected Individuals in Nairobi, Kenya: A Consecutive Sample of an Ebola Vaccine Clinical Trial

Borna A. Nyaoke*, Emmanuel Museve, Mary Masheti, Dorothy Essendi, Elizabeth Mutisya, Catherine Sereti, Valerie Awuondo, Roselyne Malogo, Sharon Lipesa, Jane Ng'anga, Rose Mahira, Catherine Ngeli, Gaudensia Mutua, Marianne Mureithi, Omu Anzala

KAVI-Institute of Clinical Research, University of Nairobi, Kenya

***Corresponding author:** Borna A. Nyaoke, KAVI-Institute of Clinical Research (KAVI-ICR), University of Nairobi, Kenya. Tel: +254722207417; +254720734479; Email: bnyaoke@kaviuon.org

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Abstract

Background: Clinical trials assign subjects to health-related interventions to evaluate the effects on health outcomes. Previous studies have categorized motivators for volunteering in clinical trials as for social and personal benefits. There exists little or no literature on HIV-infected persons' motivation for participation in non-HIV vaccine trials. This study aimed to establish volunteer motivators among HIV-infected persons in a non-HIV experimental study, in this case an Ebola vaccine clinical trial.

Method: This study used a cross sectional descriptive design. The study was conducted at the KAVI-Institute of Clinical Research, using a consecutive sample of 48 HIV-infected individuals participating in the Ebola Phase II clinical trial. Inductive approach of content analysis was used to condense raw textual data on motivation factors. Statistical Package for Social Science (SPSS) version 21 was used for descriptive and inferential analysis at 95% confidence interval. Results were presented in form of text, tables and figures.

Results: The main motivators for participation in the Ebola clinical trial were social benefits (altruism) (67.3%) and personal health benefits (32.7%). Regression model of respondents' individual factors including gender, age, marital status, number of children, sources and amount of income and volunteering in previous studies on motivators was not significant (χ^2 =25.578, df=20, p value=0.180).

Conclusion: Altruism, the main motivator elucidated was mainly defined by respondents' willingness to learn about Ebola, give back to society, and pioneer development of an Ebola vaccine in Kenya. Involvement of HIV-infected individuals in clinical trials is paramount in ensuring the clinical population of sub-Saharan Africa is properly represented thus making certain that the safety and effectiveness of new therapies is all encompassing. Targeting of these individuals to ensure adequate enrolment and retention can be done by educating them on their importance in developing these new therapies and the social benefit it brings about.

Keywords: Clinical Trials; Ebola; Ebola Vaccine; Experimental Study; HIV/AIDS; Kenya; Motivators; Nairobi; Sub-Saharan Africa; Volunteer

Introduction

Clinical trials should strive to involve subjects of different socio-demographic features such as age, sex, race and geographical locations as these factors influence the course of disease, the response to treatment and the type of adverse effects associated with the new therapy. Health-related behaviour and the degree of diversity can affect the generalizability of the results [1]. New therapies that have been developed targeting the clinical population improve the likelihood of being accepted by physicians and their patients [2]. There were 36.7 million people living with Human Immuno-Deficiency Virus (HIV)/Acquired Immune-Deficiency Syndrome (AIDS) globally in 2016. Of these, 19.4 million are in Eastern and Southern Africa, with 790,000 new infections in 2016 and almost 60%, 11.7 million of those infected accessing anti-retroviral therapy [3].

Hence in the development of any new drug or vaccine it is essential to include HIV-infected individuals in the clinical trials to ensure that the product will also be safe and effective for them. Studies have centrally placed the use of HIV positive persons in clinical trials as a source to enlighten science and promote human service; improving HIV medicine; extend needed respect to a vulnerable population; and is a crucial step toward the ideal of fair and carefully considered study participant selection that underpins clinical research [4]. The course of HIV infection is affected by various factors including the host biology and socially influenced health related behaviours [2]. HIV-infected individuals often have special needs and few options; their median household income is lower than that of typical households. Additionally when developing a new therapy for the masses they have to be taken into consideration as the pharmacokinetics and pharmacodynamics of the drug may be quite different from those of healthy volunteers and due to their immunosuppression their immune response to vaccines may be impeded [2]. HIV infection is associated with increased disease severity and immuno-deficient HIV infected individuals respond poorly to vaccination [5]. In order to test an Ebola vaccine that would be beneficial to the whole of sub-Saharan Africa it is important to increase our understanding of immunity to the Ebola vaccine in the context of underlying HIV infection.

The Ebola Virus Disease (EVD) first appeared in 1976 in two simultaneous outbreaks in Nzara, Sudan and Yambuku, Democratic Republic of Congo, near tropical forests. EVD is transmitted to humans through contact with wild animals containing the virus and from human to human through direct contact with bodily fluids. The Ebola virus causes an acute, serious disease with mortality ranging from 50%-90% [6]. In 2014-2016 an outbreak occurred in West Africa starting from Guinea and spreading to neighbouring countries Sierra Leona and Liberia resulting in very high morbidity and mortality cases [6]. A more recent outbreak occurred in the Democratic Republic of Congo in May 2017 but was quickly contained due to an early response and a well-coordinated and efficient management of the reported cases [7]. Consequently many countries including Kenya through the Ministry of health put in place strategic preparedness measures [8]. Development of preventive vaccines against EVD would therefore satisfy an urgent unmet public health and medical need across sub-Saharan Africa.

This study was nested in an on-going Phase II Ebola vaccine study sponsored by Janssen Vaccines and Prevention B.V. The Ebola vaccine regimen consists of a monovalent vaccine based on adenovirus type 26 (Ad26) vector expressing the Glycoprotein (GP) of the Ebola virus Mayinga variant (Ad26.ZEBOV) as well as the multivalent Modified Vaccinia Virus Ankara (MVA) strain containing ZEBOV, SEBOV, Marburg Virus GP and Tai Forest nucleoprotein inserts (MVA-BN-Filo). These candidate vaccines were used in a heterologous prime-boost vaccine regimen in which one vector (Ad26.ZEBOV) is used to prime a filovirus-specific immune response and the other vector (MVA-BN-Filo) is used to boost the immune response 4 to 12 weeks later. The Phase 2 trials would be conducted in healthy volunteers in Europe (France and UK) and non-epidemic sub-Saharan African countries including Kenya. HIV positive adults would also be vaccinated in African countries [9].

Different factors motivate individuals to participate in clinical trials. According to a narrative review in Ireland, the primary factor influencing participation in clinical trials amongst patients was related to obtaining a form of personal gain through participation [10]. A study in Uganda among persons who had stabilised on Antiretroviral Therapy (ART), personal reasons were frequently linked to their health and well-being as well as reduction of pill burden [11]. Motivation for clinical study participation was linked to types of benefit, that is, financial gain and therapeutic alternative including access to medical care. Altruism was not a common motivator, and when altruism was present, it was observed as a secondary motivator [12]. Globally, poor participation in clinical trials has been associated with lack of awareness on the clinical trials; a lack of trust; risk concerns; adverse health outcomes; little or no monetary compensation; privacy concerns; and worries that it takes too much time [13]. Clinical study participants have suffered from the experiments that they were subjected to and in some cases did not understand the study [12].

The influence of demographic characteristics on participation in clinical trials is debatable. A narrative review on factors affecting patient participation in clinical trials established that demographic variables considered influential including the social and economic characteristics of a specific population besides gender, race and ethnicity, sexual orientation, age, religion and income level did not have an undue influence [10]. Studies in India indicated that older groups were considered as less willing to participate which was attributed to potential cognitive impairment or less-

likelihood to comply with rigorous study protocols which could thus potentially jeopardise the study outcomes [14]. Demographic factors in other studies have shown that lower income is predictive of lower participation in clinical trials [15] and women are underrepresented in clinical trials [1]. HIV-related stigma and discrimination has also been noted to influence people's decisions to join HIV-vaccine related research [16]. To the best of our knowledge there is little or no literature on motivators to participate in a non-HIV experimental study by HIV-infected individuals.

Materials and Methods

Study Site

This study was conducted at the KAVI-Institute of Clinical Research- University of Nairobi (KAVI-ICR), which has clinics at Kenyatta National Hospital and Kangemi with Nairobi as its catchment population. Nairobi is the capital city of Kenya with a population of 6.54 million people and a HIV prevalence rate of 6.8% which is almost the same as the National rate of 6% [17]. It has approximately 2.5 million slum dwellers in about 200 settlements representing almost 60% of Nairobi's population [18].

Study Design

This study used a cross sectional descriptive design to determine the factors that would motivate HIV-infected individuals to participate in a non-HIV experimental study. A structured questionnaire with both open-ended and closed-ended questions was used to collect both qualitative and quantitative data on demographics and motivation factors to participate in the Ebola vaccine clinical trial.

Recruitment of Participants

Consecutive sampling was done until sample saturation was reached at 48 HIV-infected individuals participating in the Phase II Ebola vaccine clinical trial at KAVI-ICR. Those participating in the clinical trial were approached and invited to take part in the interview. Enrolment into this nested study took place from February 2017 when the first HIV infected volunteer was screened until May 2017. Out of the 59 subjects who were screened for the clinical trial 11 declined to take part in this study; the volunteers were not probed on their reasons for declining. To be eligible for the HIV-infected cohort in the clinical trial the participants had to be a man or woman between the ages of 18 and 50 years, have a documented HIV infection at least 6 months prior to screening, have a CD4 count of $\geq$ 350 cells/µL and be in a reasonably good medical condition. The volunteers participating in the clinical trials were not provided with any other payment except for reimbursement of costs incurred. The study was not intended to be representative of the entire population of Kenya but rather designed to identify the main motivators that lead to clinical study participation by HIV-infected individuals and whether these motivators differ by variables.

Ethics statement

The volunteers provided written informed consent to take part in the Phase II Ebola vaccine clinical trial and have information pertaining to their participation in the clinical trial collected over this period. The study protocol and informed consent documents were approved by the Kenyatta National Hospital- University of Nairobi (KNH-UoN) Ethics Review Board with the following ethics approval number: P282/05/2015

Data analysis

Inductive approach of content analysis was used to condense raw textual data on motivation factors into a brief, summary format- 'code'; and develop a thematic framework of the underlying codes that were evident in the raw data in line with Ryan and Bernard strategies [19] as shown in (Figure 1).

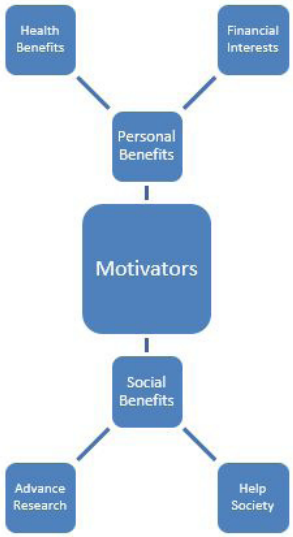

Figure 1: Motivation Codes.

Coded data on motivation factors and data on demographic characteristics were entered in to Statistical Package for Social Science (SPSS) version 21 for analysis. Descriptive statistics including frequencies, percentages, mean, median and standard deviation were used to describe study variables. Chi-square tests were used to test the association between volunteer demographics and motivators at 95% confidence interval. Results were presented in form of text, tables and figures.

Results

Respondents Characteristics

The sample comprised of a significant proportion of majority females (85.4%) (p value<0.01). The age of the respondents was negatively skewed with a proportion of 81.3% of the respondents aged more than 34 years (p value<0.01). The mean age was

39.2 (SD 6.6) within the range of 21 years to 49 years. Majority (62.5%) of the respondents interviewed were married, whereas 20.8% were separated (p value<0.01). A greater section (74.9%) of the respondents had between 2 and 4 children. However, the proportions of number of children did not significantly vary across the respondents (p value = 0.125). Majority (85.4%) of the respondents had a source of income, that is, they were either formally (14.6%) or informally (70.8%) employed (p value<0.01). The median monthly income earned by 56.3% of the respondents was between Ksh 100-10000 (p value<0.01). A section of 14.6% of the participants had participated in previous clinical trials (p value<0.01). The social demographic characteristics are highlighted in (Table 1).

Individual factors	Categories	Motivator						p-value
		Personal benefits		Social benefits				
		Health benefits		Advancing research		Help society/ country/ world		
		F	% (N=55)	F	% (N=55)	F	% (N=55)	
Gender	Male	2	3.6%	3	5.5%	2	3.6%	0.895
	Female	16	29.1%	22	40.0%	10	18.2%	
Age group	20-24	0	0.0%	0	0.0%	1	1.8%	0.273
	25-29	3	5.5%	0	0.0%	1	1.8%	
	30-34	3	5.5%	2	3.6%	0	0.0%	
	35-39	5	9.1%	12	21.8%	5	9.1%	
	40-44	2	3.6%	5	9.1%	1	1.8%	
	45-49	5	9.1%	6	10.9%	4	7.3%	
Marital Status	Married	14	25.5%	12	21.8%	9	16.4%	0.347
	Divorced	0	0.0%	1	1.8%	0	0.0%	
	Separated	1	1.8%	7	12.7%	3	5.5%	
	Widowed	1	1.8%	4	7.3%	0	0.0%	
	Single	1	1.8%	1	1.8%	0	0.0%	
	Cohabiting	1	1.8%	0	0.0%	0	0.0%	
No of Children	1	1	1.8%	2	3.6%	2	3.6%	0.895
	2	7	12.7%	9	16.4%	2	3.6%	
	3	5	9.1%	3	5.5%	5	9.1%	
	4	4	7.3%	5	9.1%	2	3.6%	
	5 and above	1	1.8%	6	10.9%	1	1.8%	
Form of Employment	Unemployed	1	1.8%	7	12.7%	0	0.0%	0.797
	Informal	15	27.3%	14	25.5%	10	18.2%	
	Formal	2	3.6%	4	7.3%	2	3.6%	
Monthly Income (Ksh)	100- 10000	11	20.0%	10	18.2%	11	20.0%	0.224
	10001-25000	6	10.9%	7	12.7%	1	1.8%	
	25001-50000	0	0.0%	1	1.8%	0	0.0%	

Support Group	No	8	14.5%	10	18.2%	4	7.3%	0.558
	Yes	10	18.2%	15	27.3%	8	14.5%	
Previous participation in clinical trials	Never participated	15	27.3%	21	38.2%	11	20.0%	0.576
	Participated	3	5.5%	4	7.3%	1	1.8%	
F- Frequency; P- Percent								

Table 1: Individual factors and Motivators.

Respondents' HIV information

All of the respondents were on ART at the time of the study as per the requisite of being eligible for the study. Majority (58.3%) of the respondents were in HIV support groups. Proportions of respondents in or not in support groups were no different (p value=0.312). The main reasons why respondents joined support groups were to acquire psychological (53.8%) and material (15.4%) support; to encourage other persons living with HIV (23.1%); and acquire HIV education (7.7%). The main reasons for non-membership in any support group included lack of interest (57.2%); departure from the groups due to internal wrangles (28.6%); and lack of enough time to participate in the groups (14.3%).

Motivators to participate in the Ebola Vaccine Clinical Trial

Fifty-five motivators were elucidated from the responses given by the 48 volunteers. These were coded and themed as in Table 2.

Motivation	Motivation theme	Motivation code	Frequency	Percent (N=55)
Personal benefits	Health benefits	Get screening and medical check-up	8	14.5%
		Acquire health education on Ebola and vaccine trial	10	18.2%
Social benefits	Advancing research	Participate in research to develop Ebola vaccine	20	36.4%
		Advance knowledge on clinical research	5	9.1%
	Help society/ country/ world	Give back to the community/ society	7	12.7%
		Acquire health education on Ebola to sensitize community	5	9.1%

Table 2: Motivators.

Social benefits were the main motivators with 37(67.3%) of the responses while Personal benefits were only revealed in 18 (32.7%) of the responses. This showed that altruism was the greatest motivation to participate in a non-experimental vaccine trial by the HIV-infected volunteers.

Personal Benefits: Personal benefits were mainly health benefits; no financial interests were expressed in the responses. A section of 14.5% of the responses indicated an attraction to the fact that they would have access to medical examination (screening and medical check-up) as shown by the following excerpts. "I was informed by a friend already in the study that I would have free screening for my health" (Female, 27) "I want to have a full examination done; some tests I hear you do such as for the heart (ECG) are not done in the CCCs (Comprehensive Care Centres)" (Female, 38) Despite there not being an outbreak of Ebola in Kenya, 18.2% of the responses revealed interest in learning more about Ebola as a disease and how vaccine clinical trials are conducted and perhaps also sensitize others as pointed out in following excerpts. "I would like to learn about Ebola, I hear it is a very bad disease and has killed many Africans. I want to know how I can protect myself." (Female, 41) "I have heard about KAVI-ICR and I wanted to know more about what you guys do in terms of diseases and research" (Female,35) "As a health worker who does community activities informing on health issues I want to be at the forefront of the Ebola vaccine research exercise before I talk to others about it." (Female, 38).

Social Benefits: Social benefits included advancing research (45.5%) and helping the society both at local and global levels (21.8%). To advance research, 36.4% of the responses were inspired by the desire to participate in Ebola vaccine trial and pioneer development of Ebola vaccine in Kenya as presented in following excerpts. "I want to be part of the first people who helped to get an Ebola vaccine and save the world. I heard even Americans got the disease." (Male, 44) "I hear the Ebola disease is very bad and many people have died from it in West Africa. I want to help get a vaccine to prevent us from catching the disease in case it reaches Kenya" (Female, 38) Of those seeking to advance research, 9.1% of the respondents intended to advance knowledge on clinical research and perhaps also understand how Ebola vaccine would work among those taking ARVs as shown in following excerpts. "I would like to find out if an Ebola vaccine would work in someone using ARVs" (Female, 38) "As a HIV person I am vulnerable to many infections and I would like to be able to protect myself against Ebola in case it comes to Kenya" (Female, 48) "Even though I have the disease (HIV) I feel motivated to be part of a clinical trial, I heard it in the community and felt I should come participate and see if your vaccine will also be able to protect us" (Female, 49) A group of 12.7% of the responses sought to participate in the Ebola vaccine trial to give back and help the community/ society; and also appreciate those persons that had previously participated in HIV drug trials as revealed by the following excerpts. "I want to give back to the society. Most people think that I am useless and cannot help them because I have HIV. If this vaccine works I will be able to help everyone." (Male,37).

"HIV does not mean I can't help others. I would like to help others get a vaccine the way they found ARVs for us and the way they are looking for a HIV vaccine" (Female, 49) "Someone else took part in a clinical trial for me to get my medication (anti-retroviral drugs), so I feel I should be able to give back to my society at this time that I am needed." (Female, 36) A proportion of 9.1% of the responses showed an interest in acquiring knowledge about Ebola and sensitizing the community as shown by the following excerpts. "I would like to learn more about Ebola and how to prevent myself and my community in case there is ever an outbreak in Kenya." (Female, 23) "As a HIV person I am vulnerable to many infections and I don't think we would be able to survive an Ebola infection. I would like to take part in this research so that I can be able to protect myself and my fellow brothers and sisters who are HIV-infected (Female, 48) "It breaks my heart when I hear innocent women and children are dying from it (Ebola), I am here to help others know how they can prevent themselves from getting it and stop more people from dying." (Female, 37)

Relationship Between Individual Factors and Motivators

Inferential analysis to establish individual factors that were significantly related to motivators used a total of 55 identified motivators. The individual factors included gender, age, marital status, number of children, sources of income, amount of income, and participation in previous clinical research by the respondents. The influence of individual factors was established using correlation and regression analysis. Multivariate logistic regression model of the individual factors on motivators was not significant (χ^2 =25.578, df=20, p value=0.180). This implied that the individual factors did not collectively influence motivators. Correlation analysis also identified no relationship between the individual factors and motivators (p value > 0.05) (Table 1).

Discussion

This study sample comprised of significant proportion of majority females. Participation of majority females in clinical trials was also reported in a systematic review of 44 cohort studies that showed an overrepresentation in women [20]. HIV clinical trials in America, Uganda, and Tanzania by Centres for Disease Control and Prevention also reported higher female participation in clinical trials. Respondents' age had a mean of 39.2 years. In different clinical trials, mean ages were almost the same at 38.5 years in an Ebola Phase I trial [21] while slightly lower at 33 years in Uganda [22]. This implied that most volunteers who participate in the trials are of mature age and understand the importance of participation. In a systematic review, older volunteers were more likely to be willing to participate in an HIV vaccine trial than younger volunteers [23]. Majority of the respondents interviewed in this study were married. This has also been observed in other studies done in the United Kingdom, Uganda and Kenya in which majority of the volunteers were married [24-27]. These results contradicted results in a study in Tanzania where majority of the volunteers were single (57.1%) [28]. A greater section of the respondents had between 2 and 4 children. A study conducted in Kenya established that the average number of children per trial participant was 2 children, within a range of 0 to 8 children [29]. Most of the volunteers in this study worked in the informal sector, this is similar to a study in Uganda where all the volunteers were working in their local area, with majority of them doing informal jobs [22]. Majority of the respondents were in HIV support groups. This was similar to a study in Uganda where majority of HIV positive respondents reported that they joined health support groups to receive psychological support followed by access to drug and financial support [30]. A study on people with HIV infection who do or do not attend support groups concluded that those who attended support groups reported less emotional distress, and had more social contact than non-attenders [31], this could explain why most of the volunteers who attended support groups were able to enrol for an experimental study. The support groups are also said to provide more knowledge on health issues and give them a sense of belonging [32]. A section of the participants had previously participated in other clinical trials which is similar to other studies [33].

This study established that the main motivators for participation in the Ebola vaccine clinical trial were altruism (67.3%) and personal health benefits (32.7%). Altruism was defined by participants' willingness to advance research and help the society both at local and global levels. Respondents were inspired by the desire to participate and learn from the Ebola vaccine trial while pioneering development of an Ebola vaccine in Kenya. In a systematic literature review it was concluded that majority of subjects identify altruistic reasons for participation in clinical trials [34]. A cross-sectional descriptive study in Kenya which looked at volunteer motivators for participating in HIV vaccine clinical trials also noted altruism as the major motivator [35]. Contrarily in Malawi, access to health care was the main motivation for volunteering in clinical trials [36]. This was similar to a study in Germany where a slight section also expected benefits for oneself in terms of individual health information [37]. A group of the respondents also wanted to participate in the Ebola vaccine trial to give back, educate the community on Ebola and help the society. Considering that these were HIV positive persons, the idea of giving back to society was based on the ideology that other persons had previously participated in HIV research that had led to the availability of the ART drugs that they were using. Similarly, in a study done on experiences of volunteers in clinical trials majority of the volunteers held very positive views about participation in clinical trial and saw it as an opportunity to help others [38]. This was also true in a study done in France where the main motivations given for participating in a clinical trial were to support research [33]. The results differ from different clinical trials in India and Brazil where the main motivation for taking part was monetary compensation which was not expressed in this study [12,39], though none of these studies involved HIV-infected participants.

Individual factors including; gender, age, marital status, number of children, sources of income, amount of income, and participation in previous clinical research by respondents did not significantly influence motivators. Similarly, a study from 2005-2006 in African-American volunteers, age was not associated with willingness to participate in a hypothetical phase 2/3 HIV vaccine trial. In Uganda, willingness to participate as a HIV positive participant in a clinical trial did not differ by age group, education status, occupation, marital status and HIV status at study baseline [40].

Limitations

- Use of consecutive sampling introduced bias to the study and its non-probability sampling diminished the generalizability of the results to the entire population.
- Social desirability bias as the questionnaire was administered by the study clinicians.
- More than one motivator was elucidated from some of the volunteers hence arriving at 55 responses for 48 volunteers. This may have affected the data analysis and interpretation.

Conclusion

Social benefits were the main motivators for participation in the Ebola vaccine clinical trial. Altruism was defined by participants' willingness to advance research, give back to the society, and educate the society on Ebola at local and global levels. Respondents were inspired by the desire to participate and learn from the Ebola vaccine trial and pioneer the development of an Ebola vaccine in Kenya. There was a general feeling that they saw this as an opportunity to give back to the society in their own way while trying to disassociate with the stigma that they were not 'of use' to their societies anymore. Personal benefits were mainly health benefits including medical check-up and a better understanding of their health status; this can be attributed to the lower socio-economic status of the participants who might not have access to proper health care. Individual factors including gender, age, marital status, number of children, sources of income, amount of income, and participation in previous clinical research by the respondents did not influence HIV-infected individuals to participate in the Ebola vaccine clinical trial.

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