

## Post-HIV vaccine trials' misperception and associated factors in Dar es Salaam, Tanzania

Edith A.M. Tarimo<sup>§1\*</sup>, Candida Moshiro<sup>2</sup>, Joel Ambikile<sup>3</sup>, Patricia Munseri<sup>4</sup>, Muhammad Bakari<sup>4</sup>, Ezekiel Matola<sup>5</sup>, Hamisa Mangara<sup>6</sup>, Theodora Mbunda<sup>7</sup>, Mary Ngatoluwa<sup>7</sup>, and Kisali Pallangyo<sup>4</sup>.

<sup>1</sup>Department of Nursing Management, Muhimbili University of Health and Allied Sciences, Dar es Salaam, Tanzania

<sup>2</sup>Department of Epidemiology and Biostatistics, Muhimbili University of Health and Allied Sciences, Dar es Salaam, Tanzania

<sup>3</sup>Department of Clinical Nursing, Muhimbili University of Health and Allied Sciences, Dar es Salaam, Tanzania

<sup>4</sup>Department of Internal Medicine, Muhimbili University of Health and Allied Sciences, Dar es Salaam, Tanzania

<sup>5</sup>Police Hospital, Kilwa Road, Dar es Salaam, Tanzania

<sup>6</sup>Tanzania Prisons Services, Segerea, Dar es Salaam, Tanzania

<sup>7</sup>Infectious Disease Clinic, Dar es Salaam, Tanzania

### Abstract

**Background:** Despite successful conduct of three Phase I/II HIV vaccine trials in Dar es Salaam, Tanzania, misperception about the trials has been reported. We describe the magnitude of misperception about HIV vaccine trials and associated factors among participating communities in Dar es Salaam, Tanzania.

**Methods:** We conducted a cross-sectional study that included 605 respondents aged  $\geq 18$  years from the communities that participated in Phase I/II HIV vaccine trials. These communities comprised of youths, Police and Prison officers. Information regarding socio-demographic and perceptions about participation in HIV vaccine trials was collected by using a pre-tested questionnaire.

**Results:** Of the 605 respondents, 156 (26%) had misperception that the researchers infected the volunteers with HIV during the trials, while 58% were not sure. The likelihood of misperception increased in participants who were aware on progress in HIV vaccine development (adjusted risk ratio (RR) =1.50; 95% CI=1.11 – 2.04), participated in an HIV vaccine sensitization meeting (adjusted RR=1.50; 95% CI=1.14-1.97) and had advanced secondary education (adjusted RR=1.92; 95% CI=1.19 – 3.09). Nevertheless, the majority (94.5%) showed a willingness to know more about ongoing HIV vaccine studies while 44.3% had reservations of participating due to fear of getting infection from the vaccine.

**Conclusions:** The misperception that researchers infected volunteers with HIV in Phase I/II trial is significant. This misperception was associated with respondents' awareness about HIV vaccine development, participation in sensitization meetings and advanced education. Partial knowledge about HIV vaccine trials was of note. Future HIV vaccine trials should strive to address this knowledge gap.

**Keywords:** Phase I/II HIV vaccine trials; Misperception; Tanzania

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<sup>§</sup> Corresponding e-mail: [edithtarimo@gmail.com](mailto:edithtarimo@gmail.com)

## **Introduction**

Human Immunodeficiency Virus (HIV) remains a major public health concern, particularly in sub-Saharan African countries. Despite the availability of already known behavioural and biomedical interventions, new infections continue to occur because these interventions are not always adhered to. Availability of a safe, highly effective and accessible preventive HIV vaccine represents the best long-term hope for controlling the HIV/AIDS pandemic (Esparza, 2001). Successfully testing the safety and efficacy of HIV vaccine depend on availability and willingness of volunteers to participate in the trial (Tarimo, 2011a). Furthermore, effective recruitment and retention depends on awareness levels of those vaccine trial is meant for. Despite the efforts of conducting these HIV vaccine trials in different parts of the world, studies revealed that people considering participation in HIV vaccine trials experience personal and social barriers that prevent such participation. Among other types of barriers (Barrington, et al., 2007; Lesch, et al., 2006; Lindegger, et al., 2007; Starace, et al., 2006), misconceptions about HIV vaccine studies appear to negatively influence participation in HIV vaccine trials. A common misconception that has been reported is, 'acquiring HIV infection from the vaccine' (de Souza, et al., 2003; Jspan, et al., 2006; Sherr, et al., 2004; Starace, et al., 2006; Van De Ven, et al., 2002).

In Dar es Salaam-Tanzania, the first phase I/II HIV vaccine trial (HIVIS-03) was conducted among members of the Police force between 2007 and 2010. The UNAIDS Good Participatory Practice Guidelines for community engagement in conduct of biomedical trials (UNAIDS, 2011) was adhered. The sensitization meetings and information booklets written in Kiswahili language was made available to all participating officers. This information, sensitization meetings and workshops enabled successful enrolment of sixty volunteers in the HIVIS-03 Phase I/II HIV vaccine trial (Bakari, et al., 2011). Following the success of the HIVIS-03, other trials called TaMoVaC-01 and TaMoVac 02 were conducted in Tanzania and Mozambique (Munseri, et al., 2015).

Despite the success of these trials, respondents reported fear towards the experimental vaccines from immediate community members and mistrust of the trial(s) itself ( Tarimo, et al., 2011b). Regular workshops were made to address this short falls and ensure participants retention (Tarimo, et al., 2011c). Nevertheless, a misperception that researchers infected the volunteers with HIV emerged and persisted for more than three years post-completion of the respective trials [E. Matola, personal communication]. This misperception may influence future participation in HIV vaccine trials. Therefore, this article describes the magnitude of misperception about HIV vaccine trials and associated factors in Dar es Salaam, Tanzania. In this study, misperception means incorrect understanding that in Phase I/II HIV vaccine trial, the researchers infect the volunteers with HIV.

## **Materials and methods**

### **Study setting and population**

The study was carried out in Dar es Salaam, Tanzania. The study population included Police officers, Prison's officers and youths obtaining reproductive health services at the Infectious Diseases Clinic (IDC). Male and female respondents aged 18 years and above, and who consented to participate in the study were included.

### **Study design**

A cross-sectional design was used to determine the magnitude of misperception about HIV vaccine trials and associated factors among police, prison officers and youth in Dar es Salam from May to August 2016.

### **Sampling and Sample size**

The estimated sample size was 600 respondents. We assumed the proportion of people with the misperception about HIV vaccine trials to be 50% (since it was unknown), an absolute precision of 4%, and a 5% significance level. Thirty-two police stations were identified. Half of the police stations (16) were selected with probability proportional to size, in which the larger stations had a higher probability of being selected. We included a convenient sample of about 19 Police officers from each selected police station adding up to 310 officers. A total of 170 Prison officers from the four prison stations were conveniently included. At the youth's clinic, we selected 125 youth using a systematic sampling method. Every 3<sup>rd</sup> youth was selected for participation in the study.

### **Data collection**

At police and prison stations, the potential respondents were requested to remain after the "baraza" (weekly morning meetings), while at the IDC potential respondents were recruited through exit interviews. The research team explained the study objectives and the procedures for data collection. Data were collected through a structured, self-administered questionnaire in Kiswahili language. The pre-tested questionnaire included information on socio-demographic characteristics, awareness about HIV vaccine, participation in HIV Vaccine trials and meetings, attitudes, perception, motivations, and barriers towards participation in HIV vaccine studies. Research assistants were trained to ensure that all sections of the questionnaire were accurately completed.

### **Data Management and Analysis**

The outcome variable was misperception about HIV vaccine trial studies (present/absent). The characteristics of the respondents were described using proportions. We measured attitude towards participation in HIV Vaccine research using four items on a four-point Likert scale system. The response categories on each item ranged from 1 (strongly disagree) to 4 (strongly agree). A respondent was classified to have a positive attitude if he/she agreed or strongly agreed in at least three out of the four items. The association between various factors and the presence of misperception were assessed using the Chi-squared test. Log-binomial regression models were used to determine whether the factors independently influenced misperception after adjusting for potential confounders. Risk ratios (RR) and 95% confidence intervals are presented. Variables with p-value <0.2 in the univariate analysis were included in the multivariable model. A p-value of less than 0.05 was considered statistically significant. All statistical analyses were performed with STATA software (version 14, Stata Corp Lake Way, College Station, Texas, USA).

## **Results**

### **Socio-demographic characteristics**

We recruited 605 respondents: 310 (51.2%) from the police force, 170 (28.1%) from the prison force and 125 (20.7%) from the youths. Majority of respondents were male, aged between 25 and 34 years, were not married and had completed four years of secondary education. Women were less likely than men to have attained advanced secondary education (of 189 women and of 416 men, 38 (20%) and 141(34%) attended secondary or higher level respectively). Sixty-three percent of men were married compared to 52% of women (Table 1).

**Table 1. Socio-demographic characteristics by sex**

Variable	Sex		Total (n=605)	P-value <sup>b</sup>
	Male	Female		

	(n=416)	(n=189)		
<b>Age group (years)<sup>a</sup></b>				
<25	73 (17.9)	55 (29.4)	128 (21.5)	0.02
25-34	142 (34.8)	59 (31.6)	201 (33.8)	
35-44	81 (19.9)	31 (16.6)	112 (18.8)	
45+	112 (27.5)	42 (22.5)	154 (25.9)	
<b>Marital status<sup>a</sup></b>				
Married	262 (63.0)	98 (52.1)	228 (37.7)	<0.001
Not married	150 (36.1)	78 (41.5)	360 (59.6)	
Divorced/widowed	4 (1.0)	12 (6.4)	16 (2.6)	
<b>Education</b>				
No formal education	0	2 (1.1)	2 (0.3)	0.001
Primary	69 (16.6)	54 (28.6)	123 (20.3)	
Ordinary secondary	207 (49.8)	95 (50.3)	302 (49.9)	
Advanced secondary	41 (9.9)	11 (5.8)	52 (8.6)	
University/college	99 (23.8)	27 (14.3)	126 (20.8)	
<b>Work Station</b>				
Police	234 (56.2)	76 (40.2)	310 (51.2)	<0.001
Prison	120 (28.8)	50 (26.5)	170 (28.1)	
Youth	62 (14.9)	63 (33.3)	125 (20.7)	

Values are number (column percent)

<sup>a</sup>Numbers do not add up to totals due to missing data; <sup>b</sup>Chi squared or Fisher's Exact test

#### **Magnitude of misperception around HIV vaccine trials**

Of the 605 respondents, 157 (26%, 95% CI=22% - 29%) had the misperception that researchers infected the volunteers with HIV during the HIV vaccine trials. The magnitude of the misperception was 77 (24.8%), 48 (28%) and 32 (26%) among the police officers, prison officers and youths respectively.

#### **Factors associated with the misperception around HIV vaccine trials**

In the univariate analysis, the prevalence of misperception was significantly higher among those who were aware of the progress that has been made on the development of HIV vaccines (106, 32%) compared to those who were not aware (51, 19%). Respondents who had participated in HIV vaccine meetings were significantly more likely to have the misperception about HIV vaccine trials (38%) compared to those who had not participated in these meetings (22%) ( $p < 0.0001$ ) (Table 2).

After adjusting for other factors, the likelihood of misperception about HIV vaccine trials was significantly higher among those who had ever heard about HIV vaccine development (adjusted RR, 95%CI) and those who had ever participated in an HIV vaccine studies sensitization meeting (adjusted RR=1.50; 95% CI=1.14-1.97). Surprisingly, the likelihood of having the misperception about HIV vaccine trials was higher among respondents with secondary education and above as compared to those with primary education (Table 3).

**Table 2. Factors associated with misperception among participating populations that researchers infected volunteers with HIV**

Variable	Total	Number (%) with perception	P-value <sup>b</sup>
<b>Sex</b>			
Male	416	109 (26.2)	0.82
Female	189	48 (25.4)	

Variable	Total	Number (%) with perception	P-value <sup>b</sup>
<b>Age (years)</b>			
<25	128	29 (22.7)	0.57
25-34	201	58 (28.9)	
35-44	112	27 (24.1)	
45+	154	42 (27.3)	
<b>Marital status</b>			
Married	228	55 (24.1)	0.53
Not married	360	99 (27.5)	
Divorced/widowed	16	3 (18.8)	
<b>Education<sup>a</sup></b>			
Primary	123	24 (19.5)	0.07
Ordinary secondary	302	85 (28.1)	
Advanced secondary	52	19 (36.5)	
University/college	126	29 (23.0)	
<b>Work Station</b>			
Police	310	77 (24.8)	0.79
Prison	170	47 (27.6)	
Youth	125	33 (26.4)	
<b>Aware about progress in HIV vaccine development</b>			
Yes	333	106 (31.8)	<0.0001
No	272	51 (18.8)	
<b>Knowledge about availability of effective AIDS vaccine in Tanzania or elsewhere</b>			
Yes	123	42 (34.2)	0.02
No	482	115 (23.9)	
<b>Participation in HIV Vaccine meetings</b>			
Yes	150	57 (38.0)	<0.0001
No	455	100 (22.0)	
<b>Attitude towards participation in HIV Vaccine research</b>			
Positive	525	132 (25.1)	0.27
Negative	80	25 (31.2)	

<sup>a</sup>Excluded 2 cases with no formal education;

<sup>b</sup>Chisquared or Fisher's Exact test

### ***HIV vaccine trials' barriers and motivations to take part in future trials***

The majority (83.5%) of the respondents were motivated to take part in HIV vaccine trials due to a desire of living an HIV free life. There was a difference ( $P < 0.01$ ) between groups in terms of having unprotected sex as a motivation to take part in HIV vaccine trials. However, 44.3% of them had reservations of taking part in HIV vaccine trials due to fear of getting HIV from the vaccine. There was a significant difference between groups regarding fear of getting HIV from the vaccine ( $P < 0.01$ ) and fear of testing for HIV if enrolled in HIV vaccine trials ( $P < 0.001$ ) (Table 4).

**Table 3. Multivariable log binomial regression analysis of factors associated with misperception about HIV Vaccine trials among participating populations**

Variable	Crude Risk Ratio (95% CI)	Adjusted Risk Ratio (95% CI)
<b>Education</b>		
Primary	Reference	Reference
Ordinary secondary	1.44 (0.97 – 2.16)	1.44 (0.98 – 2.13)

Advanced secondary	1.83 (1.13 – 3.11)	1.81 (1.12 – 2.93)
University/college	1.18 (0.73 – 1.91)	1.27 (0.80 – 2.03)
<b>Aware about progress in HIV vaccine development</b>		
Yes	1.70 (1.27 – 2.28)	1.51 (1.11 – 2.04)
No or don't know	Reference	Reference
<b>Knowledge of any available AIDS vaccine in Tanzania or elsewhere</b>		
Yes	1.43 (1.07 – 1.92)	1.29 (0.97 – 1.71)
No	Reference	Reference
<b>Participation in HIV Vaccine meetings or research*</b>		
Meetings or research	1.87 (1.44 – 2.44)	1.63 (1.24 – 2.13)
Neither of the two	Reference	Reference

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\*Excluded 13 with no misperception

**Table 4. HIV vaccine trials' barriers and motivations**

Variable	Total No. (%)	Work station			P-value
		Police No. (%)	Prison No. (%)	Youth No. (%)	
Things that may discourage one from taking part in an HIV vaccine study (multiple responses)					
1. Fear of getting HIV from the vaccine	268 (44.3)	138 (44.5)	91 (53.5)	39 (31.2)	0.001
2. Fear of testing for HIV	211 (34.9)	102 (32.9)	42 (24.7)	67 (53.6)	<0.0001
3. Fear of being labelled promiscuous	183 (30.2)	102 (32.9)	44 (25.9)	37 (29.6)	0.27
4. Cost	88 (14.5)	42 (13.5)	21 (12.4)	25 (20.0)	0.14
Things which may motivate one to take part in HIV vaccine studies (multiple responses)					
1. Desire to live HIV free life	505 (83.5)	255 (82.3)	144 (84.7)	106 (84.8)	0.71
2. To have unprotected sex	84 (13.9)	37 (11.9)	18 (10.6)	29 (23.4)	0.003
3. Desire to live with HIV positive partner	79 (13.1)	46 (14.80)	20 (11.8)	13 (10.4)	0.39

Majority (94.5%, n=572) expressed willingness to know more about ongoing HIV vaccine studies in the country and in the world.

### Discussion

The magnitude of misperception that researches infected the volunteers with HIV in this study is of great concern. This misperception was associated with having heard some information about vaccines development against HIV infection, previous participation in HIV vaccine sensitization meetings that were organized by Muhimbili University of Health and Allied Sciences (MUHAS), and having an advanced secondary level of education. Majority of the respondents expressed the intention to know more about ongoing HIV vaccine studies in the country and in the world. Although the majority would be motivated to take part in HIV vaccine studies because of a desire to live HIV free life, a significant number cited fear of getting HIV from the vaccine as a barrier to participating in HIV vaccine studies.

In the current study, the reported misperception is in line with eagerness amongst most respondents wanting to know more about HIV vaccine studies. Similarly, several studies suggest more basic HIV vaccine education to increase understanding of vaccine related concepts (Flynn, et al., 2005; Jaoko, et al., 2008; Kibuuka, et al., 2009; Mugerwa, et al., 2002; Mugenyi, 2002; Omosa-Manyonyi, et al., 2011). To promote future participation in HIV vaccine trials, various strategies are needed to suppress this misperception, one being educational campaigns that had been predicted to have a substantial impact on individual willingness to participate in research (Smit, et al., 2006). In addition to educational

campaign, a qualitative study among the current study population, suggests dissemination of HIV vaccine trial information through local television channels, flyers and former HIV vaccine trial volunteers as the methods of preference to the local communities (Tarimo, et al., 2019). The use of the former volunteers is regarded impactful given their previous experience in the HIV vaccine trials participation. Further, the authors (Tarimo, et al., 2019) anticipate that these volunteers may prevent misperception in future trials because of their acceptance in the local context.

The fact that participation in the HIV vaccine sensitization meetings increased misperception suggests that the information in these meetings was not comprehensive enough to deliver most needed facts about HIV vaccine trials. In South Africa, lack of information about the vaccines was most commonly cited concern and more information was prerequisite for willingness to take part (Lindegger, et al., 2007) implying that adequate knowledge is demanded to clear doubts about vaccine trials among community members. In Uganda, HIV vaccine awareness increased from 68% at baseline to 81% at follow-up (Kiwanuka, et al., 2004) suggesting that one meeting may not be adequate to impact vaccine knowledge on the potential respondents. Also, McGrath (McGrath, et al., 2001) complement that in vaccine trial education, adequate time is needed to ensure that respondents are able to master the complexity of information required for trial participation. In India, the knowledge scale showed a significant increase in scores after vaccine education (Suhadev, et al., 2009). Newman (Newman, et al., 2011) suggests that public discourse on HIV vaccine trials is a productive means of interpreting complex clinical trial processes and outcomes in the context of existing beliefs and experiences regarding HIV vaccines, medical research, and historical disenfranchisement. In future HIV vaccine studies, new ways may be needed to address partially informed groups to avoid spreading wrong concepts to the public.

### **Limitations**

The questionnaire was self-administered; hence, social desirability bias may have occurred. To minimize the risk of individuals answering in accordance with social desirability (answers according to what they feel the researcher may want to hear), respondents were not required to enter their names on the questionnaire. Regular transfers and duty relocations may have resulted in different levels of HIV/AIDS knowledge among the participating populations. It was also not clear why the more educated group expressed high level of misperception in the current study. In future, a qualitative method may be important to explore the reasons for different levels of knowledge regarding HIV vaccine trials among advanced secondary school participants. Despite these limitations, we believe the current study may be a reasonable source of information for researchers.

### **Conclusion**

The misperception that researchers infected the volunteers with HIV was associated with respondents' awareness about HIV vaccine development, participation in sensitization meetings and advanced education. To facilitate the conduct of future HIV vaccine trials, it is crucial to identify and address existing misperception about HIV vaccine trials. Continuous sensitization of HIV vaccines is needed to increase understanding towards HIV vaccine trials.

### **Ethics statement**

Ethical clearance for this study was obtained from the Institutional Review Board (IRB) of the Muhimbili University of Health and Allied Sciences (MUHAS), Ref.No.2015-01-15/AEC/Vol.IX/44. Permission to do the study was also obtained from heads of police stations, prisons and IDC. A written informed consent was obtained from all respondents.

### **Authors' contributions**

EAMT, CM, JA, PM, MB, EM, HM and KP designed the study. CM, JA, PM, MN, EM, TM, and HM coordinated data collection. MN took part in double data entry. EAMT, CM, and JA analyzed data. EAMT wrote the manuscript. MB, PM, and KP critically reviewed the manuscript. All authors reviewed and approved the manuscript.



### Conflicts of interests

The authors declare no conflicts of interests

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### Data availability statement

The data that support the findings of this study are available on request from the corresponding author, [EAMT].

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