

# Willingness to Participate (WTP) in HIV Vaccine Trials among Itinerant Female Hairdressers in Ibadan, Nigeria

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## Abstract

**Objectives:** Plans are in the pipeline to commence field trials to determine the efficacy of HIV vaccines amongst the Nigerian population. This study was conducted to assess the willingness to participate as subjects in HIV vaccine trials among female hairdressers in Ibadan, Nigeria.

**Materials and Methods:** A hypothetical vaccine candidate was explained to the respondents in the form of lecture modules. Interviewer-administered questionnaires were completed by 247 respondents with age ranging from 16 to 49 years. The questions were in Pidgin English which is an adulterated form of English language widely spoken among the respondents. SPSS version 10 data editor was used to analyze data. Univariate odds ratios (OR) and multivariate adjusted odds ratios (AOR) and 95% confidence intervals (95% CI) were used to evaluate the correlates of willingness to participate (WTP) in vaccine trials.

**Results:** A total of 86 respondents (35%) of the respondents reported that they will be willing to join HIV vaccine trials. Greater willingness was associated with prior sexual experience (OR=1.23, 95% CI: 1.12-1.53), involvement in high risk sexual behavior (OR=1.35, 95% CI: 1.05-1.62), higher levels of awareness about HIV/AIDS (OR=1.37, 95% CI: 1.14-1.45) and tangible incentives (OR=1.39, 95% CI: 1.02-1.42). Decreased WTP was associated with concerns about physical harm (OR=0.42, 95% CI: 0.21-0.54), social stigmatization (OR=0.51, 95% CI: 0.42-0.68), use of parenteral route for vaccine administration (OR=0.66, 95% CI: 0.53-0.76) and multiple doses of vaccines (OR=0.81, 95% CI: 0.46-0.94).

**Conclusion:** The level of WTP recorded indicates that much work still needs to be done in the area of educating potential subjects in HIV vaccine trials about the safety of these vaccines. Incentives for would-be subjects should also be a part of the planning to encourage greater participation in these trials.

**Keywords:** HIV; Vaccines; Itinerant; Hairdressers; Willingness to participate

## Introduction

There is a need for continued research to develop new prevention technology methods for HIV including clinical trials of candidate HIV vaccines. Studies on the immunogenicity and safety of candidate vaccines are ongoing in many parts of the world with plans in the pipeline to carry out such studies in developing countries [1-3]. There are plans in the pipeline for HIV vaccine trials in many parts of Africa.

Willingness to participate in hypothetical HIV vaccine trials has been found to as high as 95% among participants in a Ugandan community [4]. This study was conducted in populations believed to be at elevated risk and participants in these studies did not receive vaccine trial education before their willingness was assessed. Irrespective of the respondent population, concerns about vaccine product safety and the fear of appearance to have the AIDS virus have been found to be notable barriers to participation [5,6].

Barriers have been researched in terms of the locus and the nature of the barrier [6]. Another major type of barrier identified is perceived misconceptions [6-8]. These misconceptions include concerns about vaccine-induced seropositivity and mistrust of government and safety concerns. Females have been found to have high rates of infection of HIV in Africa.<sup>4</sup> Itinerant activities and jobs that make females come into contact with large numbers of male clients have been associated with a high prevalence of HIV [9].

Itinerant work defined as working in one place for a comparatively short time and then moving on to work in another place has been identified as a high risk group in the epidemiology of HIV in Nigeria [4,5]. This group has the potential of covering distances and has a potential for sexual networking in the population [5]. This study was

conducted to assess the willingness to participate as subjects in HIV vaccine trials among itinerant female hairdressers in Ibadan, Nigeria. The work was carried out in the months of July and August 2012 with eligible hairdressers chosen by balloting using the list of hairdressers as the sample frame.

## Methods

This was a cross-sectional study in which a total of 247 respondents were recruited by using a list of female hairdressers from the local branch of the union, the Association of Hairdressers of Nigeria (AHN). Interviewer administered questionnaires were used to elicit responses from participants after three, one hour sessions during the course of regular weekly zonal meetings of the union. These sessions consisted of modules that highlighted what HIV vaccines were. Modules included mechanisms of action of candidate vaccines, guidelines for the conduct of HIV-vaccine trials in Nigeria, and the absence of assured protection and the potential for social and physical harm to the participants. The purpose of the training was to allow the participants to understand what these vaccines were and how they could be used.

The inclusion criterion was registered membership of the union

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for six or more months prior to the commencement of the study while members who were aware of their HIV status were excluded from the study. Female hairdressers were chosen for this study because of their itinerant nature on the job which may put them at high risk of HIV hence the need to also examine the relationship between correlates of participation in phase 3 HIV vaccine trials.

A hypothetical vaccine made from a synthetic peptide was explained to the respondents. The instructions and questions were in Pidgin English which is an adulterated form of English language widely spoken among the respondents. We used a format with modules delivered in three didactic lecture sessions that had audiovisuals instructions, group discussion and exercises. The sessions were facilitated by the Principal Investigator and two professional health educators who were a part of a pre-investigation training session.

Questionnaire items included frequencies of socio-economic, perceived HIV risk, attitudes and willingness to participate in HIV vaccine trials, concerns regarding HIV vaccine trial participation, and opinions regarding possible incentives for vaccine trial participation. There were 10 questions in all on HIV transmission and management with 6 correct answers classified as good knowledge with any score below that classified as poor. The questions were adapted from the results of previous surveys [7,9-11]. There were also questions that explored the sexual history of participants with an interest in lifetime sex partners and engagement in risky sexual behavior. These questions were to determine the casual sex history of respondents. There were also questions on availability of physical or material incentives which the participants could judge as what they could be able to take away from the venues of the survey. These were termed 'tangible incentives'. Hairdressers were chosen by balloting using the list of hairdressers as the sample frame.

Data was analyzed using SPSS Analyses were used to investigate bivariate relations among nominal measures. Univariate odds ratios and 95% confidence intervals were used to evaluate correlates of willingness to participate in trials. A multivariate logistic regression model of willingness to participate was constructed from variables that were significantly associated with willingness in the univariate analysis.

## Ethical issues

Approval for this study was obtained from the Lagos University Teaching Hospital Research and Ethics board. Written informed consent was obtained from all participants. All participants had a two hour session of educational materials on New HIV prevention strategies after their participation in the survey.

New Prevention Technologies for HIV discussed included microbicides and pre-exposure prophylaxis for HIV. These sessions were in addition to the previous 3-hour sessions which dealt with the hypothetical HIV vaccine candidate. The sessions were designed with the objective of ensuring that participants benefitted from the knowledge of other prevention technologies apart from HIV vaccines. A total of 1000 naira (8USD) per day (to cover the cost of travel) and light refreshments were provided for participants during the course of the sessions.

## Results

### Socio-demographic attributes and Willingness to Participate in Vaccine trials

A total of 86 respondents (35%) of the respondents reported that

they will be willing to join HIV vaccine trials. Table 1 demonstrates the univariate analyses of education and region of residence were related to willingness to participate. Those with a primary school education (or less) were significantly more willing to participate, as were younger participants (16-25 years). Those who had been living in urban areas reported greater willingness to participate in vaccine trials (57.8% not willing to participate) than those from rural areas (87.7% not willing to participate). Marital status was not found to have a statistically significant association with willingness to participate in trials (p=0.78).

Table 2 summarizes univariate odds ratios and 95% confidence intervals for identified factors in relation to WTP. The largest odds ratio (p=0.01) in relation to willingness was the knowledge of HIV demonstrated by answering six questions correctly on HIV transmission and management. Concern about social and physical harm also had significant negative associations with willingness (p=0.03). Daily alcohol use (p=0.82) and tobacco use (p=0.35) did not elicit statistically

Variable	Not Willing to participate	%	Odds Ratio	95% CI	p-value
Age in years					
16-25years (n=149)	86	57.7	1.18	1.12-1.69	0.001
Above 25 Years (n=98)	75	76.5	1.00 (ref)		
Education					
Primary school or less (n=103)	56	54.4	1.28	1.11-1.48	<0.001
Secondary or vocational school (n=144)	105	72.9	1.00 (ref)		
Marital Status					
Single (n=112)	76	67.8	0.97	0.89-1.23	0.78
Married (n=135)	85	63.0	1.00 (ref)		
Domicile					
Urban (n=190)	111	57.8	0.64	0.55-0.95	0.002
Rural (n=57)	50	87.7	1.00 (ref)		

**Table 1:** Socioeconomic characteristics of respondents with Willingness to Participate in HIV Vaccine trials.

Variable	Not Willing to participate	%	Odds Ratio	95% CI	p-value
Casual sexual partner					
Yes (n=82)	34	41.4	0.43	0.34-0.64	0.02
No (n=165)	127	76.9	1.00 (ref)		
Knowledge about HIV					
Good (n=128)	75	58.5	1.61	1.16-1.81	0.01
Poor (n=119)	86	72.2	1.00 (ref)		
Alcohol Use					
Almost daily (n=45)	31	68.8	1.09	0.79-1.34	0.82
Weekly or less (n=202)	130	64.	1.00 (ref)		
Smoking					
Yes (n=15)	9	60.0	0.88	0.58-1.49	0.35
No (n=232)	152	65.5	1.00 (ref)		
Potential risk of vaccine					
Yes (n=187)	135	72.1	1.31	1.14-1.63	0.001
No(n=60)	26	43.3	1.00 (ref)		

**Table 2:** Univariate analysis of HIV risk behavior, knowledge and attitude associated with WTP.

Variable	Adjusted OR	95% CI	P value
Prior Sexual experience	1.23	1.12-1.53	0.03
High risk sexual experience	1.35	1.05-1.62	0.001
High awareness of HIV transmission	1.37	1.14-1.45	0.02
Tangible incentives	1.39	1.02-1.42	0.01
Concern about physical harm	0.42	0.21-0.54	0.03
Fear of social stigmatization	0.51	0.42-0.68	0.02
Fear of parenteral vaccine administration	0.66	0.53-0.76	0.03
Fear of multiple doses of vaccine	0.81	0.46-0.94	0.04

**Table 3:** Multivariate analysis of factors associated with WTP

significant inferences. Engagement in casual sex was also found to have a statistically significant association with WTP ( $p=0.02$ ).

### Willingness to participate: Multivariate model

Table 3 shows the multivariate adjusted odds ratio with the largest odds ratios produced by a set of variables which included: Greater willingness was associated with prior sexual experience (OR=1.23, 95% CI: 1.12-1.53), involvement in high risk sexual behavior (OR=1.35, 95% CI: 1.05-1.62), higher levels of awareness about HIV/AIDS (OR=1.37, 95% CI: 1.14-1.45) and tangible incentives (OR=1.39, 95% CI: 1.02-1.42). Factors which appeared to inhibit willingness to participate in trials included concerns about physical harm (OR=0.42, 95% CI: 0.21-0.54), social stigmatization (OR=0.51, 95% CI: 0.42-0.68), use of parenteral route for vaccine administration (OR=0.66, 95% CI: 0.53-0.76) and multiple doses of vaccines (OR=0.81, 95% CI: 0.46-0.94).

### Discussion

This study found that a little over a third of participants would be willing to join a vaccine trial. This agrees with studies among vulnerable groups in other parts of the world [11,12]. The multivariate model indicated a mix of motivations. Knowledge and awareness of health issues have been reported to improve awareness and knowledge especially among lower income, less educated, and minority patients thereby reducing barriers to participation and increasing willingness [13-15]. The data indicates that 73% of participants attaining secondary or vocational level education are not willing to participate while only 54% of those with primary school or less are not willing to participate. This indicates a need to develop strategies and materials for those in secondary or vocational school and ensuring that all presentations are well adapted to the target audience. Such recommendations had been made in similar studies [16]. The level of willingness to participate found in the present investigation was slightly higher than that which have been found in a similar study in the Northern part of Nigeria and Uganda [7,17]. The results are however identical to others conducted on the African continent [12,18]. The disparity between our findings and that in northern Nigeria might have been associated with the disparity in level of education between these areas. The similarity in levels of willingness to participate among this study and other investigations in other parts of Africa is of interest with regard to the method of data collection. The interviewer administered questionnaire format that we used might have yielded less willingness and more frequent expression of concerns relative to other interview studies because of the tendency to elicit response biases [19-23].

In agreement with other investigations on the African continent, concerns about stigma and possible side effects came out as major issues [12,17]. Other studies have reported a greater willingness among women to participate in HIV vaccine trials which may be related to may be related to their limited control over other means of protection

[24,25]. The level of willingness to participate in these trials may have been due to the amount of information we were able to provide to study participants.

Previous studies have indicated that incentives for would-be-subjects increase willingness to participate in HIV vaccine trials. Reported inducements have included money and the possibility of enrolment in health insurance schemes [23,25,26]. Although vaccine trials have been largely conducted in urban areas, our results indicate a greater WTP among urban residents. These results are in consonance with other HIV related studies which suggest that the poor and ethnic minorities show a less willingness to participate in clinical trials [27-30].

### Limitations

Our study was a hypothetical study that did not examine actual participation compared with others that compared hypothetical and actual willingness to participate [8]. This was also a cross-sectional study, and therefore the temporal relationship between variables and willingness to participate is hard to determine.

The present investigation also had a limitation of not being able to get the educational materials that had been used in other studies to design the modules for the participants. We also did not adopt a double-blind placebo technique which makes inferences impossible.

The use of interviewer-administered questionnaire format that was used in this survey may also be a source of response bias as respondents are likely to answer questions based on their perception of what answers may be appropriate. We tried to mitigate this by assuring respondents that the results of the survey would be primarily for research purposes.

### Conclusion

On the overall, this study shows that more attention needs to be given to address concerns about safety and ensuring that there is a high level of civic education that would accompany planned HIV trials. It is also important to design messages in such a manner as to address the concerns of people with less educational. Future studies also need to be designed to identify other anthropological and demographic factors that may moderate willingness before planning and promotion of trials. Our findings indicate that monetary incentives should also be a part of the planning to encourage greater participation in these trials.

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