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Willingness to participate in Ebola viral disease vaccine trials and receive vaccination by health workers in a tertiary hospital in Ile-Ife, Southwest Nigeria

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ABSTRACT

Background: Ebola viral disease (EVD) epidemic need to be contained through means which include vaccination of susceptible population. Vaccination has eradicated major killer diseases.
Objective: The study determined the health workers willingness to participate in EVD vaccine clinical trials and receive EVD vaccine.
Materials and methods: A descriptive cross-sectional study design involving 370 consenting health workers of Obafemi Awolowo University, Ile-Ife that completed a self administered semi-structured questionnaire. Data analysed using descriptive and inferential statistics.
Results: Mean age was 34.4 ± 8.6 years (range, 19–60 years). Most were females (60.3%), and had worked <10 years (74.3%). The health workers were mostly medical doctors (22.7%) and nurses (52.4%). EVD awareness (84.9%) was high among respondents with radio (37.2%) as major source of information. A higher proportion of respondents willing to participate in clinical trials were willing to receive vaccine (93% vs. 68%, p = 0.0001). The significant variables associated with willingness to participate in EVD vaccine trials include being male [AOR 1.58, 95%CI 1.04–2.40, p = 0.033], medical doctor [AOR 2.28, 95%CI 1.31–3.96, p = 0.003] and having safe vaccine [AOR 2.10, 95% 1.58–3.98, p = 0.0001] while the significant variable associated with willingness to receive EVD vaccine was vaccine safety [AOR 3.19, 95%CI 2.13–6.03, p = 0.029].
Conclusion: Male gender, medical doctor and vaccine safety determine willingness to participate in Ebola vaccine trials while vaccine safety determines willingness to receive vaccine when ready. Researchers should ensure gender equality and vaccine safety in vaccine trials.

1. Introduction

Ebola viral disease (EVD) is caused by the Ebola virus, a thread-like RNA virus belonging to the Filoviridae family and typically appears in sporadic outbreaks usually within a health-care setting [1]. However, on March 21, 2014, the World Health Organization (WHO) was notified of EVD outbreak in southeastern Guinea, which eventually spread to border areas in Liberia and Sierra Leone and other West African countries including Nigeria, Senegal and Mali [2]. The EVD epidemic caused unforeseen destruction especially in Guinea, Liberia, and Sierra Leone mostly from perceived fear of health care workers and family members of getting infected hence refusing to care for suspected cases leading to the death of many people from common infections as programs set up to prevent and treat malaria, tuberculosis, vaccine-preventable diseases were disrupted while most health care systems were shut [3–5]. By 15 August 2014, 2127 cases had been reported of which 1145 had died [6]. This epidemic was helped by weak health system with poor infrastructure, poor health care financing and limited health insurance coverage [6,7]. The belief that EVD is an African disease was soon proven wrong as cases were imported to USA and European countries from West Africa.

An international response was coordinated by WHO to mitigate the impact and control the epidemic. Also, many unsuspecting people get infected due to poor infection control technique and lack of personal protective equipment [8]. Nigeria reported the first case through a traveler to Lagos from Liberia on July 20, 2014 [1,9]. This epidemic was rapidly contained in Nigeria through a combination of governmental, non-governmental and international

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partners' efforts which prevented further spread within and outside to other countries in Africa and beyond [10]. Nigeria was declared EVD free by WHO on October 20, 2014. This success was achieved through effective case detection, contact tracing of suspected EVD cases, setting up EVD treatment units including training health care workers to safely care for cases, provide and correct use of personal protective equipment including safe and dignified burial for dead cases.

However, this success in Nigeria was difficult to replicate in other West African countries as there was unprecedented exponential growth of the epidemic which raised concern that control might be impossible without vaccination thereby prompting research to accelerate development of Ebola vaccines. Several promising vaccine candidates were identified, with many more in development. The two leading candidates are vectored vaccines in which the Ebola virus glycoprotein is presented in a replication-incompetent chimpanzee adenovirus 3 (cAd3) or a replication-competent vesicular stomatitis virus (VSV). Both vaccines have shown 100% protection in nonhuman primates at 4–5 weeks after single doses were administered and further phase 1 trials are ongoing to get a vaccine that will not only contain the current epidemic but reduce the possibility of a future EVD epidemic in Africa and elsewhere [11]. By September, 2014 WHO initiated a coordinated effort by the international community to accelerate vaccine development, evaluation, production and licensing of Ebola vaccines [12,13]. Although, no proven vaccine or specific treatment for EVD exists; however, human trials of potential vaccines and therapies have began. The necessity to foster hope for a long-term solution for EVD showed that developing an effective vaccine will control and lead to eradication of the Ebola virus. These efforts include the rVSV vaccine in Phase 2/3 studies in Liberia, Guinea, and Sierra Leone, Sierra Leone Trial to Introduce a Vaccine against Ebola (STRIVE), and other vaccine trials that are currently at different phases of trials in several African countries and beyond [11]. From April 9 to August 15, 2015, STRIVE enrolled 8673 participants, of whom 453 and 539 were also enrolled in the safety and immunogenicity sub-studies, respectively. As of April 28, 2016, no Ebola cases and no vaccine-related serious adverse events, which by regulatory definition include death, life-threatening illness, hospitalization or prolongation of hospitalization, or permanent disability, were reported in the study population. However, STRIVE require further evaluation for efficacy and safety [11,14]. Safety data from Phase 1 studies of both ChAd3 and rVSV vaccines indicate an acceptable safety profile in healthy adults. These studies including Phase 3 Ebola vaccine trials PREVAIL in Liberia will provide additional experience in adults, and will allow more extensive assessment of safety. No data are currently available regarding the safety of these vaccines in subjects with underlying disease or medical conditions. There are also no data regarding the safety of these products in paediatric and pregnant subjects [15].

Although the WHO declared the end of the EVD outbreak in Liberia on June 9, 2016 it is necessary to prepare for a world free of future EVD epidemic.

Therefore, licensing an effective safe vaccine will further the effort to control and prevent this deadly disease. This study was conducted to assess health workers willingness to participate in Ebola viral disease (EVD) vaccine trials and receive these vaccines whenever they become available to use.

2. Materials and methods

This descriptive cross-sectional study was conducted at the Obafemi Awolowo University Teaching Hospital Complex (OAUTHC), Ile-Ife, Nigeria, in the month of September, 2014.

The hospital clinical staff selected by proportionate sampling included medical doctors, nurses, pharmacists, medical laboratory technologists, community health workers (CHEW), medical records officer, and physiotherapists.

The sample size of 303 was calculated using a statistical formula for estimating the minimum sample size in descriptive health studies [$n = Z^2\ pq/d^2$] [16], where 28.4% of health workers were willing to receive vaccine [17]. A sample size of 370 was used after non responders being taken into consideration.

The number allocated to each group of clinical staff was determined proportionately using the formula $n/N \times 370$, where n is the number of occupational groups and N is the total number of clinical staff [18].

Consenting health workers completed a pretested semi-structured self-administered questionnaire that assessed participants' socio-demographic characteristics, willingness to participate in EVD vaccine trials and receive the vaccine whenever it is available. This questionnaire was validated by the authors using face validity and making necessary adjustments where necessary to the questions before use in the study. The respondents were allowed to fill the questionnaire in their spare time at their convenience. Questionnaire information was anonymised.

Ethical approval to conduct the study was obtained from Ife Central Local Government Ethical Review Committee. Written informed consent was taken from the respondents while they were reassured of the confidentiality of the information obtained. The data collected were entered and kept in a password protected computer.

The data obtained were analysed using SPSS version 16. Simple descriptive and inferential statistics were done. Chi square test was used for bivariate analysis. Multivariate analysis using binary logistic regression was used to evaluate socio-demographic variables and other variables that are independently associated with willingness to participate in EVD vaccine trials or receive the vaccine when ready. Criteria for inclusion of variables in the logistic regression model was a p-value <0.2 in the bivariate. Odds ratios (ORs) and 95% confidence intervals (CIs) were presented and used as measures of the strength of association. Tests were considered significant for a p value < 0.05.

3. Results

A total of 370 completed questionnaires were analysed (response rate 86.4%). Mean age (SD) was 34.4 ± 8.6 years (range 19–60 years). There were 223 (60.3%) females and 147 (39.7%) males. Most respondents were married (65.9%), had worked less than 10 years (74.3%). They were mostly medical doctors (22.7%) and nurses (52.4%) (Table 1).

EVD awareness (84.9%) was high among respondents with radio (37.2%) as major source of information (Table 2). About 25% of the respondents were aware that there was no EVD vaccine presently. A higher proportion of respondents willing to participate in clinical trials were willing to receive vaccine (93% vs. 68%, p = 0.0001). Gender distribution among the respondents show that males constitute 79.5% medical doctors, 30.8% nurses and 22.8% other health workers (p = 0.0001) (Table 3).

On logistic regression analysis, the significant variables associated with willingness to participate in EVD vaccine trials include being male [AOR 1.58, 95%CI 1.04–2.40, p = 0.033], medical doctor [AOR 2.28, 95%CI 1.31–3.96, p = 0.003] and safe vaccine [AOR 2.10, 95% 1.58–3.98, p = 0.0001] (Table 4), while the significant variable associated with willingness to receive EVD vaccine was vaccine safety [AOR 3.19, 95%CI 2.13–6.03, p = 0.029] (Table 5).