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Perceptions and acceptability of an experimental Ebola vaccine among health care workers, frontline staff, and the general public during the 2014–2015 Ebola outbreak in Sierra Leone

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Abstract

Introduction—Experimental Ebola vaccines were introduced during the 2014–2015 Ebola outbreak in West Africa. Planning for the Sierra Leone Trial to Introduce a Vaccine against Ebola (STRIVE) was underway in late 2014. We examined hypothetical acceptability and perceptions of experimental Ebola vaccines among health care workers (HCWs), frontline workers, and the general public to guide ethical communication of risks and benefits of any experimental Ebola vaccine.

Methods—Between December 2014 and January 2015, we conducted in-depth interviews with public health leaders (N=31), focus groups with HCWs and frontline workers (N=20), and focus groups with members of the general public (N=15) in Western Area Urban, Western Area Rural, Port Loko, Bombali, and Tonkolili districts. Themes were identified using qualitative content analysis.

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Author contributions

MFJ, MBJ, PS, and AA led the design of the assessment including development of the protocol and data collection instruments. MFJ, MBJ, and PS led the training of data collection teams. MFJ supervised all data collection teams. Data analysis led by MFJ. Additional data analysis and n iterative interpretations guided by HN, BW, AME, and RB. All co-authors substantially contributed to the review of data, interpretation of results, and writing of the manuscript.

Declaration of Interests

None to report.

Disclaimer

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the U.S. Centers for Disease Control and Prevention, Karolinska Institutet, FOCUS 1000, or the Sierra Leone Ministry of Health and Sanitation.

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Results—Across all participant groups, not knowing the immediate and long-term effects of an experimental Ebola vaccine was the most serious concern. Some respondents feared that experimental vaccines may cause Ebola, lead to death, or result in other adverse events. Among HCWs, not knowing the level of protection provided by experimental Ebola vaccines was another concern. HCWs and frontline workers were motivated to help find a vaccine for Ebola to help end the outbreak. General public participants cited positive experiences with routine childhood immunization in Sierra Leone.

Discussion—Our formative assessment prior to STRIVE's implementation in Sierra Leone helped identify concerns, motivations, and information gaps among potential participants of an experimental Ebola vaccine trial, at the time when an unprecedented outbreak was occurring in the country. The findings from this assessment were incorporated early in the process to guide ethical communication of risks and benefits when discussing informed consent for possible participation in the vaccine trial that was launched later in 2015.

Keywords

Ebola vaccine; acceptability; attitudes; perceptions; Sierra Leone

1. Introduction

Sierra Leone has approximately 8,000 health care workers (HCWs) nationwide [1]. During the 2014–2015 outbreak of Ebola virus disease (Ebola) in Sierra Leone, nearly 200 HCWs were infected with Ebola by October 2014, around the peak of the outbreak. Ebola acquisition risk was much higher in HCWs compared to non-HCWs partly due to poor infection control and prevention measures, as well as their exposure to Ebola patients [2, 3]. Over 28,000 Ebola cases and 11,000 deaths were reported in Sierra Leone, Liberia, and Guinea by the end of the outbreak in 2016 [4]. The prolonged outbreak took a toll on health systems, and the utilization of non-Ebola health services such as pediatric and obsteric care declined during the outbreak [5, 6].

Experimental Ebola vaccines were introduced after the peak of the outbreak in Sierra Leone [7–10], Liberia [11, 12], and Guinea [13] as part of accelerated clinical trials to assess the safety and efficacy of these vaccines. Experimental Ebola vaccines were made available during ring vaccination efforts targeting Ebola contacts in Guinea [13] and Sierra Leone [14]. Mathematical models predicted that Ebola vaccination strategies could substantially contribute to containing an Ebola outbreak, including strategies to vaccinate HCWs [15–18].

The Expanded Program on Immunization in Sierra Leone, established in 1978, provides the foundation for the country's immunization service delivery. The program increased national coverage of infant antigens, including the third dose of diphtheria-tetanus-pertussis vaccine (DTP3), from 6% to 75% between 1986 and 1990 [19]. Gains in immunization coverage were hampered during the country's civil conflict between 1991 and 2002, but coverage improved afterward. In 2014, national coverage was 88% for DTP3 and 78% for the first dose of measles-containing vaccine [20].

Prior to the 2014 Ebola outbreak, vaccine clinical trials had never been conducted in Sierra Leone, Guinea, or Liberia. Resistance to experimental vaccine introduction has been documented in other similar contexts [21]. Introducing an experimental vaccine during an evolving Ebola outbreak was complex, and required careful ethical, social, and political considerations [22–24].

In late 2014, the U.S. Centers for Disease Control and Prevention, Sierra Leone Ministry of Health and Sanitation, and the College of Medicine and Allied Health Sciences started planning for the Sierra Leone Trial to Introduce a Vaccine against Ebola (STRIVE) [25]. STRIVE was conducted in Western Area Urban, Western Area Rural, Port Loko, Bombali, and Tonkolili districts due to their ongoing Ebola transmissions [25]. By the end of December 2014, these five districts collectively accounted for over 70% of all Ebola cases in Sierra Leone [4]. Eligibility in the trial was limited to HCWs and other frontline workers with high risk of Ebola infection. STRIVE ultimately selected recombinant vesicular stomatitis virus-Zaire Ebola virus (rVSVΔG-ZEBOV) candidate vaccine for safety and efficacy evaluation, but the specific vaccine had not been selected at the time we did the formative research reported in this paper. STRIVE began enrolling participants in April 2015.

To lay the groundwork for implementation of STRIVE, we conducted formative assessments between December 2014 and January 2015 with persons from the groups that would be eligible for STRIVE to examine acceptability of any experimental Ebola vaccine and identify information they would need to make an informed decision. We also explored public perceptions of an experimental Ebola vaccine.

2. Methods

2.1 Study design, sampling, and recruitment

We conducted 31 in-depth interviews with public health leaders, 20 focus group discussions (FGDs) with HCWs and frontline workers, and 15 FGDs with the general public between December 20, 2014 and January 31, 2015 in five districts where STRIVE was being planned (Table 1).

Interviewees were purposively selected based on their roles as decision makers in public health at the national or district level. HCWs and frontline workers were purposefully selected to mirror the anticipated inclusion criteria for STRIVE, which was still in the planning phase. Categories of HCWs included were nurses, medical doctors, and community health officers. Frontline workers included burial team members, cleaners, social mobilizers, and ambulance drivers. HCWs and frontline workers were excluded if they were pregnant, were under 18 years of age, or have received any experimental vaccines. Inclusion and exclusion criteria for participation of HCWs and frontline workers in our formative assessment were set to reflect the same criteria that were being considered in planning STRIVE at the time. Although HCWs and frontline workers were the primary audience, we also wanted to explore public perceptions of experimental Ebola vaccines through FGDs. Adults aged 18 years and older were eligible to participate in the general public FGDs,

grouped by adult men aged 25 years or older, adult women aged 25 years or older, and young persons of either sex aged 18–24 years.

FOCUS 1000, a local non-governmental organization contracted to implement the assessment, liaised with the District Health Medical Teams and District Ebola Response Centers to recruit eligible HCWs and frontline workers. Data collection teams first met with the District Medical Officers (DMOs) and Ebola Coordinators overseeing the respective districts to explain the formative assessment. The DMOs and Coordinators then invited their staff to a short overview meeting where data collection teams introduced the assessment and received contact information of those who attended. Contact information for staff who were not able to attend were obtained through follow-ups with DMOs and Coordinators. Data collection staff then followed-up in person or by phone with potential formative assessment participants to gauge their eligibility. From the list of those who met inclusion criteria, the teams purposively identified those who should be followed-up with for interviews or FGDs taking into account staff cadres, roles, and gender. In each district, health and frontline workers were recruited for FGD participation from 2 health facilities: 1 hospital and 1 other peripheral health unit (Community Health Center, Community Health Post, or Maternal & Child Health Post). For the general public FGDs, eligible participants were recruited from convenient venues such as market places and community centers. One location was conveniently selected per district wherein 3 homogenous FGDs were conducted totaling 15 across all districts. While we did not keep a log of those who declined to participate, feedback from data collectors indicate that nearly everyone who were approached agreed to participate. Those who declined mainly did so due to scheduling conflicts.

2.2 Data collection

Data collection was conducted by trained teams of facilitators and note takers from a local non-governmental organization, FOCUS 1000. Each of the 3 teams comprised 1 interviewer and 1 dedicated note-taker. Data collectors comprised mixed gender teams who were all Sierra Leoneans from diverse professional backgrounds. All data collectors held a master's degree or higher in public health, social sciences, or medicine, and possessed qualitative research experience in the local context of Sierra Leone. Interviews and discussions were administered using qualitative guides (Supplemental Material). Content areas covered in the interview and discussion guides included: attitudes and beliefs about Ebola, perceptions and attitudes about experimental Ebola vaccine and vaccine trial, factors that may influence vaccine trial participation, and preferred communication channels and influencers. For ease of understanding by respondents, data collection tools used the term 'approved' vaccine as an equivalent term for 'licensed' vaccine. Interviews and FGDs were audiotaped only if participants consented. Three-quarters of all interviews and FGDs were not audiotaped at the request of participants. Note takers took extensive notes of the interviewers and discussions as well as other observations such as group dynamics and non-verbal cues. Data collection with HCWs was conducted in English or Krio while FGDs with the general public were done in Krio. FGDs conducted in Krio were translated by the team of Sierra Leonean data collectors, and those audio recorded were transcribed. Data collectors also held short debriefs at the end of each interview and FGD to discuss key themes and observations.

2.3 Analysis

Qualitative content analysis was performed [26] by the lead author and a second analyst – both of whom were involved in designing the assessment and collecting data. The analysts had extensive experience working in the Ebola response in Sierra Leone and were knowledgeable of the local context. Notes and transcripts were imported into Dedoose, a web-based platform for managing qualitative data. The first part of the analysis involved a full reading of all notes and transcripts by two analysts while keeping analytic memos and developing a list of initial codes. Codes refer to labels that capture condensed meaning units from texts in the notes and transcripts. A coding framework was developed based on analytic memos, content areas from the interview and discussion guides, and initial codes. The analysts shared their codes and resolved discrepancies through dialogue. Iterative reviewing and coding of the transcripts were performed whereby overlapping codes were consolidated and other codes revised for clarity of meaning. The lead analyst finalized the codes and created mutually exclusive categories to reflect higher level abstraction of the codes within respective categories. Finally, the categories were further interpreted into crosscutting themes. Group dynamics and non-verbal cues captured in the debriefing process at the end of each interview and FGD were used in interpreting some of the findings.

2.4 Ethical considerations

The Sierra Leone Ethics and Scientific Review Committee approved the study. All participants provided written or thumb-printed informed consent. STRIVE personnel did not directly participate in data collection and only received de-identified, anonymized findings compiled by FOCUS 1000.

3. Results

A total of 31 respondents consented to participate in the interviews (Table 1). A total of 316 respondents consented to participate in the FGDs: 184 HCWs and frontline workers in 20 FGDs (Table 2) and 132 members from the general public in 15 FGDs (Table 3). Most FGDs comprised between 6 and 8 participants. The results have been organized based on thematic areas that emerged from the qualitative content analysis: 1) overall perceptions of experimental Ebola vaccines as a function of trust, 2) safety concerns and efficacy uncertainties as major barriers to acceptance, and 3) influence of altruistic intentions and positive vaccination experiences on acceptance (Table 4).

3.1 Overall perceptions of experimental Ebola vaccines as a function of trust

Overall, participants understood the concept of what a vaccine was, locally referred to as “Marklate.” The Expanded Program on Immunization was viewed positively and noted to have helped in fighting polio and other vaccine-preventable diseases; which indicated overall trust in vaccines among the public.

> *“Marklate [vaccine] has been a good thing for us in the country. I remember when we had polio but now it’s a thing of the past. We always make sure to get our children vaccinated to help them live a strong and healthy life. Without polio*

vaccine, we would have been dealing with so many disabled children who grow to face so many challenges in life" – general public member, Western Area.

While HCWs and frontline workers had some awareness of Ebola vaccine trials being planned, their knowledge of experimental Ebola vaccine was limited. HCWs and frontline workers reported finding out about rumored trials through Ebola response staff and the media. They expressed that they had not yet been formally given the opportunity to discuss their concerns and ask questions about any of the trials that were being planned. Few participants from the general public were also aware of Ebola vaccine trials under planning in Sierra Leone. Nearly all general public members could not distinguish between an experimental and approved vaccine. General public members largely thought that for a vaccine to be administered to humans it must already be approved. HCWs and frontline workers who would be first to receive an experimental vaccine were viewed as trusted sources of information to communicate to the public about the experimental vaccine.

"I believe that the medical workers are the best to talk to people [about the vaccine] because they would have taken the vaccine. So therefore, people will believe them that the vaccine won't kill them" – general public member, Port Loko.

If an Ebola vaccine were to be introduced at the community level, general public participants cited local community leaders as key people to engage to garner community-level trust. Participants expressed that trust in any Ebola vaccine trials would be strengthened if sanctioned by the Government of Sierra Leone, MoHS, and Sierra Leone College of Medicine and Allied Health Sciences. Most HCWs frequently stated their belief that MoHS would not harm its workforce as a reason for trusting MoHS with an experimental Ebola vaccine trial. However, few HCWs expressed that the vaccine trial was politically driven, and may not be in the best interest of the people of Sierra Leone. Those who opined that the Government has not properly handled the Ebola outbreak were also more likely to cast doubts on its ability to successfully roll-out an experimental Ebola vaccine trial.

"Some people have negative views about Ebola and the Government. Even with the [recent] malaria campaign there were issues. Even with the polio vaccine it is an issue let alone with Ebola vaccine. Even if people were given the [correct] information, some will still believe that [the Government] want to kill them with Ebola" – medical doctor, Western Area.

3.2 Safety concerns and efficacy uncertainties as major barriers to accepting any experimental Ebola vaccine

Among HCWs, frontline workers, and public health leaders, safety was the most frequently mentioned concern to hypothetically accepting an experimental Ebola vaccine. Some respondents expressed that an experimental vaccine may cause Ebola in recipients, and wanted to know if such a scenario had ever occurred in earlier phase Ebola vaccine trials. They also feared unknown, long-term adverse events.

"Supposed you take the [experimental] vaccine and it results in Ebola…what if there are serious reactions to the vaccine, or any other medical complication as a result of the vaccination requiring medical treatment? What happens? These are big issues" – public health leader, Western Area.

HCWs especially wanted reassurance that the vaccine could not cause Ebola. As established in the formative assessment guide, the moderators clarified that an experimental Ebola vaccine cannot cause Ebola. Also, participants wanted to know if an experimental Ebola vaccine has ever resulted in a death in earlier phase trials. Moderators clarified that there has not been a documented death linked to any Ebola vaccine trial. Some participants shared that they had heard stories about recipients of an experimental Ebola vaccine in other countries who experienced adverse events that led to the suspension of those trials. Safety concerns emerged as a major barrier among some senior officials who cited that there was little evidence demonstrating that the vaccine is safe in the Ebola outbreak context of Sierra Leone. Noting that earlier stage trials contained small sample sizes, they remained concerned about the emergence of unknown adverse events.

> *"The only thing that will affect my decision in participating is to have more proof on the sample cases conducted [in earlier trials] and the successful results [of those trials], the lab [results], historical background, and the agency involved [in the trial] especially on their responsibilities and reliability"* – public health leader, Western Area.

> *"The [Ebola vaccine] study is a good idea because no more life will be lost in large numbers due to Ebola. But we don't want them to start with the health workers because if they were to die [from taking the vaccine] who will be there to save lives? Many of our colleagues have died during this Ebola [outbreak], so doing the test on us health workers has a question about who will survive in case of any adverse reactions* – surveillance officer, Bombali.

Participants emphasized the need for study staff to regularly follow-up with recipients during an Ebola vaccine trial. They expressed that this factor would influence their decision to participate in any future trial. They wanted assurance of prompt, quality care in the event of adverse events if they volunteered to participate in an experimental Ebola vaccine trial. Participants also strongly expressed a desire for a compensation scheme for them or their family to be instituted should they experience serious adverse events or die as a result of their participation in a future trial. Participants only raised compensation considerations in the context of adverse events following immunization including death or disability, and were not suggested as a requirement or incentive for their participation in an experimental Ebola vaccine trial.

> *"We need to know the safety principle, and the provision of post vaccination surveillance and monitoring of participants"* – public health leader, Tonkolili.

In addition to safety, efficacy concerns regarding an experimental Ebola vaccine were frequently mentioned among HCW participants. However, most HCWs were willing to accept uncertainty about the efficacy of an experimental Ebola vaccine if reassured about its safety. Some HCWs questioned the need to continue using personal protective equipment (PPE) after taking an experimental Ebola vaccine. Several insisted that the only way to determine whether it was the experimental vaccine or PPE that protected them from Ebola was to not use PPE. Most HCWs and frontline workers, however, understood the need to continue using PPE.

"I will still continue using the PPE to see first how the vaccine works. I cannot take any risks at this point" – burial team member, Bombali.

3.3 Influence of altruistic intentions and positive vaccination experiences on acceptance of experimental Ebola vaccines

Interviews with HCWs, frontline workers, and public health leaders identified several motivating factors that influenced hypothetical acceptability of an experimental Ebola vaccine. For instance, they expressed wanting to contribute to the Ebola response and to help find a vaccine for Ebola. Perceptions of ongoing Ebola transmission risk posed to health and frontline workers motivated potential participants to be willing to participate in future clinical trials of Ebola vaccines as a way to protect their patients as well as themselves from infection. Among general public participants, positive experiences with childhood vaccines delivered through the EPI program in Sierra Leone also influenced hypothetical acceptability of an experimental Ebola vaccine if offered in the future.

"I know that marklate [vaccine] is taken into your system to help build soldiers that can fight any sickness that may attack your body" – general public member, Tonkolili.

"I would be comfortable to do so [accept an experimental Ebola vaccine] in the context of trying to solve a problem, reduce the risk to humanity and give our people the chance to end a disease that has had catastrophic effects on our lives" – medical doctor, Western Area.

"Another aspect is whether people in the community would be willing to take the vaccine after proving some positive result on the frontline health workers. I agree that people would be willing to take the vaccine as they would want to get themselves protected [against Ebola] should there be any other outbreak of the virus" – nurse, Port Loko.

4. Discussion

Our formative research revealed mixed and sometimes polarized perceptions in our sample regarding any experimental Ebola vaccine prior to implementing STRIVE in Sierra Leone. Even though an experimental vaccine was a new concept to the majority of participants from the general public, nearly all of them held positive perceptions of routine childhood vaccines. For all participants, desire for effective Ebola prevention strategies coupled with Ebola infection risk were cited as motivating factors to participate in an experimental Ebola vaccine trial. However, safety concern regarding an experimental vaccine was the most serious barrier. Those who might be the first groups of people in the country receive the vaccine (i.e. HCWs and frontline workers) were largely viewed as trusted sources to communicate its safety.

Our findings guided efforts to design ethical and culturally responsive communication strategies for STRIVE's informed consent processes, which contributed to enrollment of over 8,000 participants in the vaccine trial in less than a year [25]. For instance, the findings demonstrated a need to clearly communicate differences between approved and experimental

vaccines and what was known about the vaccine's safety including reassurance that the experimental vaccine could not cause Ebola. Uncertainties regarding the level of protection provided by an experimental Ebola vaccine needed to be clarified and clearly communicated to potential participants. Related to this issue, it was important to emphasize that potential trial participants must continue to use personal protective equipment and follow all other infection prevention and control measures if they volunteered for an experimental Ebola vaccine. Participants needed to be reassured about the experimental vaccine's safety as determined from previous studies, including data showing that it did not cause Ebola, death, or disability. Potential trial participants needed accurate and complete information about any experimental Ebola vaccine to minimize misconceptions.

The findings also suggested that potential volunteers would be interested to know that participating in the vaccine trial and receiving an experimental vaccine might help protect communities against Ebola in the future. Our study found that altruistic intention was an important motivating factor to hypothetically accepting the vaccine. Altruism was also found to be a motivating factor among experimental Ebola vaccine participants who volunteered for the EBOVAC-Salone trial in Kambia, Sierra Leone.[27] While altruistic intention emerged as a salient motivating factor to accepting an experimental Ebola vaccine in an unprecedented outbreak context, careful considerations were taken to avoid unethical leveraging of altruism in promoting acceptance of any experimental vaccine. In fact, knowing that such altruistic intention existed in the target population reinforced the importance of ethical and culturally responsive communication of risks and benefits as part of the informed consent process for an experimental Ebola vaccine trial in order to avoid the possibility of coercion.

Undertaking formative assessment about an experimental Ebola vaccine during an ongoing Ebola outbreak posed important ethical considerations. In planning the assessment we debated how much information about STRIVE to provide to respondents given that details about the vaccine trial were not yet finalized [25]. The assessment therefore focused on exploring the range of possible concerns and information gaps held among potential vaccine trial participants. In responding to questions posed by respondents during data collection, it was important to find the right balance of information to provide to avoid biasing respondents' perceptions one way or the other. For instance, we avoided providing upfront information regarding post-vaccination follow-ups that were being planned as part of the trial. We instead focused on getting respondents' feedback on how they would like to be followed up on (and its importance to them) if they were to be enrolled in an Ebola vaccine trial. We also wanted to avoid getting into very specific details about any particular Ebola vaccine candidate so as to explore cross-cutting issues related to any experimental Ebola vaccine from the perspective of potential trial participants and the general public. When respondents mentioned their concerns about the vaccine's safety and specifically asked if a death had been documented in prior phase trials, our data collection team provided concise clarifications to answer what was known without getting too much into technical details that could lead to misconceptions or possibly bias subsequent responses during the interviews or focus groups. Data collectors instead focused on understanding the underlying concerns that prompted specific questions raised by respondents. Ultimately, the formative research findings were used to identify critical information gaps and concerns in near real-time

during the outbreak. STRIVE personnel later used our findings along with other data sources to plan more than 150 informational sessions with potential trial participants as part of the informed consent process across the five districts [25].

Other assessments have examined attitudes and perceptions relating to Ebola vaccines in Sierra Leone [27–29], Guinea [30], Nigeria [31, 32], and outside of Africa [33, 34]. A similar assessment conducted during another experimental Ebola vaccine trial in Sierra Leone shed light on the importance of risk communication and developing community engagement and social mobilization platforms.[28] In a national sample of Guineans, 84% expressed acceptance of a hypothetical Ebola vaccine, and hypothetical acceptance was significantly associated with living in a household with a child who had received routine vaccines.[30] In our assessment we found that past positive experiences with routine childhood vaccines influenced receptive perceptions of experimental Ebola vaccines. This raises the importance of clear communication when introducing an experimental vaccine in a population where there is already high acceptance of approved childhood vaccines. While there is a specific word in the local language for vaccines in general -- but usually associated childhood vaccines (Marklate) -- there is no specific word for experimental vaccines. This meant that more elaborate messaging was needed to carefully distinguish the differences between approved and experimental vaccines. The STRIVE team took this consideration seriously, and clearly communicated differences between experimental and approved childhood vaccines as part of the informed consent process.

Even though our data pointed to some trusted sources of information regarding experimental Ebola vaccine, we did not obtain in-depth understanding of possible underlying mistrusts within communities. A separate qualitative study conducted towards the end of the Ebola outbreak in Sierra Leone revealed community-level dissatisfactions with outbreak response measures that indicated some mistrust of authorities [35]. Use of Ebola vaccines at the community-level such as for ring vaccination efforts during Ebola outbreaks should seek to leverage lessons learned from routine childhood immunization programs that could be useful for future community acceptance of Ebola vaccines [30]. At the same time, careful efforts are required in anticipating and responding to possible unintended consequences on routine childhood immunization that may emerge from use of Ebola vaccines at the community level during ring vaccination efforts – such as the emergence of misconceptions that may derail overall vaccine confidence.

Our formative assessment is subject to several limitations. While the FGDs offered the advantage of individuals sharing experiences and building off of each other’s insights, participants may have been less likely to express attitudes that differed from emerging group consensus. These potential limitations were mitigated by skilled facilitation that offered equal opportunity to all participants to freely express their views on the range of issues discussed. We did not collect specific information on respondents’ individual level experiences with Ebola, which limits our understanding of how variability in Ebola experiences may have potentially influenced perceptions and hypothetical acceptability of experimental Ebola vaccines. Power relations between participants and interviewers may have influenced the responses generated [36], including the potential for social desirability bias or withholding of information. These limitations were likely reduced by having

experienced and well trained data collection teams who facilitated openness in dialogue. Finally, we cannot generalize our findings to populations of HCWs, frontline workers or the general population in Sierra Leone. However, generalization was not the purpose of our qualitative assessment. We instead aimed to obtain rich understanding and subjective interpretations regarding nuances and complexities related to ethical considerations for a potential experimental Ebola vaccine trial in the context of an unprecedented and ongoing outbreak.

5. Conclusions

Availability of an approved Ebola vaccine has been recognized as an important tool, along with contact tracing, case management, and risk communication, in limiting the spread of future Ebola outbreaks. [37] As progress is made towards introducing an approved Ebola vaccine, it is important to integrate socio-behavioral assessments into the process to better understand how to effectively communicate the benefits and risks of the vaccine, and avoid negative impact on uptake of routine childhood immunization. The findings from this assessment coupled with lessons learned from multi-channel communication efforts carried out during STRIVE [25] have critical implications for the introduction of experimental vaccines during outbreaks. Formative assessments can be an important tool in identifying barriers and information gaps among potential participants in a clinical trial of a new experimental vaccine during an outbreak, and should be incorporated early in the process to help guide ethical communication of risks and benefits in reaching informed consent.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Table 1.

Distribution of in-depth interviews by district and cadre, Sierra Leone, December 2014 – January 2015

District	Respondents (N=31)
Western Area Urban	7
Western Area Rural	6
Port Loko	6
Bombali	6
Tonkolili	6
Cadre	
National decision-maker	3
District medical officer	4
Burial team supervisor	4
Ebola Treatment Unit supervisor	4
Other frontline supervisor	7
Senior health care staff	9

Table 2.

Distribution of in-depth interviews with public health leaders and focus group discussions with health and frontline workers by district, Sierra Leone, December 2014 – January 2015

District	Focus groups with health & frontline workers		Total Participants
	Health facilities	Groups	
Western Area Urban	2	4	38
Western Area Rural	2	4	34
Port Loko	2	4	36
Bombali	2	4	40
Tonkolili	2	4	36
Total	10	20	184

Table 3.

Distribution of focus group discussions with general public members by district, Sierra Leone, December 2014 – January 2015

District	Focus groups with general public members				Total participants
	Adult men	Adult women	Young people	Total groups	
Western Urban	1	1	1	3	29
Western Rural	1	1	1	3	25
Port Loko	1	1	1	3	27
Bombali	1	1	1	3	27
Tonkolili	1	1	1	3	24
Total	5	5	5	15	132

Table 4.

Analytical framework of codes, categories, and themes

Code	Category	Theme
General understanding of vaccines	Knowledge of routine childhood immunization	Overall perceptions of experimental Ebola vaccines as a function of trust
Use of vaccines in children		
Universal child immunization campaign		
Vaccines prevent childhood diseases		
Hearing about trial via international media	Becoming aware of experimental Ebola vaccines	
Info from outbreak response staff		
Learning about trial from peers		
Vaccine must work to be vaccine	Inadequate understanding of experimental vaccines	
No prior experience with experimental vaccine		
No prior experimental vaccine trial		
First-takers of the experimental vaccine	Trusted information sources	
Ministry of health as gatekeeper		
Trust in health authorities		
Uncertainty about side effects	Adverse vaccination events	Safety concerns and efficacy uncertainties as major barriers to accepting any experimental Ebola vaccine
Long term adverse effects		
Death from vaccine		
Seriously sick after vaccination		
Disability from vaccine		
Vaccine causing Ebola		
Question about earlier phase safety trials		
Vaccine manufacturer withholding info	Transparency about safety	
Government withholding info		
Not having all information		
Secrecy and mystery surrounding trials		
Wanting to know vaccine manufacturer		
Prompt handling of adverse events	Post-vaccination follow-up	
Checking up with vaccine recipients		
Personal safety guarantee		
Compensation for disability	Compensation for serious adverse events	

Code	Category	Theme
Compensation for family for death		
Assurance to care for family		
Financial guarantee gives confidence		
Not knowing level of Ebola protection	Efficacy concerns	
Questioning continued need for PPE		
Risks outweighing benefits		
Cold storage challenges to maintain potency		
Wanting to help end the Ebola outbreak	Desire to help end the outbreak	Influence of altruistic intentions and positive vaccination experiences on acceptance of experimental Ebola vaccines
Help find effective prevention		
Helping to save lives of others		
Reducing Ebola transmission risk		
Personal experience with vaccines	Positive experiences with other vaccines	
No serious prior adverse events		
No experience with experimental vaccine		