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Short communication

Ebola epidemic in war-torn Democratic Republic of Congo, 2018: Acceptability and patient satisfaction of the recombinant Vesicular Stomatitis Virus – Zaire Ebolavirus Vaccine

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ABSTRACT

Background: The current Ebola outbreak in Eastern Democratic Republic of the Congo (DRC) is the second largest in history and the first in which the recombinant Vesicular Stomatitis Virus – Zaire Ebolavirus (rVSV-ZEBOV) vaccine has been used at scale. We assessed side-effects, satisfaction, and attitudes toward the new vaccine.
Methods: Cross-sectional survey questionnaire from a convenience sample of 90 vaccine recipients and 96 community controls in Eastern DRC.
Results: Side-effects were reported in 75/90 (83%) vaccine recipients but only 5 (7%) and 4 (5%) reported arthralgia and rash, respectively. 76/90 (84%) vaccinees were classified as "promoters" (would recommend vaccine to others) and 6/90 (7%) as "detractors." 69/96 (72%) of unvaccinated community controls would wish to be vaccinated if supply were available. 153/186 (82%) would accept vaccination for family members.
Conclusions: The rVSV-ZEBOV vaccine was well tolerated, with high acceptability in the community during the current outbreak in the DRC.

1. Introduction

The recently developed recombinant Vesicular Stomatitis Virus – Zaire Ebolavirus (rVSV-ZEBOV) vaccine is emerging as a key tool for control of epidemics due to Zaire Ebolavirus Disease (EVD), an often-fatal hemorrhagic fever that occurs in outbreaks in equatorial Africa. The largest of these occurred in Guinea, Sierra Leone and Liberia in 2014–2016 [1] and the second largest currently continues unabated in Eastern Democratic Republic of the Congo (DRC) since its onset in August 2018. Despite intensive control efforts, including vaccination, transmission has stubbornly persisted due, at least in part, to social resistance [4]. Understanding vaccinee experiences and community attitudes toward rVSV-ZEBOV vaccine may be important to optimize uptake of this key intervention and combat the current epidemic.

The rVSV-ZEBOV vaccine is a recombinant live viral vaccine engineered to express a surface glycoprotein of Zaire Ebolavirus. Ring vaccination trials in Guinea during the 2014–2016 West Africa outbreak showed this vaccine to offer 100% protection against EVD [2], and the vaccine is now recommended by the Strategic Advisory Group of Experts on Immunization (SAGE) for use in EVD outbreaks caused by the Zaire species of the virus [5]. The vaccine, though not yet commercially licensed, has been administered to frontline healthcare workers and case contacts since August 2018 in the North Kivu outbreak [3]. A recent report indicates that more than 40,000 people have been vaccinated [6].

We collected questionnaire responses from a convenience sample of rVSV-ZEBOV vaccine recipients and community controls at the epicentre of an ongoing EVD epidemic in North Kivu, DRC and described patient-reported side effect profiles and vaccination experiences, attitudes towards the vaccine, as well as desires for personal and community vaccination.

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2. Methods

2.1. Setting

The current EVD epidemic in the Eastern DRC is complicated by active security concerns, decimated health care infrastructure, and population displacement of over one million people [7]. On 1 August 2018, the Ministry of Health of the Democratic Republic of the Congo (DRC) declared the country's 10th EVD outbreak, which has seen a total of 543 confirmed cases (as well as 48 probable cases) and 309 confirmed deaths (with an additional 48 probable deaths) as of December 21, 2018. During the current outbreak, the rVSV-ZEBOV vaccine has been given free of charge to high-risk groups: healthcare personnel, contacts of EVD cases, and contacts of contacts (as per the WHO's ring vaccination strategy) [2].

2.2. Participants

A convenience sample of vaccine recipients and unvaccinated community members over age 18 was selected from the rural commune of Mangina, where the epidemic began, as well as the urban centre of Butembo 80 km away, where there is current ongoing transmission. We identified vaccine recipients among health workers, contacts, and contacts of contacts infected with Ebola. Controls, who had not been offered the vaccine due to ineligibility under the criteria of ring vaccination and "compassionate use," were identified through convenience sampling in the neighborhoods of Butembo.

2.3. Survey questionnaire

A 34 item questionnaire was developed, based on past KAP questionnaires used in Guinea and the DRC [4,8]. French, Kinande or Swahili speaking research team members interviewed participants in order to complete the standardized questionnaires in person. Questions included participant characteristics and key constructs relevant to the public messaging around EVD:

1. Knowledge, attitudes, and practices (KAP) with respect to EVD and its prevention. Items were adapted from previous KAP surveys [8–10]. "Comprehensive knowledge" was defined as accepting two main concepts of prevention (avoiding body fluids and adopting handwashing as a prevention practice), and rejecting three major misconceptions [11]. Affective response was assessed by the question "Are you worried about Ebola?" [9]. Participants were also asked whether they felt they were at high, intermediate or low risk of contracting EVD, and how the vaccine affected that perceived risk. We also included three items asking about EVD prevention practices [9,10]. Safe and dignified burials are another important aspect of Ebola control efforts, in addition to vaccination. We assessed individuals who expressed "resistant" attitudes to safe and dignified burials, as indicated by a negative answer to the following questionnaire item: "If a family member died of Ebola, would you accept an official burial team to care for the body?" [4].
2. Vaccination experiences, satisfaction, and self-reported side-effects. Known side effects of rVSV-ZEBOV include arthralgia, diarrhoea, asthenia, headaches, pain or induration at the site of injection, myalgia, vomiting, and generalized rash [12]. Participants were asked about these and other side effects, before being asked whether they would be willing to get vaccinated again after having experienced those events. Similar to metrics for customer satisfaction with a commercial product or service [13], we classified vaccine recipients as "promoters" if they would recommend the vaccine to a friend or family member. Conversely, respondents were classified as "detractors" if they would not recommend the vaccine.
3. Interest, acceptability, and attitude toward rVSV-ZEBOV vaccine. We included twelve items inquiring about the rVSV-ZEBOV vaccine, adapted from previous surveys [4,8]. As previously, vaccine interest was defined as affirmative response to the question: "A vaccine is needed to fight the Ebola epidemic in the DRC" and vaccine acceptability was defined as affirmative response to the question: "Would your family accept to be vaccinated with the new Ebola vaccine?" [4,8].

2.4. Statistical analysis

Data analyses were performed using R (version 3.3.3, R core team, 2017). Descriptive statistics were expressed as number and percentage for dichotomous variables and median and interquartile range for continuous variables. To examine associations between variables, two-tailed Pearson Chi-Square or Fisher's exact test were used for categorical data, as appropriate.

2.5. Ethics approval

The Comité d'Éthique du Nord Kivu (Centre Hospitalier Universitaire du Graben, Butembo, DRC) approved the study.

3. Results

We surveyed 90 rVSV-ZEBOV vaccinees and 96 community controls between 7 and 10 Sept 2018. Participant characteristics, knowledge, attitudes, and practices with respect to EVD transmission are shown in Table 1. 124/186 (67%) survey respondents had comprehensive Ebola knowledge [11]. Of note, 16/96 (17%) of unvaccinated controls would not accept an official burial team if a family member died of EVD, compared to 0/90 (0%) of vaccine recipients.

Table 2 shows self-reported side-effects and satisfaction among vaccinees. Overall, 75/90 (83%) reported one or more side-effects, the most common of which were headache, fatigue, pain at injection site, and myalgia. Vaccine satisfaction was high, with 77/90 (86%) classified as "promoters" because they would recommend the vaccine to others, and 7/90 (8%) classified as "detractors." Side effects reported by vaccine detractors included injection site pain (5), headache (4), myalgia (4), arthralgia (3), fatigue (3), and rash (1). Reflecting lower vaccine satisfaction, vaccinees reporting arthralgia were more likely to be detractors than those without arthralgia (3/5 (60%) versus 4/65 (6%), $p = 0.0058$).

Table 3 shows results of vaccine interest, acceptability and attitudes among vaccinees and unvaccinated community controls. With respect to predictors of vaccine acceptability and interest, comprehensive Ebola knowledge was associated with higher levels of vaccine interest (OR 5.8 (2.1–18), $p < 0.001$). Among unvaccinated controls, resistant attitude toward safe and dignified burials was associated with low vaccine interest (OR 12 (95%CI 1.8–84), $p = 0.0046$) and low acceptability (OR 6.7 (95%CI 1.1–38), $p = 0.018$).

Among community controls who had not received the vaccine, 69/96 (72%) would wish to be vaccinated if supply were available, 24/96 (25%) would not want to be vaccinated, and 3/96 (3%) did not know. Of those who would accept the vaccine, 59/60 (86%) would be willing to pay for it, at a price of median $3 (range $1–10). Respondents with resistant attitude toward safe and dignified burials were more likely to reject the vaccine (OR 17 (95%CI 3.0–180), $p < 0.001$).

Table 1
Characteristics and Ebola Knowledge, Attitudes, and Practices of rVSV-ZEBOV recipients and community controls in North Kivu, DRC.

	Total (N = 186)	rVSV-ZEBOV recipient (N = 90)	Not vaccinated (N = 96)	p-value
Demographics				
Age group (yrs)				0.24
18–30	94 (51)	41 (46)	53 (55)	
≥30	92 (49)	49 (54)	43 (45)	
Education				<0.001
None	32 (17)	7 (8)	25 (26)	
Some primary education	67 (36)	43 (48)	24 (25)	
Some secondary education or higher	87 (47)	40 (44)	47 (49)	
Occupation				<0.001
Farmer/Herder	61 (33)	18 (21)	43 (45)	
Student	23 (12)	4 (14)	19 (9)	
Merchant	15 (8)	6 (9)	9 (6)	
Nurse	14 (8)	10 (9)	4 (4)	
Doctor	9 (5)	8 (4)	1 (3)	
Traditional medicine practitioner	4 (2)	1 (3)	3 (1)	
Unemployed	26 (14)	19 (20)	7 (20)	
Other	31 (17)	24 (21)	7 (20)	
Knowledge				
Knowledge and perceptions				
Preventable by avoiding contact with body fluids of infected persons	171 (92)	83 (92)	88 (92)	>0.99
Immediate treatment in health facility increases chance of survival	166 (89)	86 (96)	80 (83)	0.0085
Misconceptions				
Transmissible by ambient air	12 (6)	2 (2)	10 (10)	0.034
Can protect self from Ebola by avoiding mosquito bites	22 (12)	1 (1)	21 (22)	<0.001
Preventable by bathing with salt and hot water	20 (11)	1 (1)	19 (20)	<0.001
Attitudes				
Affective response				
Worried about EVD	166 (90)	80 (90)	86 (90)	>0.99
Perceived personal risk of EVD				<0.001
High	81 (43)	19 (21)	62 (64)	
Intermediate	28 (15)	12 (13)	16 (17)	
Low	71 (38)	58 (64)	13 (14)	
I don't know	6 (3)	1 (1)	5 (5)	
Intentions if family member died at home of suspected EVD				
Would wash or touch body	19 (10)	0 (0)	19 (20)	<0.001
Would accept burial team	170 (91)	90 (100)	80 (83)	<0.001
Practices				
Prevention since onset of epidemic (proportion of respondents who…)				
Wash hands more often	186 (100)	90 (100)	96 (100)	>0.99
Avoid shaking hands and physical contact with other people	17 (9)	12 (13)	5 (5)	0.074
Avoid church, public events and crowded places	8 (4)	7 (8)	1 (1)	0.03

4. Discussion

Side-effects were commonly reported by vaccine-recipients in our study, but at a lower rate than in one phase 1/2 prospective double-blind RCT involving healthy volunteers [14]. The leading side effects in that RCT were a rash (54%) and oligoarthritis (25%) whereas, in our study, fewer vaccinees reported skin rash (5%) and arthralgia (7%). Vaccinees that experienced arthralgia were significantly more likely to be vaccine detractors, emphasizing the significance of this side-effect. Optimizing the vaccine experience with supplementary analgesia for arthralgia might increase satisfaction among vaccinees. Vaccinated respondents had lower perceived post-vaccination EVD risk compared to controls (Table 1), and 91% of vaccinees responded that the vaccine had reduced their worries about EVD. Nonetheless, 76% of vaccinees recognized the importance of maintaining precautions against EVD transmission.

Previous studies have identified the ability to observe the impacts of vaccination in other people and knowing the vaccination attitudes of one's neighbors as social factors influencing desire for vaccination [15,16]. We explored the possibility for vaccinees to act as promoters or detractors of the vaccine in their communities, based on their willingness to recommend the vaccine to others [13]. Promoters comprised 86% of vaccinees, and endorsed higher vaccine acceptability. Overall acceptability of rVSV-ZEBOV vaccine was high in our study (82%), similar to a previous report from Eastern DRC (82%) [4] and a national household survey administered in 2015 in Guinea (84%) [8]. In Guinea, interest in vaccination was higher among participants who understood EVD transmission and had previously interacted with EVD cases or EVD response teams, and vaccine acceptability was greater amongst participants who were male, wealthier, more-educated, or lived with children that had received routine vaccinations [8]. Similarly, vaccine interest was associated with higher comprehensive EVD knowledge in our study.

We found that 72% of unvaccinated respondents would accept the rVSV-ZEBOV vaccine, if available. Of these, 86% would agree to pay for the vaccine. The relationship between community vaccination attitudes and vaccine cost has previously been explored across various settings, and willingness to pay for the vaccine provides further evidence of broad support for vaccination [15,16]. On the other hand, we observed a relationship between lower comprehensive Ebola knowledge, resistance towards EVD control measures, and negative vaccination attitudes among some non-vaccinees. This finding may signal the presence of a significant sub-group of people in Eastern DRC demonstrating social resistance to EVD control efforts that require special attention, consistent with numerous media reports [17–19]. Given the highly infectious nature of EVD, incomplete community engagement with control methods may allow ongoing propagation of the epidemic [11].

Table 2
Adverse events and attitudes of 90 rVSV-ZEBOV recipients in Eastern DRC.

Characteristic	n (%)
Reason for vaccination	
Contact of a case	76 (84)
Health care worker	14 (16)
Self-reported adverse effects	
None	15 (17)
One or more:	75 (83)
Headache	52 (69)
Fatigue	32 (43)
Pain at injection site	32 (43)
Myalgia	18 (24)
Nausea	7 (9)
Fever	6 (8)
Arthralgia	5 (7)
Diarrhea	5 (7)
Generalized rash	4 (5)
Vomiting	3 (4)
Induration at injection site	0 (0)
Other[1]	4 (5)
Satisfaction	
Having received the vaccine	
If I had to do it over, I would accept being vaccinated	79 (88)
If I had to do it over, I would not accept the vaccine	8 (9)
I don't know	3 (3)
I would recommend the vaccine to a family member	77 (88)
I would not recommend the vaccine	7 (8)
I don't know	4 (5)
I no longer have to take precautions to prevent Ebola	14 (16)
I still have to take precautions to prevent Ebola	71 (79)
I don't know	5 (6)
The vaccine relieved my worries about Ebola	
Yes	82 (91)
No	6 (7)
I don't know	2 (2)

[1] limb "heaviness" (n = 3) and stiffness (n = 1).

Survey respondents were similar with respect to knowledge, attitudes, and practices around EVD when compared to other EVD surveys. For example, 92% of respondents in the current study (both vaccinated and unvaccinated) agreed that Ebola is "preventable by avoiding contact with body fluids of infected persons," as did 92% of respondents in a Guinean study [10]. Affective response and self-reported prevention practices in this survey also closely mirror previous studies [4,10]. Similarities between KAP in our study and other Ebola outbreaks suggest that our findings may be generalizable to other similar contexts.

The current study, conducted in a challenging environment during an active EVD outbreak, is current and informative, but has some limitations. With 186 respondents, the statistical power of this study was limited by a small sample size. With regards to vaccine side effects, all were self-described (as opposed to physician observed) and the study lacked a placebo group against which side-effect frequency could be compared. The sampling strategy (convenience sample of vaccine recipients) and control group selection should be considered in interpreting our study results. Because vaccination was offered in the context of an outbreak to healthcare workers and to contacts of EVD cases, vaccine recipients were likely experienced with the disease and adherent with public health recommendations inasmuch as they accepted vaccination. Thus, this group differed from the community at large (our control group), as reflected by statistically significant differences in education level, occupation, knowledge, prevention practices, and vaccine attitudes between vaccinated and unvaccinated respondents. While these differences may confound the interpretation of comparisons between study groups, the sample of unvaccinated community controls nonetheless provided an informative reference group that highlighted unique aspects of the vaccinees and revealed resistant attitudes toward vaccination and safe and dignified burials that were not detected among vaccinees.

Table 3
Vaccine interest, acceptability and attitudes among rVSV-ZEBOV recipients and community controls in North Kivu, DRC.

	Total (N = 186)	rVSV-ZEBOV recipient (N = 90)	Not vaccinated (N = 96)	p-value
Vaccine interest				
A vaccine against Ebola is needed in the DRC				0.0027
Agree	163 (88)	86 (96)	77 (81)	
Neutral	0 (0)	0 (0)	0 (0)	
Disagree	10 (5)	2 (2)	8 (8)	
I don't know	12 (6)	2 (2)	10 (11)	
Vaccine acceptability				
If the vaccine were available to them, my family members would accept the vaccine				0.012
Agree	153 (82)	81 (90)	72 (75)	
Neutral	6 (3)	1 (1)	5 (5)	
Disagree	15 (8)	4 (4)	11 (11)	
I don't know	12 (6)	4 (4)	8 (8)	
Attitudes toward universal versus *targeted vaccination*				
We should vaccinate everybody with the new vaccine				0.38
Agree	145 (78)	73 (81)	72 (75)	
Neutral	2 (1)	1 (1)	1 (1)	
Disagree	25 (13)	10 (11)	15 (16)	
I don't know	14 (8)	6 (7)	8 (8)	
We should reserve the vaccine for Ebola contacts and health workers				1
Agree	57 (31)	28 (31)	29 (30)	
Neutral	2 (1)	2 (2)	0 (0)	
Disagree	103 (55)	53 (59)	50 (52)	
I don't know	24 (13)	7 (8)	17 (18)	
The vaccine is experimental and we don't know enough about the risks and benefits to use it in the general public				0.00016
Agree	115 (62)	43 (48)	72 (75)	
Neutral	0 (0)	0 (0)	0 (0)	
Disagree	34 (18)	33 (37)	1 (1)	
I don't know	37 (20)	14 (16)	23 (24)	

5. Conclusion

The rVSV-ZEBOV vaccine has been widely used (>40,000 recipients) during the current EVD outbreak in the DRC, the largest deployment to date [6]. This is the first study, to our knowledge, to describe patient-reported side effects and satisfaction with the vaccine in the context of a large-scale roll-out. Vaccine interest, acceptability and satisfaction was high among survey respondents; however, our findings support previous observations [4] that a minority of Congolese may harbor "resistant" attitudes toward Ebola control efforts, including safe and dignified burials and vaccination. These data, collected in a challenging environment during a public health crisis, provide a timely snapshot of perceptions around the rVSV-ZEBOV vaccine that could help to guide future approaches to vaccine roll-out.

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We declare no competing interests.

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