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Clinical presentation of pregnant women in isolation units for Ebola virus disease in Sierra Leone, 2014

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Abstract

Objectives: To examine Ebola virus disease (EVD) symptom prevalence and EVD status among pregnant women in Ebola isolation units in Sierra Leone.

Methods: In an observational study, data were obtained for pregnant women admitted to Ebola isolation units across four districts in Sierra Leone from June 29, 2014, to December 20, 2014. Women were admitted to isolation units if they had suspected EVD exposures or fever (temperature >38°C) and three or more self-reported symptoms suggestive of EVD. Associations were examined between EVD status and each symptom using χ^2 tests and logistic regression adjusting for age/labor status.

Results: Of 176 pregnant women isolated, 55 (32.5%) tested positive for EVD. Using logistic regression models adjusted for age, EVD-positive women were significantly more likely to have fever, self-reported fatigue/weakness, nausea/vomiting, headache, muscle/joint pain, chest pain, vaginal bleeding, unexplained bleeding, or sore throat upon admission. In models adjusted for age/labor, only women with fever or vaginal bleeding upon admission were significantly more likely to be EVD-positive.

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AUTHORS CONTRIBUTIONS

JM contributed to the conception and design of the study, collection, interpretation and analysis of the data, and writing and revising the manuscript. FS contributed to the collection and interpretation of the data, and writing and revising the manuscript. ML contributed to the conception and design of the study, collection and interpretation of the data, and writing the manuscript. APK contributed to the collection and interpretation of the data, and writing the manuscript. DM and SE contributed to the interpretation and analysis of the data, and writing and revising the manuscript. SK contributed to the collection and interpretation of the data, and writing the manuscript. WC contributed to the interpretation of the data, and writing the manuscript. All authors participated sufficiently in the work to take public responsibility for appropriate portions of the content, agreed to be accountable for all aspects of the work, and gave final approval of the version to be published.

CONFLICTS OF INTEREST

The authors have no conflicts of interest.

Conclusions: Several EVD symptoms and complications increased the odds of testing EVD-positive; some of these were also signs and symptoms of labor/pregnancy complications. The study results highlight the need to refine screening for pregnant women with EVD.

Keywords

Ebola virus disease; Ebola virus infection; Pregnancy; Sierra Leone; Signs and symptoms; Symptom assessment

1 | INTRODUCTION

Very little information has been published about the symptoms of Ebola virus disease (EVD) in pregnant women during the recent, or in previous, EVD outbreaks. Limited evidence from previous outbreaks suggests EVD is more severe and yields higher mortality in pregnant women.[1–3] One possible reason for higher morbidity and mortality associated with EVD in pregnancy is that identification of EVD symptoms among pregnant women may be difficult owing to the overlap in symptoms of pregnancy and labor with EVD.[4,5]

Muscle/joint pain, nausea/vomiting, diarrhea, stomach pain, or unexplained bleeding are common among pregnant or laboring women and in persons suspected of having EVD.[5] During an Ebola outbreak, concerns about preventing ongoing infection through exposure to blood and bodily fluids may contribute to delayed or insufficient care for immediate obstetric needs, leading to excess morbidity and mortality for pregnant women and their fetuses.[4,6] During the 2014 EVD epidemic, prolonged turnaround time in receiving reverse transcription polymerase chain reaction (RT-PCR) EVD test results before the introduction of the rapid diagnostic EVD test impeded efforts to improve accuracy in identifying pregnant women suffering from EVD versus pregnancy complications or labor.[7]

In populations with resource constraints and high maternal mortality pre-outbreak, efforts to decrease mortality and morbidity associated with EVD among pregnant women are particularly important during EVD outbreaks.[5,8–10] Sierra Leone's maternal mortality ratio was an estimated 1100 maternal deaths per 100 000 live births preceding the 2014 EVD epidemic, one of the highest in the world.[5,9,10] An estimated 79 doctors, nurses, and midwives had died from Ebola in Sierra Leone as of May 2015, an impact that one modeling paper estimated to increase the maternal mortality ratio by 74% (95% confidence interval [CI] 51–97) compared with pre-EVD.[11]

More information is needed on the clinical presentation and symptomatology of EVD among pregnant women. By improving screening, diagnosis, and prognosis, this information could help reduce morbidity and mortality of pregnant women with suspected EVD, and will guide healthcare provision during future EVD outbreaks. The aim of the present study was to contribute to these goals by examining the prevalence of EVD symptoms and complications, and associations between EVD symptoms and EVD status among pregnant women admitted to isolation units in Sierra Leone.

2 | MATERIALS AND METHODS

An observational study design was used to retrospectively abstract medical record data for isolation unit admissions that occurred from June 29, 2014, to November 6, 2014, and prospectively collect data from November 7, 2014, to December 20, 2014. The study selected EVD isolation units that accepted pregnant women, as not all units did so. EVD isolation units were established at hospitals and clinics across Sierra Leone as places to isolate, test, and confirm the EVD status of persons with high-risk exposures or suspected EVD. Pregnant women were admitted to the EVD isolation units based on the criteria outlined in Figure 1. These criteria served as the case definition until further confirmation with laboratory testing. On admission to isolation units, women or healthcare providers provided information on pregnancy status. Women who were not pregnant were excluded. The study sample consisted of pregnant women admitted to EVD isolation units across four districts in Sierra Leone: Western Area Urban, Port Loko, Bombali, and Bo. The study was determined to be non-research by the Centers for Disease Control and Prevention (CDC) and the need for patient consent was waived, in line with the IRB exemption obtained for this project. It was also approved by the Sierra Leone Ministry of Health and Sanitation.

Sources of data for chart abstraction included CDC case investigation forms, medical charts, laboratory data, and isolation unit screening forms. Information was collected on patient demographics, isolation unit arrival date, EVD test date, EVD test result, weeks of pregnancy, current and previously reported EVD symptoms and complications, pregnancy complications, and maternal and perinatal outcomes. Results from analysis of maternal and perinatal outcomes of pregnant women admitted to isolation units in Sierra Leone using this data have been published previously.[12]

The outcome variable, EVD status, was determined by RT-PCR testing and reported as positive or negative. Independent variables for the analysis were classified as symptoms and complications upon admission and included: fever (temperature >38°C) obtained by screening station staff, self-reported abdominal pain, fatigue or weakness, nausea or vomiting, headache, muscle/joint pain, diarrhea, chest pain, anorexia, vaginal bleeding, other unexplained bleeding, sore throat, vision changes, cough, unexplained bruising, and rash. Pregnant women could report more than one symptom or complication as they were not mutually exclusive. Additionally, demographic variables were collected: age, marital status (married/unmarried), occupation (farmer/trader, nurse, other) and labor status. The “other” category included self-reported occupations such as hairdresser, housekeeper, housewife, police officer, seamstress, stone breaker, student, and unemployed. This study included a subsample of pregnant women suspected of having EVD who reported whether or not they were in labor (labor status) upon arrival at the isolation unit. Labor status was defined as whether a woman arrived in labor and/or delivered within 24 hours of arrival.

Univariate analysis included mean age and prevalence of other demographics, EVD symptoms and complications, and EVD status. X^2 tests were used to examine differences in EVD symptoms and complications by EVD status. Separate logistic regression models were used to examine associations between each EVD symptom, complication, and EVD status. Associations in unadjusted and age-adjusted models were examined to control for

confounding by age. A subanalysis of age- and labor-adjusted models was performed to control for confounding by age and labor. $P<0.05$ was considered statistically significant. All analyses were conducted with SAS 9.3 (SAS Institute, Cary, NC, USA).

3 | RESULTS

Of the 176 pregnant women included in the study sample, and allowing for missing data, 55/169 (32.5%) tested positive for EVD (Table 1). Women in the sample had a mean age of 25 years and 80/101 (79.2%) were married. About half had occupations as farmers/traders (55/109, 50.5%) or were in the "other" (49/109, 45.0%) category (Table 1). Of 62 women with data on labor status, 30 (48.4%) arrived at the EVD isolation unit in labor or delivered within 24 hours of arrival. The three most common symptoms and complications were fever (114/163, 69.9%), self-reported abdominal pain (115/163, 70.6%), and self-reported fatigue or weakness (105/163, 64.4%). These were also the three most common EVD symptoms and complications among pregnant women who tested positive for EVD (n=55) (Table 2) and all women who arrived in labor regardless of EVD status (n=30) (data not shown).

Comparing the prevalence of self-reported EVD symptoms and complications and fever upon admission by EVD status, and allowing for missing data of seven women, the study found that pregnant women who tested positive for EVD were significantly more likely to have fever (n=46, 86.8%), fatigue or weakness (n=43, 81.1%), nausea or vomiting (n=34, 64.2%), headache (n=35, 66%), muscle or joint pain (n=31, 58.5%), vaginal bleeding (n=17, 32.1%), unexplained bleeding (n=11, 20.8%), and sore throat (n=7, 13.2%) compared to pregnant women who tested negative for EVD ($P<0.05$ for all comparisons) (Table 2).

Unadjusted and age-adjusted results from separate logistic regression models examining the odds of EVD associated with each EVD symptom and complication are presented in Table 3. In general, results from each unadjusted and age-adjusted model of EVD symptoms and complications and fever at admission show higher odds of positive EVD status compared to negative EVD status among pregnant women, although some confidence intervals were very wide. In unadjusted models, there were significantly higher odds of positive EVD status among pregnant women reporting any of the following eight symptoms and complications at admission compared to women without each symptom: fever, fatigue or weakness, nausea or vomiting, headache, muscle or joint pain, vaginal bleeding, unexplained bleeding or sore throat. In the age-adjusted models, fever, fatigue or weakness, nausea or vomiting, headache, muscle or joint pain, vaginal bleeding, unexplained bleeding, and sore throat at admission remained significantly associated with positive EVD status. There was little difference in odds of being EVD positive by EVD symptoms and complications and fever across unadjusted and age-adjusted models. For example, pregnant women who reported nausea or vomiting upon admission had a 2.64 (95% CI 1.33–5.24) higher odds of testing EVD positive in unadjusted models and a 2.40 (95% CI 1.19–4.81) higher odds of testing EVD positive than women who did not have nausea or vomiting in age-adjusted models.

Table 4 shows results from the subanalysis using separate logistic regression models adjusted for age and labor to examine the odds of EVD associated with each EVD symptom and complication using the subsample women with information on labor status. In age and

labor adjusted subanalysis, fever and vaginal bleeding remained significantly associated with positive EVD status. Specifically, pregnant women with fever (adjusted odds ratio [AOR] 5.38, 95% CI 1.29–22.54) and vaginal bleeding (AOR 5.10, 95% CI 1.38–18.90) had significantly higher odds of testing EVD positive compared to pregnant women without the previously listed symptoms.

4 | DISCUSSION

Results from the present study were able to inform clinical management for pregnant women with suspected EVD by providing information on EVD symptoms and complications associated with EVD positivity. Several EVD symptoms and complications were associated with increased odds of testing EVD positive, and some of these were also signs and symptoms of labor and pregnancy complications, making EVD diagnosis, based on symptoms, in pregnant women particularly difficult. It is likely that EVD symptoms are also similar to complications from other Ebola-like illnesses or endemic infections such as Lassa fever and typhoid fever.[6]

The present study emphasized the challenges of identifying EVD among pregnant women in isolation units during an EVD outbreak. When EVD status is unknown, ensuring appropriate and timely clinical care, potentially including isolation, is strikingly difficult.[13–15] Specifically, discerning symptoms of EVD from complications of labor and pregnancy can hinder triage and patient management. In the study, the majority of pregnant women tested negative for EVD, and 55 (32.5%) tested positive. However, EVD-negative women admitted to the EVD isolation unit with pregnancy complications or in labor with symptoms similar to EVD often did not receive the care they needed until their EVD status was confirmed, a process that often took several days. The correct identification and triage of pregnant women with EVD is critical to reducing infections, allocating resources appropriately and ensuring lives are saved. In the EVD isolation units, clinical care was also hampered as maternal and newborn guidelines for care and management of those with suspected or confirmed EVD were not available until early December 2014. These guidelines, devised by the maternal and newborn technical working team led by the Ministry of Health and Sanitation in Sierra Leone, changed the scope of care for pregnant women with suspected or confirmed EVD from virtually no care to care with provision of intravenous infusion, antibiotics, and treatment for malaria. Invasive procedures, such as labor induction, amniotomy, and surgical delivery were still prohibited after the new guidelines were available. In addition, laboratory tests to diagnose infections such as malaria or typhoid were not performed to limit waiting time in the facility; to limit exposure to the blood of potential EVD positive women; and to prevent delays in obtaining results of EVD screening tests. Instead, in many cases women were treated presumptively for malaria.

This present study, and other studies,[6,13,16] demonstrate the challenges in developing EVD screening criteria for pregnant women owing to the similarity of the symptoms suggestive of EVD in the case definition to those of pregnancy complications and labor. In the present study, the broad criteria in Figure 1 was used as the preliminary case definition in the hope of identifying all the true cases. The use of the criteria in Figure 1 was standard practice during the EVD outbreak in Sierra Leone. In addition to difficulties in discerning symptoms

of pregnancy complications and labor from EVD, there was also concern over EVD in asymptomatic pregnant women and women masking symptoms of EVD, thus complicating our ability to properly screen for EVD. Shedding of Ebola virus in an asymptomatic pregnant woman was reported in Liberia. In this case, the patient was afebrile and reported no contact with EVD suspects, thus not meeting the “case definition” criteria. She developed symptoms on day three and died 7 days from admission.[17] Similarly, in the present study, there were reports of pregnant women who tested positive for EVD who developed fever 1–2 days after admission. Self-medicating and masking fever, while not confirmed in the study population, was not uncommon during the outbreak and is also verified in other studies.[18] Continued documentation of vital signs after admission, among many other measures, is needed to guide treatment and management. Such management should be implemented to decrease deaths among patients and providers. EVD case fatality rate during pregnancy has been reported to range between 50% and 70%.[13,19] Any efforts to improve early identification and treatment of EVD infected pregnant women may reduce the case fatality rate.

There were several strengths and limitations associated with the present study. To date, albeit small, this study represented the largest collection of symptomatology data among pregnant women with EVD. Limitations associated with this analysis included self-reported symptom and complication data collected at the time of admission, which may have been subject to recall bias and missing information. Also, isolation unit staff did not draw antibody titers or other diagnostic tests to determine if women had EVD infection prior to entry in the isolation unit: information on whether a pregnant woman had previous EVD infection was important given evidence that pregnant women who tested negative for EVD may still have had EVD positive amniotic fluid, placenta, and fetal blood samples.[4,13,20] Additionally, the study sample was limited to women who reported to hospitals and isolation units during the EVD epidemic. These women may or may not have had more severe illness or pregnancy complications. Utilization of maternity delivery services in health facilities was about 54% in Sierra Leone prior to the EVD outbreak, declining approximately 23% by October 2014.[9,21] Women with severe pregnancy complications may have been more likely to seek care at health facilities during the EVD outbreak despite decreased confidence in the health system, loss of healthcare staff and perceived risk of contracting EVD.[5,9] Missing data was a common occurrence, not unusual in a challenged healthcare system exacerbated by an outbreak. More complete record keeping and medical chart data documentation on pregnant women upon admission and during isolation would provide increased knowledge of symptom, complication, and morbidity information. The present study sample was not nationally representative and focused on four districts with data on pregnant women suspected of EVD and admitted to EVD isolation units. In addition, the sample was not representative of the population of all pregnant women in Sierra Leone during the EVD epidemic. Finally, numerous confidence intervals were wide owing to small sample size.

In conclusion, the study documented the challenges in differentiating pregnant women who have EVD from those who are in labor or have complications of pregnancy, but without EVD. Despite statistical significance, the high prevalence and similarity between EVD symptoms and complications and those of labor and pregnancy complications provides little help in establishing reliable criteria for pregnant women and guiding clinical decisions for

EVD in pregnancy. The results of the study highlighted challenges associated with recognizing symptoms of EVD in pregnant women and represented a starting point for establishing an EVD case definition during pregnancy. There is a need for additional research into the clinical presentation of EVD in pregnant women compared to pregnant women without EVD during EVD outbreaks. Such information would improve and refine EVD screening of pregnant women, strengthen treatment measures, and improve patient prognoses.

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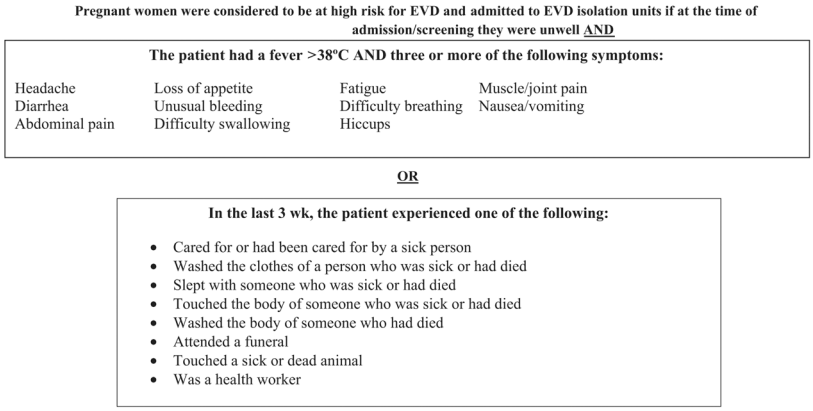

FIGURE 1.

Criteria for admitting pregnant women to EVD isolation units, Sierra Leone, 2014. Abbreviations: EVD, Ebola virus disease. Figure adapted from.[12]

TABLE 1

Characteristics of the study population (n=176).[a]

Characteristic	Value[b]
Age, y	
Missing	6
Overall	25 (6.6)
13–18	32 (18.8)
19–24	42 (24.7)
25–34	75 (44.1)
≥35	21 (12.4)
Marital status	
Missing	75
Married	80 (79.2)
Occupation	
Missing	67
Farmer/trader	55 (50.5)
Nurse	5 (4.6)
Other[c]	49 (45.0)
Self-reported EVD symptoms/complications and fever (>38°C) upon admission[d]	
Missing	13
Abdominal pain	115 (70.6)
Fever	114 (69.9)
Fatigue/weakness	105 (64.4)
Nausea/vomiting	79 (48.5)
Headache	71 (43.6)
Diarrhea	69 (42.3)
Muscle/joint pain	66 (40.5)
Chest pain	37 (22.7)
Anorexia	35 (21.5)
Vaginal bleeding	30 (18.4)
Unexplained bleeding	18 (11.0)
Sore throat	9 (5.5)
Vision changes	6 (3.7)
Cough	4 (2.5)
Amniotic fluid	4 (2.5)
Unexplained bruising	1 (0.6)
Rash	1 (0.6)
EVD status	
Missing	7
EVD positive	55 (32.5)
EVD negative	114 (67.5)

Characteristic	Value[b]
Subsample: Labor status	
Missing	114
Arrived in labor (delivered within 24h of arrival)	30 (48.4)
Did not arrive in labor or deliver within 24h of arrival	32 (51.6)

Abbreviations: EVD, Ebola virus disease.

[a] Categories do not total 176 due to missing.

[b] Values are given as mean (SD), number, or number (percentage).

[c] Other category included pregnant women who reported being a hairdresser, housekeeper, housewife, police officer, seamstress, stone breaker, student, or unemployed.

[d] Categories are not mutually exclusive.

TABLE 2

Demographic characteristics, pregnancy/labor symptoms, and EVD symptoms and complications by EVD status.[a]

	EVD status[b]		
Demographics	**Positive (n=55)**	**Negative (n=114)**	***P* value[c]**
Age, y			0.023
13–18	13 (24.5)	18 (16.2)	
19–24	16 (30.2)	23 (20.7)	
25–34	23 (43.4)	51 (46.0)	
≥35	1 (1.9)	19 (17.1)	
Marital status			0.965
Married	27 (79.4)	13 (21)	
Unmarried	7 (20.6)	49 (79)	
Occupation			0.072
Farmer/trader	12 (34.3)	39 (56.5)	
Nurse	3 (8.6)	2 (2.9)	
Other[d]	20 (57.1)	28 (40.6)	
Self-reported EVD symptoms/complications and fever (>38°C) upon admission[e]			
Abdominal pain	40 (75.5)	71 (68.3)	0.348
Fever	46 (86.8)	66 (63.5)	0.002
Fatigue/weakness	43 (81.1)	58 (55.8)	0.002
Nausea/vomiting	34 (64.2)	42 (40.4)	0.005
Headache	35 (66)	31 (29.8)	<0.001
Muscle/joint pain	31 (58.5)	32 (30.8)	0.001
Diarrhea	28 (52.8)	39 (37.5)	0.066
Chest pain	16 (30.2)	20(19.2)	0.123
Anorexia	13 (24.5)	21 (20.2)	0.533
Vaginal bleeding	17 (32.1)	12 (11.5)	0.002
Unexplained bleeding	11 (20.8)	6 (5.8)	0.004
Sore throat	7 (13.2)	2 (1.9)	0.004
Vision changes	3 (5.7)	3 (2.9)	0.391
Cough	3 (5.7)	1 (1.0)	0.077
Leaking amniotic fluid	1 (1.9)	3 (2.9)	0.708
Unexplained bruising	1 (1.9)	0	0.160
Rash	0	1 (1.0)	0.474

Abbreviations: EVD, Ebola virus disease.

[a] Values are given as number (percentage), unless otherwise specified.

[b] Seven women with missing data on EVD status. Data missing for each demographic characteristic are specified in Table 1.

[c] χ^2 test; $P<0.05$ for significant difference in EVD symptoms and complications by EVD status.

[d]Other category included pregnant women who reported being a hairdresser, housekeeper, housewife, police officer, seamstress, stone breaker, student, or unemployed.

Categories are not mutually exclusive.

TABLE 3

Associations between individual EVD symptoms and EVD among pregnant women.

	Unadjusted odds of EVD (n=157)		Adjusted odds of EVD[a] (n=155[b])	
Model	**Odds ratio (95% CI)**	***P* value**	**Odds ratio (95% CI)**	***P* value**
Self-reported EVD symptoms/complications and fever (>38°C) upon admission[c]				
Abdominal pain	1.43 (0.68–3.03)	0.350	1.46 (0.68–3.15)	0.329
Fever	3.78 (1.55–9.21)	0.003	3.28 (1.33–8.10)	0.010
Fatigue/weakness	3.41 (1.55–7.51)	0.002	3.13 (1.40–6.97)	0.005
Nausea/vomiting	2.64 (1.33–5.24)	0.005	2.40 (1.19–4.81)	0.014
Headache	4.58 (2.26–9.29)	<0.001	4.05 (1.97–8.31)	<0.001
Muscle/joint pain	3.17 (1.60–6.30)	0.001	2.96 (1.47–5.97)	0.003
Diarrhea	1.87 (0.96–3.65)	0.068	1.64 (0.83–3.25)	0.158
Chest pain	1.82 (0.85–3.89)	0.125	1.67 (0.76–3.63)	0.200
Anorexia	1.29 (0.58–2.82)	0.533	1.17 (0.52–2.65)	0.706
Vaginal bleeding	3.62 (1.57–8.33)	0.003	3.65 (1.54–8.65)	0.003
Unexplained bleeding	4.28 (1.48–12.33)	0.007	4.25 (1.46–12.36)	0.008
Sore throat	7.76 (1.55–38.78)	0.013	9.87 (1.82–53.59)	0.008
Vision changes	2.02 (0.39–10.37)	0.400	2.10 (0.41–10.87)	0.377
Cough	6.18 (0.63–60.92)	0.119	5.32 (0.45–63.20)	0.186

Abbreviations: EVD, Ebola virus disease; CI, confidence interval.

[a] Age was modeled as a continuous variable.

[b] Two women were missing data for age, thus sample size is reduced by two in age-adjusted models.

[c] Models were analyzed separately for each EVD symptom.

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TABLE 4

Associations between individual EVD symptoms and EVD among pregnant women.

	Adjusted odds of EVD (n=58)[a]	
Model	**Odds ratio (95% CI)**	***P* value**
Self-reported EVD symptoms/complications and fever (>38°C) upon admission[b]		
Abdominal pain	2.54 (0.63–10.20)	0.189
Fever	5.38 (1.29–22.54)	0.021
Fatigue/weakness	2.67 (0.78–9.11)	0.117
Nausea/vomiting	2.38 (0.73–7.73)	0.151
Headache	3.69 (0.98–13.87)	0.054
Muscle/joint pain	2.51 (0.76–8.29)	0.132
Diarrhea	2.49 (0.73–8.49)	0.146
Chest pain	4.70 (0.83–26.74)	0.081
Anorexia	1.01 (0.28–3.63)	0.983
Vaginal bleeding	5.10 (1.38–18.90)	0.015
Unexplained bleeding	4.91 (0.42–58.09)	0.207
Sore throat	2.52 (0.31–20.51)	0.389
Vision changes	3.37 (0.51–22.35)	0.208
Cough	1.82 (0.08–41.08)	0.708

Abbreviations: EVD, Ebola virus disease; CI, confidence interval.

[a] N=58 is the number of observations read for each individual age- and labor-adjusted model of odds of EVD with each symptom/complication. Data were missing for both age and labor. The missing data are not are not mutually exclusive.

[b] Models were analyzed separately for each EVD symptom.