Retrospective population-based mortality survey in an urban and rural area of Sierra Leone, 2015

Study proposal

V2 02/03/2015
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Katina Kardamanidis
<table>
<thead>
<tr>
<th>Second version</th>
<th>03/03/2015</th>
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</thead>
<tbody>
<tr>
<td>Study design</td>
<td>Retrospective mortality survey</td>
</tr>
<tr>
<td>Study period</td>
<td>4-5 weeks</td>
</tr>
<tr>
<td>Study site</td>
<td>Bo Town and Bo District, Sierra Leone</td>
</tr>
</tbody>
</table>
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List of abbreviations

<table>
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<th>Abbreviation</th>
<th>Description</th>
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<tbody>
<tr>
<td>CMR</td>
<td>Crude Mortality Rate</td>
</tr>
<tr>
<td>95% CI</td>
<td>95% confidence interval</td>
</tr>
<tr>
<td>DOA</td>
<td>Dead on arrival</td>
</tr>
<tr>
<td>EVD</td>
<td>Ebola virus disease</td>
</tr>
<tr>
<td>MOHS</td>
<td>Ministry of Health and Sanitation</td>
</tr>
<tr>
<td>MSF</td>
<td>Médecins sans Frontières</td>
</tr>
<tr>
<td>WHO</td>
<td>World Health Organization</td>
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</table>
1. Introduction

1.1. Context

Bo district is located in the Southern Province of Sierra Leone and had a population of 463,668 in 2004\(^1\).

The district and its capital Bo town is a main thoroughfare from Freetown in the West to Kenema and Kailahun districts in the East, where the first Ebola virus disease (EVD) was reported in May 2014.

After the capital Freetown, Bo town is the second largest city, and the second leading financial, educational, commercial and urban centre of Sierra Leone.

The importance of Bo town and the geographical location makes Bo district vulnerable to the spread of Ebola through travel and trade activity (Figure 1).

The first case in Bo district was reported around the middle of July 2014. The case was a man who travelled from Kenema district, where transmission of Ebola was occurring, to Bo town. This man apparently did not infect others.

At the end of July, Baoma chiefdom saw the first large cluster of EVD cases, introduced by a woman who had attended a funeral in Kailahun. Subsequently the outbreak spread to 11 of its 15 chiefdoms\(^2\).

Up to the 25\(^{th}\) February 2015, the local Ministry of Health (MOHS) has reported 314 confirmed Ebola cases in Bo district\(^3\), representing almost 4% of the total number of confirmed cases in the country (8,320). The last reported case in Bo district was on 14 January 2014 (week 2).

On 24th February 2015, after passing 42 days without any confirmed cases, Bo district was declared an Ebola free zone\(^4\).

The Sierra Leonean population was recovering from years of civil war (1991-2002) which resulted in approximately 50,000 deaths and displacement of half of the population.

Sierra Leone has the highest maternal mortality ratio in the world, with 890 deaths per 100,000 live births, and the second highest infant mortality rate, at 269 deaths per 1000 live births\(^5,6\).

During the Ebola outbreak, 444 health care workers (HCWs) have contracted EVD in Sierra Leone, of whom 221 have died. Thus the outbreak has further weakened already fragile social and health systems.

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1. 2004 Sierra Leone Census
2. Personal communication with MSF Health Promotion supervisor, and on another occasion, by another epidemiologist, with 3 MoH case investigators
5. WHO Maternal and Perinatal Health Profile, 2013 http://www.who.int/maternal_child_adolescent/epidemiology/profiles/maternal/sle.pdf?ua=1
6. Country profile of Environmental Burden of Disease, Sierra Leone http://www.who.int/quantifying_ehimpacts/national/countryprofile/sierraleone.pdf?ua=1

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Figure 1: Geographical position of Bo District (red circle around Bo town)
1.2. MSF presence in Bo District

The project in Bo run by Médecins Sans Frontières (MSF) in collaboration with the Ministry of Health and Sanitation (MoHS) was launched in 1995 as a response to the devastating impact of the ongoing armed conflict.

The major focus of the project became malaria control, and then from 2003 MSF managed a 220-bed hospital, Gondama Referral Centre (GRC), offering emergency pediatric and obstetric services near Bo Town. In October, MSF suspended medical activities at GRC since they could not guarantee an environment safe from the risk of infection with Ebola for patients and staff.

On 19 September 2014, MSF opened an Ebola Management Centre (EMC) just outside Bo town (Bandajuma), admitting Ebola patients from all over Sierra Leone. Along with activities in the EMC, MSF conducts outreach activities in Bo district, focusing on social mobilization, support of survivors, case finding and case investigation efforts conducted by the District Ebola Response Committee (DERC).

From 19 September 2014 to 27 February 2015, a total of 152 suspected Ebola cases residing in Bo district were admitted to the EMC, of which 134 (88%) tested positive for Ebola.

Of the positive cases, 56 died and 77 were discharged cured (CFR: 41.8%). One patient was transferred. MSF received Ebola cases from 11 of 15 chiefdoms in Bo district. There have been no cases admitted from the chiefdoms of Bagbwe, Komboya, Lugbu and Selenga (Figures 2 and 3).

**Figure 2:** Cumulative admissions to the EMC of confirmed cases by Chiefdom of residence, Bo district, week 39 2014, to week 7 2015
Figure 3: Admissions to the EMC of confirmed cases by chiefdom of residence, Bo district, week 39 2014, to week 7 2015
1.3. **Background - Justification for the study**

This mortality survey will provide an overall estimate of mortality (due to EVD and non-EVD) and morbidity in Bo district during the Ebola outbreak.

Particularly in the early stages of the outbreak, community-based surveillance was weak and laboratory diagnosis limited. Education and social mobilization activities in the community were not yet taking place. Ebola was previously unknown to the local population.

As such, there was no knowledge either amongst health-care workers or in the community about routes of transmission and strategies to control it, such as safe burials, isolation of patients, contact tracing and quarantine of contacts. There were also poor infection prevention and control measures and materials in place in many health care centres.

The early reactions of the population and health-care workers were characterised by fear and distress. This is believed to have resulted in avoidance of health care services by patients due to fear of contracting Ebola, and health-care workers turning patients seeking healthcare away out of fear of Ebola. Also, some health care services, such as the MSF GRC were closed. For these reasons, we believe that there will have been an excess of deaths not only due to Ebola, but also due to other causes, during the time of the Ebola outbreak.

Much of what is known about the Ebola epidemic in Bo district has come from the MSF EMC, including the majority of case data, inpatient case fatality rate and routes of transmission. The actual burden of the Ebola epidemic on the population in terms of mortality and the broader effects on access to routine health-care services, and consequent changes in health-seeking behaviour, are largely undocumented.

The crude mortality estimate will be compared with previous surveys carried out by MSF in the same district over the last decade (2005-2008). In all of the previous surveys, mortality rates were high and in some were above the emergency threshold for both adult and children under five. The main reported cause of death was fever/malaria. This survey provides a unique opportunity to compare mortality and morbidity data with the surveys carried out in previous years, and allow measurement of the extent to which the Ebola outbreak has contributed to excess mortality. The survey will also assess how the outbreak affected access to health services and health-seeking behaviours.

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2. Objectives

2.1. Primary objectives

The Primary objective of the survey is to:

✓ Estimate mortality in a sample of the population in the urban and rural area of Bo District from the approximate start of the Ebola outbreak in Sierra Leone (mid May 2014) until the day of the survey.

2.2. Secondary objectives

✓ Estimate overall and cause-specific mortality (EVD and non-EVD) in children under the age of 5 years, and the population aged 5 years and older within the study area, with particular attention to the period prior to the MSF Ebola Management Centre (EMC) opening in Bo district (19 September 2014) and the period during which it was receiving cases from the district (last confirmed case exited 26 January 2015);
✓ Estimate overall and cause-specific mortality (EVD and non-EVD) in quarantined and non-quarantined households; and contact-traced and non-contact-traced households;
✓ Describe health seeking behaviour in terms of whether health care was sought, where health care was sought and whether access to health care was possible.
### 3. Study design

This is a retrospective mortality survey, using a two-stage cluster survey methodology. A retrospective mortality survey is a recognised and well-documented approach to generate an estimate of mortality and can supplement vital data in developing countries and crisis-affected settings\(^8\,^9\). Retrospective surveys are less costly and time consuming than other methods (e.g. prospective community surveillance) and can yield estimates reflective of the events of interest in a period in the past.

To estimate urban and rural mortality rates attributable to EVD and non-EVD, we will stratify the study population according to setting. Two independent surveys will be conducted. One survey will be carry out in Bo town and another in Bo district, representing urban and rural strata respectively.

Due to the route of transmission of Ebola disease we estimate that people living in an Ebola affected household or location have a shared raised risk of Ebola infection and death (for example due to attending the same funerals, or caring for a sick relative) that differs from people who do not live in an affected household or location, thus reducing the variability of risk within a cluster/village compared with that expected from a random sample. This is known as the cluster effect, which results in an overall loss in sampling variability and decreases the precision of a mortality estimate.

To our knowledge, no mortality survey in this Ebola-affected context has yet been published. To allow for the expected cluster effect, we plan to allow for a design effect of 4, which will require a larger number of clusters but provide a more precise mortality estimate.

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4. Study area and period

The study will be carried out in Bo district, which constitutes an area of 5,473.6 km$^2$. One study will be carried out in Bo town (urban area of Bo district) consisting of 20 sections. A second study will be carried out in Bo district (rural area) which consists of 15 chiefdoms and 969 villages (Table 1). The survey will be carried out in 4 to 5 weeks.

5. Study population

Bo district consists of 15 chiefdoms. The lowest administrative level in the rural area is villages. In Bo town (urban area), the lowest administrative level is section/ward.

The entire population (Table 1) is considered the study population and the beneficiaries of the study. However, data will only be collected from a sample of administrative units (cluster sites: see section sample size), i.e. about 4800 people (2400 in urban and 2400 in rural areas).

Table 1: Population size and administrative subdivision of the study area, Bo District and Town

<table>
<thead>
<tr>
<th>Chiefdom</th>
<th>Population size</th>
<th>Population size – 2014 estimate*</th>
<th>Number (N) of administrative units (section/villages)</th>
<th>Median population per administrative unit (range)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Urban area</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bo Town</td>
<td>178446</td>
<td>N of sections</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rural Chiefdoms</td>
<td>N of villages</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gbo</td>
<td>4,505</td>
<td>6060</td>
<td>37</td>
<td>164</td>
</tr>
<tr>
<td>Selenga</td>
<td>10,074</td>
<td>6495</td>
<td>29</td>
<td>224</td>
</tr>
<tr>
<td>Niawa Lenga</td>
<td>14,382</td>
<td>13330</td>
<td>39</td>
<td>342</td>
</tr>
<tr>
<td>Bagbwe</td>
<td>16,794</td>
<td>13085</td>
<td>39</td>
<td>336</td>
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<tr>
<td>Wunde</td>
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<td>11871</td>
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<tr>
<td>Valunia</td>
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</tr>
<tr>
<td>Badjia</td>
<td>18,903</td>
<td>9224</td>
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<td>Lugbu</td>
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<td>Bumpe Ngao</td>
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<td>235</td>
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<tr>
<td>Tikonko</td>
<td>47,668</td>
<td>43468</td>
<td>99</td>
<td>439</td>
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<tr>
<td>Baoma</td>
<td>73,986</td>
<td>53053</td>
<td>85</td>
<td>624</td>
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<tr>
<td>Kakua</td>
<td></td>
<td>35009</td>
<td>84</td>
<td>417</td>
</tr>
<tr>
<td>Total</td>
<td>649,466</td>
<td>538751</td>
<td></td>
<td></td>
</tr>
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</table>

* Administrative level 3 (chiefdom) extrapolated 2014 population from Statistics Sierra Leone
5.1. Inclusion and exclusion criteria

The entire household will be included in the study if informed consent has been given by an adult member of the household (see section 6 for the definition of household and section 10.1. for details on the informed consent form). Only non-consenting household will be excluded.

6. Definitions and inclusion criteria

Definition of household
A household is defined as a person or a group of persons, related or unrelated, who live together and who share a common source of food over the recall period.

Definition of suspected Ebola cases
Standard case definition recommended by local MOHS:
Any person who experienced fever plus 3 of the following symptoms: vomiting, headache, nausea, diarrhoea, difficulty breathing, fatigue, abdominal pain, loss of appetite, muscle or joint pain, unexplained bleeding, difficulty swallowing or hiccups or anyone who was ill and:
  cared for someone with Ebola
  or
  attended a funeral of someone with Ebola
or any unexplained death

Definition of suspected secondary Ebola cases
Anyone who meets the above case definition and was linked to a chain of Ebola transmission

Definition of confirmed Ebola case
Any suspected or probable case with a positive laboratory result through detection of virus RNA by reverse transcriptase-polymerase chain reaction (RT-PCR).

Definition of Quarantine
Separation (the household was cordoned off) and restriction of movement of people who may have been exposed to an individual infected with Ebola. The duration of quarantine is generally the maximum length of the disease's incubation period (21 days for Ebola), taking into consideration the individual's suspected time of exposure.
6.2. Recall period for reported deaths

A local events calendar for the chosen recall period will be generated in order to determine more accurately the time of deaths by allowing interviewees to place them in time sequence with locally well-known events.

In Sierra Leone the first EVD cases was reported on mid May 2014, before the opening of the MSF EMC (on 19 September 2014). The last confirmed case from Bo District was discharged on 26 January 2015.

The recall period will be divided into 2 segments, before and after the EMC opened:

- the period after the first recognised Ebola case in Sierra Leone until the opening of the MSF EMC in Bo (approximately 12 May – 19 September 2014), which gives a recall period of approximately 129 days;
- the period between the opening of EMC and day of the survey (March), a period of approximately 193 days.

Crude Mortality rate (CMR) and Ebola-related mortality rate will be calculated over the entire period, as well as before and after the opening of the MSF EMC.

7. Sample size and sampling

Sample size

The calculation of the sample size is based on the expected crude mortality rate. The all-cause mortality rate in Sierra Leone has been estimated prior to the current EVD epidemic at between 0.5 and 0.7 deaths per 10000 people per day\(^{11}\). We estimate the crude mortality rate to have increased by ~30% due to Ebola and decreased access to health services including the MSF GRC in Bo town.

To determine the required sample size a range of scenarios were forecast using different estimates of expected CMR, required precision and assumed design effect (Table 2). Estimates were constant for recall period (approximately 280 days), household size (5.5) and non-response or refusal rate (10%). The most likely set of estimates (highlighted in Table 2) was considered to be a crude mortality rate of 1.0 deaths/10,000 people/day with a precision of ±0.5 deaths and a design effect of 4. Using ENA (2011) software, a required sample size for each stratum (urban, rural) was calculated as 2390 individuals in 483 households. A minimum of 30 clusters will be assessed, but if logistically feasible the total sample may be obtained from a slightly higher number of clusters (n=35) in an attempt to reduce the design effect and increase the geographical variability.

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\(^{11}\) Crude mortality rate in Sierra Leone estimates:
2012, UNICEF country statistics: 0.47 per 10,000 per day based on death rate of 17.4 per 1000 (http://www.unicef.org/infobycountry/sierraleone_statistics.html)
2007, MSF OCB mortality survey in Bo district: 0.7/10 000/day (95% CI 0.6–0.9) (internal report)
2006, MSF OCB mortality survey in Bo district: 0.6/10 000/day (95% CI 0.4–0.8) (internal report)

Study proposal: Retrospective mortality survey during Ebola outbreak, Sierra Leone, MSF, 2015
Table 2: Sample size estimation scenarios*

<table>
<thead>
<tr>
<th>Scenario</th>
<th>Estimate CMR (per 10,000/day)</th>
<th>Desired precision of CMR</th>
<th>Design effect*</th>
<th>Total population required</th>
<th># HH</th>
<th>If 30 clusters, # HH per cluster</th>
<th>If 35 clusters, # HH per cluster</th>
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<tr>
<td>1</td>
<td>0.5</td>
<td>0.5</td>
<td>4</td>
<td>1195</td>
<td>241</td>
<td>8.0</td>
<td>6.9</td>
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<td>2</td>
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<td>0.5</td>
<td>2</td>
<td>597</td>
<td>121</td>
<td>4.0</td>
<td>3.5</td>
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<tr>
<td>3</td>
<td>0.5</td>
<td>0.25</td>
<td>4</td>
<td>4779</td>
<td>966</td>
<td>32.2</td>
<td>27.6</td>
</tr>
<tr>
<td>4</td>
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<td>0.25</td>
<td>2</td>
<td>2390</td>
<td>483</td>
<td>16.1</td>
<td>13.8</td>
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<tr>
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<td>676</td>
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<td>19.3</td>
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<tr>
<td>10</td>
<td>1</td>
<td>0.5</td>
<td>4</td>
<td>2390</td>
<td>483</td>
<td>16.1</td>
<td>13.8</td>
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<tr>
<td>11</td>
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<td>0.5</td>
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<td>241</td>
<td>8.0</td>
<td>6.9</td>
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<tr>
<td>12</td>
<td>1</td>
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<td>4</td>
<td>9559</td>
<td>1931</td>
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<td>55.2</td>
</tr>
<tr>
<td>13</td>
<td>1</td>
<td>0.25</td>
<td>2</td>
<td>4779</td>
<td>966</td>
<td>32.2</td>
<td>27.6</td>
</tr>
</tbody>
</table>

* Constants: Recall period 280 days; household size 5.5; non-response rate 10%
** Influenced by number of clusters selected

**Sampling**

Population estimations by section (in Bo town) and chiefdoms in rural areas (or village if possible) will be obtained from the MOHS of Bo. These lists will constitute the sampling frame from which the clusters will be selected.

In the first stage, clusters will be selected with probability proportional to population size (or estimated population size).

In the second stage, the starting household will be chosen within a village cluster using the standard WHO/EPI methodology. A pen will be thrown on the ground in the central point of the village and a line will be drawn in its direction towards the edge of the village. Households along this line will be counted, and one of these will be selected using a random number table as the first to be interviewed in the cluster. In order to reduce possible cluster effect that might occur through including geographically close households, subsequent households in the cluster will be selected systematically as every nth household (where the interval n is determined as the total estimated households in the village from the village population estimate) divided by the number of households to be included (see Table 2 – final number depends on number of clusters). The next (nth) household will be selected by counting households to the left with the surveyors back to the door of the household just completed. If a household is empty, another 2 attempts later in the day will be made before replacement. Replacement, including due to refusal, will be with the next closest household on the left.

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If the number of households to complete the cluster is insufficient then the team will continue by selecting the (geographically) closest village. There again the standard WHO/EPI methodology described above will be used to select the first household in the village.

In case population data are not be available for Bo town, clusters will be selected using random spatial sampling techniques. Satellite images or local maps will be used to set town boundaries. Images will be geo-mapped and the desired number of starting points will be randomly drawn within the boundaries using Quantum GIS™ software (QGIS™) (Version 2.6.1). Points will be transferred to a GPS enabled device, which will allow the identification of the starting household for that survey cluster.

8. Data collection

Standard instruments and guidelines already in used in previous mortality survey by MSF will be adapted and refined with the input of local figures of authority to ensure that they are culturally appropriate and reflect the community sensitivities related to the Ebola outbreak. These include a standard household mortality survey questionnaire (Annex 1).

Within each cluster, surveyors will collect information from every consenting household on:
- Household size;
- Change in household composition (births and in- and out-migration) household during the recall period;
- Deaths among household members during the recall period, including date of death when available;
- Reported cause of death (according to the respondent);
- Morbidity in the household during the recall period and healthcare seeking behavior (place of treatment and reason for not seeking healthcare (traditional and not traditional care);
- Whether the household had been placed under quarantine and if any of the household member was put under contact tracing.

The questionnaire and consent forms (see Annex 1 and 2) will be verbally translated into Mende and back-translated to English to ensure consistency (Mende does not have a written tradition). Group consensus on translations will be sought during the home visitor training. Questionnaires will be piloted prior to beginning the survey.

9. Data entry, analysis and retention

All of the data will be collected by a team of trained interviewers using paper forms. Double data entry for the survey will be done using a data entry mask in Epi Data by the expat epidemiologist and two data entry clerks in the project.

All indicators (i.e. sex and age of the survey population) will be calculated as proportions with 95% confidence intervals (95%CI). Estimates of actual design (cluster) effect will also be calculated for each variable and those with effects greater than 1 will be reported. Where appropriate, differences in proportions will be measured using Pearson χ2 test and p-value (p) will be presented.
Mortality rates per 10,000 per day will use mid-point population estimates for the denominator. Mid-point population will be calculated taking into account deaths and newborns.

Identifiable data will not be collected; consequently no nominal data will be recorded in the database. Only unique identifiers will be used.

A database will be generated from the paper questionnaires and this will be password protected. The paper versions of the questionnaires and consent forms (paper versions) and the electronic database will be stored at the MSF-OCA Headquarters in Amsterdam for a period of 5 years after the survey. Access to the electronic and paper version of the survey will be restricted to the co-investigators of the study and the Medical Coordinator. After 5 years the paper copies of all the questionnaires will be destroyed.

10. Ethical issues

The study will be conducted in accordance with the World Health Assembly of 1975 concerning ethical aspects in human tests, and with the Helsinki declaration.13

The study protocol will be submitted to the Ethics Review Board of MSF. It will also be presented to the Ministry of Health and Sanitation (MOHS) in Freetown and to Bo district MoHS authorities for approval.

This study protocol is an adaptation of the research protocol of previous retrospective surveys already validated and approved by the Ethical Review Board.

The long-term presence of MSF in the area and its contribution on the Ebola response has resulted in a close and fruitful collaboration with the local Ministry of Health and local community.

Authorities and communities (such as village heads, religious leader) in the study area will be informed about the purpose of the study. An information sheet will be provided and their endorsement will be sought by a field visit and an official letter.

In the selected households the purpose of the survey will be explained to the head of the household and oral consent obtained to conduct the interview.

MSF commits to sharing study results with everybody who has participated in the study. The local community will be involved and informed through follow-up visits. The local MoHS and MSF medical team will decide about the best venues to display the results.

The MSF medical responsible in the field will advise the study team on the referral practices when finding sick people in the study villages as well as procedures regarding psychosocial issues uncovered during the interviews.

10.1. Consent form

Verbal witnessed consent, recorded by an interview team, will be sought from all heads of households participating in the study and an information sheet translated in the local

language will be offered to each head of household when their consent is requested (Annex 2).

All subjects included in the surveys will have the investigations explained to them in a language with which they are familiar. Everyone will be offered the opportunity to refuse participation in the study at any time without penalty, and no incentives or inducements will be provided to any respondent. Everyone is completely free to participate or not.

**10.2. Risks and benefits of the study and contingency plans**

**Risks**

This study does not pose any risk of physical harm to participants. Nevertheless, asking the heads of households for details of recent deaths of household members may be upsetting and relatively intrusive. In village contexts there may be limited privacy. There is a risk of community members being punished by the local authorities for having previously withheld information about illness episodes and deaths. This is minimised by the fact that all data will be unidentifiable when reported, and by the fact that all households will be eligible to be surveyed, conveying to the community that the study is not targeting a particular group (such as households with confirmed or suspected EVD). We will negotiate with any authorities to ensure that they agree to not pressure us to disclose this information so we can assure participants of the confidentiality of their interactions with the survey team. Using local staff and careful training on interview techniques can mitigate these risks. It should also be noted that MSF has strong links with this community through activities over many years including recent provision of the EMC.

Risks for MSF will mostly relate to operating in an Ebola context and usual precautions to be taken.

**Benefits**

The mortality estimation and morbidity data will provide a robust estimate of the burden of Ebola and non-Ebola deaths in this community during this distressing outbreak.

Data on access on health centre will be used to support local MoHS to identify immediate unmet heath needs, and inform advocacy activities.

There will be no specific benefit to individual participants.

**11. Collaboration**

This study will be carried out in collaboration between MSF-Operational Centre Amsterdam (OCA) and the MoHS of Sierra Leone which will be a co-investigator. The MoHS of Sierra Leone will support to carry out training and will provide support to the project through translation of documents and by giving their endorsement to the activities.

MSF-OCA is the study sponsor and is responsible for providing the resources to carry out the survey. It is in charge of the field part of the study, the analysis and report writing. Permission for publication must be obtained from MSF-OCA and the MoHS.

Study results will belong to MSF-OCA and the MoHS of Sierra Leone.
12. Implementation of the study in the field

12.1. Selection and tasks of the study teams

The task of the interviewers will be to collect the necessary data for the study. We will organise 2 cars, which will be able to transport 2 teams consisting of 2 x 2 interviewees, 1 supervisor, and 1 sprayer (max. of 6 people in the back of a car) to 2 to 3 villages (clusters) per day. This is going from the premise that an interview takes 0.25 hours, and that in each village 14 households need to be interviewed: 14 x 0.25 = 3.5 hours/2 teams = 1 hour and 45 minutes per village. Time needs to be included to talk to the Chief of the town, so at least 2-3 hours per village is needed.

So assuming 1 car with 2 teams can on average do 2 villages per day, and the other car on average 3 villages a day. 5 villages a day means that 35 villages would take 5-6 days to complete.

The urban area would take less than 5 days to complete, so in 2 weeks (which is actually 6 working days) we can easily do both surveys.

General selection criteria for all interviewers:

- Able to read and write in English and
- Fluent in the local language, and
- Available for the ENTIRE time of the study (training and interview days), and
- Motivated to participate in the study, and
- Not biased in expectations of the outcome of the study
- Experience with interviews in difficult settings and study populations would be an advantage

12.2. Supervision

The principal investigator is the overall responsible for the final version of the protocol, overall quality of the survey and data analysis, and the final report.

The principal investigator is responsible for the quality of the research, the data analysis and report writing. She will implement the field part of the study together with the field investigator who will closely supervise the field component during the entire study period.

The principal investigator and field investigator will ensure that the following tasks are performed:

- Preparation of all necessary documents (protocol, questionnaires, informed consent forms) for the study
- Preparation of the field component of the study (training of the study teams, logistics, materials) together with the MSF team in the field
- Follow-up of the field component of the study
- Data entry
- Data analysis
- Report writing
- Data sharing
12.3. **Suggested MSF support in the field**

- Administrative support for study preparation at the field level and during field part, such as presentation of the survey protocol to the ethics committee of the MoHS and payment of study teams.
- Human resources support, such as extending the contracts if necessary to allow the continued employment of the existing study team/interviewers.
- 4 team (of 2 interviewers) and 2 supervisors;
- Logistic support for study preparation at the field level and during field part, such as organizing sufficient cars including drivers for the field part of the study, providing communication tools and MSF ID (e.g. aprons, vests or arm bands) to the study teams, stationary, printing the questionnaires and consent forms.

12.4. **Training of the study team and pre-testing of the questionnaires**

Two days training will be given to all interviewers to familiarise them with the background of the study, the questionnaires, the information sheet and the informed consent form. The training will be given in English by the principal investigator and/or field investigator. It consists of an intensive review of the questionnaire and the information sheet including role-plays. As the interviews will be held in the national language, the field investigator should ensure that all interviewers are using the same and correct wording for providing information to the households and for the interviews.

The 2-days training will be finished with a pilot study in a place which is outside of the study area. The pilot study allows for the testing of study instruments, verifying data collection skills, sharing difficulties met during data collection and adjusting procedures accordingly.

12.5. **Timeframe in the field**

An indicative timeframe is included below (Table ) as a preliminary plan of the field part of the study.

| Table 3: Preliminary plan of the field part of the mortality study in Bo district |
|--------------------------------------------------|------------------|
| **Activity**                                             | **Period**           |
| Protocol development and study sites identification       | March 2015         |
| Ethical approval                                          | March 2015         |
| Training and pilot phase                                  | March 2015         |
| Recruitment/ interviews                                   | March 2015         |
| Data analysis and report preparation                      | March-April 2015  |

13. **Logistics**
13.1. Supplies needed

Supplies for the conduct of the study (Table ) will be purchased in Bo Town. Questionnaires and informed consent forms will be developed by the principal investigator. Photocopies of all necessary documents will be done in Bo town. A computer record entry form will be prepared by the principal investigator.

<table>
<thead>
<tr>
<th>Item</th>
<th>No. needed per team</th>
<th>No. needed for 4 teams</th>
</tr>
</thead>
<tbody>
<tr>
<td>Back pack/shoulder bag</td>
<td>1</td>
<td>6</td>
</tr>
<tr>
<td>Clipboard</td>
<td>2</td>
<td>4</td>
</tr>
<tr>
<td>Pencil</td>
<td>2</td>
<td>4</td>
</tr>
<tr>
<td>Rubber</td>
<td>2</td>
<td>4</td>
</tr>
<tr>
<td>Sharpener</td>
<td>1</td>
<td>4</td>
</tr>
<tr>
<td>Ink pad</td>
<td>1</td>
<td>4</td>
</tr>
<tr>
<td>vests, arm bands or similar with MSF identification / logo</td>
<td>2</td>
<td>10</td>
</tr>
<tr>
<td>Plastic folder (for protection of questionnaires against rain and dust)</td>
<td>3</td>
<td>30</td>
</tr>
<tr>
<td>GPS or phone with GPS capacity</td>
<td>1</td>
<td>5</td>
</tr>
</tbody>
</table>

13.2. Transport needed

Two cars are needed to reach the study population (households in the different villages) within 2 weeks. For remote villages, we would need 2 motorcycles for 1 team (2 interviewees, 1 sprayer and 1 supervisor).