



## **Maternal and child health care seeking behaviour: a household survey and interview study in an urban and rural area of Sierra Leone, 2016**

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# **Maternal and child health care seeking behaviour: a household survey and interview study in an urban and rural area of Sierra Leone, 2016**

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**Study proposal v2431**

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Dr Kostas Danis**

<b>First version</b>	<a href="#">27/06/1618/084/16</a>
<b>Study design</b>	Household survey of health and health seeking Structured and in-depth interviews
<b>Study period</b>	Survey and structured interviews: 3-4 weeks, <a href="#">September-October - November 2016</a> In-depth interviews: 2 weeks, <a href="#">October-November - 2016December 2016</a>
<b>Survey site</b>	Magburaka town and Yoni chiefdom, Tonkolili District, Sierra Leone.
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<b>Protocol and study design</b>	Dr James Elston Dr Grazia Caleo Dr Kostas Danis Dr Kamalini Lokuge Dr Benjamin Black Nell Gray
<b>Collaborating institutions</b>	Ministry of Health and Sanitation Sierra Leone

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## LIST OF ABBREVIATIONS

CI	Confidence interval
DHMT	District Health Management Team
DHS	Demographic and Health Survey
KAP	Knowledge, Attitude and Practice
MoHS	Ministry of Health and Sanitation
MSF	Médecins sans Frontières
MSF- OCA	Médecins sans Frontières – Operational Centre Amsterdam
WHO	World Health Organisation

# 1 INTRODUCTION

## 1.1 CONTEXT

Sierra Leone is one of the poorest countries in the world, ranked 181<sup>st</sup> out of 188 countries according to the United Nations Development Programme Human Development Index.<sup>1</sup>

Life expectancy at birth is estimated to be 46 years.<sup>2</sup> The country has the highest child under 5 years mortality rate,<sup>3</sup> the highest reported maternal mortality ratio, and the highest lifetime risk for women dying in childbirth worldwide.<sup>4</sup>

The comparison with high income countries is stark; for example compared to the UK the Sierra Leone the under 5 mortality rate and maternal mortality ratio are over 36 and 113 times higher respectively (Table 1).<sup>5</sup> The vast majority of these deaths are preventable with infections the leading cause of death in childhood (acute respiratory tract infection, malaria and diarrhoea account for 44% of deaths combined in Sierra Leone).<sup>6</sup>

The majority of maternal deaths are almost certainly due to avoidable complications relating to pregnancy and childbirth (such as severe bleeding, infections, high blood pressure, delivery complications and unsafe abortion);<sup>7</sup> however there is little available data from Sierra Leone.

**Table 1: Comparison of under-five and maternal mortality in Sierra Leone and UK<sup>3-5</sup>**

Indicator	Sierra Leone	UK
Child < 5 years mortality rate	182 per 1000 live births	5 per 1000 live births
Maternal mortality ratio	1360 maternal deaths per 100,000 live births	12 maternal deaths per 100,000 live births
Lifetime risk of maternal death	1 in 17 women aged 15-49	1 in 4600 women aged 15-49

1

United Nations Development Programme; Human Development Reports. <http://hdr.undp.org/en/countries/profiles/SLE> [Accessed 20 April 2016]

2

World health Organisation; Country Profiles: Sierra Leone. <http://www.who.int/countries/sle/en/> [Accessed 20 April 2016]

3

[Unicef](http://www.unicef.org)UNICEF country statistics: Sierra Leone. [http://www.unicef.org/infobycountry/sierraleone\\_statistics.html](http://www.unicef.org/infobycountry/sierraleone_statistics.html) [Accessed 20 April 2016].

4

World Health Organization (2015); Trends in maternal mortality: 1990 to 2015. Estimates by WHO, UNICEF, UNFPA, The World Bank and the United Nations Population Division

5

[Unicef](http://www.unicef.org)UNICEF country statistics: United Kingdom. [http://www.unicef.org/infobycountry/uk\\_statistics.html](http://www.unicef.org/infobycountry/uk_statistics.html) [Accessed 20 April 2016]

6

WHO Sierra Leone Country Profile. <http://www.who.int/countries/sle/en/> [accessed 20 April 2016]

7

Say L, Chou D, Gemmill A, Tunçalp Ö, Moller AB, Daniels JD, et al. Global Causes of Maternal Death: A WHO Systematic Analysis. *Lancet Global Health*. 2014; 2(6): e323-e333.

The recent Ebola outbreak has proved devastating to the population of Sierra Leone. The outbreak led to considerable morbidity and mortality with the reported 14,122 clinically compatible Ebola cases and 3955 deaths in the country almost certainly gross underestimates.<sup>8</sup> The outbreak placed unprecedented strain on an already under-resourced health system. Health care workers were disproportionately affected by Ebola, and resources were prioritised to Ebola outbreak response activities at the expense of essential healthcare services.<sup>9,10</sup> It is apparent that there has been a breakdown in trust in healthcare systems which were unable to respond to the needs of patients, leading to widespread disengagement with health care services at population level.<sup>10,11</sup>

These negative impacts have had the greatest impact on pregnant women and young children with reduced service provision and marked reductions in healthcare utilisation almost certainly leading to greatly increased morbidity and mortality.<sup>10,12,13,14</sup>

It is well documented that delays in access to emergency obstetric care and treatment are major contributing factors to maternal death, particularly in the resource poor setting.<sup>15</sup>

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8

World Health Organisation (2016). Ebola Situation Report- 30 March 2016. <http://apps.who.int/ebola/current-situation/ebola-situation-report-30-march-2016>. [Accessed 20 April 2016].

9

Fasina FO, Adenubi OT, Ogundare ST, Shittu A, Bwala DG, Fasina MM. Descriptive analyses and risk of death due to Ebola Virus Disease, West Africa, 2014. *J Infect Dev Ctries* 2015; 9(12):1298-1307. doi:10.3855/jidc.6484

10

Impact of the Ebola outbreak on health systems and population health in Sierra Leone Elston JWT, Moosa AJ, Moses F, Walker G, Dotta N, Waldman RJ, *Wright Journal of Public Health* 2015;doi:10.1093/pubmed/fdv158

11

UNICEF and Ministry of Health and Sanitation. Sierra Leone Health Facilities Survey 2014: Assessing the Impact of the EVD Outbreak on Sierra Leone's Health System. Freetown: Government of Sierra Leone Ministry of Health and Sanitation, 2014.

12

Brolin Ribacke KJ, van Duinen AJ, Nordenstedt H, Höjjer J, Molnes R, Froseth TW, et al. The Impact of the West Africa Ebola Outbreak on Obstetric Health Care in Sierra Leone. *PLoS ONE* 2016 11(2): e0150080. doi:10.1371/journal.pone.0150080

13

World Bank Group (2015); Evans D, Goldstein MP, Popova A. The next wave of deaths from Ebola? The impact of healthcare worker mortality.

14

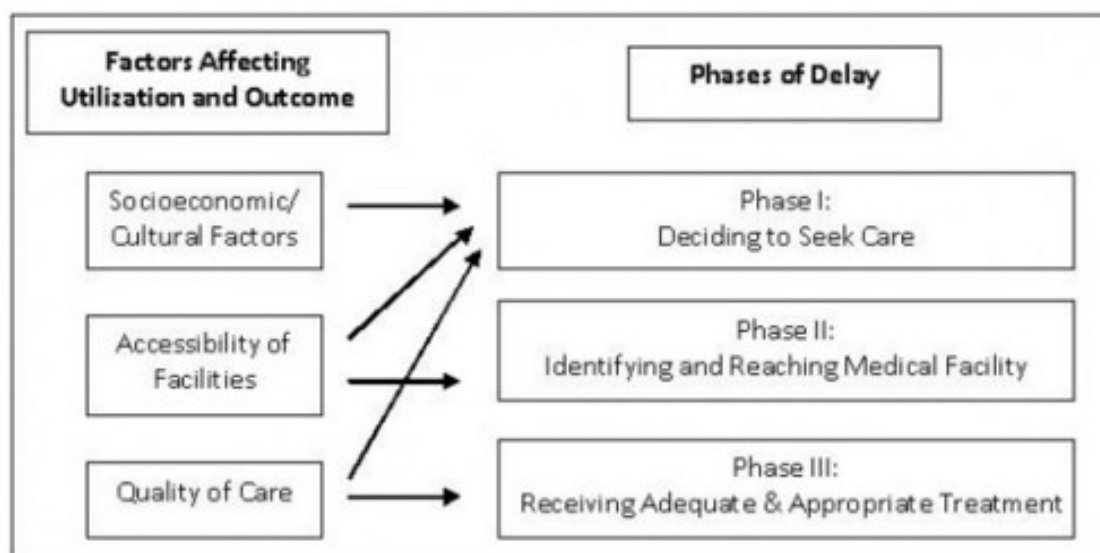
Menedez C, luca A, munguambe K, Langer A. Ebola crisis: the unequal impact on women and children's health. *Lancet Glob Health* 2015, 3, e130

15



High maternal mortality is often attributed to the “three delays model”. These are: 1). delay in deciding to seek care, 2). delay in reaching care, 3). delay in receiving adequate healthcare (Figure 1)<sup>16</sup> [Delay in receiving adequate care during febrile illness is also perceived to be a major contributor to morbidity and mortality in children and therefore this model may equally be applied in relation to under 5 mortality.](#)<sup>16</sup>

**Figure 1: The three delays model.**<sup>17</sup>



Improving healthcare provision and access to care for women and children are national priorities for Sierra Leone. The Free Health Care Initiative was launched in 2010 with the

Nyamtema AS, Urassa DP, van Roosmalen J. Maternal health interventions in resource limited countries: a

systematic review of packages, impacts and factors for change. BMC Pregnancy Childbirth.

2011;11(1):30

16

[Samuelson H, Pinkowski T, Tersbøl B, Said Mbuyita S. Do health systems delay the treatment of poor children? A qualitative study of child deaths in rural Tanzania. BMC Health Services Research 2013, 13:67](#)

17

Thaddeus S, Maine D. Too far to walk: maternal mortality in context. Social Sci Med 1994; 38:1091–1110.

intention that healthcare should be provided free of charge at the point of care for pregnant and breastfeeding women and for children aged <5 years.<sup>18</sup>

Reducing maternal and neonatal morbidity and mortality and reducing child morbidity and mortality are key objectives of the Reproductive, Newborn and Child Health Strategy 2011-2015 produced by the Ministry of Health and Sanitation (MoHS), Sierra Leone.<sup>19</sup>

## **1.2 THE HEALTH SYSTEM IN SIERRA LEONE**

The health system in Sierra Leone is usually described in three categories: primary, secondary and tertiary care. Primary healthcare is delivered from peripheral health units (PHUs) at three basic levels: Maternal and Child Health Posts (MCHPs), Community Health Posts (CHPs) and Community Health Centres (CHCs).

MCHPs are the first level of contact for patients at grassroots level and are staffed by Maternal and Child Health Aides (MCHA) supported by Traditional Birth Attendants (TBAs) and other Community Health Workers (CHWs), who provide basic health care, routine antenatal care and supervise deliveries. CHPs provide the same services as MCHPs and additional curative functions and should additionally be staffed by State Enrolled Community Health Nurses (SECHNs). CHCs are generally located at chiefdom headquarter towns and should have facilities for inpatient care. In addition to providing all the services provided at CHPs, CHCs should manage obstetric complications and severe illness and provide more extensive outpatient services. CHCs should be staffed with a Community Health Officer (CHO) in addition to SECHN(s), midwives and MCH Aides. Secondary care hospitals include District Government Hospitals. Tertiary Care Hospitals are mainly concentrated in Freetown and the Western Area.

The health system in Sierra Leone is chronically underfunded, under-resourced and understaffed.

## **1.3 MSF PRESENCE IN TONKOLILI DISTRICT, SIERRA LEONE**

Tonkolili District (area~7003 km<sup>2</sup>) is located in the Northern Province of Sierra Leone (Figure 1) and has a population of 434,937 according to projections based on the 2004 census.<sup>20</sup> The capital and largest city is Magburaka. The district comprises eleven chiefdoms.

The district has a poor road network and many areas prove inaccessible during the rainy season.

In Tonkolili health services are delivered through a network of health facilities consisting of 107 PHUs comprising 13 CHCs, 10 CHPs, 81 MCHPs and 3 hospitals. Five CHCs are considered Basic Emergency Obstetrics and Neonatal Care (BEmONC) centers.

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18

Government of Sierra Leone. Free healthcare services for pregnant and lactating women and young children in Sierra Leone, November 2009.

19

Ministry of Health and Sanitation. Sierra Leone. Reproductive, Newborn and Child Health Strategy (2011 - 2015). Freetown, Government of Sierra Leone Ministry of Health and Sanitation

20

2004 Population and Housing Census. Appendix 6: Projected Projected Population for Local Councils/ Administrative Unit of Sierra Leone. Based on the Medium Variant Projections; 2005 to 2014

The District Health Management Team (DHMT) oversees the health system in the district and represents the MoHS in the district. Amongst their responsibilities the DHMT also are responsible for surveillance of disease in the district and leadership and management of health programmes. According to the Demographic and Health Survey (DHS) 2013 in the five years prior to the survey just 35.2% of live births in Tonkolili District were delivered in a health facility and only 37.8% of women received assistance in delivery from a skilled provider.<sup>21</sup> According to DHS 2013, 72.2% of women in the district reported at least one serious problem accessing healthcare and 57.3% of children aged 12-59 months in Tonkolili had received all basic vaccinations.<sup>21</sup> During the Ebola outbreak transmission in Tonkolili was intense and there were 456 confirmed cases of Ebola Virus Disease.<sup>22</sup> It is perceived that healthcare utilization in Tonkolili decreased substantially during the outbreak and that utilisation of healthcare services by women and children under 5 years remains lower than before the outbreak; however, the current situation is uncertain.

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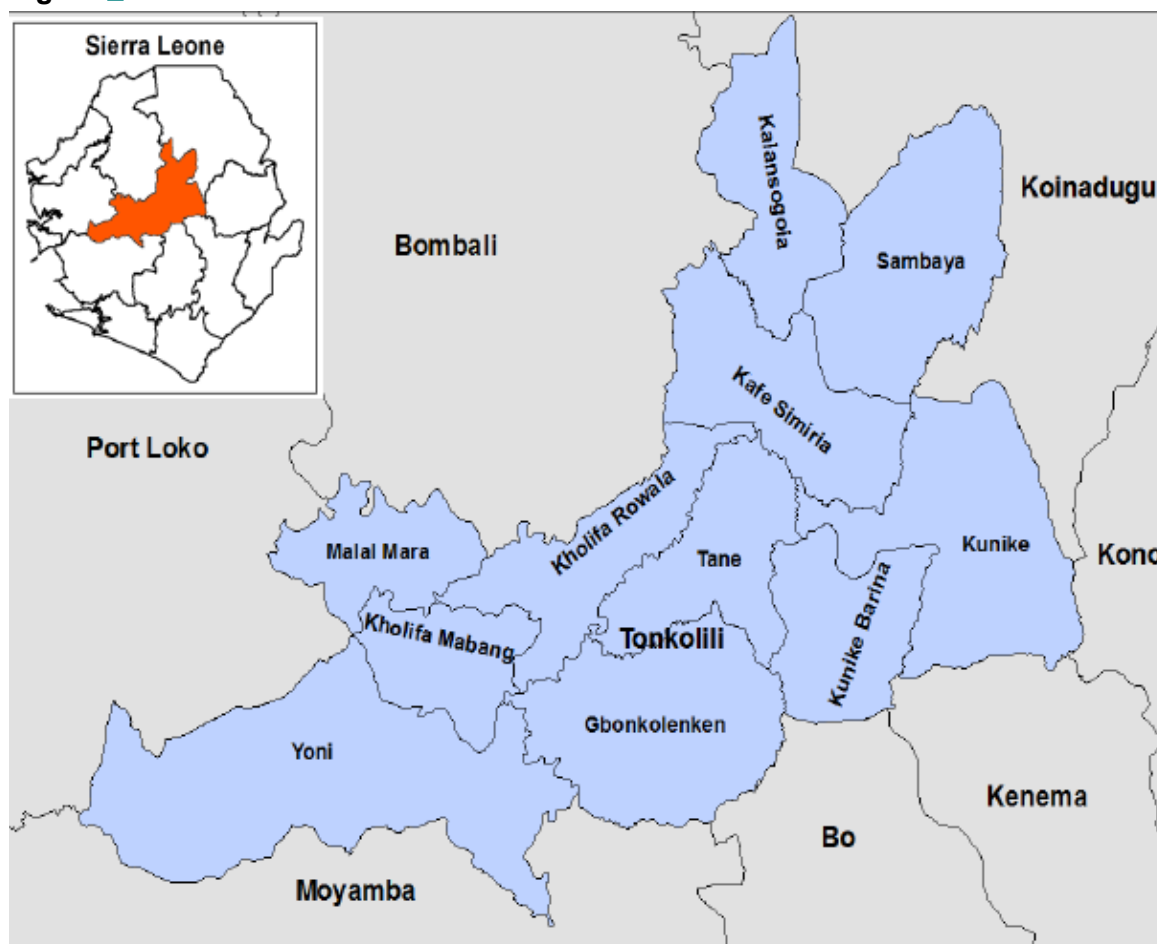
21

Statistics Sierra Leone and Ministry of Health and Sanitation (2014). Demographic and Health Survey 2013. Freetown, Government of Sierra Leone Ministry of Health and Sanitation

22

National Ebola Response Center (NERC), Sierra Leone (2016). [www.nerc.sl](http://www.nerc.sl) [Accessed 18 April 2016]

Figure 24: Tonkolili District and chiefdoms<sup>23</sup>



Between December 2014 and May 2015 MSF-OCA ran an Ebola Management Center (EMC) in Tonkolili and has provided ongoing care for survivors of Ebola virus disease. In January 2016, MSF-OCA began supporting reproductive and child health service provision at Magburaka Government Hospital. From March 2016 MSF-OCA has supported provision of maternal child health services at Magburaka MCHP and at Mile 91 CHC in Yoni chiefdom. MSF-OCA provides hands-on practical support in the form of HCWs, delivers training, and provides essential medical supplies, and support for human resources.

Improving access to quality primary and secondary care for children aged <5 years, and improving access to quality comprehensive sexual and reproductive health services, including neonatal care, are explicit objectives for MSF-OCA in Tonkolili District.

MSF-OCA is currently planning to extend health care provision and support to healthcare facilities particularly in Yoni chiefdom.

MSF-OCA is also providing technical and practical support to the DHMT.

An MSF epidemiologist and a Community Health Officer support activities of the DHMT surveillance officers including training of HCWs, facilitating routine data collection and analysis. This support has facilitated the extension of routine surveillance to include deaths, with particular focus on improving the reporting and recording of maternal deaths and deaths occurring in children aged <5 years.

MSF-OCA is also planning to conduct health facility inspections of all PHUs in Tonkolili within the next two months to explore provision of quality care in the district (Phase 3 of the three delays model).

Reproductive health data received from Magburaka hospital (supported by MSF-OCA) indicate very high frequency of obstetric complications even accounting for the fact it is the referral hospital for the District. For example, in March 2016 of 142 pregnancy related maternity admissions 67 (47.2%) experienced serious complications including: post-partum haemorrhage (25, 17.6%); post abortion complications (9, 6.3%); obstructed labour (8, 5.6%); eclampsia (5, 3.5%); and ruptured uterus (3, 2.1%). Many of these complications and their severity are perceived be attributed to delays in receiving obstetric care and treatment. In March there were 197 admissions to Magburaka hospital for children aged < 5years, 77 (39.1%) were for severe malaria, 20 (10.2%) for neonatal sepsis and 19 (9.6%) were lower respiratory infections.

MSF-OCA is in the process of developing its Delay Reduction Strategy (DRS) aiming to reduce maternal mortality and morbidity associated with delay in accessing and receiving obstetric care. It is also the intention to extend DRS aiming to reduce mortality and morbidity of children aged <5 years. The DRS sets out the intention to address contributing factors as outlined in the three delays model, through complex intervention including: health promotion; community engagement; provision of transport; support for essential systems (e.g. communications); training for health care workers; support for health facilities; and promoting advocacy for women and children.

Through successful and effective collaboration it is perceived that MSF-OCA has established an excellent working relationship with the MoHS in Tonkolili District.

#### **1.4 BACKGROUND - JUSTIFICATION FOR THE STUDY**

In order to plan and deliver effective and efficient services which are culturally appropriate and acceptable to the local population it is first necessary to assess population health needs and gain sufficient understanding of health behaviours and their determinants.

Whilst MSF-OCA is gaining practical experience of the context, a key current priority is to assess population health needs and in particular gain greater insight into health seeking behaviour of women and children in the localities of MSF-OCA current and planned operations. This is considered critical to DRS strategy development and implementation, and fundamental to ensuring provision of culturally appropriate services at all MSF supported health facilities and in the community. In addition there is a requirement for up-to-date robust and detailed baseline health information at local level is required in order to systematically plan MSF-OCA interventions and to evaluate their impact in the future use for future evaluation of their impact.

Although DHS 2013 did include Tonkolili, there is little recent information on health status and health behaviour at a local level. It is therefore proposed to conduct surveys of health behaviour.

Health behaviour is defined as action taken by a person to maintain, attain, or regain good health and to prevent illness.<sup>24</sup> Health behaviour can be assessed by identifying and measuring indicators at population level. Ideally indicators should be strongly associated with a health outcome(s) and be measurable. In this context key indicators include the proportion of pregnant women attending a health care facility for childbirth, proportion of children attending health facilities when unwell with fever, and the proportion of children receiving recommended routine childhood vaccinations,. These indicators are considered important and relevant reflecting morbidity in the population and have implications for health policy and action. Health behaviour reflects a person's health beliefs and the situational context. Health behaviour surveys permit identification of beliefs, perceptions and the context. Health behaviour surveys may be complimented by qualitative research methods such as interview studies to enable in-depth exploration of these factors. Health behaviour surveys in combination with qualitative methods should allow identification of barriers to accessing and utilising healthcare (past and current) and provide insight as to how these might be mitigated.

An estimation of actual health outcome in the population is also important and relevant for planning. Mortality is often considered the gold standard indicator of health status. However, primarily measuring mortality using a mortality survey does not necessarily provide the depth of information to allow understanding of the contributing factors. In addition there are a number of issues that present practical and logistical challenges to mortality estimation. Maternal mortality in Sierra Leone (though extremely high relative to other countries) remains a rare outcome at population level so estimation requires a prohibitively large sample size perceived to be beyond available resources at the current time. MSF-OCA is however, currently supporting the DHMT to strengthen routine surveillance capacity to include death reporting, building on systems developed during the Ebola outbreak. It is anticipated that mortality estimates may be derived from this work and may be monitored over time more efficiently than repeated large mortality surveys. Indicators of health outcomes may however also be collected during a health behaviour survey. Mortality data can be gathered during a health behaviour survey and be used to supplement and triangulate with information from other sources in order to provide a more comprehensive estimate of mortality.

Thus in this context it is perceived that the information derived from health behaviour surveys in combination with qualitative methods will be directly relevant to current service planning [for both MSF and the MoHS](#). The study will also provide robust and detailed baseline health information enabling future evaluation of the impact of MSF programmes and interventions in area of intervention.

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Mosby's Medical Dictionary, 9<sup>th</sup> edition. 2009, Elsevier.

## 2 AIM AND OBJECTIVES

### 2.1 OVERALL AIM

To describe health seeking behaviour during pregnancy, for childbirth and in children under the age of five years, and to identify barriers to accessing and receiving healthcare services at the time of the ~~survey study~~ and ~~in the preceding two years (following the~~since the start of the Ebola outbreak) in an urban and rural area of Tonkolili District.

### 2.2 PRIMARY OBJECTIVES

1. To estimate utilisation of health facilities by women for childbirth in Magburaka town and Yoni chiefdom ~~in the two years preceding the day of the survey~~since the start of the Ebola outbreak ;
2. To estimate utilisation of healthcare services by children aged <5 years in Magburaka town and Yoni chiefdom during their most recent febrile illness within the three month period preceding the day of the survey.
3. To identify and describe factors influencing utilisation of health services and delays in seeking and receiving adequate healthcare during pregnancy and for childbirth
4. To identify and describe factors influencing utilisation of health services and delays in seeking and receiving adequate healthcare for febrile illness in children aged <5 years
- ~~To describe factors influencing utilisation of services during pregnancy, childbirth and in children <5 years (perceptions of barriers and enablers).~~

### 2.3 SECONDARY OBJECTIVES

5. To estimate utilisation of antenatal care facilities by women during pregnancy in Magburaka town and Yoni chiefdom in the two years preceding the day of the survey;
6. To estimate vaccination coverage for measles and polio in children aged <5 years in Magburaka town and in Yoni chiefdom on the day of the survey;
7. To identify and describe health beliefs and perceptions (of risk, barriers and enablers) in relation to the decision to seek healthcare (Phase 1 of the three delays model) in Magburaka town and in Yoni chiefdom since the start of the Ebola outbreak:
  - a. for women in relation to pregnancy and childbirth
  - b. for carers of children aged <5 years in relation to childhood febrile illness
8. To identify ~~and describe perceptions of barriers and enablers to accessing healthcare (Phase 2 of the three delays model) and factors associated with delays in receiving treatment~~ in Magburaka town and in Yoni chiefdom ~~in the two years preceding the day of the survey~~since the start of the Ebola outbreak:
  - a. for women in relation to pregnancy and childbirth

- b. for carers of children aged <5 years in relation to childhood febrile illness
  - c. ~~for women during their most recent pregnancy-~~
  - o ~~for women relating to their most recent childbirth-~~
  - d. ~~for children aged <5 years during their most recent febrile illness within the three month period preceding the day of the survey~~
9. To identify and describe perceptions of barriers and enablers to receiving adequate and appropriate treatment healthcare (Phase 3 of the three delays model) in Magburaka town and in Yoni chieftdom since the start of the Ebola outbreak:
    - a. for women in relation to pregnancy and childbirth
    - b. for carers of children aged <5 years in relation to childhood febrile illness
    - c.
  10. To estimate all-cause mortality in children under the age of 5 years within the two combined study areas in the two years preceding the day of the surveysince the start of the Ebola outbreak
  11. To estimate all-cause maternal mortality in the two years preceding the day of the surveysince the start of the Ebola outbreak
  12. To measure estimate the Long-Lasting Insecticide-Treated bed net (LLITN) coverage ratio for children under five years of age



### 3 METHODS

This study will use a mixed methods sequential explanatory design. This will consist of two distinct phases: quantitative data will be collected and analysed, followed by qualitative data. Qualitative data will be used to help explain, or elaborate on, the quantitative results obtained in the first phase. Preliminary analysis of the quantitative phase will inform the qualitative phase. The rationale for this approach is that the quantitative data and their subsequent analysis will provide a general understanding of the research problem. The qualitative data and their analysis will refine and explain those statistical results by exploring participants' views in more depth.

Methods will include a household survey, structured interviews and in-depth interviews. The household survey will be employed primarily in order to address objectives relating to Phase 2 of the three delays model (objectives 1-2, 5-6) and mortality estimation and LLITN use (objectives 10-12); however will also be used to identify factors influencing health behaviour (objectives 8-9) which will subsequently be explored by qualitative methods. Structured interviews will be employed primarily in order to estimate maternal mortality (objective 11). In-depth interviews will subsequently be employed primarily in order to address objectives relating to Phase 1 and Phase 3 of the three delays model (objectives 3-4 and 7-9). Data collected during the PHU evaluation conducted by the MSF team will be triangulated with the study findings to complement understanding of Phase 3 of the three delays model.

#### 3.1 SURVEY DESIGN

The primary study design is a health behaviour survey using a two-stage cluster sampling methodology as an adaptation of the standardized method recommended by the World Health Organization (WHO)<sup>25</sup> (described further in section 7.2).

The household survey will be used to elicit information to describe:

- health seeking behaviour of women during pregnancy and childbirth
- health seeking behaviour of children aged <5 years
- birth history of women (to derive mortality rates for children <5 years)
- LLITN coverage

The household survey will be split into two component parts. The first component, *maternal health and health seeking behaviour* will focus on health seeking behaviour of women in pregnancy and childbirth, and will also be used to obtain a birth history from women in order to estimate child mortality. The second component, *child health and health seeking behaviour* will focus on health seeking behaviour relating to children aged <5 years. The questionnaire used for the survey will be split into two sections accordingly.

A household may be eligible to complete one or both sections or be ineligible (see section 5). It is anticipated that often the same informant will be eligible to be interviewed to complete the questionnaire concerning both sections of the survey questionnaire; for example if the informant was a mother of child(ren) aged <2 years. However, in order to avoid selection bias and for logistical reasons the survey will not be restricted to mothers of children aged <2 years.

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Henderson RH, Sundaresan T. Cluster sampling to assess immunisation coverage: A review of experience with simplified sampling methodology. Bulletin of the World Health Organization 1982(60):253-60

### 3.2 STRUCTURED INTERVIEWS

In addition to the household survey, in order to estimate maternal mortality, structured interviews will be conducted (subject to verbal consent) with one or more of key informants (Head of village/section or to include at least one healthcare worker) (informants) at each cluster site. ~~Where possible~~ This will be pre-arranged so that informants are able to prepare information. Informants will be asked to estimate the number of maternal deaths occurring in the preceding two years and the total number of women aged 15-49 years and children aged <5 years in the cluster at the time of the survey. This is an adaption of the informant method used elsewhere.<sup>26</sup> Information on likely cause of death and barriers to accessing care will also be elicited. Descriptive epidemiology of available routine death data and data derived from pregnant woman death review, held by the DHMT will be undertaken separately.

### 3.3 IN-DEPTH INTERVIEWS

As a third element of the study a qualitative component will be included that is considered sequential to the survey. in order to explore and explain quantitative results. -In-depth interviews will be based on a topic guide which will be adapted based on findings of the quantitative data. To enable a deeper examination and understanding of barriers and enablers to accessing care during pregnancy, childbirth and for children under 5 safe birth, flexible, iterative and participatory techniques will be included. Information will be captured based on conversations with selected participants and allowing emergent themes (as well as discrepancies from majority themes) to be further explored and tested. ~~In-depth qualitative interviews (IDIs): will be conducted achieve this allowing for more detailed descriptions that might include more sensitive information.~~

IDIs are expected to require 45-60 minutes and will be piloted to ensure the responses are natural, and -that -the technique is working to capture an optimal descriptive response. ~~They will be and~~ conducted by study team members trained in qualitative methods. All interviews will be tape audio recorded. Daily debriefing sessions will occur with all field teams to assure quality assurance and strong communication amongst the study team members.

#### 4 STUDY AREA AND PERIOD

The survey will be conducted separately in two localities. The first locality will be Magburaka town (urban area), where the lowest administration level is a section. The second locality will be Yoni chiefdom (rural area) where the lowest administrative level is a village. Structured interviews will be performed concurrently.

The surveys and structured interviews will be conducted over 3-4 weeks in ~~October-~~  
~~November~~~~September~~ 2016. In-depth interviews will be performed over 2 weeks in October 2016.

The second qualitative phase will take place in locations selected purposively from the survey sites to ensure both a variety of characteristics and rich data collection. Locations for IDIs will include both urban and rural areas.

In-depth interviews will be performed over 2 weeks in ~~Novemer~~~~November-December~~~~October~~ 2016.

## 5 STUDY POPULATION

The study population will comprise the following population groups of Magburaka and Yoni chiefdoms:

- Women that gave birth (live or stillbirth) [since the start of the Ebola outbreak within the previous two years of the day of the survey \(survey & IDIs\)](#)
- [Carers of Children](#) aged <5 years on the day of the survey
- [Key community members \(village elders, head of transport unions, youth groups etc.: structured interviews and IDIs\)](#)
- [Health workers \(PHU staff, traditional birth attendants/healers, 'pepper' doctors etc.: IDIs\)](#)

However, data will only be collected from a sample of administrative units (cluster sites: see section 7.1).

Information on current population estimates is based on national census projections from 2004. Population figures for section/ electoral ward and or village has been derived from PHU catchment population estimates held by the DHMT. Using current census estimates the current populations of Magburaka and Yoni chiefdom are estimated to be around 124,000 and 120,000 respectively. Extrapolating from DHS 2013 it is estimated that women who have given birth in the last two years and children aged <5 years comprise ~6% and ~16.6% of the typical household respectively.<sup>21</sup> Thus the estimated study population of women who have given birth in the two years preceding the survey is 7,440 and 7,200 in Magburaka and Yoni respectively. The estimated study population of children aged <5 years is 20,584 and 19,920 in Magburaka and Yoni respectively.

### 5.1 INCLUSION AND EXCLUSION CRITERIA

#### [Survey](#)

A person will be included in the first component of the survey (*maternal health and health seeking behaviour*) if she satisfies all of the following criteria:

- Woman in the selected household who has given birth (live or stillbirth) in [in Tonkolili District since the start of the Ebola outbreak the previous 2 years](#).

*And*

- Informed consent has been given by the head of the household [and the eligible woman in the selected household](#).

A person will be included in the second component of the survey (*child health and health seeking behaviour*) if s/he satisfies all of the following criteria:

- Adult member of the selected household responsible for care of children within the household and sufficiently informed in order to provide information on all children within the household

*And*

- Informed consent has been given by the head of the household [and the eligible individual in the selected household](#).

A person will be excluded from the survey if s/he satisfies one of the following criteria:

- Refusal to participate in the survey

or

- Inability to locate the Head of Household after two attempts to trace him/her

Although the two component parts of the survey are considered separate and may involve interviewing a different informant within a household it is anticipated that they will often be performed within the same household consecutively subject to the presence of individuals meeting the criteria above.

#### Structured interviews

Individuals will be selected for structured interviews by convenience if they are a Head of village/ section healthcare worker or ~~recognised authority figure~~ in the sampled community.

#### In-depth interviews

A person will be selected and invited for in-depth interview ~~if she satisfies the same criteria as for the first component of the survey (above).~~ based on the following criteria:

- Woman who has given birth (live or stillbirth) in the previous 2 years since the start of the Ebola outbreak

Or

- Caregiver for children under 5

Or

- Key community member

Or

- Health worker

A person will be excluded from participating in IDIs if s/he meets one of the following criteria:

- Does not consent/assent to be interviewed

Or

- Parent/caregiver does not consent to interview (for participants aged 15,16,17)

Or

- Is identified by MSF medics as too unwell to be interviewed

## 6 DEFINITIONS

### 6.1 HOUSEHOLD DEFINITIONS

#### *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.<sup>21</sup> For the survey all person(s) meeting inclusion criteria will be included per household, no matter the relation with the other members of the household.

A household will be excluded from the survey if none of the household members fulfil all these criteria.

### 6.2 ILLNESS AND RECALL DEFINITIONS

#### *Definition of febrile illness*

Illness with fever (an abnormally high body temperature usually accompanied by shivering).

#### *Recall period and start of Ebola outbreak (approx. 2 years)<sup>27</sup>*

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

For most outcomes the recall period begins at 'start of the Ebola outbreak'. The start of the Ebola outbreak is defined as the date that Ebola outbreak officially recognised in Sierra Leone mid-May 2014). And is perceived to be memorable for people in the district. is two-years. The two-year recall period will be divided into 2 segments considered crudely as peri- and post- Ebola outbreak in the district. The peri-Ebola outbreak period will be considered as 1<sup>st</sup> Junemid May 2014- 31<sup>st</sup> May 2015 and post-Ebola period from 1<sup>st</sup> June 2015 to the day of the survey. Crude Mortality rate (CMR) and Ebola-related mortality rate will be calculated over the entire period, as well as peri- and post- Ebola outbreak.

A recall period of three months has been selected for utilisation of a health facility for febrile illness as: nearly all children <5 years in the study area are expected to have experienced febrile illness in that time which is an important consideration for sampling (see section 7.1), and it is considered that febrile illness affecting a child in the household and taking a child to health facility, or the decision not to do so, should be sufficiently memorable for the informant within this timeframe.

### 6.3 OUTCOME INDICATOR DEFINITIONS

Multiple outcomes will be investigated in this study. Here we define some major~~The main indicators~~outcomes that will be measured in this study; are described with their definitions below.

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We refer in the protocol to a 2 year recall period which is approximately equivalent to the period since the start Ebola and the implementation of the study.

*Utilisation of health facilities by women for childbirth in the two years preceding the day of the survey:*

Woman who attended a health facility (PHU or hospital) during their most recent labour and gave birth in the health facility (live or stillbirth), at any time in the two years preceding the day of the survey.

*Utilisation of healthcare services by children aged <5 years during their most recent febrile illness in the three months preceding the time of the survey:*

Child aged <5 years on the day of the survey who was taken to a health facility (PHU or hospital) or otherwise sought advice or treatment from a healthcare provider during their most recent febrile illness (definition above) with symptoms whatever the underlying cause, at any time in the three months preceding the day of the survey.

*Utilisation of antenatal care facilities by women during pregnancy in the two years preceding the day of the survey:*

Woman who received antenatal care from a skilled provider (doctor, nurse, midwife or MCH Aide), either at a health facility or via outreach services, during their most recent pregnancy in the two years preceding the day of the survey (note that the number of such encounters will be assessed).

*Vaccination for measles in children aged <5 years at the time of the survey:*

Child aged <5 years at the time of the survey who has received one or measles vaccination(s) at any time as evidenced by vaccination card or as reported by the woman or member of household (note that the analysis will include age of child and nature of evidence of vaccination).

*All-cause mortality in children under the age of 5 years within the two combined study areas in the two years preceding the time of the survey:*

Child who was live born and subsequently died at any time in the two years preceding the day of the survey (from any cause) *and* was aged <5 years at the time of death.

*All-cause maternal mortality in the two years preceding the time of the survey:*

Woman who died from any cause whilst pregnant or during childbirth or within two months of the birth or termination of pregnancy at any time in the two years preceding the day of the survey.

## 7 SAMPLE SIZE AND SAMPLING

### 7.1 RELEVANT PARAMETERS FOR SURVEY

Calculation of the estimated sample size required for the survey is based on estimates of a number of parameters including: the prevalence of the key outcome(s) in the study population, design effect, non-response rate, and population size from which the sample will be selected; and the desired precision of the derived estimate(s). These are described below in relation to this study:

#### *Prevalence of key outcomes*

The key outcomes in this study relate to the two primary objectives and the two components of the survey and are:

1. Utilisation of health facilities by women for childbirth in the two years preceding the day of the survey;

and

2. Utilisation of health facilities by children aged <5 years during their most recent febrile illness in the three months preceding the day of the survey.

According to DHS 2013 35.2% of childbirths in Tonkolili were conducted in health facilities in the five years preceding the survey.<sup>21</sup> It is perceived that healthcare utilisation for childbirth had steadily increased in more recent years, though the Ebola outbreak may have reversed this trend. To reflect uncertainty in anticipated prevalence of this outcome, an estimated prevalence of 50% has been chosen which is considered to reflect maximal uncertainty and will generate the largest sample size.

According to DHS 2013 17.2% of children in Tonkolili experienced fever in the preceding 2 weeks,<sup>17</sup> so with extrapolation it might be reasonable to estimate that over a three month period nearly all children would be expected to have experienced illness with fever. According to DHS 2013 advice or treatment from health facility or provider was sought for 63.5% of febrile children aged <5 years.<sup>21</sup> There are perceived to have been improvements in access to healthcare in recent years (the Free Health Care Initiative was implemented after the start of the DHS 2013 recall period), however these may have been offset by behaviour change during the Ebola outbreak. For sample size calculation an estimated prevalence of 50% has been again been chosen to reflect maximal uncertainty.

#### *Design effect*

For this survey we are using cluster sampling. As respondents in a cluster are likely to be similar to one another in some characteristics of interest a clustered sample may not be as varied as if respondents had been selected randomly from the population so that the effective sample size is reduced. This loss of effectiveness is the design effect and should be accounted for in sample size calculation. For this survey we are using two estimates of design effect relating to the two components of the survey.

For the first survey component (*maternal health and health seeking behaviour*) we anticipate a low prevalence of women meeting the inclusion criteria per household (see section 7.2) so individuals will most likely be sampled relatively intermittently (e.g. a greater distance between eligible households compared to the second survey component) and a relatively large number of clusters will be selected to achieve the required sample size (see section



7.3). A design effect of 2 is perceived adequate for this survey and is in keeping with published work from a similar setting (design effect of 1.95 can be derived from a cluster-RCT conducted in Malawi (MaiKanda) in relation to births attended by a skilled provider for which the estimate was 52.9%).<sup>28</sup>

For the second survey component (*child health and health behaviour*) it is likely that children within the village/ section will exhibit similar health seeking behaviour (largely determined by community norms which may have been influenced by the incidence of Ebola virus disease in the locality for example) thus reducing the variability in behaviour within a cluster compared with that expected from a random sample. To allow for the expected cluster effect we plan to allow for a design effect of 4 for the child health seeking component which will require a larger number of clusters but provide a more precise estimate. A design effect of 4 has been used previously in MSF mortality surveys in the Ebola context.<sup>29</sup>

### *Population size*

The populations from which the samples will be drawn are Magburaka town (pop. ~124,000) and Yoni ~~chiefdom~~chiefdom (pop. ~120,000). However the study population concerns women who have given birth in the preceding two years, and children aged <5 years for the two survey components respectively. From DHS 2013 it can be derived that ~23% of the typical household in Sierra Leone is composed of women aged 15-49 years (childbearing age) and that ~10.5% of these women in household were overtly pregnant at the time of the survey.<sup>21</sup> There are (24÷9) ~2.67 x nine month periods in two years so the proportion of the household population that were women who were overtly pregnant in the preceding two years or who were pregnant at the time of the survey is estimated to be:  $0.23 (0.105 * 2.67) \approx 0.064$  (0.38 per average household of 5.9 people).<sup>21</sup> The proportion of women who gave birth in the last two years is likely to be similar so the estimated study population of interest for maternal health behaviour in Magburaka is approximately  $(124,000 * 0.06) \approx 7440$  and in Yoni is  $(120,000 * 0.06) \approx 7200$ . Extrapolating from DHS 2013 ~16.6% of the typical household is composed of children aged 0-59 months. Therefore the study population of interest for child health seeking behaviour is approximately 20,584 in Magburaka and 19,920 in Yoni.

### *Non-response rate*

There was a 3% household non-response rate for DHS 2013.<sup>21</sup> This survey will be conducted in a similar manner to DHS 2013 in partnership with the DHMT/ MoHS. Prior engagement with communities and local stakeholders will be commenced before initiating the work and current relations with communities are perceived to be strong. A household non-response rate of 6% has been proposed for both surveys.

### *Desired precision of the derived estimates*

It is anticipated that any MSF intervention in the locality should result in meaningful change in healthcare utilisation for childbirth and health seeking for childhood febrile illness. Therefore a desired precision of 10% is deemed adequate for both surveys (for example an increase in healthcare utilisation of below 10% would not be considered successful nor worth detecting assuming current estimates are somewhere near the actual population prevalence).

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28

Pagel et al.: Intracluster correlation coefficients and coefficients of variation for perinatal outcomes from five cluster randomised controlled trials in low and middle-income countries: results and methodological implications. *Trials* 2011 12:151.

29

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

## 7.2 SURVEY SAMPLE SIZE CALCULATION

Required sample size for each of two components of the survey (*maternal health and health seeking and child health and health seeking*) was calculated using OpenEpi.<sup>30</sup> Sample size estimates and parameters used in calculation of sample size relating to achieving primary objectives are presented in Tables 2 and 3 below:

**Table 2: Sample size to estimate utilisation of health facilities for childbirth in the two years prior to survey**

Locality	Study pop. Size	Prev. of outcome (%)	Precision (confidence limits) (%)	Design effect	Total no. of individuals required	Household non-response rate (%)	No. of households to search to recruit sample
Magburaka	7440	50	10	2	<b>190</b>	6	576
Yoni	7200	50	10	2	<b>190</b>	6	576

**Table 3: Sample size to estimate utilisation of healthcare services by children aged <5 years for most recent febrile illness in the three months prior to survey**

Locality	Study pop. Size	Prev. of outcome (%)	Precision (confidence limits) (%)	Design effect	Total no. of individuals required	Household non-response rate (%)	No. of households to search to recruit sample
Magburaka	20584	50	10	4	<b>383</b>	6	415
Yoni	19920	50	10	4	<b>383</b>	6	415

For estimation of the number of households to be searched to recruit the required number of individuals it is necessary to estimate the number of individuals in the study population per household (household prevalence). It can be derived from DHS 2013 there were approximately 0.35 women per household who had given birth within the last two years, and 0.98 children per household aged 0-59 months.<sup>21</sup> The number of households required to achieve the required sample size should also be adjusted to account for an anticipated 6% non-response rate. Therefore the estimated number of households to assess in order to recruit the required number of individuals is therefore: the sample size divided by the estimated household prevalence, multiplied by 1.06 (for example in Table 1 the number of households required to meet sample size in Magburaka is  $(190/0.35)*1.06 \sim 576$ ). The

survey will only be completed for a given household if individuals within the household meet inclusion criteria; therefore the estimated number of households to assess merely gives an indication of the practical implications in sample recruitment in order to facilitate survey planning.

Sample size calculations for secondary objectives have also been calculated similarly. However, sample size for child <5 years mortality estimation was calculated using “ENA for SMART 2011” software.<sup>31</sup> An estimated crude mortality rate (CMR) of 3.0 was used in this calculation; there is considerable uncertainty in this estimate during the Ebola outbreak given likely reversal of previous population health gains. The CMR estimate chosen of 3.0 is ~20% lower than that measured for children <5 years by MSF in a neighbouring district in 2006.<sup>32</sup> Desired precision and need to combine the two study areas for mortality estimation reflect the practical constraints.

**Table 4: Sample size to estimate utilisation of antenatal care facilities by women in the two years prior to survey**

Locality	Study pop. Size	Prev. of outcome (%)	Precision (confidence limits) (%)	Design effect	Total no. of individuals required	Household non-response rate (%)	No. of households to search to recruit sample
Magburaka	7440	90	5	2	<b>272</b>	6	824
Yoni	7200	90	5	2	<b>272</b>	6	824

**Table 5: Sample size to estimate measles vaccination coverage in children aged 12-59 months on the day of the survey**

Locality	Study pop. size	Prev. of outcome (%)	Precision (confidence limits) (%)	Design effect	Total no. of individuals required*	Household non-response rate (%)	No. of households to search to recruit sample*
Magburaka	16864	65	10	4	<b>348*</b>	6	462*
Yoni	16320	65	10	4	<b>348*</b>	6	462*

31

SMART methodology (2011) <http://www.nutrisurvey.de/ena2011/main.htm> [Accessed 1 April 2016]

32

MSF (2007) [www.msf.org.uk/sites/uk/files/Mortality20sierra20leone2041\\_200804164259.ppt](http://www.msf.org.uk/sites/uk/files/Mortality20sierra20leone2041_200804164259.ppt) [Accessed 10 April 2016]

\*N.B the above sample size relates to children aged 12-59 years. To approximate the numbers of children <5 years to achieve the above sample size then we need to divide estimates for sample size and households required by 0.80. So for both localities we would require  $(348/0.8) \sim 435$  children <5 years and we would need to search  $(463/0.8) \sim 578$  households.

**Table 6: Sample size to estimate LLITN use for children aged <5 years the night prior to the survey**

Locality	Study pop. Size	Prev. of outcome (%)	Precision (confidence limits) (%)	Design effect	Total no. of individuals required	Household non-response rate (%)	No. of households to search to recruit sample
Magburaka	20584	50	10	4	<b>383</b>	6	415
Yoni	19920	50	10	4	<b>383</b>	6	415

Note this sample size is identical to that calculated for Table 3.

**Table 7: Sample size to children <5 years mortality rate (in both areas combined)**

Est. CMR (per 10,000/day)	Desired precision of CMR	Recall period (years)	Design effect	Non-response rate (%)	Total population required	Households (HH)
3.0	1.0	2	4	6	<b>687</b>	746

### 7.3 SURVEY SAMPLING STRATEGY

A two-stage cluster sampling methodology will be chosen as an adaptation of the standardized method recommended by the WHO<sup>33</sup>.

To achieve the required sample size to meet primary and secondary objectives:

- Thirty clusters will be selected from all sections in Magburaka and thirty clusters will be selected from all villages in Yoni.
- Ten women meeting inclusion criteria will be recruited at each cluster site
- Informants sufficient to provide information relating to 15 children <5 years will be recruited at each cluster site.

Sampling will continue until the above minimum sample size per cluster is achieved. The selection of 30 clusters in each locality is to facilitate adequate recruitment given the expected prevalence of the target population per household and to achieve a representative sample of the population within practical constraints and minimise design effect. Primary objectives could be achieved with a smaller number of clusters and a smaller sample size (for example 20 clusters of 10 women and 20 children aged <5 years per cluster would be sufficient). However the advantages of achieving secondary objectives, achieving representativeness and the adequate resources at hand permit more extensive sampling.

Cluster allocation will be by systematic sampling with probability of allocation proportional to the respective population size of each village/ section (probability proportional to size or PPS). Cluster allocation will be performed at least two weeks before the survey commencement date in order that consultation with the selected communities can be undertaken and permissions sought.

The standard WHO/EPI methodology will be used to select households within a cluster: accordingly, a pen will be thrown on the ground in the central point of the cluster, and a line will be drawn in its direction towards the edge of the cluster. To prevent centre bias the team will walk in the direction of the pen until the edge of the cluster is reached, throw the pen again and households along this line will be counted until the edge of the cluster is reached. The survey team will delineate the edge of the cluster in advance of household selection with the assistance of the Head of village/section. One of these will be selected using a random number table as the first to be assessed for eligibility in the cluster and individuals within the household will be interviewed if inclusion criteria are met. If inclusion criteria are not met the next household following in order of physical proximity will then be assessed +/- individuals interviewed. Physical proximity is defined as being the household whose front door is closest to the left of the front door of the household that was just assessed. If the household is eligible and individuals are interviewed the next household to be assessed will be the third house to the left. This procedure will be continued until the desired number of individuals has been sampled in the cluster.

If all households of a selected village (rural) or section (urban) are included in the study before completing the required number of households, the cluster will be continued by selecting the (geographically) closest village/ section (this will be pre-determined corresponding to numbers used in the original selection process). The chosen sampling methodology will again be used in the closest village/ section to select the first household in the village/ section.

If for unforeseen reasons a selected village/ section (cluster) cannot be visited, it will be replaced by selecting the (geographically) closest village/ section. The chosen methodology will again be used in the closest village/ section to select the first household.

#### **7.4 SELECTION AND SAMPLE SIZE FOR STRUCTURED INTERVIEWS**

One structured interview with one or more participants will be conducted in each cluster site. Selection of participants will be based on convenience subject to the inclusion/ exclusion criteria.

## 7.5 SELECTION AND SAMPLE SIZE FOR IN-DEPTH INTERVIEWS

As this is a qualitative study, sample size is not generally defined prior to beginning the research; rather, sample size is determined as the study progresses<sup>34</sup>. Study team members may continue interviewing until no new information is provided from additional interviews (i.e., the point of saturation is reached)<sup>35</sup>. in this instance at least 12 participants will be approached per key informant group. Guest (2006) validates that saturation occurs for such research design 'within the first twelve interviews, although basic elements for meta-themes were present as early as six interviews'<sup>36</sup>.

The focus of data collection is on richness of information, with an adequate sample size being one that sufficiently answers the research question (i.e., that is large enough to capture a range of experiences but not so large as to be repetitive)<sup>37</sup>. As such, although it is expected that there may be up to 12 participants in the research, if no new information is being generated before this figure is reached, the data collection can end; conversely, data collection may continue beyond 12 participants if additional information continues to be generated.

Participants will be selected purposively, allowing for the researcher to select key informants who will have experience of pregnancy and useful perspectives on child birth. Participant selection will be based on the inclusion criteria outlined above, and will be recruited from the community using knowledge of the quantitative data collection team, MSF outreach teams and MSF project liaison.

To enhance the credibility of this sampling, a maximum variation sample will be used to ensure the consideration of key demographic variables likely to have an impact on participant's views, for example, age, ethnicity, and occupation. This aims to ensure that the sample within the selected groups is both diverse and representative of the communities in question, and so maximise a fair share of perspectives and views.

Based on this the following sample is foreseen (please note, the variables will be elaborated further with the mission team):

**Table 8: Overview of sampling for in-depth interviews**

<u>Participant group</u>	<u>Foreseen variables to be considered per participant group</u>	<u>Foreseen variables for all groups</u>
1. <u>Women who have given</u>	<ul style="list-style-type: none"> <li>• <u>Number of children</u></li> <li>• <u>Delivery/seeking care for</u></li> </ul>	<ul style="list-style-type: none"> <li>• <u>Location of residence (rural/urban)</u></li> </ul>

34

Marshall MN. Sampling for qualitative research. Fam Pract 1996;13(6):522-525.

35

Green J, Thorogood N. Qualitative methods for health research. 2009. London, Sage Publications.

36

Guest G. How Many Interviews Are Enough?: An Experiment with Data Saturation and Variability. Field methods. 2006;18(1):59-82.

37

O'Reilly M, Parker N. 'Unsatisfactory Saturation': a critical exploration of the notion of saturated sample sizes in qualitative research. Qualitative Research 2013; 13(2):190-197.

<p><u>birth since Ebola outbreak /caregiver of child under 5</u><sup>38</sup></p>	<p><u>child in/outside facilities</u></p> <ul style="list-style-type: none"> <li>• <u>Child living/deceased</u></li> <li>• <u>Position in household (e.g. female head; polygamous marriage etc.)</u></li> <li>• <u>Marital status</u></li> </ul>	<ul style="list-style-type: none"> <li>• <u>Age</u></li> <li>• <u>Language</u></li> <li>• <u>Ethnicity</u></li> <li>• <u>Education level</u></li> </ul>
<p>2. <u>Key community members</u></p>	<ul style="list-style-type: none"> <li>• <u>Gender</u></li> <li>• <u>Position (elder; religious leader; representative of women's/youth group; transport union etc.)</u></li> <li>• <u>Parent/caregiver</u></li> </ul>	
<p>3. <u>Health workers</u></p>	<ul style="list-style-type: none"> <li>• <u>Gender</u></li> <li>• <u>Position (nurse; midwife; TBA; other PHU staff; 'pepper' doctor etc.)</u></li> <li>• <u>Location of work (government facility; private clinic; MSF facility; home etc.)</u></li> <li>• <u>Parent/caregiver</u></li> </ul>	

~~Interviews will be organised and conducted in a designated place so as to optimise privacy and confidentiality. Appropriate venues will be identified during the planning phase of the study as a neutral space, and will be selected in collaboration with the MSF team.~~

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Please note, this participant group may be refined/divided should significant disparities be observed during preliminary data analysis or during the interview process.

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## 8 DATA COLLECTION

### 8.1 SURVEY

Selected villages/ sections according to the sampling (see section 7.3) will be engaged by the MSF-OCA outreach team in the field, permissions will be sought and sensitisation conducted at least one week before the ~~informed before the~~ data collection teams will visit them.

The heads of the villages/ sections will be visited ~~by the data collection teams the day of the survey at this stage~~ and the purpose of the survey will be explained before conducting interviews in their villages. Furthermore it will be clearly explained to the heads of the villages/ sections, that they are freely allowed to decline the participation of their village/ section without any consequences or penalty. In this case it will be replaced by selecting the (geographically) closest village/ section.

In the households randomly selected according to the above methodology, the purpose of the survey will be explained to the head of the household in the language he or she is familiar with and written or verbal witnessed consent obtained to conduct the interviews

Information forms and consent forms to be used in the study for all components of the study are provided [Annex 1].

For each selected household containing eligible individuals (for either component) the survey questionnaire [Annex 2] will include:

- Age and sex of all household members
- Use of malaria bed nets

For the first component of the survey (*maternal health and health seeking*) the survey questionnaire [Annex 3] will include the following sections:

- Age, sex and pregnancy status of all persons who met the inclusion criteria
- Health behaviour in pregnancy
- Health behaviour for childbirth
- Barriers to healthcare
- Birth history

For the second component of the survey (*child health and health seeking*) the survey questionnaire [Annex 4] will include the following sections:

- Age, sex of all persons who met the inclusion criteria
- Health behaviour during illness
- Barriers to healthcare
- Vaccination status

### 8.2 STRUCTURED INTERVIEWS

Structured interviews will be conducted in each cluster concurrently with the survey and permissions for the structured interviews will be sought and explanations given at the same time as the survey as outlined above.

Participants will be selected to the inclusion criteria, the purpose of the survey will be explained to participants in the language he or she is familiar with and verbal witnessed consent obtained to conduct the interviews.

A bespoke questionnaire [Annex 5] will be used to collect information relating to the number, cause and circumstances of maternal deaths in the locality and the number of women resident in the locality. No personally identifiable data will be collected.

### **8.3 IN-DEPTH INTERVIEWS**

In-depth interviews will be conducted subsequent to the survey and structured interview components.

Interviews will be organised and conducted in a designated place so as to optimise privacy and confidentiality. Appropriate venues will be identified during the planning phase of the study as a neutral space, and will be selected in collaboration with the MSF team.

For interviews scheduled to be conducted at home, names, addresses and phone numbers will be recorded on paper for selected participants consenting to participate in the study, in order for team members to locate their residence. This information will only be available to the study staff and will be destroyed six months after the end of the study.

Each interviewee participant within the study will be allocated a unique identifying number. This unique identifying number will be written on all study forms, audio files and transcriptions.

Interviews will be conducted using a topic guide [Annex 6]. Interviews will be audio recorded. In addition, interviewers may take written notes concerning the interview.

## 9 DATA ENTRY AND ANALYSIS

### 9.1 QUANTITATIVE DATA

Quantitative data arising from household questionnaires and structured interviews will be entered into an electronic survey software on Sony Experia tablet devices by the data collection team.

The software and hardware are being fully tested in the field by OCA in other surveys now so will be fully field ready. Data security protocols meet OCA and external (such as EU) data security compliance requirements (including data access and storage on devices, data transfer to servers and data storage on servers). This electronic data collection will act as a final field test of the electronic data collection software. A desk-based benchmarking review and a field evaluation will have already been completed.

Full training on use of devices will be given.

All data will be anonymised (names are not collected) and electronic files stored password-protected by MSF. Only survey investigators will have access to these data files. Data cleaning will be done to check for inconsistencies in data entry and responses. Data analysis will be conducted using STATA v14.

After the survey, the questionnaires and written consent forms will be archived for at least 5 years in headquarters at the MSF-OCA Headquarters in Amsterdam for a duration 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.

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 of the main variables. Where appropriate, Prevalence Ratios (PR), and differences in proportions will be measured using Pearson  $\chi^2$  test and p-value (p) will be presented.

### 9.2 QUALITATIVE DATA

Data will be entered on computers specifically dedicated to the study. Computers will be password protected. Paper study forms and audio recordings will be stored for 10 years at the MSF-OCA Headquarters in Amsterdam. Electronic data will be anonymous. Back-ups of the electronic data will be done on external support (CD or external hard disk) and encrypted. All study forms and study data will be stored in a locked room in a secured area, with controlled access available only to study team members.

#### Transcription and translation

All audio recordings of interviews will be transcribed by the study team in the language of the interview and then translated into English. -Translators/transcribers will be hired and trained locally. Training will include guidance on transcription techniques and ethics and confidentiality (see section 12.4). Quality control mechanisms will include back translation of transcriptions by a second transcriber (exchanging and back translating each other's work);

checking of a subsection of transcripts by the research assistant/translator; and ongoing supervision).

The data collection team will be trained thoroughly on privacy and confidentiality and will sign a confidentiality agreement. Audio files will be anonymised and no names or locations will be linked to the identifying codes. (utilizing forward and backward translation techniques)

~~for exporting into NVivo ©11 qualitative data management software for coding and analysis.~~

The study team recognizes the role of translation in constructing knowledge, and the role of translators as active agents in the research. Therefore, the transcription by a trained local transcriber and translation methods will reflect the interpretative approach underpinning the qualitative research, aiming to convey as fully as possible the experiences and representations of the participants.

### Analysis of Data

Data will be analysed using NVivo ©11 qualitative data analysis software. Both inductive qualitative content analysis and analytical principles from grounded theory will be used. All interview transcripts will be imported into NVivo after translation and transcription, where they will then be coded. A coding framework will be developed based on themes emerging during the interviews, as well as themes pre-identified by the study team whilst survey results are made available. Emergent categories and themes will be identified based on meticulous and systematic reading and coding of the transcripts. Codes and sub-codes will be refined during the analysis. Data coding and analysis will begin whilst data collection is ongoing, to allow for the refining of questions and the in-depth exploration of certain themes if required. A coding manual will be developed with the study team in order to adequately reflect emerging themes. This manual will be discussed, revised and validated by the study team. Agreement between researchers will be obtained for all final coded data. Similarities and differences across sub-groups will be explored.

## 10 ETHICAL ISSUES

The survey will be conducted in accordance with the World Health Assembly of 1975 concerning ethical aspects in human tests, and with the Helsinki declaration.<sup>39</sup>

The survey protocol will be submitted to the Ethics Review Board of MSF. It will also be presented to the ethics committee of the MoHS of Sierra Leone for approval.

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

MSF-OCA commits to sharing survey results with everybody who has participated in the survey. 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 coordinator responsible in the field will advise the data collection team on the referral practices when finding sick people in the survey villages as well as procedure regarding psychosocial issues or victims of violence.

### 10.1 CONSENT FORM

All ~~potential participants subjects included in the surveys~~ will have the study explained to them in a language with which they are familiar. Everyone will be offered the opportunity to refuse participation in the ~~survey~~ study at any time without penalty and no incentives or inducements will be provided to any respondents. It will also be explicitly clarified that participation is in no way linked to receiving (or not receiving) services or other benefits. Everyone is completely free to participate or not.

#### Survey and structured interview

A verbal ~~witnessed~~ consent, recorded by the interview team will be sought from all heads of households and individuals participating in the survey. Consent will sought first from the head of household. Should consent be refused by either the head of household or the eligible individual the survey team will not proceed.

~~All subjects included in the surveys will have the study explained to them in a language with which they are familiar. Everyone will be offered the opportunity to refuse participation in the survey at any time without penalty and no incentives or inducements will be provided to any respondents. It will also be explicitly clarified that participation is in no way linked to receiving (or not receiving) services or other benefits. Everyone is completely free to participate or not.~~

A separate verbal consent will be sought from informants for the structured interview study.

~~and the in-depth interviews~~

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World Medical Association (WMA) Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Subjects <http://www.wma.net/en/30publications/10policies/b3/> [Accessed 01 May 2016].

A separate consent form will be used for the in-depth interviews (see Annex 1). Written consent will be obtained when possible. If a participant cannot sign his/her name a thumb print will be used. subject to the same conditions above.

In the case of younger participants who are between 15 and 17 years of age, permission of the parents or legal guardians will be sought as both the legal age of consent and the minimum age of marriage is 18. Alongside parental consent, assent from the young person will be included as part of the consent, meaning there is a signal that the young person is willing to take part and we will endeavour for his to be in private, without the parent present.

## **10.2 RISKS AND BENEFITS OF THE STUDY AND CONTINGENCY PLANS**

The health behaviour survey does not cause any physical harm to participants. Nevertheless, asking to enter the home of the household members may be upsetting, relatively intrusive and in village contexts there may be limited privacy.

Prior to implementation extensive consultation with local stakeholders will be undertaken. In order to minimise impact on participants, interviews will be undertaken by trained interviewers using tools developed with local stakeholders and piloted to ensure the study is undertaken in a culturally appropriate and sensitive manner.

Identifiable information will be minimised (e.g. names will not be collected) and confidentiality Every effort will be made to protect the confidentiality between survey the study team and participants will be assured and to minimise the risk of residual disclosure. For both quantitative and qualitative teams the training will thoroughly cover issues of confidentiality, and all members of the study team will be require to sign a confidentiality agreement. – Identifiable information will be minimised (e.g. names will not be collected and all data collected (audio files, transcriptions, questionnaires) will be labelled with an anonymous code. – and Where possible local researchers will allocated to collect data in study sites that are not their own village/ immediate community. Ongoing supervision of the data collection teams will ensure oversight and quick resolution of any issues arising.

There is also a risk that using local researchers may lead to distrust and lack of candour by the participants. In addition to the careful allocation of team members to collect data outside their home community, efforts will be made to ensure participants feel comfortable with the research team members. Time will be taken to carefully explain the study objectives, the roles of the team members, provisions regarding confidentiality and to answer any questions the participant may have. This is particularly relevant for the in-depth interviews, where time will be taking to introduce the research team and build a rapport prior to commencing the interview.

Participation in the in-depth interviews could result in some loss of time and possible emotional discomfort (especially for participants who might have lost relatives due to child birth). Importantly, participants are free to end their study participation at any time. Breaches of confidentiality are also possible; however, the developed study procedures will limit these risks. There is a risk implicit in qualitative research that A risk that participants during an interview participants may disclose information that poses a significant individual or public medical risk (for example allegations of abuse, hidden outbreaks/deaths in post-Ebola context etc.) This not known prior to the interview as is the nature of qualitative research will be dealt with prior to the interview by stating that any disclosures deemed to present such as

risk (in a situation where failure to disclose information would expose the participant or someone else, to a risk of serious harm (including physical or sexual abuse or death) that pose a significant individual or public medical risk will be managed on a case-by-case basis. They will be managed in line with MSF protocol and in collaboration with the mission team and local MoHS- as far as possible, in line with standard MSF protocol and where appropriate if necessary seeking expert advice will be sought.

Should psychological distress occur as a result of participating in interviews interviewees will be referred to ~~local~~ psychosocial support services supported by MSF and MSF who will facilitate attendance.

There is a risk in qualitative research that the views of the researcher may be incorporated in the interviews. As there will be two data collection teams there is also risks linked to the potential inconsistencies in interview style and content. These issues will be minimised by ongoing close collaboration between the two researchers (during training, daily debriefings, and by reviewing each other's audio recordings). In addition a third researcher (based in London) will provide oversight of the qualitative process, review the transcripts etc. in order to optimise quality and consistency and minimise potential bias. In addition all team members will keep field notes in order to enhance reflexivity and triangulate with data collected during in-depth interviews.

There is no direct immediate benefit for participants of this study. Benefits to the population of Tonkolili are expected over the long term as result of targeted and effective health interventions which will be developed by MSF using data derived from this study.

No major external threats to conducting this work have been identified.

## **11 COLLABORATION**

The study will be carried out in collaboration between MSF-OCA and the MoHS of Sierra Leone, who will also be a co-investigator.

MSF-OCA is the study sponsor and is responsible for the funding. 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 DATA COLLECTION TEAMS

#### Quantitative data team

The task of the data collectors will be to collect the necessary data for the survey and the structured interviews.

Each data collection team is composed of two data collectors. To finalise the field part in a reasonable time we need eight to nine data collection teams of two people each (see also section 12.5.).

General selection criteria for all data collectors:

- Able to read and write in English, *and*
- Fluent in the local language (predominantly Temne but specific to the area visited), *and*
- Available for the ENTIRE time of the survey (training and interview days), *and*
- If necessary: willing and able to work on weekends and holidays during the survey time (see section 12.5. for a possible timeframe in the field), *and*
- Motivated to participate in the survey, *and*
- Not biased in expectations of the outcome of the survey
- Experience with interviews in difficult settings and survey populations would be an advantage

#### Qualitative data team

~~Two data collection teams will be used, each consisting of a Interview teams for the in-depth interviews will comprise of a trained qualitative researcher and a local ,-translator/ research assistant. Two additional transcribers will also be recruited locally in order to ensure timely transcription. The team and transcriber of interview data, will be selected and trained by the qualitative researcher.lead.~~

~~General selection criteria will be the same as for the data collectors above, with the additional desirable criteria of translation/qualitative research experience and excellent interpersonal skills.~~

### 12.2 SUPERVISION

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

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

- Preparation of all necessary documents (protocol, questionnaires, informed consent forms) for the survey
- Preparation of the field component of the survey (training of the data collection teams, logistics, materials) together with the MSF team in the field
- Follow-up of the field component of the survey

- Data entry
- Data analysis
- Report writing

A qualitative research implementer will select, train and guide the research team carrying out the in depth interviews and will be responsible for the analysis and write up of this part of the study in close collaboration with the principle investigator.

### 12.3 SUGGESTED MSF SUPPORT IN THE FIELD

- Administrative support for study preparation at the field level and during the field part, such as presentation of the study protocol to the ethics committee of the MoHS and payment of data collection teams.
- Human resource support, such as hiring data collectors, and providing a translator for the principal investigator.
- Logistic support for study preparation at the field level and during the field part, such as organizing sufficient cars including drivers for the field part of the survey, providing communication tools and MSF ID (e. g. aprons, vests or arm bands) to the data collection teams, stationary, printing the questionnaires and consent forms.

### 12.4 TRAINING OF THE DATA COLLECTION TEAM AND PRE-TESTING OF ~~THE~~ QUESTIONNAIRES STUDY TOOLS

#### Quantitative component

~~Four~~Two days training will be given to all data collectors to familiarise them with the background of the survey, the questionnaires, the tablet and software, the information sheet and the informed consent form. The training will be given in English with translation if needed by the principal investigator. It consists of an intensive review of the questionnaires and the information sheet including role-plays. As the interviews will be held in the regional language, the principal investigator should ensure that all data collectors are using the same and correct wording for providing information to the households and for the interviews.

The 2-day training will be followed by 2 days finished with a for a pilot survey. The pilot will be conducted in a village/ section not included in the study and selected after study cluster allocation has been performed. in a place, which is outside of the survey area. The pilot survey allows for the testing and possible final adaptation of the questionnaires and informed consent to field conditions. We intend to conduct a minimum of one test interview for the maternal and child health components per data collection team (with 8 teams), so a minimum of sixteen pilot interviews. Training and implementation will be conducted in collaboration with the local MoHS.

#### Qualitative component

For the qualitative component in-depth interviews a 2-day training will be conducted followed by a one day pilot of the topic guides. Pilot interviews will be held in order to pre-test the tools with each participant group. with practical approaches to teaching will consist of: Following the pilot a debriefing/review of the pilot will be conducted to ensure

appropriateness of tools, consistency between data collection teams and address any challenges faced. Throughout the data collection tools may be refined through daily discussions of interviews and issues emerging.

**Table 9: Overview of training/pilot plan for qualitative data collection**

<u>Day 1</u>	<ul style="list-style-type: none"> <li>• <u>introduction to study and methods</u></li> <li>• <u>introduction to qualitative research</u></li> <li>• <u>translation skills</u></li> <li>• <u>risks of bias</u></li> <li>• <u>ethical considerations</u></li> <li>• <u>confidentiality</u></li> </ul>
<u>Day 2</u>	<ul style="list-style-type: none"> <li>• <u>run through and discussion of topic guide</u></li> <li>• <u>practical exercises with topic guide, audio recording</u></li> <li>• <u>feedback, questions and lessons learned</u></li> </ul>
<u>Day 3</u>	<ul style="list-style-type: none"> <li>• <u>pilot of topic guides</u></li> </ul>
<u>Day 4</u>	<ul style="list-style-type: none"> <li>• <u>review of pilot: challenges and lessons learned</u></li> <li>• <u>discussion of topic guide and amendments necessary (language, discussion flow etc.)</u></li> <li>• <u>discussion of consistency between two data collection teams</u></li> <li>• <u>definition of ongoing supervision and support</u></li> </ul>

~~principles of qualitative techniques, translation skills, risks of bias and ethical considerations.~~

Transcribers will also receive a half day training including background information on MSF, the study, and practically focussing on transcription techniques and research ethics, with a focus on privacy and confidentiality, and data management and storage.

Training materials developed specifically for this context will be used, and training methods will be participatory with a focus on practical exercises (e.g. role play, problem solving, discussion etc.) and provide opportunities for the team to reflect upon and share their existing knowledge and experience. This will be supported with ongoing supervision and support, largely through daily debriefings, to address any issues arising.

## 12.5 TIMEFRAME IN THE FIELD

A preliminary plan for the field element of the survey and structured interviews is displayed in Table 8 below.

**Table 108: Preliminary plan of the field part of the health behaviour survey for qualitative data collection, Tonkolili, Sierra Leone, 2016**

<u>Date [2016]</u>	<u>Day</u>	<u>Nr. of days</u>	<u>To do</u>
<u>Phase 1:</u>		<u>3</u>	<u>Travel days for arrival</u>
<u>quantitative</u>		<u>2</u>	<u>Final preparation of the survey</u>
<u>data collection</u>		<u>52</u>	<u>Training including the pilot survey</u>

8            *Field part*  
34         *Buffer days / debriefing*  
3            *Travel days to return*  
Total: 242 days

*Phase 2:  
qualitative data  
collection*

3            *Travel days for arrival*  
4            *Final preparation for the data collection*  
2            *Training including the pilot survey*  
6            *Data collection*  
4            *Buffer days / debriefing*  
3            *Travel days to return*  
Total: 22 days

~~In-depth interviews: The interviews will be conducted over a 2-week period. In addition 1-month data analysis and write-up will be planned for.~~

## LOGISTICS

### 12.6 SUPPLIES NEEDED

Supplies to conduct the survey will be purchased in Tonkolili. A preliminary list of supplies required is displayed in Table 9 below. Health seeking behaviour questionnaires and informed consent forms will be developed by the principal investigator. Photocopies of all necessary documents will be done in Tonkolili.

**Table 119: Supplies needed for the field part of the health behaviour survey and structured interviews study, Tonkolili Sierra Leone, 2016**

Item	No. needed per team	No. needed for 8 teams with 3 supervisors
Back pack/shoulder bag	1	11
Tablet	1	8
Clipboard	2	8
Pencil	3	12
Rubber	2	12
Sharpener	2	8
Aprons, vests, arm bands or similar with MSF identification / logo	2	19
Plastic folder (for protection of questionnaires against rain and dust)	3	12
<u>Tablets</u>	<u>1</u>	<u>11 (including reserve devices)</u>

For the in depth interviews additional resources in terms of transportation and essential materials may be needed. Resource requirements for this component will be determined during detailed planning after completion of the survey.

## 12.7 TRANSPORT NEEDED

Four cars will be need during the [study period quantitative data collection](#).

[One car will be needed during the qualitative data collection](#).