Retrospective mortality survey in the MSF catchment area in Mayendit county, Unity State, South Sudan

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Study protocol

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First version	Version 1.0
Study design	Retrospective mortality and nutrition survey
Study period	Four weeks
Study site	Randomly selected villages within catchment area of MSF in Mayendit county, Southern Unity State, South Sudan
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Collaborating institutions	Ministry of Health, South Sudan

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LIST OF ABBREVIATIONS

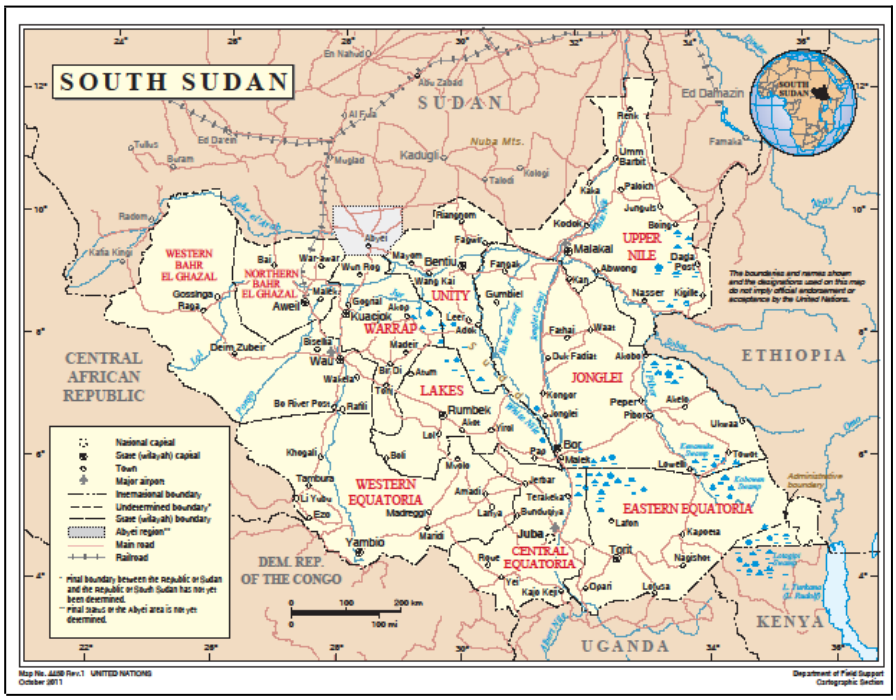
CMR	Crude Mortality Rate
95% CI	95% confidence interval
GAM	Global Acute Malnutrition
IPTp	Intermittent preventive treatment in pregnancy
IRC	International Rescue Committee
MoH	Ministry of Health
MSF	Médecins sans Frontières
MSF-OCA	Médecins sans Frontières – Operational Centre Amsterdam
MUAC	Mid-Upper Arm Circumference
SAM	Severe Acute Malnutrition
U5MR	Under 5 mortality rate (mortality rate in children under 5 years of age)
WHO	World Health Organization

1. INTRODUCTION

1.1. CONTEXT

In July 2011, after 25 years of civil war, South Sudan gained its independence from Sudan. The war resulted in vast displacement of the population, the collapse of the healthcare system, and a fragile security situation. In December 2013, fighting broke out among security forces in South Sudan's capital, Juba. Armed clashes between supporters of President Salva Kiir and the government SPLA forces, and the 'In Opposition' IO (led by former Vice-President Riek Machar), rapidly spread to other regions of the country, especially Jonglei, Unity, and Upper Nile States. Fighting continued between the SPLA and the IO and their respective allied armed groups, to date forcing hundreds of thousands of people to flee their homes due to increased fighting, and widespread and deliberate violence against civilians.

Figure 1. South Sudan, by state



1.2. MSF PRESENCE IN THE COUNTRY

MSF-OCA has been providing medical care in Unity State since 1988. Before the conflict broke out in December 2013, MSF-OCA was providing comprehensive healthcare services in Leer (outpatient and inpatient services including surgery, nutrition treatment, reproductive health services, and care for people living with HIV/TB). The hospital in Leer was the only secondary healthcare facility and hospital for around 300,000 people in the area.

After MSF-OCA teams evacuated Leer in January 2014 and the hospital was looted and partially destroyed, the facility was closed for more than three months. In March 2014, MSF-OCA opened nutrition and emergency care programs in the catchment area (Nyal (Panyjiar) and Mayendit) where many people were displaced to (Figure 2). In May 2014, as populations returned to Leer, MSF-OCA restarted medical activities in the town, first with therapeutic feeding programs, and then scaling up primary and secondary healthcare services in Leer hospital.

One year later, in May 2015, MSF-OCA medical services in Leer were interrupted again as staff and populations fled renewed fighting. MSF-OCA then scaled up medical activities, including inpatient care, for children under five in Nyal where IDPs from Leer and Mayendit were fleeing to. In August 2015, a small team returned to Leer area to attempt to provide emergency healthcare and mobile clinics outside of Leer town alongside local staff, and from September on in Leer town, also stabilising weapon-wounded and treating victims of sexual violence. Medical activities were suspended again on 3 October 2015 following violence against MSF.

In mid-November 2015, MSF restarted emergency healthcare and nutrition activities in Leer and Mayendit areas with mobile clinics in Leer, Kak, Rubkwai, Kok Island, and a day-care unit in Thonyor, and conducting a blanket supplementary feeding program for 8,655 children under five in these areas. To date, there are a small number of other NGOs present: however, MSF-OCA is the primary health care provider in this area.

1.3. BACKGROUND - JUSTIFICATION FOR THE STUDY

Due to accessibility issues, there is very little data available regarding the health of the populations in these states. A survey conducted in Southern Unity State showed that 93% of all deaths (all age groups) were directly related to conflict violence during May 2015 to February 2016, mainly because of gunshot injuries[1]. Among children aged under 5 years of age, violence accounted for approximately 47% of deaths. It concluded that the crude mortality rates in Southern Unity State were more than double the emergency threshold for mortality (2.23 deaths per 10,000 per day, 95%CI: 1.8-2.7) in that period[2]. A SMART survey conducted in January and February 2017 showed a CMR of 4.1/10,000/day and an U5MR of 0.8/10,000/day in Mayendit county, Unity State.

At the same time, in January 2017, Leer and Mayendit county in Southern Unity State were declared in famine, defined as a GAM prevalence of>30%, a CMR of >2/10.000/day, as well as < 2.100 kcal food intake and <4 litres of water per person per day[3]. After implementation of emergency nutrition response, both counties were declared to be no longer in famine in May 2017. However, both were still facing a food security emergency. A SMART survey conducted in Leer county found an estimated GAM prevalence of 20% and a SAM prevalence of 5% in April 2017. Nutrition surveys in Mayendit county, however, are lacking. Recent mass MUAC screenings in Mayendit county showed the highest malnutrition rates in Rubkuay district with a GAM and SAM prevalence of 15% and 2%, respectively. However, this sample might not be representative of Rubkuay districts and/or surrounding districts. Levels of acute malnutrition were expected to deteriorate due to the approaching peak of the hunger season in July 2017.

As the main primary healthcare provider in Southern Unity, MSF would like to measure the health status of the population to understand the impact of the recent conflict on the catchment population and to better target its medical programs and advocacy. Therefore, we aim to conduct multiple combined mortality and nutrition survey in Southern Unity, where reliable malnutrition and mortality data is lacking but mortality rates were above critical levels in the beginning of 2017, and recent data indicated high malnutrition rates in this area). This survey will also serve as a baseline for future surveys, which will allow us to monitor health changes in the population over time, measure the impact of our interventions and to address key health issues in Southern Unity.

2. OBJECTIVES

2.1. PRIMARY OBJECTIVES

- To estimate retrospectively the crude mortality rate for the total population and for children under five years of age in the MSF catchment area

2.2. SECONDARY OBJECTIVES

- To describe the population surveyed by sex and age
- To measure crude mortality rate for the total population and for children under five years of age
- To obtain an indication of the major causes of death, as well as the age and sex distribution of the deceased
- To determine the rate of severe and global acute malnutrition in 6-59 month olds;
- To identify the most prevalent morbidities in the population in the two weeks preceding the survey;
- To gain knowledge of violence-related events

3. STUDY DESIGN

Retrospective mortality survey using a *two-stage cluster sampling methodology as an adaptation of the standardized method recommended by the World Health Organization (WHO)*[1] *[this methodology is described in Chapter 7.2]*

4. STUDY AREA AND PERIOD

The study area will be part of the catchment area of the MSF-OCA Southern Unity project. Due to time restrictions and security issues, we will not be able to cover the whole catchment area. The study will be conducted in July, during the peak lean season and the early start of the rainy season, which usually peaks in July to September.

The recall period will include 9 months (see also chapter 6.2.)

5. STUDY POPULATION

The study population will consist of all people living in the villages, which are situated in the study area.

Information on current population estimates is based on knowledge of the area of local MSF staff, such as the Community Area Supervisor, Community Health Promotor and the Community Healthcare Workers.

The total population is difficult to assess due to a mobile population resulting from food scarcity and violence, but is likely to be between 20.000 and 30.000 inhabitants. The standard population estimations for children under 5 years of age will be used, which is 20% of the total population.

5.1. INCLUSION AND EXCLUSION CRITERIA

A person will be included in the study if s/he satisfies all the following criteria:

- Living in the randomly selected household (see chapter 6.1. for the definition of a household)

and

- Informed consent has been given by the head of the household (see chapter 6.1. for the definition of the head of household and chapter 10.1. for details on the informed consent form)

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

- Refusal to participate in the study

or

- Inability to locate the potential participant after one attempt to trace him/her

[1] 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

6. DEFINITIONS

6.1. HOUSEHOLD DEFINITIONS

Definition of household

A household will be defined as a group of people who slept under the same roof the previous night. The whole household will be included, no matter the age of the household member or the relation with the other members.

Definition of head of household

The head of household is defined as follows:

- Adult household member *>18 years], and*
- Can give accurate information on all demographic and mortality issues in his/her household (can describe with reasonable accuracy the events that occurred during the recall period), *and*
- Has lived in the household the entire recall period, *and*
- Is present at the time of the survey

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

Definition of permanent member of the household

A permanent member of the household is defined as a person who is part of the household per the household definition and is present at the time of the study or slept in the house the previous evening.

6.2. RECALL PERIOD FOR REPORTED DEATHS

We want to include both the rainy and the dry season in the recall period. This gives us a recall period of around 365 days; 180 days for the rainy season from July to October 2016 and May and June 2017 and 180 days for the dry season from November 2016 to April 2017.

With a chosen recall period of 365 days we will be able to compare CMR of previous studies carried out in 2015.

The exact beginning of the recall period will be discussed with the team in the field, especially considering the experience of the national staff. The end of the recall period will be the day before the start of the interviews in the field.

Together with the field team an events calendar will be generated for the chosen recall period to determine more accurately the dates the deaths occurred.

7. SAMPLE SIZE AND SAMPLING

7.1. SAMPLE SIZE

Sample size was calculated with the help of EAN for SMART 2011 software.

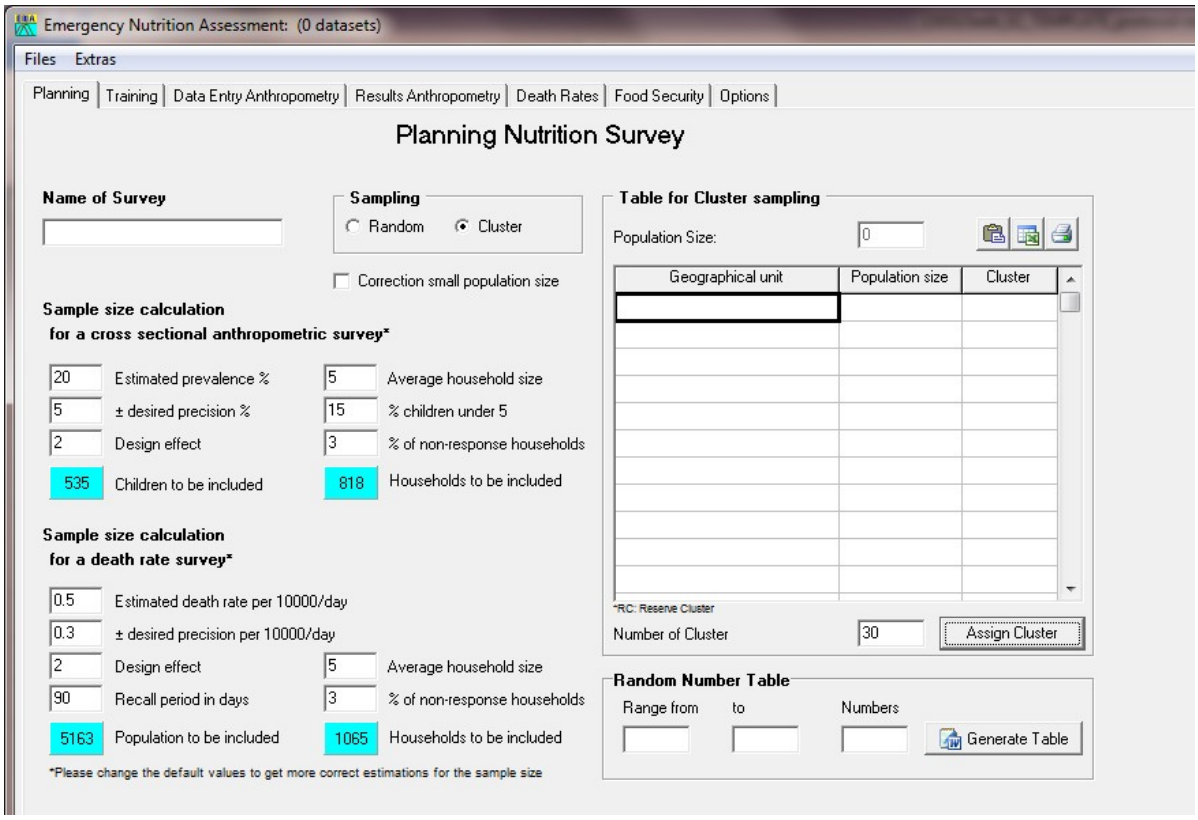


Figure 1 : Sample size calculation example using ENA for SMART 2011

The criteria listed in Table 1 were taken into consideration for the calculation of the sample size.

Table 1 Criteria for the calculation of the sample size, MSF-OCA, Mayendit county, Unity State, South Sudan

Criteria	CMR[1]	GAM
Expected mortality of 10 000/day	0.5	
Expected GAM prevalence		15%
Precision of 10 000/day	0.3	
Precision (%)		5%
Design effect	1.5	1.5
Recall period in days	180	
No. population to be sampled	1936	
No. children <5 years old to be sampled		320
Proportion non-response households	10%	10%
No. households to be sampled (assuming a household size of 6)	359	387

An estimated number of 367 households need to be sampled to deduce CMR. Therefore, we will sample 20 clusters of 18 households. This will allow teams to visit one village (i.e. cluster) per day.

7.2. SAMPLING

A two-stage cluster sampling methodology will be chosen as an adaptation of the standardized method recommended by the WHO[2].

In the first stage, 20 clusters will be selected from all villages situated in the study area. Cluster allocation will be systematic sampling with probability of allocation proportional to the respective population size of each village (probability proportional to size or PPS).

In the second stage, the 2005 standard WHO/EPI methodology will be used to select [insert number of households per cluster] 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. One of these will be selected using a random number table as the first to be interviewed in the cluster. A random number table is provided in the annex part of this document. The next household following in order of physical proximity will then be interviewed until the desired cluster of [insert number of households per cluster] households will be completed. Physical proximity is defined as being the household which front door is closest to the front door of the household that was just interviewed. If more than one house could be selected, chose the house to the left as you stand looking out of the doorway of the household just interviewed. This method is the least favoured of the 3 options as it is less likely to produce a probability based sample.

If all households of a selected village are included in the study before completing the required number of households, the cluster will be continued by selecting the (geographically) closest village. The chosen sampling methodology will again be used in the closest village to select the first household in the village.

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

8. DATA COLLECTION

The local Community Area Supervisor will inform the selected villages (i.e. clusters) according to the sampling (see chapter 7.2.) before the survey teams will visit them.

The purpose of the survey will be explained by locally hired staff to heads of the villages on the day of the survey before conducting interviews in their villages. Furthermore, it will be clearly explained to the heads of the villages, that they are freely allowed to decline the participation of their village without any consequences or penalty. In this case the village will be replaced by selecting the (geographically) closest village. Village refusals will be noted and a village participation ratio included in the survey report.

In the households randomly selected according to the above methodology, the interviewer team will explain the purpose of the survey to the head of the household in the language he or she is familiar with and verbal consent obtained to conduct the interviews. If they decline to participate this will be accepted, written down and the next household approached; the

[2] 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

number of household refusals should be noted and a household participation ratio included in the study report.

The household interviews will be based on a household/mortality questionnaire that consists of the following sections:

- Age and sex of all persons who had arrived, had left, were born or had died in the household during the recall period of the survey
- Cause of deaths and time of deaths (e.g. rainy or dry season) for all deceased persons in the household
- Illness that were experienced in the last two weeks
- Consumption of food (meat, fish, egg or milk) in the household
- Violence-related events

9. DATA ENTRY AND ANALYSIS

Data will be entered into Epidata v4.2.0.0 by the principal investigator. All data will be anonymised (names are not collected) and electronic files stored password-protected by MSF. Only study 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 14 (StataCorp, College Station, TX, USA).

No name-related data will be collected during the survey, reducing the risk that participants will be identifiable after the survey has been completed. An electronic database will be generated from the paper questionnaires and this database will be password protected. The paper versions of the questionnaires (paper versions) and the electronic database will be stored at the MSF Headquarters or country management level for 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 variable and those with effects greater than 1 will be reported. Where appropriate, differences in proportions will be measured using Pearson $\chi 2$ test and p-value (p) will be presented.

The end of the recall period will be calculated individually for each member of the household present at the start of the recall period or born within the recall period. The recall period will end either with the day of the study or the day of death of the household member. An average of all recall days will be taken.

Denominators for mortality rates will correspond to the mid-period population sizes, assumed to be the total population at the end of the period minus half of persons joining the sample during the recall period (new-borns and new household members) plus half of persons leaving the sample during the recall period (deaths or absenteeism).

Ninety-five percent confidence intervals will be calculated and adjusted for the design effect.

10. ETHICAL ISSUES

The study will be conducted in accordance with the Council for International Organisations of Medical Sciences (CIOMS) International Ethical Guidelines for Biomedical Research Involving Human Subjects[3] and International Ethical Guidelines for Epidemiological Studies[4].

The MSF Ethics Review Board approved the standardized survey protocol used in this study. The MSF-OCA Medical Director determined that this particular survey met the MSF Ethics Review Board's criteria exempting it from further review by the MSF ERB.

Authorities and communities (such as village heads, religious leaders, opinion makers) 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 inviting a community meeting to present the study. Community engagement shows respect to the community and should improve survey content relevance and enhance security for both survey staff and participants.

MSF-OCA commits to sharing study results with everybody who has participated in the study. The local community will be involved and informed through providing the Community Health Promotors. Results will be communicated to the community via posters at the MSF or MoH clinics. A preliminary report will be disseminated to all partner agencies within 2 weeks of completion of the study and a final report will be disseminated within 4 weeks of completion of the study. A manuscript will be submitted for journal publication within 3 months of completion of the study (if appropriate). Moreover, abstract submission for conferences/external meetings will be led by the principal investigator and based on the concept paper and protocol (if appropriate).

The MSF medical responsible in the field will advise the study team on the emergency and non-emergency referral practices when finding sick people in the study villages as well as procedure regarding psychosocial issues or victims of violence.

The Principal Investigator is overall responsible for ethical compliance of the study.

Participant privacy will be respected during the interviewing process. Staff will be trained in how to assess for appropriate conditions to help maintain confidentiality during the interview process, including choosing the optimal location when a setting makes privacy difficult (e.g. single room dwelling).

10.1. VERBAL CONSENT FORM

A verbal consent will be sought from every household, with the designated head of household answering the questionnaire for all relevant members of the household. He/she may choose to delegate answering the questionnaire to another member of the household, or to individuals regarding their own vaccination status if relevant.

[3] Council for International Organizations of Medical Sciences (CIOMS). International Ethical Guidelines for Biomedical Research Involving Human Subjects. CIOMS Geneva 2002. http://www.cioms.ch/index.php/publications/printablev3/541/view_bl/65/bioethics-and-health-policy-guidelines-and-other-normative-documents/19/international-ethical-guidelines-for-biomedical-research-involving-human-subjects?tab=getmybooksTab&is_show_data *(accessed June 29, 2017)*

[4] Council for International Organizations of Medical Sciences (CIOMS). International Ethical Guidelines for Epidemiological studies. CIOMS Geneva 2009. http://www.cioms.ch/index.php/publications/printablev3/541/view_bl/65/bioethics-and-health-policy-guidelines-and-other-normative-documents/47/international-ethical-guidelines-for-epidemiological-studies?tab=getmybooksTab&is_show_data=1*(accessed June 29, 2017)*

Privacy and confidentiality in the data collected from the participants will be ensured both during and after the conduct of the survey. Participant names will not be recorded on questionnaires, and individual person records will be linked only to a household number throughout the data entry and analysis process. Any data that could be combined with other data sources to make individual records potentially identifiable will not be distributed outside the study location, or appear in any report or publication. All participants 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 respondents. Everyone approached for the survey is completely free to participate or not.

10.2. RISKS AND BENEFITS OF THE STUDY AND CONTINGENCY PLANS

The retrospective mortality survey does not cause any physical harm to participants. Nevertheless, asking the heads of households for details of recent deaths of household members may be upsetting, relatively intrusive, and even re-traumatising. Additionally, in village contexts there may be limited privacy. Using local staff and careful training on interview-techniques can mitigate this. In addition, psychological first aid should be added to the interviewer training as well as referral procedures for cases of re-traumatisation.

There is also the risk to communities of breach of confidentiality and/or stigmatisation at community level.

However, benefits can be seen both at the study participant level and at the community level. A better understanding of the rates and causes of mortality in the area will allow better tailored programming and more efficient use of resources. Accurate data on mortality and estimates regarding causes of mortality are of tremendous importance for advocacy on national and international level.

An external threat could be unstable or worsening weather conditions such that some areas become inaccessible. This will be monitored and responded to appropriately. Similarly, insecurity might cause the survey to be delayed, interrupted or cancelled, this cannot be predicted in advance.

11. COLLABORATION

This study will be carried out in collaboration between MSF-OCA and the MoH of South Sudan.

MSF-OCA is the study sponsor and is responsible for the funding. It oversees the field part of the study, the analysis and report writing. Permission for publication must be obtained from MSF- OCA and the MoH.

Study results will belong to MSF- OCA and the MoH of South Sudan, the country where the study will be conducted.

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.
Each study team is composed of two interviewers. To finalise the field part in a reasonable time we need 4 study teams of two people each (see also chapter 12.5.).

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*
- Have no known conflict of interest, *and*
- 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 will ensure that the following tasks are performed:

- Preparation of all necessary documents (protocol, questionnaires, informed consent forms) for the study
- Secure the necessary local approvals (including that of the local ethics committee if needed)
- 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
- Ensuring ethical compliance during implementation of the study through supervision and training

12.3. SUGGESTED MSF SUPPORT IN THE FIELD

- Human resources support, for *hiring study team/interviewers.*
- Logistic support for study preparation at the field level and during field part, such as *providing communication tools and MSF ID (e. g. aprons, vests or arm bands) to the study teams, stationary and printing the questionnaires.*

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. It consists of an intensive review of the questionnaires and the information sheet including role-plays. As the interviews will be held in the national language, the principal 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 and possible final adaptation of the questionnaires and informed consent to field conditions.

A 'training' meeting will be held with associated staff such as logisticians, community liaisons, drivers and data clerks to explain the overall study and their roles and expectations.

12.5. TIMEFRAME IN THE FIELD

One day will be needed for final preparation of the study in the field, such as defining the final study area, to finalise the sampling, to discuss the start of the recall period with experienced people who know the local context, to plan the survey days, to check materials for the survey, to organise photocopies of questionnaires and further required information, to define working conditions of the selected interviewers, such as working hours, per-diem (which usually should cover food and water during the time in the villages), payment.

Training, including the pilot study, will take two day.

It is expected that on average 1 team can finish 1 cluster of 18 households in 1 day. Having 4 survey teams, it will take 5 days to finish the survey.

13. LOGISTIC

13.1. SUPPLIES NEEDED

Supplies for the conduct of the study will be purchased via the MSF-OCA base in Lokichogio in Kenya. See table 3 for a list of required supplies.

Mortality questionnaires and informed consent forms will be developed by the principal investigator. Photocopies of all necessary documents will be done in Thaker in Mayendit county. A computer record entry form will be prepared by the principal investigator.

Table 3 Supplies needed for the field part of the mortality study, MSF-OCA, Southern Unity, South Sudan, Africa, 2017

Item	No. needed per team	No. needed for 4 teams
Back pack/shoulder bag	1	4
Clipboard	1	4
Pencil	2	8
Sharpener	1	4
Pencil eraser	1	4
Aprons, vests, arm bands or similar with MSF identification / logo	2	8

Plastic folder (for protection of questionnaires against rain and dust)	3
Random number table (see annex)	1

13.2. TRANSPORT NEEDED

No transport is needed, because all villages are reachable by foot.

14. REFERENCES

[1]Duncombe J, Siddiqui R, Lenglet A, Cramond V, Dada M (2016) Baseline Health Survey in Southern Unity/Liech State, South Sudan (2016). MSF-OCA survey report.
[2]Minimum standards in health services (2004). The Sphere Project: Humanitarian Charte and Minimum Standards in Disaster Response. Oxford, UK: Oxford Publishing.
[3]Integrated Food Security Phase Classification (2017) Republic of South Sudan: Current and Projected (January-July 2017) Acute Food Insecurity Situation. Available at: http://www.ipcinfo.org/ipcinfo-detail-forms/ipcinfo-map-detail/en/c/471270/