



Retrospective mortality and baseline health survey in Ofua village, Rhino settlement camp, Uganda

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Retrospective mortality and baseline health survey in Ofua village, Rhino settlement camp, Uganda

Study protocol

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Study design Retrospective mortality and baseline health survey

Study period March-April 2017

Study site Randomly selected households within zones of Ofua village, Rhino settlement camp, Uganda

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LIST OF ABBREVIATIONS

CMR	Crude Mortality Rate
95% CI	95% confidence interval
ERB	Ethical Review Board
GAM	Global acute malnutrition
GIS	Geographic Information Systems
GPS	Global Positioning System
LLITNs	Long-Lasting Insecticide Treated bedNets
MenAfriVac	Meningococcal meningitis group A vaccine
MoH	Ministry of Health
MSF	Médecins sans Frontières
MSF-OCA	Médecins sans Frontières – Operational Centre Amsterdam
MTI	Medical Team International
MUAC	Mid Upper Arm Circumference
OCV	Oral cholera vaccine
PCV	Pneumococcal virus
SAM	Severe acute malnutrition
SGBV	Sexual and gender-based violence
SIA	Supplementary Immunization activity
SPLA	Sudan People’s Liberation Army
U5MR	Under 5 mortality rate (mortality rate in children under 5 years of age)
UNHCR	United Nations High Commission for Refugees
WHO	World Health Organisation

1. INTRODUCTION

1.1. CONTEXT

The advance of the SPLA into Equatoria in June 2016 has led to a mass influx of refugees into Uganda. Almost 700,000 South Sudanese refugees have flooded over the border into North-Western Uganda since June 2016.

The Ugandan government pursues a “settlement policy”, by which refugees are allocated plots of land that are stretched out over larger areas than conventional camps, which are designed to allow for both shelter and agricultural production. The settlements in Uganda are being designed for the clustering of household plots of 30 x 30 metres.

Rhino settlement originally opened 25 years ago, since July of 2016 they have received 66,000 new refugees, bringing the total population up to 86,118. This settlement is large, Ugandan villages are dispersed, with approximately 15,000 new refugees settling in these areas. The majority (approx. 46,000) of the refugees have been settled in Ofua to the north and west, where there has been limited service provision (Figure 1). Due to the distance to the established settlements, Ofua can be considered a separate settlement. The closest health care facility available to the population in Ofua is 13km.

Medical Teams International (MTI) and Ministry of Health are the Primary medical actors but given the scale of the emergency, MSF is now providing surge medical support.

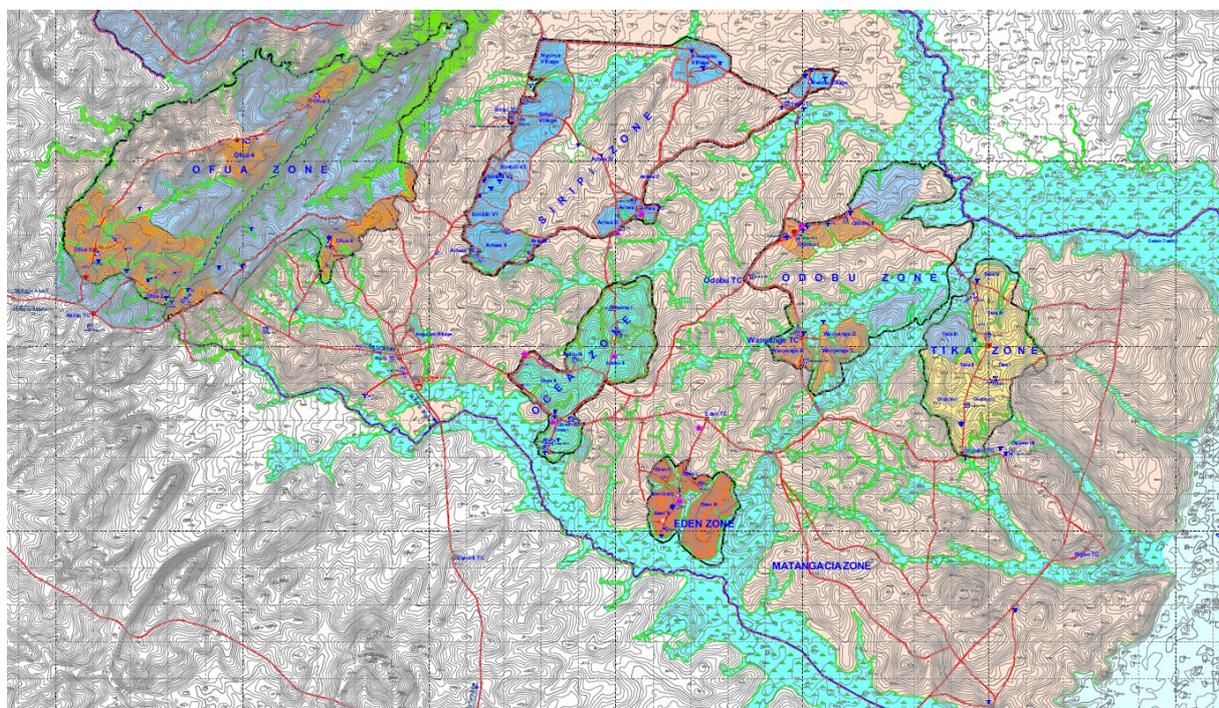


Figure 1 : Map of Rhino settlement camp, Uganda

1.2. MSF PRESENCE IN THE COUNTRY

MSF-OCA has not had a presence in Uganda since 2010.

MSF-OCA is setting up 3 health centres: in zone 3 (level 3 facility), between zones 4 and 5 (level 2) and in zone 6 (level 2), MSF-OCA is also providing surge medical support and water

and sanitation support in the most recently settled camp, Palorinya (MSF is setting up 5 clinics in Zone 1 and 3).

MSF-OCP is responding to the refugee emergency in neighbouring Bidibidi and Mvepi settlement camps.

MSF-OCG is not operational but has a supply centre in Kampala, Uganda.

1.3. BACKGROUND - JUSTIFICATION FOR THE STUDY

Due to the dynamic nature of the current crisis, which has severely restricted access to the population in this catchment area, the scale and severity of the current crisis is not clear.

There is little real-time knowledge and understanding of the health status of the populations of Rhino (Ofua). There is only clinic-based surveillance, and it is suspected that many patients arrive late or do not access health care at all due to the long distances. There is no active case finding and cases of epidemic-prone diseases and malnutrition may only be noted once they arrive in the health facility in high numbers. Community deaths may not be notified as the health facilities are only reporting hospital deaths and community health workers are not yet active in the camps. The nutritional status of the population is unclear, though health centres are not reporting concerning SAM or GAM rates.

Health risks (e.g. low vaccination rates) include:

- Meningitis: during the dry / dusty months of December to March before the first rain showers begin in the region. Mass vaccination with a single-dose conjugate vaccine against meningococcal meningitis group A vaccine (MenAfriVac), was performed in January 2017 but vaccination coverage rates are uncertain;
- Pneumonia: tends to be seen all year round, but peaks during rainy season and in conditions of overcrowding. Pentavalent and PCV vaccination rates are unknown;
- Cholera: endemic in the area and possibly imported by the refugee influx. The rainfall season starts in March and continues all the year up to November peaking in September. Most of the outbreaks in the region happen during the heavy rainfall season of July to September. Considering the poor quality and quantity of water availability, usage of water from river beds frequented for washing and drinking, the risks of an outbreak are high. OCV vaccination are likely low or non-existent.
- Measles: vaccination coverage in South Sudan is low but due to systematic measles (and polio) vaccination at the reception and transit points, the risk of a measles outbreak in Rhino is thought to be low.
- Hepatitis E: Due to poor water and sanitation conditions, large numbers of displaced populations in poor health and previous experience of a Hepatitis E outbreak in neighbouring Kitgum, the potential for a hepatitis E outbreak is high.
- Malaria: Malaria follows rainy season which begins in March in this setting. There have been some systematic bednets distributions to newly arriving population but coverage and practice is unknown; its assumed malaria rates are likely to be high during peak season.

There is an urgent need to understand the scale of the current emergency (**mortality**) and the health status of the population (**morbidity, nutrition**). In addition, the risk of epidemic-prone diseases is high so estimation of **vaccination coverage** rates for historic and recent (MenAfriVac) vaccination campaigns will help guide potential mass vaccination strategies. In addition, current **bednet coverage** needs to be estimated to guide bednet distributions. The number and capacity of health centres are limited in this setting so it's important to

understand the impact on **health-seeking behaviour** (delayed clinic visits, alternative healthcare etc).

Finally, these refugees are known to have fled a conflict in Central Equatoria, South Sudan and are likely to have experienced or have family members that experienced **violence or mortality during this period**. Similarly, violence, including sexual and gender-based violence (SGBV), may be a major issue in current camp life. An understanding of the former will support any evidence-based advocacy about the situation in Central Equatoria and the latter will guide our provision of SGBV and/or trauma services in MSF clinics.

The planned survey will help MSF-OCA to better target its medical programmes to address the major causes of morbidity and mortality in this catchment area. In addition, this survey will serve as a baseline for future surveys, which will allow us to monitor changes in the population over time, as well as to measure the impact of our interventions and to address key health issues, in Rhino (Ofua) camp.

2. OBJECTIVES

2.1. PRIMARY OBJECTIVES

To estimate the scale of the emergency through measurement of crude mortality rate for the total population and for children under five years of age

2.2. SECONDARY OBJECTIVES

- To estimate the size of the population in Rhino (Ofua) settlement camp
- To describe the population in terms of age, sex and household composition;
- To determine the coverage of measles, polio, MenAfriVac, DPT-Hib-HepB (Pentavalent) and pneumococcal virus (PCV) vaccination in 6-59 month olds;
- 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 describe the health seeking behaviour in terms of access to primary and secondary care;
- To estimate crude mortality rate for the total population and for children under five years of age before and after the SPLA advance into Equatoria, South Sudan;
- To identify major causes of death, by age group and sex;
- To gain knowledge of violence-related events
- To determine the coverage of Long-Lasting Insecticide Treated bedNets (LLITNs)

3. STUDY DESIGN

Retrospective mortality and baseline health survey using simple random sampling, a method by which households are selected by chance (random GPS coordinates within the area of interest)

4. STUDY AREA AND PERIOD

The study area will be the entire catchment area of the MSF-OCA project in Rhino (Ofua) settlement camp. 4 surveys are planned in Ofua 1 and 2; Ofua 3; Ofua 4 and 5; and Ofua 6.

The recall period will include the period from the start of the advance of the SPLA in Equatoria in July 2016 until the commencement of the survey (March 2017), approximately 270 days (see section 6.2) and should include a period in South Sudan, the journey to Uganda and a period in the Ugandan settlement.

5. STUDY POPULATION

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

Information on current population estimates is based on current UNHCR biometric registration.

The total population was 43178 on 6th March 2017.

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 section 6.1. for the definition of a household)

and

- Informed consent has been given by the head of the household (see section 6.1. for the definition of the head of household and section 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 two attempts to trace him/her

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. Information on 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 aged ≥ 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*
- 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.

6.2. RECALL PERIOD FOR REPORTED DEATHS

We will use a recall period of approximately 270 days; from July 2016, when the SPLA advance started in South Sudan, prompting displacement of Equatorian communities, until the start of the survey (March 2017). The precise beginning of the recall period will be discussed with the team in the field, considering the experience of the national staff. The end of the recall period will be the day prior to 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.

We want to include both the period before displacement and the period after, to understand the experience of the population and its impact on health. This gives us approximately 75 days (pre-displacement) and 195 days within the camp as Ofua residents arrived mid-September 2016.

7. SAMPLE SIZE AND SAMPLING

7.1. SAMPLE SIZE

Sample size was calculated with the help of "ENA for SMART 2011" software¹. Although surveys are usually powered on the primary objective, in this case, in order to be able to achieve the secondary objective of detecting significant malnutrition, the sample size was instead powered on detecting a global acute malnutrition (GAM) rate above the emergency threshold of 15% (i.e. with the lower 95% CI above 15%). An estimated number of 255 households will therefore be included per survey.

Criteria	CMR	GAM
Population	43,178	43,178
Expected crude mortality rate (CMR, per 10 000/day)	0.5	
Global acute malnutrition rate (GAM, %)		16
Precision (per 10 000/day)	0.3	

1

<http://www.nutrisurvey.de/ena2011/main.htm>

Precision (%)		5
Design effect	1	1
Recall period (days)	270	250
No. population to be sampled	790	
No. Children aged <5 years to be sampled		207
Average household size	5	5
Proportion non-response households (%)	10	10
Number of households to be surveyed (assuming average household size of five persons)	176	255

Table 1 : Criteria for sample size calculation

7.2. SAMPLING

Simple random sampling of households will be carried out using randomly-generated GPS coordinates. Using GIS or conducting a perimeter walk around the study area, an electronic outline of a village can be replicated in software such as Google earth or Epop². Using this outline, the software can create random points within this perimeter corresponding to the number of households that need to be visited inside that area. Teams using either GPS receivers or android phones with GPS localisation functionality, will visit the households that are identified to be physically closest to randomly generated GPS points and interview these households. This does create a bias as households in rural areas, with large distances between households, are more likely to be selected than households in densely packed urban areas. However in this setting where the distances are fairly similar, the bias becomes negligible.

If for unforeseen reasons a selected household cannot be visited, it will be replaced by the household at another randomly-generated GPS coordinate. This will be reported as a limitation of the survey.

8. DATA COLLECTION

Currently there is not a fully operational system of block leaders that can be informed beforehand of the survey. In the instance where consultation with block leaders cannot occur in the days prior to the start of data collection to seek permission from block leaders to conduct the survey in that location. Instead in the households randomly selected per the above methodology, the purpose of the survey will be explained to the head of the household in the language in which s/he is familiar. It will be clearly explained to the heads of households during the consent process, that they are freely allowed to decline participation without any consequences or penalty. If the head of household agrees, written consent will be obtained to conduct the interviews (see section 10.1. for details on the informed consent form). If s/he declines to participate this will be accepted, written down and the next

2

Epop population estimation software, Epicentre (v0.1.0.343 viewed 7th March 2017)

household approached; the 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 questionnaire that consists of (for example):

- Age and sex of all household members
- MUAC and Oedema assessment of those between the ages of 6m-59m
- Vaccination enquiry and viewing of vaccination cards of household members
- Movements of household members (i.e. who arrived, who left, who was born or who had died in the household during the recall period of the survey).
- Recent morbidity and health seeking behaviour among people in the household.
- Information on episode(s) of violence experienced.
- Cause and time of deaths for all deceased persons in the household.

Due to the sensitive nature of the questions concerning violence, these will be directed at the head of the household who it is assumed will have knowledge of all violent events that have been experienced by members of the household during the recall period. The aim is to interview him/her alone at that stage of the questionnaire (if the head of the household is unsure of the details, we will ask for the oral consent of the survivor to be interviewed alone if that person is aged >18 years. Anyone aged <18 years, will not be asked to provide oral consent, so it is assumed their information will not be gathered if not provided by the head of the household).

9. DATA ENTRY AND ANALYSIS

Data will be entered into EpiData by the study investigators if collected on paper forms. If collected electronically, databases will be automatically generated so EpiData will not be needed. All data will be anonymised (names are not being 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 13 (StataCorp, College Station, TX, USA).

No identifiable (name-related) data will be collected during the survey and all GPS coordinates will be destroyed; reducing the risk that participants will be identifiable after the survey has been completed. The electronic database will be password protected. The paper versions of the questionnaires (if used), ~~written consents~~ and the electronic database will be stored at the MSF-OCA 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 χ^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 departure). 95% CIs will be calculated and adjusted for the design effect.

10. ETHICAL ISSUES

The study will be conducted in accordance with the Council for International Organizations of Medical Sciences (CIOMS) International Ethical Guidelines, 2016³ and the World Medical Assembly (WMA) Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Subjects, 2013⁴ for Biomedical Research Involving Human Subjects⁵ and International Ethical Guidelines for Epidemiological Studies⁶.

This protocol will be submitted to MSF-ERB for expedited review as it complies with the standard mortality survey template that has been re-submitted to the MSF-ERB (after responding to MSF-ERB comments). It will also be presented to the local and central health authorities and UNHCR Health coordinators.

MSF-OCA commits to sharing study results with everybody who has participated in the study. The refugee community will be involved and informed through posters at the MSF clinics. The MSF medical team will decide about the best venues to display the results.

The MSF medical responsible in the field will advise the study team on the referral practices when finding sick people (for life threatening cases and information for non-emergency cases) in the study sites 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. WRITTEN ORAL CONSENT FORM

A written Oral consent will be sought from all heads of households on behalf of the household participating in the study.

3

<http://cioms.ch/ethical-guidelines-2016/WEB-CIOMS-EthicalGuidelines.pdf>

4

<http://www.wma.net/en/30publications/10policies/b3/>

5

~~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=1 [insert (accessed month dd, 20XX)]~~

6

~~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 [insert (accessed month dd, 20XX)]~~

~~All subjects-household members included in the survey~~present will have the study explained to them in a language in which they are familiar and be offered an information sheet to keep (see Appendices). Every household member will be offered the opportunity to refuse participation in the study at any time during the interview without penalty, and no incentives or inducements will be provided to respondents. Everyone is completely free to participate or not.

~~All data will remain anonymous throughout the data entry and analysis process. Identifiable data will not be distributed outside the study location, or appear in any report or publication.~~

All data will remain anonymous throughout the data entry and analysis process. Identifiable data 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 is completely free to participate or not.~~

10.2. RISKS AND BENEFITS OF THE STUDY AND CONTINGENCY PLANS

The 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 will 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. This risk will be explained to participants.

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. Benefits at the individual level include referral for medical treatment for current morbidities.

An external threat could be security issues due to an unstable context, which might result in the exclusion of some parts of the study area. This is impossible to foresee.

11. COLLABORATION

This study will be carried out in collaboration with the MoH of Uganda, who will be a co-investigator. MSF-OCA is the study sponsor and is responsible for the funding. It oversees the field component of the study, the analysis and report writing.

Study results will belong to MSF-OCA and the MoH of Uganda.

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 carry out informed consent, ensure privacy and confidentiality during the interview, decide on referral for medical or psychological reasons if needed, perform psychological first aid for cases of re-traumatisation and 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 6 study teams of two people each (see also section 12.5). All teams will work in pairs to support each other through the interview process and to ensure an efficient procedure by helping to answer questions from the household and local population, performing MUACs and verifying vaccination cards (whilst the other interviewer records the information), and by providing 'crowd management', particularly when the violence section is reached and the other interviewer requires privacy with the head of household.

General selection criteria for all interviewers:

- Able to read and write in English, and
- Fluent in one of the local languages (Bari, Atcholi, Arabic, Mari, Kiku or Pakua, *and*
- Available for the entire time of the study (training and interview days), *and*
- 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 study, *and*

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 through delegation to the field epidemiologists (study coordinators) and emergence medical coordinator:

- Preparation of all necessary documents (protocol, questionnaires, informed consent forms) for the study;
- Secure the necessary local approvals;
- 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 (if needed);
- Data analysis;
- Report writing;
- Ensuring ethical compliance during implementation of the study through supervision and training

12.3. SUGGESTED MSF SUPPORT IN THE FIELD

- Administrative support for study preparation at the field level and during field work, such as presentation of the survey protocol to the ethics committee of the MoH, payment of study teams, etc.
- Human resources support, such as hiring study team/interviewers.
- Logistics support for study preparation at the field level and during field work, such as organizing sufficient cars including drivers for the field part of the study, providing communication tools and MSF ID (e. g. aprons, vests or arm bands) to the study teams, stationary, printing the questionnaires and consent forms.

12.4. TRAINING OF THE STUDY TEAM AND PRE-TESTING OF THE QUESTIONNAIRES

Two days training will be given to all interviewers to familiarise them with the background of the study, the questionnaires, the information sheet and the informed consent form. The training will be given ~~in~~ by the study coordinator. It consists of an intensive review of the questionnaires and the information sheet including role-plays. As the interviews will be held in English, the study coordinator 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~~ end with a pilot study in households that have not been selected for the survey ~~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. The households will be informed that their interview will be used for training purposes only and that their information will not be kept. However, they will still receive protection of privacy and confidentiality, as well as referral for medical or psychological care when needed (see section 10.2).

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

A preliminary plan of the field part of the study is indicated in **Table 2**

Date [2017]	Day	Days	To do
07-15 March	<i>Wed-Wed</i>	8	Final preparation of the study
16-18 March	<i>Thurs-Sat</i>	3	Field work, including training and pilot testing
20-25 March	<i>Mon-Sat</i>	6	2 surveys in parallel (Ofua 1 and 2; Ofua 3)
27 March-1 April	<i>Mon-Sat</i>	6	2 surveys in parallel (Ofua 4 and 5; Ofua 6)
3-8 April	<i>Mon-Sat</i>	6	Data analysis/initial report
		Total: 29 days	

Table 2 : Preliminary plan for the field component of the survey

13. LOGISTIC

13.1. SUPPLIES NEEDED

Supplies for the conduct of the study will be purchased via the Uganda mission (Table 3).

Mortality questionnaires and informed consent forms will be developed by the principal investigator. Photocopies of all necessary documents will be done in Kampala, Uganda.

A computer record entry form will be prepared by the principal investigator.

Item	No. needed per team	No. needed for 6 teams
Back pack/shoulder bag	1	6
Clipboard	2	12
Pencil	3	18
Rubber	2	12
Sharpener	2	12

Aprons, vests, arm bands or similar with MSF identification / logo	2	12
Plastic folder (for protection of questionnaires against rain and dust)	3	18
MUAC strips	1	6
Height stick (65cm, 110cm)	1	6
Referral slips	20	120
Raincoat	1	6
Gumboots (pair)	1	6
Sunhat	1	6
SMARTPHONE/TABLET (if electronic platform used)	1	3

Table 3 : Supplies needed for the field part of the survey

13.2. TRANSPORT NEEDED

At each site: 1 car, 1 driver, fuel. We may need to consider motorcycles to ensure teams reach all required households (each team must interview ~14 households per day)