Malnutrition, morbidity and vaccination coverage in Bokoro District, Chad, 2016 (Final Survey).

Survey protocol 1613C

Study Summary Table

Study design	Cross sectional population survey (s)
Study period	Baseline survey March-April 2016 Follow up survey July 2016 Final survey October-December 2016
Study site	Randomly selected villages within Bokoro district, Chad
Principal investigator	Annick Lenglet Epidemiology Advisor, MSF-OCA Email: Annick.lenglet@amsterdam.msf.org
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Collaborating institutions	Ministry of Health of Chad

1 LIST OF ABBREVIATIONS

CMR	Crude Mortality Rate
95% CI	95% confidence interval
IPTp	Intermittent preventive treatment in pregnancy
IPV	Intramuscular Polio Vaccine
MoH	Ministry of Health
MSF	Médecins sans Frontières
MSF-OCA	Médecins sans Frontières – Operational Centre Amsterdam
OPV	Oral Polio Vaccine
Penta	Pentavalent vaccine which include diphtheria, pertussis, tetanus, Hemophilus influenza, hepatitis B
U5MR	Under 5 mortality rate (mortality rate in children under 5 years of age)
WHO	World Health Organization

2 INTRODUCTION

2.1 CONTEXT

Every year, the Chadian regions in the Sahel belt faces nutrition crises during hunger period from June to September. In 2015, it was estimated that about 2.4 million people would face food insecurity, around 428,000 people would be in severe food insecurity and 350,000 children would likely develop malnutrition, of would be 96,000 will be severe acute malnutrition (SAM).

Bokoro district (Figure 1) is among the 15 Health Districts of Chad that was the most affected during 2015 by the nutritional crisis. There are multiple causes of the recurrent nutrition crisis, and the contribution of specific underlying causes of recurrent malnutrition in Bokoro is not clear.

Figure 1: Map of Bokoro District, Chad, with district circled.[1]

[1] Source: http://web.archive.org/web/20071010023828/http://www.un.org/Depts/Cartographic/map/profile/chad.pdf

2.2 BACKGROUND

The underlying causes for malnutrition have been summarised in a conceptual framework by UNICEF (http://www.unicef.org/nutrition/training/2.5/8.html), this includes household food insecurity, inadequate care, an unhealthy household environment (poor water, sanitation, shelter etc.) and a lack of access to health services (and high prevalence of disease). Addressing chronic malnutrition therefore requires a comprehensive approach to the problem through addressing food insecurity, access to safe drinking water, sanitation, vaccination, health services and treatment, prevention of malaria etc.

2.3 MSF IN BOKORO DISTRICT

Médecins Sans Frontières OCA (MSF-OCA) has intervened in Bokoro District in Chad in four consecutive years with emergency feeding programs to address the high rates of severe acute malnutrition (SAM). These activities resulted in the implementation of Ambulatory Feeding Centres (ATFCs) and Inpatient Feeding Centres (ITFCs) to also address the co-morbidities in several malnourished children.

For 2016 it is envisioned to try and address the malnutrition cycle in a more comprehensive and preventative way in Bokoro District in collaboration with the Ministry of Health and UNICEF. It is anticipated that by investing more in prevention and improving water and sanitation for households and basic health care for mothers and children in the District we will have a more profound impact on the malnutrition cycle in the district. Additionally, this approach will aim to better understand the underlying causes of malnutrition from an anthropological perspective.

2.4 JUSTIFICATION FOR THE SURVEY

As part of the efforts to monitor and measure the impact of the preventative approach for malnutrition in Bokoro District, different sources of information will be used. Routine reporting from the MSF-OCA supported health facilities and therapeutic feeding centers will be used to monitor trends for morbidities and malnutrition in the District. Tally sheets around specific distribution campaigns (hygiene kits, food distribution, mosquito net distribution etc.) and vaccination activities will be compiled to understand the scale of activities in the population for disease and malnutrition prevention. Finally we envision conducting three cross sectional surveys: one as a baseline, a second in the peak period of the likely hunger gap and a final survey, to try and measure to some extent the impact of the program on the population. This survey protocol focuses on the final survey.

3 OBJECTIVES

3.1 PRIMARY OBJECTIVES

To estimate the impact of an integrated program targeted at preventing malnutrition on children under 5 years of age in Bokoro district.

3.2 SECONDARY OBJECTIVES

- To describe the population in terms of age breakdown, sex, household composition etc.
- To estimate overall mortality rate and under 5 mortality rate
- To estimate the prevalence of severe and global acute malnutrition (SAM and GAM) in the under 5 year age group and in children between 6 and 23 months that are the specific target of MSF prevention activities;

- To estimate the coverage of insecticide treated bednets in the community;
- To estimate the coverage of soap and hygiene practices in the community
- To estimate coverage of plumpydoz (nutritional food) in children between 6 months and 2 years of age and to investigate practices around plumpydoz.

4 METHODS

4.1 STUDY DESIGN

We will conduct three cross-population surveys throughout the year 2016. The sampling strategy will involve two-stage cluster sampling.

4.2 STUDY AREA, POPULATION AND PERIOD

The study area will include the whole of Bokoro district which is accessible within MSF-OCA security regulations. The estimated target population includes 84,000 children under the age of 5 years based on a comprehensive population count conducted in early 2016.

This final survey will be implemented in November-December 2016. This will be approximately one month after the final round of distributions for 2016.

4.3 INCLUSION AND EXCLUSION CRITERIA

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

- Living in the randomly selected household

and

- Informed consent has been given by the head of the household

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

4.4 DEFINITIONS

Definition of household

A household will be defined as a group of people who were under the responsibility of one person or head of household during the previous six months. 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 or caretaker

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 according to the household definition and is present at the moment of the study or slept in the house the previous evening.

4.5 RECALL PERIOD FOR REPORTED DEATHS

As part of the survey we envision to ask questions around deaths in the household in a specific recall period in order to be able to calculate crude mortality rates (CMRs) and under-5-mortality rates (U5MR). The recall period will probably be adjusted for each of the three surveys, but we aim to have a 3 month recall period for this final survey.

The precise date for recall will be discussed with the team in the field, especially taking into account 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 in order to determine more accurately the dates the deaths occurred.

4.6 SAMPLE SIZE

Due to the sheer number of outcome indicators we will be measuring in this survey, we need to ensure that the sample size will be large enough in order to accommodate each of these. Different calculations for sample size were done using the different assumptions, these are shown below. All calculations were done with OpenEpi or with ENA for SMART.

1) **Prevalence of GAM in children <2 years of age:**
    - Estimated prevalence of 8.6%
    - Precision of 3.5%
    - Design effect=2, alpha error: 5%
    - Required number of children =493
    - 0.78 children below the age of 2 years per HH.
    - Total 632 households to cover the initial calculated sample size of 493;
    - Assuming a non-response rate of 20% for the anthropometric measures, we need to include 790 households in this survey for this specific outcome indicator.

2) **Coverage of plumpydoz in children between 6 and 24 months of age**:
    - Estimated 75% coverage of plumpydoz in children between 6-24 months of age;
    - Precision in the estimation ±5%
    - Design effect=2.5; alpha error: 5%
    - Required number of children = 571 children in that age group;
    - Assuming 0.78 children of this age group per household as per the last population count conducted by MSF
    - Therefore 732.1 households

- Adding a 3% due to non-responses
- Total sample size of 805 Households.

3) Crude mortality rate

- Estimated CMR= 0.6 /10,000 persons/day;
- Precision=0.3; design effect: 2 (likely deaths are more clustered); recall period of 112 days); alfa error 5%.
- Required number of persons required= 4979 persons.
- Assuming average household size of 6.4 with 3% non-response, total de 802 households.

Based on these calculations we assume that a total household sample of 800 households will be adequate to detect the main outcomes of interest with sufficient power and precision. We will achieve this sample size by 40 clusters of 20 HH each.

4.7 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, 40 clusters will be selected from all villages situated in the study area. Cluster allocation will by systematic sampling with probability of allocation proportional to the respective population size of each village (probability proportional to size or PPS). The population data used for this purpose is based on the comprehensive population count that was implemented by the MSF team in Bokoro in early 2016.

Once the village has been selected as a cluster, the household selection in that village using simple random sampling from a comprehensive household list (that was constructed during the MSF population count in early 2016).

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 for sampling of households will again be used in the closest village to select the first household in the village.

4.8 DATA COLLECTION

Selected villages (=clusters) according to the sampling will be informed before the survey teams will visit them. This will be done by sending official communications to the heads of the selected villages several weeks prior to the survey using the Community Health Workers (CHW) system. The CHWs

[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

report to the Chief Medical Officer for the survey who is well informed of the survey plans and has agreed to do this information sharing with the heads of the village in the selected survey clusters.

Also, the heads of the villages will be visited by the survey teams the day of the survey and the purpose of the study will be explained 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 it 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 purpose of the survey will be explained to the head of the household in the language he or she is familiar with and written consent obtained to conduct the interviews. If they decline to participate this will be accepted, written down and the next 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 household and individual questionnaire that consists of the following sections:

- Demographic breakdown of the households, including births, deaths (and cause), incoming and outgoing members;
- Prevalence of malnutrition in children <5 years in the household (measured by MUAC);
- Height as measured by a measuring board;
- Prevalence of self-reported morbidities (fever, diarrhea, cough etc.) in children <5 years in the household in the previous two weeks;
- Coverage of MSF therapeutic programs;
- Coverage of MSF distribution of preventive Plumpydoz and utilization practices;
- The ownership of mosquito nets and quality of nets in the households;
- The ownership of soap and hygiene practices

The questionnaires to be used are shown in Annex 1 and Annex 2.

4.9 DATA ENTRY AND ANALYSIS

Data entry will be done by transcribing paper questionnaires into pre-established Epi Data Entry masks for an electronic database. 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 Excel, ENA for SMART and STATA12.

No name-related data will be collected during the survey; therefore no participants will be identifiable after the survey has been completed. 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 reported. Where appropriate, differences in proportions will be measured using Pearson $\chi 2$ test and p-value (p) will be presented. Mortality rates will be calculated as numbers of deaths/10,000 persons/day, using the precise person-day contribution of all persons enrolled in the survey. Confidence intervals (95%CI) around all appropriate outcomes will be calculated as well as the design effect in the sample.

5 ETHICAL ISSUES

The study will be conducted in accordance with the World Medical Assembly (WMA) Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Subjects[3].

The original protocol 1613 was submitted and approved by the MSF ERB and the Chadian MOH in April 2016. This original protocol approved the completion of three surveys under one heading.

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 (Annex 4). Household heads will also receive an information sheet about the surveys with contact details of the field epidemiologist in case they would like to ask questions after study teams have left the relevant village (Annex 5).

MSF-OCA commits to sharing study results with everybody who has participated in the study. The MSF medical team will decide about the best venues to display the results to the communities that were involved in the survey.

The MSF medical responsible in the field will advise the study team on the referral practices when finding sick people in the study villages. As several of the questions in the survey might be considered intrusive or might elicit emotional reactions in persons responding to the questions, all the teams will be trained on psychological first aid so as to be able to respond calmly and adequately if such a situation were to present itself.

5.1 WRITTEN CONSENT

A written consent will be sought from all heads of households/caretakers participating in the study (Annex 3). As literacy levels are known to be low in this part of Chad, verbal consent will also be accepted and will be recorded by the interviewer conducting the survey.

All data will remain anonymous throughout the data entry and analysis process. Identifiable data (i.e. village name and household lists used for sampling) will not be distributed outside the study location, or appear in any report or publication. All subjects included in the surveys will have the investigations explained to them in a language with which they are familiar. Everyone will be offered the opportunity to refuse participation in the study at any time without penalty and no incentives or inducements will be provided to any respondents. Everyone is completely free to participate or not.

5.2 RISKS AND BENEFITS OF THE STUDY AND CONTINGENCY PLANS

This survey is a snapshots of the status of the population addressing key indicators that the MSF programme in Bokoro is trying to address. This will provide crucial information on where the programme is possibly challenged to have an impact and will better direct the targeting of certain activities in future months and years.

There are no direct risks to the population anticipated from this survey. This survey might however highlight not only failings or limitations of MSF activities, but also of other actors and stakeholders in the area. As the results should be used for direct and immediate advocacy, this might strain relationships between MSF and the other stakeholders.

6 COLLABORATION

This survey will be carried out in collaboration between MSF-OCA and to the extent possible with the national and district level Ministry of Health representatives.

[3] [http://www.wma.net/en/30publications/10policies/b3/]

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 MoH.

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

7 IMPLEMENTATION OF THE STUDY IN THE FIELD

7.1 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 6 study teams of two people each which will be divided in two working groups covering different villages.

We anticipate that each survey will take around 25-30 min to complete, and with a group of 6 teams we aim to complete an average of 5 clusters per day. Depending on distances etc. we aim for a total 10 days of field work. All interviewers will be recruited in Bokoro.

General selection criteria for all interviewers:

- Able to read and write in French;
- Able to communicate in French and Arabic;
- 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, and
- Motivated to participate in the study, *and*
- Not biased in expectations of the outcome of the study (i.e. has not previously worked in plumpydoz distributions or vaccination campaigns)
- Experience with interviews in difficult settings and study populations would be an advantage

7.2 SUPERVISION

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

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

Preparation of all necessary documents (protocol, questionnaires, informed consent forms) for the study

- Preparation of the field component of the study (training of the study teams, logistics, materials) together with the MSF team in the field
- Follow-up of the field component of the study
- Data entry
- Data analysis
- Report writing

7.3 SUGGESTED MSF SUPPORT IN THE FIELD

- Administrative and human resource support for study preparation at the field level and during field part, such as ensuring all HR issues are taken care of (facilitating recruitment of

staff, making contracts, explaining rules and regulation to interview teams, paying salaries etc.).

- Logistic support for study preparation at the field level and during field part, this will include: facilitating planning of survey team movements, ensuring drivers are familiar with all security rules, training interview teams on security guidelines, ensuring cars are in good condition for movement (fuel, water etc.), and maintaining overall vision on all survey team movements together with the field epidemiologist. Also, it would be appreciated that logistics facilitate the purchasing of materials for the interview teams, including the making of photocopies etc.

7.4 TRAINING OF THE STUDY TEAM AND PRE-TESTING OF THE QUESTIONNAIRES

Three to four days training will be given to all interviewers to familiarise them with the background of the study, the questionnaires, the anthropometric measures, the information sheet and the informed consent form. The training will be given in French by the field epidemiologist. It consists of an intensive review of the questionnaires, techniques for using measuring tables and MUAC bands, and the information sheet including practices and role-plays. As the interviews will be held in the national language, the field epidemiologist should ensure that all interviewers are using the same and correct wording for providing information to the households and for the interviews.

The 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.

8 LOGISTICAL ISSUES

8.1 SUPPLIES NEEDED

Supplies for the study will be purchased in Ndjamena. Informed consent forms have been developed (Annex 3) and these will be photocopied in Ndjamena or Bokoro prior to the survey.

8.2 TRANSPORT NEEDED

It is envisioned that at least 2 cars will be required for the duration of the survey.

All teams will follow Bokoro project security guidelines. Villages to be visited might have to be adapted at the last minute if security constraints deem this necessary.

9 ANNEX

9.1 ANNEX 1: HOUSEHOLD QUESTIONNAIRE

9.2 ANNEX 2: INDIVIDUAL QUESTIONNAIRE

9.3 ANNEX 3: CONSENT FORM

9.4 ANNEX 4: INFORMATION SHEET VILLAGE

9.5 ANNEX 5: INFORMATION SHEET HEAD OF HOUSEHOLD