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**Countrywide Mortality Surveillance for Action
(COMSA) – Mozambique
(Formative research)**

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ABSTRACT

The Countrywide Mortality Surveillance for Action (COMSA) investment, funded by the Bill & Melinda Gates Foundation, aims to address the measurement and monitoring challenges by supporting Mozambique to develop and implement an approach of sample registration system (SRS) of pregnancies, births, and deaths, with cause of death assessment in the total population.

The COMSA will implement a stratified systematic random sampling with probability proportionate to size (PPS) to select 700 clusters in the eleven provinces of Mozambique. We aim to collect data on pregnancies, birth outcomes (pregnancy loss, stillbirths and births), deaths and their causes determined using the verbal autopsy method. A cluster will be represented by a census enumeration area (EA) or group of EAs of about 300 households.

Prior to starting the implementation of the SRS, a formative research will be carried out in purposively selected provinces of the country to learn about existing platform or structure for pregnancies, births and deaths identification and reporting, the cultural contexts of reporting of these events and feasible strategies for complete identification of reporting of these events. It will also assess community's interest in learning about major causes of deaths and acceptability of verbal and social autopsy interviews. The current document lays out methods and expected results of this qualitative study.

Key words: *Pregnancies. Births. Deaths. Cause of death. Sample registration system. Mozambique.*

1. Introduction

Mozambique is one of the few countries in sub-Saharan Africa that has met the Millennium Development Goal (MDG) four by reducing its -under-five mortality rates (U5MR) by over two-thirds that was estimated at 79 deaths per 1000 live births in 2015. Reaching the newly set target under the Sustainable Development Goals (SDG) of U5MR at least as low as 25 by 2030 will require greater efforts in health program strategies but also precise, accurate and timely measurement of mortality and cause of death to inform these programs. Similar to most low-income countries, Mozambique does not currently have a functioning civil registration and vital statistics (CRVS) system that is able to produce complete and high quality mortality data for monitoring recent trends in mortality and cause of death. Mozambique currently relies on national household surveys such as the Demographic and Health Surveys (DHS) and the Multiple Indicator Cluster Surveys (MICS) to measure mortality but these sources are not able to generate recent and timely mortality data. For example, in DHS and MICS, child mortality estimates are calculated on the past five years preceding the survey for national level estimates and on the past ten years for provincial level estimates. These rates are not reflective of recent program implementation effects. Furthermore, the surveys do not produce estimate beyond provincial levels. Innovative approaches are urgently needed to support countries to effectively monitor levels and trends in mortality as well as cause of death.

With support from the Bill & Melinda Gates Foundation, the Institute for International Programs at Johns Hopkins University (in Baltimore, USA) is collaborating with the Mozambique National Institute of Statistics (INE) and the National Institute of Health (INS) to implement the Country Mortality Surveillance for Action (COMSA). The COMSA investment aims to address the mortality and causes of death measurement and monitoring challenges by supporting Mozambique to develop and implement an approach of sample registration system (SRS) of pregnancies, births, and deaths, with cause of death assessment in the total population using verbal autopsy.

Prior to starting the implementation of the SRS, a formative research will be carried out in purposively selected provinces of the country to learn about existing platform or structure for pregnancies, births and deaths identification and reporting, the cultural contexts of reporting of

these events and feasible strategies for complete identification of reporting of these events. It will also assess community's interest in learning about major causes of deaths and acceptability of verbal and social autopsy interviews. INE/INS will identify a qualified social scientist and qualitative data collectors to carry out activities and produce the final report.

2. Objective

The main objective of the qualitative formative research is to provide the information needed to develop clear and effective procedures for identifying and recording of vital events (pregnancies, births outcomes, and deaths) by community surveillance assistants in their communities, and carrying out verbal and social autopsy interviews for cause of death determination. More specifically, the formative research will help learn about the following:

- Existing community approaches, structures or platforms of identification and recording of pregnancies, births, and deaths (e.g. village registers held by community chiefs)
- Acceptable and culturally sensitive strategies for pregnancy surveillance, including collection of gestation age and birth weights (In general women may be reluctant to show or talk about their pregnancy during the first months. What is culturally acceptable for the population and how to get women and their partner to disclose the pregnancy?)
- Perception by the community of the value of mortality and cause of death surveillance and their acceptability of the verbal and social autopsy approaches
- Recommendation for effective strategies for identifying and reporting pregnancies, births, and deaths, including existing community resource persons capable of serving as community surveillance assistants and key informants
- Strategies for engaging community buy-in and participation for effective mortality and cause of death surveillance (How to approach the population to collect events? What are the desired/required criteria for the CSA to collect the data?)

3. Methodology

3.1. *Implement a formative research to document procedures for identifying and recording of vital events*

A qualitative formative research will be carried out in selected communities learn about existing community structures and platforms that can facilitate implementation of the mortality surveillance and how to engage the communities to increase buy-in and active participation. The formative research will also collect data from selected national, regional and district level government personnel as well as community leaders on appropriate incentive structures, likely person to appoint as community surveillance focal point and key community informants that can support the identification of events such as pregnancies, births, and deaths. We expect the formative study to be opportunistic, building on existing information from government or existing partners, rather than duplicating efforts. We will work with government counterparts to identify at least three regions across the country, within which communities will be selected for the study. The formative study is expected to be completed within the first six months of onset of the project, with preliminary results available for discussion with the government and its partners to inform the design of the SRS.

3.2. *Sample size for the qualitative formative research*

The goal of sampling in this qualitative work is to systematically identify and seek out the full range of responses from each group of respondents, not to recruit a representative sample. The sample size is therefore not predetermined, but instead is defined as the study proceeds and the investigators learn more about alternative perspectives on the study questions. However, the plan is to conduct semi-structured interviews at the national, provincial and district levels, and focus group discussions with women at the community level. Sample size in table 1 below is indicative and may be modified as the study proceeds to ensure most pertinent information is collected.

Table 1: Study participants, type of data collection and indicative sample size

Participants	Type of data collection	Selection	Total sample size
National, provincial and district health officials; Government staff involved in CRVS	Individual semi-structured interviews	3 national, 6 provincial (2 per province), 9 district level (3 per province)	18
Community and local leaders, key informants, existing community	Individual semi-structured	In each community: 2 local leaders; 2 key informants; 1	72

health workers/community volunteers, women of reproductive age	interviews	existing community health worker/community volunteer, 3 women of reproductive age (total 24 interviews in each province)	
Mothers of young children living in study community	Focus group discussion	1 FGD with 8-10 women in each community (9 FGD in total)	90
Women of reproductive age with no children	Focus group discussion	1 FGD with 8-10 women in each community (9 FGD in total)	90
Fathers of young children	Focus group discussion	1 FGD with 8-10 women in each community (9 FGD in total)	90
Total potential sample size of study participants			360

3.3. Study population and eligibility

The formative study will be carried out in three provinces, ideally distributed across the country and culturally diverse (1 in the south, 1 in the center and 1 in the Northern provinces). Zambézia Province, in the Central region, has been chosen for its high population density precisely different of Niassa the least populated province in the country and that was chosen for the North region. In the South Gaza is the selected province due to the number of health facilities present. Within each province, at least three communities will be purposively identified with the help from local provincial INE and MISAU staff. INE will determine the final list of study communities in collaboration with INS and DNPS.

Focus group discussions will be held with mothers of young children, and women of reproductive age with no children, and fathers of young children, and semi-structured interviews will be carried out with community key informants, leaders, and selected women of reproductive age. The formative research will also collect data from selected national, provincial and district level government personnel on appropriate person to appoint as community surveillance focal point and key community informants that can support the identification and reporting of events such as pregnancies, births, and deaths, potential barriers to the surveillance and how these can be addressed.

Table 2 below describes the study participants in the formative research and the criteria for selection.

Table 2: Potential study participants

Participant	Selection	Enrollment
National, provincial and district health officials; Government staff involved in CRVS	Purposively sampled/invited to participate based on work position (e.g. Head of DNSP or Community Health at MISAU, Head of Provincial Health; District Health Officers, CRVS officers)	Contacted via official letter from the INE/INS about the study; meeting times set up in person or via telephone.
Community and local leaders, key informants, existing community health workers / community volunteers	All leaders in the selected communities will be identified and invited to participate in the study. A snow-ball sampling technique may be used, where a participant may refer the study team to key informants.	Contacted via in-person visit from the study team, with potential for advanced notice of visit from INE or study team where possible.
Mothers young children, and women of reproductive age with no children, fathers of young children living in study community	Identified with help from community leaders as residing in the community	Contacted via in-person visit from the study team

3.4. Procedures

A. Recruitment Process

A social scientist and four qualitative data collectors will carry out the formative research. When they arrive in the community, they will inform the community leaders and officials and seek help from them to identify women and fathers to invite them to participate either in semi-structured interview or focus group discussion. In all cases, oral informed consent will be obtained from the study participants before start of interview. The consent forms, written in Portuguese will be translated to the local language on the spot.

B. Consent Process

An experienced social scientist and qualitative data collectors will obtain oral consents from study participants before enrolling them in the study.

National level officials will be contacted via phone or email (script attached) to request an appointment at their office. The consent discussion will occur at their office, immediately before the interview. For semi-structured interviews and focus group discussions, the consent discussion will occur at community level during recruitment of the respondent. The local community leaders will help identify community women and fathers within the community for the semi-structured and focus group discussion.

National level respondents will be selected based on their position within the Ministry of Health. For community members participating in focus group discussion, specific screening questions will be asked based on the composition of the group. For example, for mothers with young children, question on whether the respondent currently has any young child, preferably under age five. Similar question will be asked to fathers. For other members participating in semi-structured interview, there is no specific eligibility questions except that the respondent selected must not be minor and visibly of reproductive age.

C. Study Implementation

This study is entirely qualitative, consisting of semi-structured interviews and focus group discussions. Data will be collected in selected three communities (1 urban and 2 rural) in each of three identified provinces of Gaza, Niassa and Zambezia. Within each province, health officials will help select the communities to survey. All selection must be conducted prior to data collection. Where feasible, advanced notice will be given to provincial and community leaders prior to visits for data collection.

At each study province level, data collectors will introduce the study to INE and health officials and work with them identify relevant persons to select for the semi-structured interview. Consent will be obtained from the selected persons via phone call and interview time scheduled. The chief/leader of selected study communities will also be notified and asked to help with selection of key informants for semi-structured interviews and groups of women for the focus group discussion.

Both semi-structured interviews and focus group discussions will be conducted by social scientists, recruited by INE/INS who have participated in training and practice sessions. For FGD, a single team of at least two data collectors will conduct the interview. Team members must be fluent in the local the local language of the areas to be visited.

Semi-structured interviews and FDGs will be conducted using written guidelines based on the study questions and will be audio-taped. Data collectors will also take notes during the interviews. Summaries of each interview and FDG will be prepared within 24 hours using standardized forms. Each page of the raw data will be labeled with a unique identifier that allows a link to the individual providing the information.

Participants will be contacted only once during active data collection. The overall study will table 4 months. However active data collection is expected to take only one month.

3.5. *Data analysis*

Completed summary forms for each interview and FGD will be reviewed by the study team (assistant researcher and field assistants) within 24 hours of data collection. Any gaps or inaccuracies will be noted and corrected. The forms will then be given to senior Social Scientist, who will conduct a second review for completeness and legibility. The forms will then be entered into appropriate data registry for the study and organized for analysis.

Descriptive analysis will focus on listing the range of answers provided to each of the study questions – in detail and summarized by themes – for each type of respondent. Content analysis will be used to identify key themes. The thematic qualitative analysis will be carried out to respond to each study question.

3.6. Data management

A Data Access Policy has been developed and agreed upon with the INE and the Sponsor. Data stored on secured server will be accessed by INE data managers. They will review and analyze to calculate basic tallies and summary indicators. These will then be published on a public website for access to wider audience. The data access plan provides details on each step of the data sharing, access, storage and data confidentiality.

4. Archive

All relevant documents of the COMSA project will be stored in an appropriate place at INE. Only competent and authorized personnel will have access to the documents. After data collection, all pilot-related documents will be stored and maintained up to one (1) year after the publication of the results. All COMSA-related documents will be placed in a locked archive whose keys are accessible only to authorized investigators and personnel.

5. Ethical considerations

COMSA will follow ethical principles as outlined in the declaration of Helsinki and its revisions (last in 2013) and will be performed in compliance with the guidelines of Good Clinical Practice and Good Clinical Data Management Practice. All essential documents will be archived for 3 years. All information will be treated in a strictly confidential manner and will be linked to a unique ID number and not to personal identifiers.

5.1. Ethical review

This protocol will be reviewed by the INS Review Board (*Comité Institucional de Bioética para Saúde, CIBS-INS*) and by the Johns Hopkins University prior to implementation.

5.2. *Informed consent*

For all data collection, an oral consent process will be used given the low level of literacy of the population. In addition, oral consent will put respondents at ease to provide accurate responses and not fear any repercussion from information they provide, thus increase the accuracy of the study. This will allow encouraging the buy-in of the project by the population. The consent information will be programmed on the phone or tablet of data collector and will be read it to the participant, in Portuguese or local language, before any data collection. If the participant consents to participate, the interview will begin and if not, the interview will end. Reasons for refusal to participate to the study will be asked in order to improve the implementation procedures.

No witness will be needed for the consent process. This will guarantee privacy and confidentiality on information provided and put the respondent at ease.

No minor will be enrolled into the study.

An experienced social scientist and qualitative data collectors will obtain oral consents from study participants before enrolling them in the study.

5.3. *Compensation*

The participation in this study will not require any kind of payment and respondents will not obtain any compensation for providing information regarding the pregnancy, birth outcome, death or cause of death.

6. *Limitations*

Due to logistic limitations the formative research can only be performed in 3 of the 11 provinces of Mozambique. To overcome this limitation the formative research will be implemented in rural and urban settings in each of the provinces in order to capture different realities and scenarios.

Because the results from this formative research is crucial for the implementation of COMSA project there is limited time to collect information.

7. *Dissemination of results*

COMSA results will be disseminated through different channels:

1. Public available - online (COMSA, INE, National Health Observatory)

COMSA data regularly processed, cleaned, de-identified and published on web based portal for public access. A link to access to COMSA results will be displayed at the INE, MISAU, INS websites.

2. National and international meetings and conferences

INE will delegate coordination roles to the MOH and INS to convene regularly national stakeholders for review and dissemination of findings from COMSA. The team will prepare and share technical materials (reports, flyers, etc) and presentations required for meetings such as National Advisory Committee Meeting, National Stakeholders' meeting or other government technical functions.

The COMSA technical team will identify relevant scientific meetings (e.g. Meeting of the International Union for Scientific Study of Populations (IUSSP), the Population Association of America (PAA), the Union for African Population Studies (UAPS) and others) to prepare abstract for submission at these meetings.

3. Scientific papers

The COMSA will write results for publication in peer-review journals with in-country investigators leading as first authors on key publications or included as co-authors.