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Countrywide Mortality Surveillance for Action (COMSA) – Mozambique

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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.

Data analysis will include a statistical plan to generate annually-updated, geographically-specific, cause-specific mortality rates using more refined advanced Bayesian modelling. The approach to estimating age and cause-specific mortality is to estimate:

(1) *all-cause mortality*: the spatial-temporal distribution of under-5, infant, and neo-natal mortality, focusing on year x region values for each age category;

(2) *cause of death*: the fraction of total deaths attributable to each of the 3 top causes: pneumonia, malaria, prematurity or other causes (4 categories).

Over a period of three years, we aim to achieve the following outcomes:

(a) A sustainable and country owned sample registration system (SRS) for mortality and cause of death surveillance enabling national and subnational comparison leading to action,

(b) improvements in measurement of causes of death through implementation of hospital mortality surveillance to validate and improve verbal autopsy-based cause of death,

(c) annual national and subnational mortality and cause-specific rates generated using directly the SRS data but also through sound statistical modelling, combining data from the SRS and other available national surveys such as DHS and MICS leading to production of subnational distribution of mortality burden that is used for action,

(d) a sustainable system for mortality and cause of death data collection, analysis and use in place in Mozambique by the end of the three-year project, owned and run by the government, generating frequent national and subnational mortality and cause specific rates that responds to government's and partners' needs for program, policy planning, and resource allocation.

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

1. Introduction

Mozambique is one of the few countries in sub-Sahara 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.

2. Objective

The project aims to establish a Countrywide Mortality Surveillance for Action (COMSA) in Mozambique consisting of a nationwide sample registration system to record pregnancies, births and deaths; verbal and social autopsy (VASA) of deaths identified; hospital mortality surveillance to complement the cause of death determination from the VASA.

3. Methodology

3.1. *Design*

1. Implement a countrywide SRS to track mortality and causes of death nationally and sub-nationally

a) Sampling of SRS Clusters

A representative nationwide sample of clusters for routine surveillance of pregnancies, birth outcomes (pregnancy loss, stillbirth, birth) and deaths will be set up. A cluster will be represented by a census enumeration area (EA) or group of EAs of about 300 households. The cartography database from the 2007 population and housing census will be used as sampling frame for random selection of the SRS clusters. An appropriate technique will be used to arrange the frame such as to create clusters of 300 households (in some cases by combining adjacent EAs). The SRS EAs will be drawn randomly to ensure representativeness at regional level and national level. We will consult with international sampling experts to design an optimal random sampling of SRS EAs that responds to these needs, while ensuring tradeoff between precision, feasibility, and cost. We will aim to implement a stratified systematic random sampling with probability proportionate to size (PPS). The provinces will represent the strata, and we will distinguish urban areas from rural. The allocation of SRS EAs to urban and rural areas will be determined by the distribution of the population by urban-rural residence obtained from the 2011 Mozambique Demographic and Health Survey. However, we do not aim to produce precise mortality estimates by urban and rural within each province.

b) Pregnancies, births, and deaths surveillance

In each SRS EA, a Community Surveillance Assistant (CSA) will be appointed to carry out the surveillance of the community to identify pregnancies, births, and deaths, and collect required information on a smartphone provided for this purpose. These events will be collected from the resident population, excluding visitors. The data will be uploaded in real-time to a secure cloud based server. We will work with each community to appoint an appropriate person who meets minimum criteria while also receiving full endorsement from the community leaders. The CSA may be an existing worker, volunteer or government community worker who has time to take on the SRS responsibility. He or she will receive a monthly salary from the COMSA project. The CSAs will be responsible for conducting monthly or bimonthly household visits to identify vital events, including pregnancies. During their initial household visits, they will list all member of each household along with limited demographic characteristics (sex, age and marital status) to

help establish the baseline population of the SRS EA. In each SRS EA, key informants such as chiefs, religious leaders, community representatives, birth attendants, health professionals will be identified and invited to support the CSAs in the identification of vital events. For pregnancies identified, data will be collected on gestational age or expected day of delivery. Each month, accounts of all pregnancies likely to have resulted in birth outcome will be followed-up by the CSAs to ensure that the birth outcome is recorded. The CSAs will also be trained to distinguish between pregnancy loss, stillbirths, and early neonatal deaths.

c) Verbal and social autopsy data collection

We will work with in-country partners to train and establish a team of qualified data collectors to carry out verbal autopsy (VA) data collection on all deaths, including stillbirths, as they occur in the SRS EAs. Members of the verbal autopsy data collection team will be residents of the SRS EA or the surrounding. Typically, deaths are identified and reported by the CSA. The team will then visit the home of the deceased to carry out VA interviews after the mourning period had passed or during an appropriate period decided by the family of the deceased.

The latest WHO standard verbal autopsy tool will be selected for use. This VA instrument includes separate modules for neonatal deaths (under 4 weeks, including identification of stillbirths), child deaths (4 weeks to 11 years), and deaths of persons aged 12 years and above.

While knowledge of the biological causes of child death is important, effective delivery of child survival interventions depends on better understanding of modifiable cultural, social and health system factors affecting health care access and utilization. Social Autopsy findings detail the most common household (e.g., mother's and father's education, pregnancy and wellness care, care seeking and constraints), community (e.g., residence place, time to reach health care in an emergency, social capital) and health system (e.g., ANC content, delivery care, newborn and child care, child illness care) factors that contributed to the deaths. Social autopsy findings are useful for guiding effective delivery of child survival technologies by informing health policy and program development for increased access and utilization of preventive and curative health care. During VA data interviews, social autopsy data will be collected on deaths of children under age 12. The verbal and social autopsy data will be collected using electronic tablets and uploaded directly on a secured cloud server.

Through its BMGF-supported CHERG (Child Health Epidemiology Reference Group) and MCEE (Maternal and Child Epidemiology Estimation) projects, JHU developed a verbal and social autopsy (VASA) tool to examine the biological causes and social (household, community,

and health system) determinants of neonatal and child deaths. The VASA tool integrates the PHMRC VA questionnaire and a new social autopsy (SA) instrument developed by JHU/CHERG. The VASA tool has been simplified and standardized both to the WHO standard VA tool and with the INDEPTH SA tool, as well as to the wording of equivalent DHS and MICS questions. We will use the VASA tool for collection of VA and SA data with the VA component fairly aligned with the 2016 WHO VA tool.

d) Roll out of the SRS implementation

To increase likelihood of successful implementation with high quality and sustainability, gradual phase-in implementation would be necessary. We propose to initiate implementation in five provinces: Tete, Cabo-Delgado, Zambezia, Nampula and Sofala (phase 1). The remaining six provinces will be covered at the beginning of the second year (phase 2), such that by the end of the third year, mortality and cause of death data will be available for at least 18 months in each province.

e) Annual update of SRS population and data quality assessment

The 2007 population census will serve to establish the baseline population and sampling frame. The population database from the census will be updated by the CSAs during the surveillance. In the middle of year 3 of project implementation a full census of the SRS population will be carried out to update the population of the SRS. In addition, data will be collected on births and deaths that have occurred to SRS cluster residents in the past twelve months. The census will be carried out independently from the surveillance system by a separate team so the data can be used to double check the surveillance data. However, household identification established at baseline will be used to allow matching of the households and vital events. Births and deaths data collected during this census will be matched against the surveillance data to assess level of completeness of the surveillance data. Matching will be done based on variables such as household identification and geocode, date of events and characteristics of the events such as date of birth, age, sex, mother and father's age, as well as resident status in the cluster. In addition to individual matching, neonatal, infant and under-five mortality rates from the two sources will be compared. An amendment to the current protocol will be done in year 3 to provide further detail on the design of this activity, the tools and the informed consent forms.

f) Setting up the SRS data team

The SRS will be managed and led at central level by the INE in collaboration with the Public Health Department of the Ministry of Health and the INS. At provincial level, we will appoint, in

agreement with provincial INE and MOH staff, one SRS coordinator to oversee and coordinate data collection activities. A total of 11 provincial level coordinators will be recruited. Two teams of VASA data collectors composed of 1 supervisor and 2 data collectors will be hired in each of the four high burden regions that will be oversampled to generate annual mortality estimates. In the remaining of provinces one team will be recruited, consisting of 1 supervisor and 2 data collectors. The VASA data collectors will be responsible for supervising SRS clusters in their communities. In each SRS EA, a Community Surveillance Assistant (CSA) will be appointed to oversee the surveillance of the community to identify pregnancies, births and deaths, collect required information on a smartphone and report the data.

2. Hospital deaths surveillance

To improve the determination of cause of death using VASA, we plan to use information from the Zambezia central and general hospitals for carrying out the death surveillance study.

COMSA will train and assign a data collector to selected sites. Prior to establishing the surveillance, careful discussion will be held with the hospital director and relevant personnel. This discussion will be facilitated by INS and the Ministry of Health.

COMSA will obtain cause of death results from the hospital record and use them in the analysis of verbal autopsy and mortality data to generate improved estimates of cause of death in Mozambique.

3. Demonstrating sustainability, country ownership and demand for data

The COMSA project will be designed from inception to incorporate essential principles of sustainability such as country leadership and ownership, implementation through existing government structures, with emphasis on capacity building and low cost. To create an environment for sustainability and demand for COMSA data, we will develop a plan that includes the following features:

- While data are generated and uploaded, we will work with the government and key partners to identify relevant questions for the government and that COMSA that can contribute to answer. Mortality and cause of death data generated by COMSA can be linked to DHIS-2, bringing COMSA side by side with other data on subnational coverage of health interventions, and other contextual factors to respond to questions that are relevant to the government of Mozambique for programming, policy

decision-making and resource allocation. Furthermore, the INS is in process of setting up a National Health Observatory (NHO) in the country. COMSA will engage with this initiative and be part of the committee and ensure that COMSA data are reviewed and included in the NHO.

- COMSA data will be used with existing data to demonstrate progress toward the Sustainable Development Goal 3.2, bringing more recent subnational data on overall mortality and cause of death.
- We will build capacity of in-country partners to collect, analyze and interpret the data to respond to pressing questions.
- We will make use of existing planning and evaluation tools such as the Lives Saved Tools (LiST) and EQUIST to demonstrate the usefulness of COMSA data and how these data can be translated into policy messaging.
- We will make use of capacity building framework (STATFRAM) and data analysis tools (Stats Report) that create an environment for learning and capacity building and simplify complex analysis.

3.2. *Sample size and sampling methods*

1. Sample size of SRS clusters per province

Key indicators of interest are neonatal, infant, under-five, and adult mortality rates and related cause of death fractions and rates. The sample size and number of SRS enumeration areas (EAs) must therefore reflect the need for adequate precision or margin of error for these indicators over a reference period (preferably annual) and measurement domains such as subnational regions. Although it would be desirable to power the sample to detect annual changes in these overall mortality and cause specific mortality rates in each province, doing so would lead to a very large unsustainable sample. Furthermore, given rapid decline in mortality, such a sample much constantly be increased to continue to detect annual changes in overall and cause specific mortality rates.

Lessons from multi-country implementation of community based recording of pregnancies, births and deaths in Africa suggest that clusters with smaller size or ratio of worker to population yield better accuracy and completeness of information.[1] In addition, large number of small SRS EAs will generate a more efficient (smaller variance) sample than small number of large SRS EAs. An SRS EA would be defined as a combination of census enumeration areas and villages with no

[1] Bryce J, Amouzou A, Victora CG, Jones G, Silva R, Hill K, et al. (2016) "Real-Time" Monitoring of Under-Five Mortality: Lessons for Strengthened Vital Statistics Systems. PLoS Med 13(1): e1001904. doi:10.1371/journal.pmed.1001904

more than 300 households (or about 1500 population), that can be feasibly monitored by a designated community focal point person.

Estimate of sample size is based on projected infant mortality rate (IMR) in each region to 2016. We used 7 deaths per 1000 live births as error margin in the four regions with highest under-five mortality. In all other regions, we used a relative error margin (absolute error margin divided by the IMR) between 25 and 30%. Based on these assumptions, the total number of clusters for SRS is estimated at 700 (table 2, column 3), yielding an estimated total of 2,649 under-five deaths, 1,805 infant deaths and 9,230 total deaths. Four high mortality burden provinces are oversampled to provide annual mortality estimates with increased precision (Manica, Cabo Delgado, Tete, and Zambezia).

Table 1: Sample of SRS clusters by province

Province	U5MR (DHS 2011)	# SRS clusters	# Annual births	Annual under-five deaths	All deaths (based on CDR=0.010)	Households	Estimated total population in SRS clusters
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)
Inhambane	0.058	49	2,516	92	614	14,845	61,362
Nampula	0.067	53	2,390	101	583	16,009	58,290
Maputo City	0.080	36	2,132	108	520	10,651	52,009
Maputo Province	0.096	36	1,904	116	464	10,668	46,432
Niassa	0.101	40	2,132	136	520	12,033	52,009
Sofala	0.105	29	1,767	117	431	8,551	43,103
Gaza	0.110	36	2,062	143	503	10,746	50,289
Manica	0.114	**85**	4,550	328	1,110	25,405	110,977
Cabo Delgado	0.116	**113**	5,758	422	1,404	33,933	140,439
Tete	0.129	**106**	6,022	491	1,469	31,948	146,882
Zambezia	0.142	**118**	6,611	593	1,612	35,304	161,239
Total		**700**	**37,844**	**2649**	**9,230**	**210,093**	**923,031**

2. Hospital mortality surveillance

There is no predetermined sample size for the mortality surveillance at selected hospitals.

3.3. *Study population and eligibility*

1. The SRS

The SRS will be implemented in 700 selected clusters in the eleven provinces of Mozambique to produce continuously annual data on mortality and cause of death at national and subnational levels. The population study is estimated at approximately 920,000. The entire population of these clusters will be enrolled in the surveillance which will collect information on all pregnancies, birth outcomes and deaths. A verbal autopsy will be carried out on an estimated 9230 deaths.

A. **Inclusion Criteria:**

For the SRS, all individuals who live in SRS clusters will be included in the study.
For the hospital surveillance, all deaths from selected hospitals will be recorded.

B. **Exclusion Criteria:**

Individuals or households' heads that do not consent to participate in the study will be excluded. Individuals who migrate outside the SRS cluster will also be excluded from the study population.

3.4. *Procedures*

a. The SRS data collection

In each province, INE will recruit and train teams of data collectors. Each team will be composed by a supervisor, two VASA data collectors and all provincial CSA. A provincial coordinator, an INE existing staff, will coordinate data collection at provincial level. The CSA may be an existing worker, volunteer or government community worker who has time to take on the SRS responsibility. The CSA will work directly with community key informants, health facility and community workers to collect and report at provincial level all pregnancies, births and deaths using tools developed by the research team and programmed in their mobile phones provided by the project. The CSAs will be responsible for conducting monthly/bimonthly household visits to identify vital events, including pregnancies and will report all vital events occurring in its community. At the start of their activities, the CSAs will carry out a full listing of all households and household members within their cluster. They will approach every household, obtain oral informed consent from the head of the household before doing the listing and asking for any events such as pregnancies, births, and deaths in the household. The CSAs will obtain informed consent from the head of household only once. The head of households will be asked to consent for subsequent household visits during the first visit. However, to collect data on pregnancies, births and deaths, the CSAs will obtain oral informed consent for every case.

The VASA data collectors will systematically follow up all identified deaths through a visit of the household of the deceased to conduct the VASA interview after the mourning period. They will be guided into the household by the local CSA. They will then obtain oral informed consent from the appropriate member of the family closest to the deceased. For child deaths for whom the mother or caretaker is also a minor, permission will be obtained from the parent/guardian and assent obtained from the mother or caretaker. The data collectors will proceed with interview using handheld tablet after informed consent is obtained. VASA interviews will be conducted in local language, which must be translated on-the-spot during the interview from the Portuguese questionnaire.

Pregnancy: The CSA will work with key informant, health facility and community health workers to identify any pregnant women in the community. In addition, on monthly or bimonthly basis, the CSA will visit every household to collect vital events. Information on pregnancy will be based on the respondent's report. No pregnancy test will be conducted by the CSA. During home

visits, the CSA will collect information related to any new pregnancy that has not been previously reported.

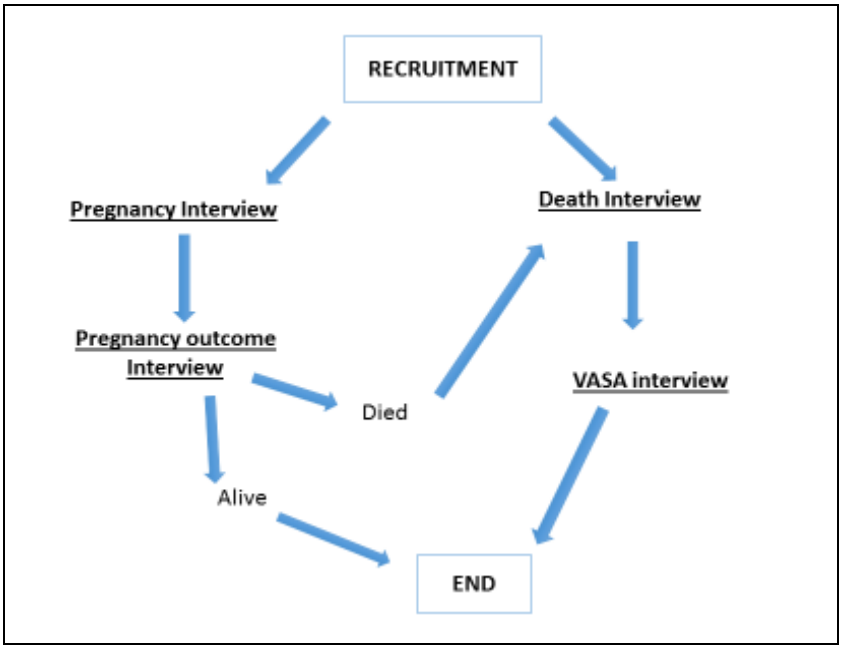
Pregnancy outcome (pregnancy loss, stillbirths, births): Each pregnancy will be closely monitored by the research team. The CSA will visit the household or health facility around the expected date of delivery to record the outcome of the pregnancy. In any case where the CSA was informed or notified that a pregnancy has ended before the expected date of delivery, he or she will visit the household or health facility to record information related to outcome of the pregnancy using a form that will be developed and validated by the research team.

Death: For each death identified, first the CSA will visit the household or health facility to record information related to the deceased on his/her phone using the appropriate form. Such information will be then transmitted to the server at the INE office at provincial level.

For verbal and social autopsy data collection: After the mourning period, the VASA data collectors will follow-up with family member of the deceased to perform the VASA interview. Individual who were present during the period preceding the death will be selected for the interview, in general the mother for children under-five years of age. The respondent will be asked to confirm the death before proceeding with the consent and interview.

That collection will be exclusively based on interviews with eligible respondents. Entry points for interviews will be either a pregnancy, a pregnancy outcome (pregnancy loss, stillbirth and live birth), or a death. Thus, depending on number of events, a participant or household may be contacted several times. For a pregnancy, women will be interviewed by the CSA to fill the pregnancy form, including the gestational age and expected date of delivery. The CSA will follow up until the delivery and depending on the outcome of the pregnancy, only the birth form will be filled if the mother and baby are still alive. In addition, a death form will be filled if a death occurred. Information will then be uploaded to the server. In cases of deaths, the study team will visit the family of the deceased, after the mourning period (2-3 weeks) to conduct the VASA interview. The figure describes steps that participants will undergo:

Figure 1 : Steps for data collection



Active data collection will take two years. The SRS clusters will be on continuous surveillance during this period. Individuals and households will be followed-up based on the frequency of the relevant events that occur to them. Similarly, active surveillance at hospitals will take two years.

b. The hospital mortality surveillance

For the hospital surveillance, a data collector assigned to the hospital will work with hospital manager and ward coordinators. Once a death occurs, the data collector will be alerted by these coordinators. He or she will extract from death registers all medical and background information of the deceased that will be used to complement the cause of death determination from the VASA.

3.5. *Data analysis*

Direct empirical estimates

Similar to any SRS system, the COMSA will generate observed empirical estimates computed directly from data collected as part of the SRS, the VA and the hospital surveillance. Table 5 presents the list of empirical estimates that will be generated at national and subnational levels and by age group.

Table 2: Direct empirical estimates that will be generated using COMSA and MITS data and level of disaggregation

Type of data	Direct empirical estimates	Geographical level	
		National	Subnational (regional)
Births and deaths from SRS	• Crude birth and death rates by age • All-cause mortality rate by age (neonatal, 1-59mo, infant, under-five, 5-14, 15-49, 50+)	✓	✓
Verbal autopsy of deaths	• Cause specific mortality rates by age (neonatal, 1-59mo, infant, under-five, 5-14, 15-49, 50+) • Cause specific mortality fraction by age (neonatal, 1-59mo, infant, under-five, 5-14, 15-49, 50+)	✓	✓
Hospital surveillance	• Cause specific mortality rates by age (neonatal, 1-59mo, infant, under-five, 5-14, 15-49, 50+) • Cause specific mortality fraction by age (neonatal, 1-59mo, infant, under-five, 5-14, 15-49, 50+)	✓	✓

Note: annual sub-national empirical estimates will be produced for regions with sufficient sample size.

Statistical modelled estimates

We will develop a statistical plan to create annually-updated, geographically-specific, cause-specific mortality rates. The proposed approach to estimating age and cause-specific mortality is to estimate: (1) *all-cause mortality:* the spatial-temporal distribution of under-5 (U5), infant, and neo-natal mortality, focusing on year x region values for each age category; (2) *cause of death:* the fraction of total deaths attributable to each of the 3 top causes: pneumonia, malaria, prematurity or other causes (4 categories). The age and cause-specific rates will be obtained as the product of the all-cause mortality rates times the cause of death fractions from the two steps above. The first step of statistical modelling will produce Bayes estimates of the age-group and region-specific rates of mortality from all causes using a log-linear hierarchical models. The second step is to use the COMSA verbal autopsy (VA) and hospital data as summarized in the table above to estimate the fraction of deaths attributable to pneumonia, malaria, prematurity and other causes. Two phases of models will be developed for this goal. In the first phase, we will assume that the hospital data are the gold standard, that is, each hospital cause of death determination is the true cause. In the second phase, we will explore model extensions that acknowledge the potential for error in the hospital cause of death determination. Given Bayesian

posterior estimates for the all-cause mortality rates by age and region and for the age-region cause of death fractions, we will combine these two results to obtain posterior estimates for their product, the cause-specific mortality rates.

All software used for estimation is or will be open source and disseminated via the project website. All analytic results will be reproducible using the literate programming tool KNITR (https://cran.r-project.org/web/packages/knitr/knitr.pdf).

3.6. *Data management*

Data collection will be done by using electronic devices (such as tablets and smartphones) through an open source named Open Data Kit (ODK). Tools include mainly the pregnancy, birth outcome and death recording tools and the verbal and social autopsy tools.

The database will be configured in a local network where the electronic devices will be connected to the network to perform the download of the tools. Thus the forms will be available in phone and tablet and field workers can make the collection of data without any network connection (i.e., offline). After the survey, the devices will be reconnected to the local network in order to transfer the data to the cloud server.

The COMSA central team will be trained to be able to set up and troubleshoot on their own the electronic data capture system from community level to the central level. The team will monitor the system, process and manage the data. A data manager will be recruited by INE to oversee the system, with support from the INE senior IT technician.

4. Quality assurance and quality control (QA/QC)

We will establish three levels of data assessment that will ensure quality. The first level will rely on controls and checks implemented in the electronic data reporting software. The electronic data reporting system will be established from the community to the central level. Open Data Kit will be used for reporting of vital events and uploading of data into a cloud. All data forms will be programmed with appropriate quality controls, checks, filters and warning to minimize data entry errors, missing data and inconsistent data.

A second level assessment will be conducted monthly by the regional level SRS coordinators. They will be tasked to visit a random sample of reported events to verify accuracy of information reported. This verification scheme will be setup in the data reporting system such that on monthly basis, the sample of events confirmed will be accessible to and verifiable by the project investigators. This assessment, however, will only be able to confirm accuracy of events reported. It will not be able to indicate level of completeness of reported events within the SRS cluster.

A third level of data assessment will be carried out during the third year census of SRS population (see above). The census will collect data on vital events (births and deaths) occurring to the resident population in the past twelve months. These events will be matched with the surveillance data to determine the level of completeness of the surveillance data. The census data will be used to correct any error in the surveillance data.

5. 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.

6. 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.

6.1. *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.

6.2. *Informed consent*

For all data collection, written consent process will be used. 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.

i. SRS data collection

The community surveillance assistants (CSA) and the VASA data collectors will obtain informed consent before any data collection. The CSA will be an existing worker, volunteer or government community worker who has time to take on the SRS responsibility. Key criteria for recruitment of the CSA will include literacy (especially with ability to use smartphones), residence in the selected SRS cluster, and full endorsement by the community leaders (chiefs and key informants).

The verbal and social autopsy (VASA) data collectors will be recruited in each province to ensure that they are familiar with the localities, speak the language and able to hit the ground running with data collection and supervision. They will be contracted full time on COMSA for renewable annual period. Criteria for recruitment include at least secondary schooling with experience in survey data collection. INE will identify potential data collectors from its existing pool of survey data collectors.

The consent form will be programmed on tablets and phones of data collectors. The consent discussion will occur at the community level before the interview. The data collector will require to read the information on the consent form and will request the participant to consent in order to participate to the survey. In case of the participant declines, the interview will not be performed.

For the SRS, it is possible that events such as pregnancies or death of a child occur to a minor (<18 years). In these cases, if information on pregnancy, birth and cause of death has to be collected, the data collector will have an assent document that will be program on the device and an oral assent will be obtained from the participant and permission obtained from the parent/guardian before the survey.

For the hospital surveillance, the consent for retrieval of death information from registers will occur only once at the start of the study.

6.3. *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.

7. Limitations

1. **Short project implementation time leading to premature ending of the project**
   Developing project protocol together with in-country partners and pulling together all the logistics for a successful implementation will take time. Furthermore, data collection will require some learning and course correction at the beginning before stabilizing. We will also need to dedicate the last six months of the project to data analysis and reporting. At the end of three years, usable data may be available for just about eighteen months. Phasing out abruptly may risk losing momentum and any sustainability gains established in the project.

2. **Limit sample size**
   Given the rapid decline in mortality in Mozambique, an annual estimate by province will be preferable to monitor the impact of health programs. However, such annual mortality estimates could only be produced in the four oversampled high burden provinces of Zambezia, Tete, Cabo Delgado and Manica. Also, due to sample size, our estimates could not be produced beyond the provincial level (at the district level).

8. 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.